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**A randomised controlled trial of the effects  
of the energy-based complementary therapy of Healing Touch  
on the functional health status  
of community-dwelling single older women**

Submitted November, 2012

to the School of Nursing, Midwifery and Nutrition

For the Degree of

**Doctor of Philosophy**

at

James Cook University

by

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This research presented and reported in this thesis was conducted in accordance with the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research, 2007. The proposed research study received human research ethics approval from the JCU Human Research Ethics Committee Approval Number H 3077, from the Townsville Health Service District Approval Number 35/08; and from Spiritus/Anglicare Approval Number ECO0341:2009:02.

\_\_\_\_\_

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## **Dedication**

I dedicate my doctoral dissertation to Muriel F. Wicking, my mother-in-law, who provided us with a stellar example of healthy ageing in action.

She inspired me to explore how to help other older Australian women to remain as functionally independent as she did, so they too can enjoy being '90-something' as thoroughly as she enjoyed it. She was an icon, at home and abroad: at the Caulfield race course in Melbourne and cruising all over the high seas on the Queen Elizabeth II.

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## ABSTRACT

### A Randomised Controlled Trial (RCT) of the effect of Healing Touch versus placebo on the functional health of community dwelling older women

#### BACKGROUND:

Both government and the health care industry are keenly aware of the burgeoning older adult population in Australia and globally. The risk for functional decline leading to placement in residential aged care is accentuated for older women who live alone, who may experience lower social support and/or touch deprivation. Frail older adults in one prior small qualitative study reported gains in functional ability after receiving Healing Touch treatments, while findings from two prior experimental studies with methodological limitations contributed suggestive but conflicting evidence for the benefit of Healing Touch on functional ability for hospice patients and women with cancer. The aim of this research was to clarify the existing evidence base with a methodologically rigorous placebo-controlled trial of adequate power to detect an effect on functional health. A series of weekly sessions of the complementary therapy of Healing Touch was provided in the homes of community-dwelling women to ascertain if this nursing intervention, which uses gentle direct and indirect touch on specific locations of the body in a prescribed sequence for each technique, could assist them in managing and optimising their current functional and global health status, as well as providing them with a source of healthy touch and social connection.

#### TRIAL DESIGN:

A parallel, two-arm randomised placebo-controlled trial was conducted to assess the effects of the energy-based complementary therapy of Healing Touch on the functional, social, psychological and spiritual health status and overall quality of life of community dwelling older women.

#### METHODS:

##### Participants/Setting:

Inclusion criteria: women over 65 living alone in the community in a regional city in northern Australia in houses, units or retirement villas, who were receiving some assistance in their homes from any source including family, friends, neighbours or volunteers. Exclusion criteria were existing cognitive impairment, the presence of a room-mate or live-in caregiver, or recent experiences with Healing Touch or other similar energy-based touch therapies. Participants received a series of weekly treatments of Healing Touch or mimic healing touch (placebo) in their residences between January 2009 and December 2010. A Research Assistant blinded to group allocation collected the data in the participants' residences at baseline (Week 0), at completion of the seven week treatment series (Week 8), and six months after completion of the treatment series (Week 33).

### Interventions:

Participants in the Healing Touch group received a series of seven weekly treatments, each lasting an average of 30 minutes, consisting of one of 35 possible Healing Touch techniques, from the established curriculum taught by the Colorado Center for Healing Touch and approved by the American Holistic Nurses Association. Timing and duration of sessions were similar for the participants in the placebo group, who received one mimic healing touch technique as per the placebo protocol developed by the Principal Investigator(PI). The PI delivered all interventions to preserve blinding and ensure protocol adherence.

### Hypothesis:

The Healing Touch group will experience statistically significantly smaller declines in functional health than the placebo group.

### Outcome Measures:

The primary outcome was functional health as measured by the Older American Resources Survey's Functional Multidimensional Assessment Questionnaire (OARS-FMAQ), consisting of two sub-scales: Basic Activities of Daily Living (ADLs) and Instrumental ADLs, which are summed for a Total ADL score. Secondary outcome measures included the Medical Outcomes Study Social Support Survey (MOS-SSS), the Paloutzian and Ellis Spiritual Well-Being Scale, the Ryff Psychological Well-Being Scale-short form, and the Duke Health Profile.

### Randomisation:

Computer generated random numbers were used to create a sequence of blocked and balanced random allocations, in groups of ten, concealed in opaque envelopes. Participants were advised of the placebo design prior to consent. Envelopes were opened by the PI immediately prior to administering the selected protocol at the first treatment session.

### Blinding:

Participants, family members, referral sources, co-providers, data collectors and data analysis verifiers were blinded to group allocation.

## **RESULTS:**

### Number of participants:

191 women were screened and enrolled, but 18 did not keep their appointments and 5 failed their screening MMSE, leaving 168 who progressed to randomisation: 84 participants in each treatment group. Attrition causes included: onset of illness (5); death (1); relocation (4); too busy for appointments (1) or participants being unable to tolerate lying on the massage table and/or wearing the sleeping mask (4). A modified intention-to-treat analysis was conducted for the 153 participants with data from all three time points, regardless of protocol adherence: 75 participants in the placebo group and 78 in the Healing Touch group.

### Outcome Measures:

Despite randomisation, treatment groups were not comparable on the key demographic variable of living arrangement, with a greater number of retirement village residents in the Healing Touch group, thus requiring a stratified analysis.

For the stratum of participants already living in retirement villages, there was a statistically significant difference ( $p = 0.025$ ) between the change in the Healing Touch group's scores from Week 0 to Week 33 as compared to the change in the placebo group's scores, on the Basic Activities of Daily Living (BADL) sub-scale. The Healing Touch group showed a small but clinically relevant improvement in the BADL sub-scale (median 0.0, inter-quartile range 0.0, +1.0), while the placebo group showed a small but clinically relevant decline (median 0.0, inter-quartile range -1.0, 0.0).

The change over time in the two other measures of functional health, the Instrumental Activities of Daily Living (IADL) sub-scale and the Total ADL scale, were comparable between the Healing Touch group and the placebo group for the retirement village stratum; and all functional health measures (BADL, IADL, and Total ADL) were comparable between the two treatment groups for the stratum of participants living in their own homes or units in ordinary residential neighbourhoods.

The Social Support measure also showed a statistically significant difference ( $p = 0.012$ ) between treatment groups, but only in the stratum of participants still living in their own homes or units in ordinary residential neighbourhoods. Again the Healing Touch group showed a modest improvement from Week 0 to Week 33, while the placebo group showed a decline.

#### Harms:

No harms related to the treatment were reported, although alternative positions in a reclining chair or shorter treatments were required for 4 participants who could not tolerate lying supine on the massage table for a full treatment session.

#### **CONCLUSION:**

Healing Touch may have a beneficial effect for selected older adult populations on selected health dimensions, depending on their area of deficit:

1. Retirement village residents may respond with improvements in their functional health. These findings are congruent with some of the earlier qualitative and experimental research on functional health, but conflict with more recent RCTs with younger but acutely ill participants.
2. Socially isolated residents in ordinary residential neighbourhoods may respond with improvements in their social health. These findings conflict with earlier studies of younger but acutely ill participants, where no benefits for social health were observed.

#### **TRIAL REGISTRATION:**

Australian New Zealand Clinical Trial Registry Number ACTRN12612000788875.

World Health Organisation Universal Trial Number is 1111-1132-2783.

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## **Glossary of Terms and Abbreviations**

Week 0 (zero): pre-intervention or the baseline measurement. Data collected by RA 1-14 days prior to first intervention home visit by PI.

Week 8: post-intervention series measurement. Data collected by RA later the same day or within a maximum of 14 days of the final intervention home visit by PI.

Week 33: Follow up measurement. Data collected by RA 6 months (usually 180 days) +/- 18 days from the date of the last intervention home visit by PI.

CCI: The Charlson Co-Morbidity index

ADL: Activities of Daily Living

BADL: Basic Activities of Daily Living

IADL: Instrumental Activities of Daily Living

Total ADL: the sum of the BADL and IADL sub-scales

OARS-FMAQ: Older American Resources Survey Functional Multidimensional Assessment Questionnaire

PWB: Psychological Well-Being

SWB: Spiritual Well-Being

MOS-SSS: Medical Outcomes Study-Social Support Survey

MMSE: Mini-Mental Status Examination

The Duke: Duke Health Profile

## **CHAPTER ONE: Introduction and Background**

## **Introduction to Thesis**

This dissertation will detail the conduct of a research project undertaken in fulfilment of a doctor of philosophy degree. Chapter One will discuss the background of the project, including the problem of functional decline in older adults, its significance to both the Australian and the global health industry and the theoretical premise that the complementary therapy of Healing Touch may be an effective intervention to minimise or delay functional decline in certain groups of older adults. This premise will be tested through the design and conduct of a randomised controlled trial (RCT). Chapter Two will focus on presentation of the research up to 2008 at the time of designing this present research study, including an overview of both qualitative and quantitative research, with a focus on both the beneficial effects noted in recipients of Healing Touch, and also on the methodological challenges and strategies encountered, all of which informed the design of this present study. Chapter Three will then outline the Methods used to conduct the study, covering all phases of the study from designing the proposal, acquiring ethical approval, recruiting the participants, delivering the Healing Touch intervention and the placebo control intervention, collecting and analysing the data and disseminating the findings. Chapter Four, Results, will begin with a description of the sample at baseline, both as a whole and by comparing the baseline characteristics of the two randomly allocated treatment groups. Chapter Four will then proceed with a comparison of the two treatment groups on primary outcome measures, secondary outcome measures and ancillary analyses. Chapter Five, Discussion, will contextualise the findings of this present study against the backdrop of the current body of evidence, including a comprehensive update of the literature published after commencement of this present study. These 14 later studies will also be more fully described in Appendix A for the reader's convenience. The Discussion will also identify the contribution of this present study to building the evidence base and upholding and advancing standards of methodological rigour as defined by the evidence based practice (EBP) paradigm. Limitations will also be identified, followed by recommendations arising from this present study, for future practice, policy and research. A summary of the dissertation will complete the body of the text, followed by a comprehensive reference list and a thorough collection of appendices of supporting documents used in successive phases of the study, including ethics approval, recruitment and intervention.

## **Background and Significance**

### **Older Adults and Functional Ability versus Functional Decline**

Australia's population growth is projected to result in a quarter of the population being above the age of 65 years old by 2050 (Prime Minister's Science, Engineering and Innovation Council (PMSEIC), n.d.). The population segment of those Australians aged 65 to 84 years is doubling, while the segment over 85 years of age will be quadrupling (Australian government: The Treasury, 2010). Meeting the health care needs of this rapidly expanding sector is a primary concern of the Australian Government (PMSEIC, n.d.), of the health care industry sector and perhaps most importantly, of older adults themselves. Projected workforce shortages of health care professionals (HCPs) to meet this approaching population profile are one concern (Swerissen, 2009). Even with sufficient HCPs available, the cost of meeting the health care needs of older adults is a related concern, given the known dramatic rise in expenditure that

correlates with advancing age. “Costs are about four times higher for those aged over 65 and significantly higher again for those aged over 80” (Swerissen, 2009), and this financial burden is shared by State, Territory and Federal Governments, as well as by older adults themselves and/or their families. Adequate physical and human resource infrastructure of acute care hospital beds, aged care community support packages and long term residential placements are all predicted to be strained beyond capacity if projected trends are realised (Australian government: The Treasury, 2010; Swerissen, 2009).

Healthy Ageing is a national health priority and a government strategy intended to offset some of the dire predictions noted above, and the vision of healthy ageing is described as “an active and productive Australia in which people not only live longer but live longer in good health, staying mentally and physically active and able to participate and enjoy life until they die at an advanced old age” (PMSEIC, n.d., p. 13). A key component of the philosophy of healthy ageing includes research into supportive interventions that enable older adults to improve or sustain their optimal health status, including their functional independence, and thus decrease their utilisation of expensive and scarce health care services, particularly residential aged care placements (Australian government: The Treasury, 2010).

In contrast to the ideal of healthy ageing, functional decline is an unpleasant reality experienced by many older Australians, and one that often results in relocation to a more supported living arrangement, including residential aged care facilities (RACFs). A definition of functional decline provided by the clinical Epidemiology and Health Services Evaluation Unit—Melbourne Health, 2004 (as cited in Hill, Schwarz & Winbolt, 2009, p. 189) describes it as “the reduced ability to perform tasks of everyday living, for example, walking or dressing, due to a decrement in physical and/or cognitive functioning.” Although most older Australians self-report their health as excellent, very good or good, by contrast, “almost a quarter of older people (23%) had a severe or profound disability in 2003, meaning that they sometimes or always needed help with self-care, mobility or communication” (ABS, 2004, as cited in Australian Institute of Health and Welfare (AIHW), 2010, p. 321).

Placement into residential aged care facilities (RACFs) can be triggered by factors such as functional decline, specifically the declining ability to perform activities of daily living at an independent level (Bharucha, Pandav, Shen, Dodge & Ganguli, 2004). Depleted social support can also be a triggering factor, when caregivers are no longer able or available to fill the gap between the older adult’s abilities to complete their own ADLs and the level of functional independence required to remain in a community dwelling (Bharucha, et al, 2004). Personal social support may be replaced or supplemented by government-subsidised assistance in the home (AIHW, 2007), but the options available will be constrained by the shrinking resources noted above. Cognitive impairment can also directly trigger residential care placement (Brown, 2007) or indirectly contribute to placement through its detrimental effect on the older adult’s ability to perform ADLs safely and independently. Overall physical health status can also impair the ability to undertake ADLs, as can a decline in emotional health status, with issues such as anxiety and depression potentially further limiting an older adult’s ability to maintain their independence in the community.

Miller’s Functional Consequences Theory (2012) looks at the issues of functional ability from a broad and positive perspective. She discusses the cumulative and interactive effect of a variety of age-related physiological changes and numerous risk factors on the older adult’s ability to function safely in their current environment, and the subsequent effect of their level

of functionality on their overall quality of life (2012). She directs the recommended nursing interventions towards teaching about health promotion, addressing risk factors and referring for additional care or support. The desired effect of these nursing interventions is to promote and optimise each individual older adult's current functional capacity, thus resulting in an improvement in quality of life (Miller, 2012), a similar goal to that of healthy ageing described above.

Similar to Miller's Functional Consequences Theory, the hallmark nursing theorist Dorothea Orem also provided a relevant perspective to the discussion of functional independence versus functional decline. Orem's central question was "When and why do people require the health service [of] nursing?" (Hartwig, 1991, p. 11). From this central question she postulated her Theory of Self-Care Deficit (or Dependent Care Deficit), one of her three interrelated theories. She conceptualised nursing services as being required when certain self-care limitations occur, and listed age as once such internal limitation that might place the client in need of nursing services (Hartwig, 1991). Her conceptualisation of a self-care deficit occurring when the self-care demand exceeded the self-care agency (or ability) echoes the concerns of functional independence raised in Miller's Functional Consequence Theory. In both theories, the ideal is to support the individual to remain as functionally independent as possible, or in Orem's terminology, to have a sufficient self-care agency to meet their current self-care demand (Hartwig, 1991), in order to avoid functional decline and the resulting dependence on others that it may precipitate.

The cost of functional decline extends beyond the financial burden to government and individuals. The deterioration in quality of life experienced by older adults undergoing functional decline presents in many ways, long before it results in residential care placement. Quality of life consequences stemming from functional decline include lost opportunities for social interaction with family and friends, with the benefits these provide not just to the older adult, but to their family members, such as unpaid child care or support with household duties such as cleaning and ironing (AIHW, 2007). With the increasing participation of younger adult women in the workforce, the tasks performed by helpful older adult mothers or mothers-in-law often enable their adult daughters to successfully balance their paid employment and household tasks concurrently. Another consequence of functional decline in the older adult can be the loss of volunteer or employment opportunities with their flow-on effect of lost services and expertise to those employing organisations or individuals. Older adults are vital members of their communities, often providing the bulk of volunteer services for organisations that are pivotal to the social fabric of a community (AIHW, 2007). Functional decline is not just a negative outcome for the individual older adult, but also for their family, neighbourhood, community, the health care industry and for society at large.

Older adult women living alone in the community are seen to be at particular risk for the cascade of functional decline described above, as they have often already experienced substantial shrinking of their social networks through widowhood or the death of their same-age peers. Statistics for residential aged care facilities indicate that female residents comprise 70% of the population in RACFs in Queensland (AIHW), 2012, p.22). They are the highest users of in-home assistive support packages such as Home and Community Care (HACC), Community Aged Care Packages (CACP), Extended Acute Care at Home (EACH), and EACH-Dementia (EACH-D) (AIHW, 2007). While wives providing caregiver support for husbands is the most common pattern, in many couples, the caregiving support is mutual, with each member providing some function(s) that the other spouse is unable to perform. When women are left

residing alone in the home, either through widowhood, divorce, or the entry of the husband in to residential care, they lose the practical support and/or emotional support provided by the departing spouse. If the departing spouse had been ill for some time, the older woman may be relieved of a large burden of care-giving, but their personal vulnerability as a single resident emerges and may, over time, impact negatively upon their ability to maintain functional independence in the community.

The Australian Bureau of Statistics (ABS) predicts that almost two-thirds of the growth in lone person households will be comprised of women over the age of 60 (ABS, 2011 Census of population and housing), with total growth in lone person households projected “at 2.2 per cent per year from 1.9 million in 2006 to 3.2 million in 2031” (ABS, 2011).

For the reasons outlined above, older women living alone in the community were chosen as the focus for this present study. It was postulated that a supportive and relaxing health promotion nursing intervention like Healing Touch might be able to mitigate or buffer some of the risk for functional decline and eventual residential care placement in this susceptible population.

## **Healing Touch and Functional Ability**

Three prior studies about Healing Touch indicated a potential beneficial effect on functional ability for participants receiving this complementary therapy. In her qualitative study, Peck (2007) noted that interviewed participants reported an improvement in their functional ability (BADLS and IADLs) after 3-4 months of Healing Touch treatments. Her study followed 12 frail elders whose functional limitations qualified them for assisted living or skilled nursing home placement, but instead they were being managed in their own homes with agency support. They received between 6 and 14 Healing Touch treatments in their own homes, so the population of frail elders, the setting of the participants' homes for the delivery of the treatments, and the range of the number of treatments provided, were all similar features to the present study.

For their randomised study of hospice patients, Ziembroski, Gilbert, Bossarte and Guldberg (2003) reported that both groups had worsening scores over time on the physical functioning sub-scale of the Missoula Quality of Life instrument, as would be expected for a palliative care population receiving treatment in a hospice setting. In this respect they were likely to be experiencing greater frailty and functional decline than the participants in this present study, and also more frailty than the ones described above in Peck's (2007) study. Ziembroski et al. (2003) reported that the standard care control group (26 participants) had a (presumably non-significantly) larger incremental decline in their physical functioning than the Healing Touch group (29 participants). Inferential statistics were not conducted.

Cook, Guerrerio and Slater (2004) conducted the only parallel RCT comparing Healing Touch to a placebo or mock version of Healing Touch located prior to the commencement of this present study. Their sample of 62 female patients receiving radiation treatment for breast or gynaecological cancer, received six Healing Touch or placebo treatments. A well-established instrument was used, the Medical Outcomes Study SF-36, which is comprised of nine sub-scales covering domains of health, including physical functioning and physical role functioning. Within group comparisons showed statistically significant improvements occurring in both treatment groups. For the genuine Healing Touch group, the improvements were on the three

sub-scales of emotional role functioning, mental health and health transition. For the mock Healing Touch group, the improvements were on the two sub-scales of physical role functioning and health transition. More stringent statistical analyses for between-group comparisons were also conducted, based on the change over time in the Healing Touch group versus the change over time in the placebo group. The Healing Touch group outperformed the placebo group at a statistically significant level on three sub-scales: pain, vitality and physical functioning.

The intriguing results from these three studies prompted the theoretical premise that Healing Touch may be a beneficial supportive therapy to assist older adults to retain their functional ability to perform ADLs, with the many consequential advantages that such independence can confer.

## **The complementary therapy of Healing Touch**

### **Historical Development of Healing Touch**

The collection of techniques and the underlying philosophy for providing this energy-based complementary therapy were first organised into a structured curriculum program for nurses and taught by Janet Mentgen, a Registered Nurse and Nurse Educator, as a continuing nursing education program in 1989 at the University of Tennessee (Wardell & Mentgen, 1999). Mentgen had been using these techniques in her work as a community nurse and teaching the techniques at Red Rock Community College in a complementary therapy course (Bulbrook, 2011). Mentgen “was foremost a nurse and secondly a holistic nurse” (Bulbrook, 2011, p. 13). The techniques were collected by Mentgen from energy healers and teachers with established healing practices, including Alice Bailey, Barbara Brennan, Rev. Roslyn Bruyere, Dr. Brugh Joy, Rev. Rudy Noel, Rev. John Scudder, Australian Rod Campbell and the technique for Therapeutic Touch as taught by Dr. Dolores Kregier and Dora Kunz (Hover-Kramer, 2002; Mentgen, 2001; Wardell, 2000). Mentgen founded the Colorado Center for Healing Touch (CCHT), which offered training for instructors to adhere to the structured curriculum, which was endorsed by the American Holistic Nurses Association (AHNA) as a continuing education certification program in 1989 (Bulbrook, 2011; Hover-Kramer, 2002;) and taught to increasingly large volumes of students across the USA and around the globe, including in Australia as early as 1990 (Bulbrook, 2011; Wardell, 2000). As early as 2002, the Colorado Center for Healing Touch recorded that over the previous ten years, 54, 867 students had participated in 3, 801 Healing Touch classes (Hover-Kramer, 2002).

The structured curriculum spans six levels of training, the first three comprised of approximately 15 hours of continuing education delivered in a weekend experiential workshop format (Wardell & Mentgen, 1999), while the fourth and fifth levels are structured as four day intensives in a residential retreat setting with a minimum of a one year mentored apprenticeship in between the two levels and submission of an extensive portfolio, including written case studies and a minimum of 100 documented Healing Touch sessions (Mentgen, 2001). Certification is available after completion of Level Five training, through either Healing Touch International or through the Healing Touch Program, both of which are endorsed by the AHNA. Hover-Kramer (2002) reported that there were 1, 020 Certified Healing Touch Practitioners, most of whom were nurses; and 1,020 certified Healing Touch instructors, again most of whom were nurses. The sixth level of training is for instructor preparation, and

requires multiple workshop attendances over a period of months or years and a supervised mentorship/apprentice model. The researcher for this present study achieved Level Four training prior to commencement of the research, and functioned as the Principal Investigator (PI) for the project team, and delivered all Healing Touch treatments herself, in the absence of any other nurses trained in Healing Touch in her local regional city, with a population of approximately 190,000 people.

The first textbook regarding Healing Touch was published in 1996 (Hover-Kramer, 1996), with a second edition in 2002 (Hover-Kramer, 2002), and a third edition in 2010 (Hover-Kramer, 2010). Responsibility for the administration of the process of certification of practitioners was transferred from the American Holistic Nurses Association to the peak professional body, Healing Touch International, in 1996, due to the AHNA's requirement to restrict their direct certification process to registered nurses only. While most students of Healing Touch are nurses, other health care professionals and even lay persons are allowed to study Healing Touch and achieve certification if they meet the standardised requirements. Annual conferences have occurred since 1990, with the conference in 2000 attracting over 500 attendees (Hover-Kramer, 2002). The Australian Foundation of Healing Touch, Incorporated (AFHTI), is an affiliated country association of Healing Touch International (HTI), and administers the curriculum, with endorsement for nursing continuing professional development credit available through the Royal College of Nursing Australia (RCNA). While only one to two dozen classes per year are conducted in Australia, the annual schedule for more densely populated countries like the USA routinely includes over 200 classes per year.

## **Description of Healing Touch**

Healing Touch is a collection of 35 energy-based techniques that use gentle touch directly on the body or above it at specific locations in prescribed sequences, with the purpose of balancing the physical, emotional, mental and spiritual energy systems to promote overall health and well-being (Hover-Kramer, 2002; Mentgen, 2001; Wardell & Mentgen, 1999). The central premise in this and other energy modalities is that they are used to facilitate and activate the innate self-healing that every human being possesses and can access in order to foster their own ability to achieve health, which is defined as wholeness rather than the mere absence of disease (Hover-Kramer, 2002; Mentgen, 2001).

Healing Touch techniques can vary in their use of either direct gentle touch on the patient's body through clothing, or indirect touch where the practitioner holds or moves their hands above specific locations on the client's body (Mentgen & Bulbrook, 1994). Within the collection of 35 techniques (see Appendix B), some are considered full body techniques, with hand positions that span from head to toe, while others are localized techniques that focus on a particular part of the body, such as the head (Mentgen, 2001). Often hand locations include the joints, which are considered to be minor chakras, and/or the major chakras located midline from the base of the spine to the crown of the head. The word chakra is a Sanskrit word meaning 'wheel' and is used to indicate the energy centers in specific locations on the body (Brennan, 1987; Hover-Kramer, 2002; Mentgen & Bulbrook, 1994). Chakras are postulated within the theory of energy medicine to be an access point where universal energy flows in to and sustains each human being's energy system and physical body (Brennan, 1987; Hover-Kramer, 2002; Mentgen & Bulbrook, 1994), and both minor and major chakras are

assessed and treated during Healing Touch sessions (Mentgen & Bulbrook, 1994; Hover-Kramer, 2002).

Healing Touch techniques can be administered with the client lying supine for most techniques, and prone for a few of them, while a sub-set of techniques can be performed with a client sitting in a chair or even standing (Hover-Kramer, 2002). Most clients experience all of the techniques as being relaxing and pleasant, but many of them have specific purposes besides general relaxation (Hover-Kramer, 2002). For instance, a technique taught in Level Three of the curriculum entitled Lymphatic Drain is intended to be used for clients experiencing threats to their immune system, while a Level One technique entitled Magnetic Clearing is intended for use in clients who are detoxifying from anaesthesia or other substances such as nicotine, alcohol or street drugs (Hover-Kramer, 2002). Similarly, a local technique also taught in Level One classes, with hand positions only around the head and neck is entitled Mind Clearing and can be used for headache relief on a physical level, or on a mental level, for restoring mental clarity and focus for clients who have reported feeling 'scatter brained' or agitated (Hover-Kramer, 2002).

## **Underpinning Theory of Healing Touch: Energy Medicine**

"Energy field disturbance" is one of the nursing diagnoses listed by the North American Nursing Diagnosis Association (NANDA) (Ackley & Ladwig, 2006), and is defined as "a condition in which a disturbance of the human energy field manifests a disharmony in the human-environmental energy field mutual process" (McFarland & McFarlane, 1997, as cited in Wardell & Mentgen, 1999, p.35). The identification of an energy field is indicative of the early influence of the nursing theorist Martha Rogers and of Therapeutic Touch instructor Dr. Dolores Kreiger (Hover-Kramer, 2002). Energy therapies include other modalities besides Healing Touch and Therapeutic Touch, such as Reiki, acupuncture and acupressure, and self-care practices such as yoga and Tai Chi (Mentgen, 2001). The energy system is conceptualized in ancient cultures by other names, such as 'chi' in China or 'prana' in India (Mentgen, 2001), but the universal concept of a vivifying life force or life flow is noted by different names across many ancient cultures, including 'pneuma' in ancient Greece, 'ankh' in ancient Egypt, 'ki' in Japan, 'mana' in Polynesia, and 'orenda' in the Native American tribe of the Iroquois (Hutchison, 1999).

The underlying philosophy of these energy modalities and practices relates to a conceptualization of the human energy system, or biofield, as surrounding and interpenetrating our tangible physical body, and influencing it in a profound way (Bradford, 1993; Brennan, 1987; Gerber, 2001; Hover-Kramer, 2002; Hutchison, 1999; Mentgen, 2001; Oschman, 2000; Wardell & Mentgen, 1999). A disturbance, imbalance or congestion in the flow of energy in the biofield, the meridians or the network of major and minor chakras, is purported to precede and later eventuate in a physical expression of a symptom or disease state (Hover-Kramer, 2002; Hutchison, 1999; Mentgen, 2001; Wardell & Mentgen, 1999). Using energy modalities such as Healing Touch to re-balance, strengthen and support the biofield is theorized to activate the innate drive towards self-healing available within every human, and in so doing, prevent the onset of later illness and thereby promote or maintain physical, emotional, mental and spiritual health (Hover-Kramer, 2002; Hutchison, 1999; Mentgen, 2001; Wardell & Mentgen, 1999). If this theory is true, it would be reasonable to expect that a group of clients exposed to a Healing Touch intervention would experience a

lower incidence of onset of illness or functional decline than that experienced by a comparison group followed over the same time period.

A guiding principle in energy work, constantly re-emphasized by Mentgen (as cited in Hover-Kramer, 2002), is for the Healing Touch Practitioner (HTP) to set an intention for the client's highest good, and not to presume to know or declare what that outcome will be in any given session. This is a philosophical difference between the theoretical principles of energy therapies and the research principles in the positivist paradigm, where an outcome measure that is expected to be influenced by the intervention is pre-selected and then measured prior to treatment commencing and at pre-determined intervals after treatment occurs. A key decision in any intervention study is the appropriate choice of outcome measure(s), and earlier publications of expert opinion, case reports, qualitative research and program evaluation reports are all suitable and worthwhile sources to consider when selecting outcome measures for subsequent quantitative designs. However, while the pre-selection of an outcome measure is necessary in the design of an RCT, the individual Healing Touch practitioner performing the Healing Touch intervention according to the curriculum as taught by the Colorado Center for Healing Touch, would preface each individual treatment session with a more general intention for the treatment to be directed to the client's highest good, regardless of the pre-selected outcome measures included in the study design. This principle was observed during each treatment session (see Appendix C, Pre-Treatment Centering Meditation) and in fact the clients themselves in both treatment groups were given the same affirmation to repeat to themselves regarding an open-ended intention to receive whatever benefit they most needed to receive for that session (see Appendix D, Pre-treatment Session Briefings). So the apparent contradiction in paradigms was resolved in the present study by both designing the pre-selected outcome measures required in the positivist paradigm, but also by honouring the philosophical underpinnings of the holistic therapy of Healing Touch, which state that the treatment may affect each participant differentially, depending on their greatest area of need.

## **Complementary and Alternative Medicines (CAMs) and Older Adults**

Healing Touch is a therapy intended to be used to complement mainstream biomedical treatments, and as such is considered a complementary modality under the umbrella of Complementary and Alternative Medicines (CAM), or more appropriately for this dissertation, Complementary and Alternative Therapies (CATs). CAMs and CATs have long enjoyed an ever-growing popularity among older consumers (Howell, 1993), with an increasingly wider participation by older adults (Cherniak & Pan, 2004). A recent report from the National Center for Complementary and Alternative Medicine (NCCAM) commissioned by the American Association of Retired Persons (AARP) in the USA reported 22% of adults over 50 years old used some type of body work therapy, such as massage, chiropractic or other bodywork (AARP/NCCAM2011). Health care professionals also voice an interest in CAMs and report both personal use and professional recommendations to their clients (Cutshall, Derscheid, Miers, Ruegg, Schroeder, Tucker & Wentworth, 2010). Consumer demand for CAM/CAT is particularly prevalent in those conditions for which allopathic medicine cannot provide a cure, such as long term conditions (Murcott, 2005). The normal physiological changes of ageing, as well as the higher incidence of particular chronic diseases associated with ageing, can also

prompt exploration in to complementary therapies (Murcott, 2005). Healing Touch in particular was requested by 31% of patients in one study of 76 Clinical Nurses Specialists working across a variety of settings within the Mayo clinic, a large and renowned academic medical center in central U.S.A. (Cutshall, et al., 2010).

Older adults can be considered at particular risk for unethical marketing of unproven CAMs or CATs that claim to relieve pain, retard the effects of ageing or extend lifespan. The sometimes harsh realities of the ageing body may prompt older adults to consider treatments despite the lack of a scientific evidence base for their efficacy, with the most common source of information about CAMs coming from friends or the media, rather than research or health care professionals (AARP/NCCAM, 2011). Very few of these CAMs or CATs come without a price tag attached. Many older adults are struggling to manage their finances on a fixed and lower income than the one they enjoyed in their earlier employment years, particularly in light of increased costs in their later years, for items like prescription medicines, assistive mobility aids, home modifications, hearing aids, glasses and other new costs associated with adaptations to age-related changes in their bodies (AIHW, 2007). With less discretionary income than their younger peers (AIHW, 2007), and higher health care costs (AIHW, 2007), the judicious spending of their health care dollars is paramount, and they have every right to demand of the health care profession that there be a solid evidence base of robust research for CAMs and CATs, rather than potentially exploitative marketing claims of ‘the fountain of youth.’ Health care professionals, particularly registered nurses who have high levels of credibility with the public and frequent contact with older adults accessing health care services, need to participate in the consumption and production of robust research (Vickers, 1997, as cited in Targ, 2003) that enables the health care industry to provide sound guidance and direction to health care consumers who want to optimize their own health with valid and efficacious therapies. One widely prevalent paradigm for evaluating the rigour of existing research and for advocating for the conduct and dissemination of high quality research to inform consumer and clinician decisions, is discussed further in the following section.

## **The Value of the Evidence Based Practice (EBP) Paradigm for Complementary Therapies**

The Evidence Based Practice (EBP) paradigm represents the standard of practice expected of health care professionals when considering the evidence available from research to assist them in choosing interventions to administer or recommend to their patients. While patient preference and clinician expertise are also considerations for the individual practitioner at the point of care for each client, the evidence based paradigm urges clinicians to stay abreast of the current and best evidence that research has provided (Sackett, Rosenberg, Gray, Haynes & Richardson, 1996). Similarly, the EBP paradigm urges clinicians to employ very specific and rigorous criteria to distinguish the weight of value to assign to often conflicting pieces of evidence from various research projects (National Health and Medical Research Council (NHMRC), 2000a; NHMRC 200b; NHMRC, 2009). The type of research consulted will be governed by the clinical question being posed. Qualitative research is well suited to describing the holistic experience of a client in undertaking a particular intervention or in managing a particular condition, or in providing early descriptive information regarding new phenomena that have not yet been well-researched (DeCenso, Guyatt & Ciliska, 2005). If however, the question is one of efficacy (i.e. is this particular nursing intervention effective in achieving this

desired clinical outcome for this particular type of client?) then the higher levels of the evidence hierarchy are best suited to provide the answer to a clinical question regarding efficacy (NHMRC, 2000a; NHMRC 200b; NHMRC, 2009), such as the one being posed in this present study.

All research methodologies provide important and distinctive information in advancing the discipline-specific knowledge base for nursing specifically (DeCenso, Guyatt & Ciliska,2005), as well as advancing the inter-disciplinary knowledge base for health professions in general. Knowledge can be constructed from all research paradigms (DeCenso, Guyatt & Ciliska,2005), and blended at the point of care to arrive at individualised plans of care for each unique individual. But the component of that knowledge construction regarding the efficacy of a particular intervention to achieve the therapeutic outcomes desired by the client and their health care team, can best be judged according to the evidence-based paradigm (NHMRC, 2009). Such criteria-based critiquing of individual research studies most typically is undertaken by research consumers after the research has been completed. However, in the quest to create reliable new knowledge regarding efficacy, those same criteria that are used to judge the weight of a piece of evidence from a completed research study, can also be usefully employed in the design phase, when planning a future research project. When the future project being designed is intended to fill the identified pre-existing gaps in the body of knowledge regarding efficacy, by providing a rigorous piece of research that can withstand the scrutiny of the lens of the EBP paradigm, then the evidence base is strengthened, clarified and progressed. Such a strengthened evidence base serves as a better tool for clinicians to consult at the point of care, as part of their expert decision-making process of how to address each client's unique presentation, in order to better achieve the goals of treatment that have been arrived at through consensus between clinician and client.

The hierarchy of evidence assigns greater evidentiary weight to those research designs that are conducted in such a way as to minimize the threats to internal validity, meaning that the causal link between the intervention and its beneficial effect is clearly elucidated and is unlikely to be attributable to some other systematic distinction between the intervention group and the control group (NHMRC, 2000a; NHMRC 200b; NHMRC, 2009). The more rigorous the research, the greater confidence a practitioner can have that a treatment will achieve the desired beneficial effect. In the EBP paradigm, the randomised controlled trial (RCT), preferably with blinding of both the provider as well as the client whenever possible, is considered the most robust design for an individual research study. Similarly a systematic review of multiple high quality RCTs that all provide congruent evidence of the intervention's efficacy to achieve the desired treatment outcome is the pinnacle of evidence (NHMRC, 2000a; NHMRC 200b; NHMRC, 2009).

Unfortunately, for many nursing interventions, the evidence base does not exist at this pinnacle level, and therefore lower levels of evidence have to be consulted to make a determination of treatment recommendations for patients. Many complementary medicines and therapies also lack high level evidence. There exists a clear gap in the evidence base, so the EBP paradigm would recommend that evolving systematic programs of research should strive to fill that gap, as evidenced by the statement of the National Institutes of Health (NIH) Panel Report on CAM Research Methodology, which states "the underlying assumptions are that:

- Research is always feasible-and essential, regardless of the therapy under consideration

- Research rarely provides unequivocal answers
- Good research aims to minimize the effects of bias, chance variation and confounding
- Our priority is research that investigates whether treatments do more good than harm.” (Vickers, 1997, as cited in Targ, 2003, p.326).

Yet a counterbalancing tension against the EBP paradigm also exists. The reasons for this tension are many. The most basic reason is that many complementary therapists point to the positive feedback they receive from their own clients, who continue to return for additional treatment, and they are satisfied with this level of anecdotal evidence, as are their existing clients (Murcott, 2005). These CAM/CAT providers may also take exception to what they perceived as a reductionist method of measuring isolated units of health that is foremost in the RCT design, and feel that such a reductionist approach is fundamentally opposed to their own holistic approach to client treatment (Murcott, 2005). Others take ethical exception to a study design that denies a potentially beneficial therapy to a group of clients in the control group, or that requires the use of deception by not disclosing to a client in a placebo control group that they are in fact, in the group receiving only the placebo (Murcott, 2005). Still other CAM/CAT providers feel that it is not logistically possible to credibly simulate their particular CAT, or to provide an inert version of it, thus making the option of comparison to a placebo version of their CAT not feasible (Murcott, 2005). Many of the above philosophical arguments against the EBP paradigm and its reliance on the RCT, (particularly the ideal version of an RCT, the double-blinded placebo-controlled trial), have been expressed by CAM/CAT providers.

However, the EBP paradigm is not so easily dismissed. It is the language of the health care industry in which CAT providers function and deliver care. More importantly, it is also the language used by decision makers, both in government and in private health care insurance arenas. Without support for efficacy that aligns with the EBP paradigm, CATs are unlikely to receive funding from Medicare for public providers, nor from private insurers for private providers. If a CAT is truly effective, then its benefits will be denied to all but the rich and desperate, who have the discretionary funds to purchase their own CATs, and are willing to forego a body of evidence about its efficacy in hopes that it will work, at least for them, for now. Alternatively, if a CAT is actually not effective, or even harmful, the public will be denied this important information on which to base their spending decisions, and will instead continue to spend their limited health care dollars on treatments that are not helpful, rather than using those same funds for treatments that will in fact provide a clearly demonstrable benefit. In order to provide robust evidence that meets the criteria employed by the EBP paradigm, which can thus be influential to policy-makers, insurers, health care providers and consumers, this present study strives to create and execute a robust piece of evidence for a complementary therapy, for which placebo-controlled trials have been scant in the past. Such an undertaking is in accordance with the recommendations of the only systematic review of randomised controlled trials for Healing Touch (Anderson & Taylor, 2011), which found that many of the RCTs located were unable to be included in their systematic review as they were “inadequate in design, such as appropriate controls, blinding and adequate sample size, but promising enough to warrant further research” (p.226). They go on to state that “proper integration of biofield therapies such as Healing Touch in to the health care system requires scientific justification equal to more conventional therapies” (Forgues, 2009, as cited in Anderson & Taylor, 2011, p.226). Although this systematic review was not published until after the present study had been designed and conducted, their comments echo both the

concerns noted in the literature review in Chapter Two, and also the robust methodological features designed into the present study, as detailed in Chapter Three Methods.

The EBP paradigm's preference for a placebo-controlled trial strives to demonstrate efficacy of a treatment at a level that is statistically significantly different, and superior, than any efficacy demonstrated by a mere placebo. However, if a preponderance of evidence from multiple rigorous placebo-controlled trials demonstrates that a particular CAT is no more effective than a placebo, that finding in and of itself contributes to an interesting philosophical discussion. Some CAT providers feel that an ability to trigger a placebo effect is actually a therapeutically useful function of a CAT, even if the CAT does nothing further beyond triggering that placebo effect, as doing so can in itself result in an improvement in the client's status beyond what had been previously achieved by standard care alone, thus providing the client with much needed relief that is literally better than nothing (Murcott, 2005).

As professionals in the health care industry, the discipline of nursing is obligated to pursue rigorous research that protects the public and provides clients, insurers and policy makers with the best possible information on which to make well informed health care spending decisions, particularly in regards to nursing interventions. This present study will provide rigorous research to assist in clarifying the evidence base for the nursing intervention of the complementary therapy of Healing Touch, and to do so for an outcome measure of great importance and impact for the rapidly growing older population, that of functional independence in their ability to perform activities of daily living.

## **Aim of the research**

This aim of this study is to observe the effect of Healing Touch on the holistic health of older women living alone in the community, including cognitive, physical, emotional, spiritual, and particularly their functional health, which is often determined by the interactive effect of the status of the other above-stated health dimensions.

## **Research Question**

Will Healing Touch promote and maintain the health status of older women in the community by preventing, delaying or minimizing functional decline?

## **Null Hypothesis**

The experimental group and the placebo group will experience the same level of functional decline over the course of the study.

## **Alternative Hypothesis**

The experimental group will experience a clinically relevant and statistically significantly smaller amount of functional decline than the placebo group, by at least one unit on the scale of the chosen instrument for measuring functional ability to perform activities of daily living.

## **Chapter Summary**

This chapter has provided the background for the research study that was conducted for this doctoral dissertation. The chapter began with a discussion of the problem of functional decline in the rapidly growing older adult population, and its impact on the individual, their family and the health care industry. A brief introduction to some key studies regarding the potential benefit of Healing Touch in preventing functional decline was presented next. Healing Touch was then described in detail, including its historical development, a description of the administration of this complementary therapy, and the underlying theoretical premise of energy medicine. The discussion turned next to a consideration of complementary therapies and the high consumer demand for them that is not matched by a commensurate evidence base. The EBP paradigm was discussed next, including contrasting opinions about its primacy in the health care arena. The EBP framework guided the design of this present study, leading to the final section, which stated the research aim, question and hypothesis.

## **CHAPTER TWO: A Review of the Literature regarding Healing Touch**

## Introduction

The purpose and process of this literature review will be delineated first, followed by a discussion of the scope and structure utilized herein. Then a summary of existing research about Healing Touch will be structured and presented according to a composite framework based primarily on the Levels of Evidence as defined by the National Health and Medical Research Centre of Australia (NHMRC, 1999; NHMRC, 2009). Lastly, an analysis of key methodological features of previous research will be presented, given that the analysis informed the decisions about optimizing methodological rigour in this present study. Most of the research described below was undertaken by nurse researchers, either alone or in concert with other members of a multi-disciplinary health care research team, unless otherwise identified.

The purpose of the literature review presented in this chapter was to survey the body of research on Healing Touch to identify gaps in the body of evidence which might be addressed by the design and conduct of this present study, with the aim of providing a unique contribution to the field. While a brief critique of key features of some individual studies will be undertaken, the presentation of a full critical appraisal of all features for each individual study, such as that done in the preparation of clinical practice guidelines and systematic or integrated reviews, is beyond the scope of this literature review. Research studies were included if Healing Touch was identified as the intervention or independent variable in a quantitative study, or the key concept of interest in a qualitative study. The absence of substantive primary source information was deemed an exclusion criterion for the purposes of this review.

## Methods

Literature was obtained for this review through a number of processes, extending beyond published literature to include some primary sources of grey literature, such as unpublished master's theses or doctoral dissertations. The ProQuest database was accessed, using the search string "healing touch" with the limitations being English language only and no book reviews, up to mid 2008, when the study was designed. No date restriction was used to restrict eligibility, with all older studies accepted. In addition, Wardell and Weymouth (2004) presented a narrative literature review of Healing Touch research to date, and ancestry searching was performed on all sources cited in that publication. A number of the studies discussed by Wardell and Weymouth (2004) were not formally published in professional journals, and the only available information for some of them consisted of an incomplete secondary source (usually an abstract published in the biennial Research Survey self-published by the professional organization, Healing Touch International). When primary sources were available, including master's theses and doctoral dissertations, these were obtained, reviewed and included. In most cases the thesis formed the source of information, but if later journal publication(s) regarding the same study were available, these were also accessed and reviewed.

In addition, the ongoing bibliography available on the Healing Touch International (HTI) website was used to locate any primary sources through a hand search of the references cited by HTI. Many of these sources were informal, non-academic publications such as media

coverage in the popular press, or in health care institution newsletters. As primary sources were obtained through the above processes, ancestry searching was performed on each of the reference lists of these primary sources, to discover any other further pertinent primary sources. All quantitative studies located during the initial literature review in 2008 were appraised using the worksheets from the System for the Unified Management, Assessment and Review of Information (SUMARI) tool from the Joanna Briggs Institute (JBI) for Evidence-Based Practice (Pearson, Laschinger, Porritt, Jordan, Tucker & Long, 2007). The intention was to provide a critical review of the literature from which to inform the design of this present study, rather than presenting a systematic review; therefore, no meta-analysis or additional analyses were performed.

The above lengthy processes were necessary to ensure that all primary source publications about Healing Touch research were identified, as some may have been published in less well-known journals that are not included in conventional collections captured through database search programs. The above search strategies produced a substantial number of publications regarding Healing Touch, but only 35 of those were reporting on formal studies, including one narrative review, 10 qualitative and 24 quantitative research studies. This initial literature review informed the design of the present study, and the presence of only one randomised placebo-controlled trial in the literature to date in mid 2008 (Cook, Guerrerio & Slater, 2004) prompted the decision to structure the present study as an RCT with a placebo as the control group for comparison.

## **Structure of literature review**

The literature review is presented according to a synthesized framework of Levels of Evidence, starting with an overview table that presents all publications located and mapped against the evidence hierarchy. The chapter will then move in to a discussion of the studies, progressing further up the evidence hierarchy as the chapter continues, noting methodological limitations within studies, in order to inform the design of the present study.

The evidence hierarchy is conceptualised somewhat differently by various sources. The framework used as the organising structure for this literature review is primarily based on the numeric levels of evidence and glossary definitions as per the National Health and Medical Research Centre (NHMRC), specifically for the purpose of evaluating the evidence-base for an intervention, as opposed to those definitions of levels of evidence recommended to evaluate the evidence base for diagnostic accuracy, prognosis, aetiology or screening interventions (NHMRC, 2009, Table 3, p. 15). Numeric levels of evidence in this schema are determined based upon study design, while other criteria for assessing other aspects of study quality, besides the study design itself, are further detailed in related NHMRC checklists specific to each category of studies, i.e. intervention studies (NHMRC, 2009).

It is acknowledged that any given research study can be of poor or high quality due to other factors besides the study design, and frameworks from other sources attempt to blend these other quality parameters, along with the level of evidence based upon the basic study design, thus resulting in varying definitions for “Level 1 evidence” where not only the type of study but also its quality or other characteristics can result in a different numeric level ranking. In the NHMRC literature, these additional aspects are instead considered and synthesized through the process of completing an Evidence Matrix, which then leads to the generation of an alphabetically ranked level of recommendations for practice (NHMRC, 2009, p. 8). These

recommendations resulting from the body of evidence matrix are based not only on the level of evidence as dictated by the study design, but also on the quality of the studies, the consistency of their findings, clinical impact, generalisability and applicability (NHMRC, 2009).

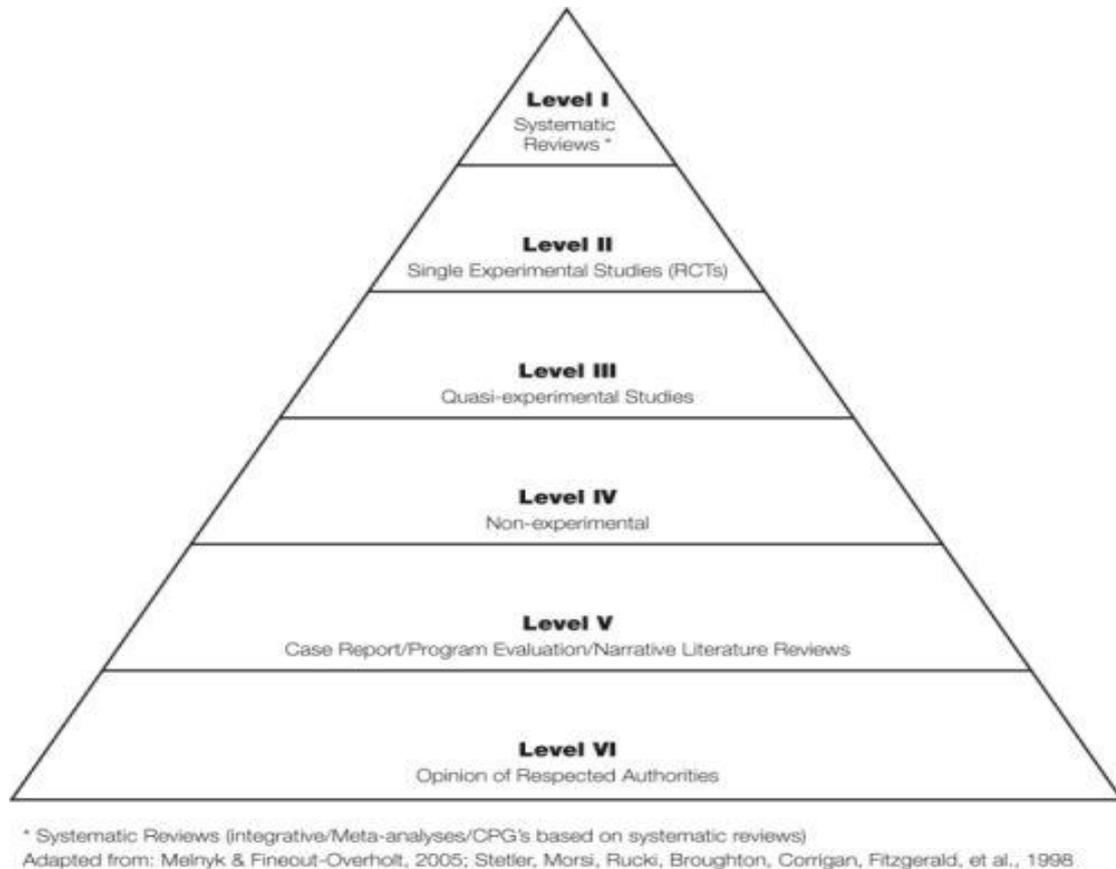
For ease of reference, primarily the NHMRC Level of Evidence Hierarchy will be used to sequence the presentation of studies in this chapter, although other aspects of study quality will be critiqued and summarized, particularly for other RCTs (Level II evidence). The quality assessment beyond basic study design was fully addressed in the preparation of this literature review, as all quantitative studies located during the initial literature review in 2008 were appraised using the SUMARI tool from the Joanna Briggs Institute (JBI) for Evidence-Based Practice (Pearson, Laschinger, Porritt, Jordan, Tucker & Long, 2007). In addition, the NHMRC checklist for appraising the quality of studies of interventions (NHMRC, 2000a, Box 6.1, pg 45) was also consulted in reporting this literature review. The noted limitations from previous studies reviewed were then minimised or removed in the design of this present study, whenever possible, and similarly, the noted strengths in prior studies were replicated, whenever possible, within the constraints of the student researcher context.

A brief summary of the qualitative research will also be presented, including formal research on multiple patients, and published accounts of individual case studies, despite these sources of evidence being excluded in the NHMRC schema. The decision to include qualitative studies in this literature review is based on two considerations. Firstly, the body of qualitative evidence provides a broader context for methodological considerations in the design of this present study, in particular to inform the choice of outcome measures, which is an appropriate contribution of qualitative studies in an evolving program of research (DeCenso, Guyatt & Ciliska, 2005). Secondly, qualitative research and expert opinion can be useful sources of evidence in their own right, particularly in the discipline of nursing (DeCenso, Guyatt & Ciliska, 2005), where many nursing interventions have not yet been scrutinized by quantitative methods and/or where health outcomes of interest represent complex phenomenon that are not always able to be easily reduced to measurable units.

The synthesized framework for levels of evidence used to structure this chapter also draws from the evidence hierarchy used by the Joanna Briggs Institute in order to appropriately situate the qualitative findings that will be included for the reasons stated above (<http://www.joannabriggs.edu.au/Levels%20of%20Evidence%20%20FAME>). The JBI framework represents a broader and more inclusive model than the NHMRC schema for design-based Levels of Evidence, but also attempts to integrate other aspects of research quality besides merely the design of the study in its FAME matrix (Feasibility, Applicability, Meaningfulness, Effectiveness and Economic evidence). Within the JBI framework of FAME, a single qualitative study of high quality or a meta-synthesis of text/opinion with credible synthesised findings are ranked as Level 3 evidence in the columns for feasibility, appropriateness and meaningfulness. However, these sources are not included at all in their column for effectiveness, the column most analogous to the NHMRC schema. Drawing from the JBI framework, an argument could be put forward to include qualitative research and to situate it at a Level 3.

The third and final source used to create the synthesized framework used to structure this chapter draws from the evidence pyramid pictured below, which is used by the Hartford Institute for Geriatric Nursing ([http://consultgerirn.org/evidence-based\\_practice](http://consultgerirn.org/evidence-based_practice)), who reprinted it on their website with permission from Levin, Singleton & Jacobs (2008) as cited in

Capezuti, Zwicker, Mezey & Fulmer, (Eds.) (2011). This schema incorporates and ranks the less rigorous study designs that are excluded by the NHMRC, while at the same time avoiding the more complex matrix approach that is undertaken by JBI. In doing so, this framework adds two additional tiers of evidence: Level 5 and Level 6. The Hartford framework's definitions of Levels 1 through 4 are congruent with the NHMRC levels, although they do not provide the sub-level specificity that is present in the NHMRC schema.



**Figure 1. Levels of quantitative evidence**

Reprinted here and on the Hartford Institute for Geriatric Nursing website with permission from Springer Publishing Company, New York, USA. (see Appendix E) from Levin, R.F., Singleton, J.K., Jacobs, S.K. (2008) as cited in Capezuti, Zwicker, Mezey & Fulmer, (Eds.) (2011) Evidence-based geriatric nursing protocols for best practice, 4th edition. Chapter One, Figure 1.2, "Levels of quantitative evidence" page 8.

Although not specifically stated, most qualitative methodologies would appear to fit in to the Hartford Institute's Level V tier, given that qualitative research on a group of people could be reasonably expected to provide descriptive data that is at least equal to or more credible than the evidence provided by a single descriptive case report of an individual client (National Cancer Institute, 2010).

Hartford also ranks program evaluation evidence at Level V, which relates to a group of individuals receiving a service or intervention through a program, with the success of the program being evaluated by the collection of either quantitative and/or qualitative data. When an intervention is performed and qualitative data are collected after the intervention

occurs, as is the case in most existing qualitative studies of Healing Touch, then this qualitative research process is similar to program evaluation, although program evaluation often provides numeric data as well as descriptive textual data. Program evaluation tends to focus on the effectiveness and/or efficiency of a particular program, policy or process. While it is a systematic process, it tends to be oriented toward achieving outcomes for a wider circle of stakeholders than those normally affected in the sample observed in a qualitative study.

Therefore the formal methods used to ensure credibility in qualitative studies, for both small and moderate sample sizes, would position the evidence obtained from a well-conducted qualitative study at the Level V tier in the Hartford framework, inferior to program evaluation with its tendency to collect quantifiable data, yet superior to descriptive case reports that focus only on a textual description of the response of an individual client to an intervention or a description of their course of illness over time. These considerations would result in a ranking of V-3 for qualitative research in the Hartford schema.

After consideration of the above potentially complementary frameworks, the Principal Investigator (PI) has drawn from each of them to construct the synthesized framework shown in Table 1, which represents an amalgamation of the NHMRC, JBI and Hartford Institute’s schema. This synthesized framework has been mapped against an overview of the studies regarding Healing Touch that were located in the preparation of this literature review in 2008. In addition, an updated literature review conducted in 2012 is included as Appendix A, and the table below is similarly updated to include the additional 14 studies found in the 2012 updated literature review, presented as Table 63, within Appendix A.

**Table 1. Levels of Evidence mapped against studies of Healing Touch as of mid 2008**

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication
I	Systematic Review	0		
II	Randomised controlled trial (RCT)			
<b>Level II: RCT, Two parallel arm designs:</b>		5		
	Healing Touch vs. Placebo	1	Healing Touch vs Placebo	Cook, Guerrero & Slater, 2004
	Healing Touch vs. Standard Care	1	Healing touch vs Standard Care	Ziembroski, Gilbert, Bossarte, & Guldborg., 2003
	Healing Touch vs An active comparator	3	HT with music playing vs. Rest with music playing	Taylor, B., 2001
			HT vs Guided Progressive Relaxation	Wardell, Rintala, Duan & Tan, 2006

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication	
			HT vs. Being read to from Big Book of Alcoholics Anonymous	Dubrey, 2006	
<b>Level II: RCT, three or more parallel arm designs</b>					
5					
Healing Touch vs. standard care (std) vs. active comparator(s)		4	Std or massage	Silva, 1992; Silva, 1996	
			Std or acupuncture	Kaye, et al., 2003	
			Std care or off-site prayer or imagery or stress relaxation	Krucoff, et al., 2001; Seskevich et al., 2004 (MANTRA I -- pilot)	
			Std or prayer alone or MIT alone or both prayer & MIT (MIT = music, imagery and Healing Touch)	Krucoff et al., 2005 (MANTRA II)	
			Std or visitor	MacIntyre et al., 2008	
Healing Touch vs. Two or more active comparators		1	Massage or Supportive visit	Rexilius, Mundt, Megel & Agrawal, 2002	
<b>Level II: Crossover RCTs</b>					
3					
Level II: Crossover RCTs		1	Randomised in to either HT group or Wait list control group, who then went on to also have HT next.	Wheeler Robins, 1999	
			1	HT or Massage or Rest with presence (Also modified crossover: randomised in to 2 sequences: standard care then intervention vs intervention then standard care)	Post-White, et al., 2003
			1	HT or coaching or both or neither (i.e. standard care). Wait list control group, who then got either HT or coaching	Dowd, Kolcaba, Steiner & Fashinpaur, 2007
<b>III-1</b>	Pseudo-randomised controlled trial	0			

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication
<b>III-2 Comparative study with concurrent controls</b>	Non-randomised experimental trial	2	HT vs Chiropractic	Weymouth, 1999
			HT vs Standard care	Wang & Hermann, 2006
	Cohort study	0		
	Case control study	0		
	Interrupted time series with a control group	0		
<b>III-3 Comparative study without concurrent controls</b>	Historical control study	0		
	Two or more single arm study	0		
	Interrupted time series without a parallel control group	0		
<b>IV Case series with either post-test or pre-test/post-test outcomes</b>	IV-1 Case Series: pre-test/post-test	1 group, 3 consecutive conditions	Randomised into different sequences of 3 sequential conditions: HT, sham HT & interview re their chronic pain.	Slater, 1996
	10	3	All had in same order: 1: Rest w/CHTP in room; 2: Healing Touch; 3, 4, 5, 6: Healing Touch with music & guided imagery	Wilkinson, et al., 2002
			All had in same order: 1: Rest w/ RA at Univ. 2: Rest w/ CHTP @ her private practice room. 3, 4, 5, 6: Healing Touch @ CHTP's private practice room.	Wilkinson, 2004
			1 group, 1 condition	1 group, 1 condition (Healing Touch)
	3	3		Kemper et al., 2006
				Maville, Bowen & Benham, 2008

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication
	IV-2 Case series: post-test only	2	n/a	Collinge, Wentworth & Sabo, 2005
			n/a	Dowd et al., 2006
	IV-3 Qualitative studies (case series: post-test only, but collected data consists of textual data, not numeric data)	Refer below to Level V-3	n/a	
V-1	Narrative Literature Review	1	n/a	Wardell & Weymouth, 2004
V-2	Program evaluation reports	13	Queens' Medical Center	Walker & Irvine, 1997
			The Toledo hospital, Toledo, Ohio	Villaire, 1999
			Naval Medical Center, San Diego, California	Hess, 1999
			Fairview Univ. Med Ctr & Queen's Hospital	Umbreit, 2000
			No. Hawaii Cmty Hosp	Becker, 2000
			Boca Raton Cmty Hosp, Boca Raton, FL	Chilton, 2001
			Scripps Center for Integrative Medicine, San Diego, California	Edelblute, 2003; Kiesling, 2004; King, 2005; Gazella, 2005; Mason, 2006
			Health East Care System, Minnesota	Svendsen & Bolles, 2005
			Wake Forest Uni Baptist Med Ctr	Larrimore, 2006
			Grant Medical Center, Columbus, Ohio	Galewitz, 2007
			New York Univ Med Ctr	Rodrigues, 2007
Suburban hospital, Bethesda, Maryland	Pierce, 2007			

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication
			Greenwich Hospital, Greenwich, Connecticut	Blanchet, 2008
V-3	Qualitative studies about patients receiving Healing Touch	10	n/a	Moreland, 1997
				Cristiano, 1997
				Holbrook, 1998
				Kelly, 1999
				Wardell, 2000
				Kopecki, 2001
				Tatsumura, 2003
				Van Aken, 2004; Van Aken & Taylor, 2010
				Ka'oppua, Gotay & Boehm, 2007
Peck, 2007				
V-3	Qualitative studies about <u>practitioners</u> of Healing Touch	7	n/a	Engebretson, 1996
				Geddes, 1999
				D'Eramo et al., 2001
				Wardell, 2001; Wardell & Engebretson, 2006
				Weymouth, 2004
				Miller & Rudenick, 2006
Sharoff, 2008				
V-4	Descriptive case reports of individual patient(s)	11	n/a	Wetzel, 1993
				Ercums, 1998
				Chapman, 1998
				Umbreit, 2000
				Weber, 2003
				Slater, 2004
				Guarneri & King, 2005
				Burr, 2005
				Scandrett-Hibdon, 2005
				Kissinger & Kaczmarek, 2006
Wardell, Rintala & Tan, 2008				

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication
VI	Expert opinion	5	n/a	Mentgen, 1996
				Wardell & Mentgen, 1999
				Mentgen, 2000
				McSweeney, 1999
				Kemper, 2004

## Level VI: Expert Opinion

As mentioned in Chapter One, Healing Touch techniques from various recognized experts in the field of energy medicine were compiled into a continuing education program for registered nurses in 1989 by Janet Mentgen, who was a registered nurse, a nurse educator, and an energy healer herself. Early publications were expositions of the theory and practice of Healing Touch by Mentgen (1996, 1999) and others she had trained (Mentgen & Wardell, 1999; Wardell, 2000), explaining what Healing Touch involved as a nursing intervention, and discussing their experiences using the Healing Touch techniques in their own practice areas of midwifery (McSweeney, 1999), and of paediatrics (Kemper, 2004). McSweeney (1999) notes benefits for the baby and parents to include relaxation and stress reduction, while Kemper (2004) notes benefits of increased relaxation, diminished anxiety and pain, and enhanced sense of well-being, again for the child who is the patient as well as for their family. These publications have been classified as Level VI Expert Opinion in the table above.

## Level V Evidence: Case Reports, Program Evaluation reports, Qualitative Research and Narrative Literature Review

### Level V-4: Case Reports

Detailed case reports of individual clients began to appear in the literature as early as 1993, covering a wide range of conditions and demographic profiles, which will be briefly summarized in chronological order. These publications have been classified as Level V-4. Wetzel (1993) reported on a 24 year old Hispanic woman with an infected abdominal wound of 7cm by 4cm by 3cm following an emergency cesarean section, which healed completely within 6 weeks, while similar wounds in other patients required 16 weeks to heal. Ercums, Curtis and DeMilley (1998) reported on a male patient with Stevens-Johnson syndrome with tissue sloughing over 50% of his body resulting in severe pain, who verbalized that his experience of receiving daily Healing Touch treatments was pivotal in making a decision to 'stay and heal' versus desiring death as a means to escape the pain. He recovered and was discharged home.

Chapman (1998) used a case study methodology in her doctoral dissertation, where she delivers eight sessions of Healing Touch as part of spiritual-energetic psychotherapy to a 54 year old female RN with a history of sexual abuse, chronic inflammatory demyelinating polyneuropathy (CIDP) that developed after insertion of breast implants following a double mastectomy, and presenting with anxiety and stress 7/10 as she handled a divorce and a lawsuit regarding the implants. Benefits noted by the client and/or practitioner included relaxation, decrease in anxiety, a sense of release and forgiveness regarding the sexual abuse, deepening spiritual connections, improved physical status, the ability to set boundaries and a stronger sense of self.

Weber (2003) relates her own story of survival and recovery from the often fatal condition of necrotizing fasciitis, present in a thigh wound that extended 21 inches by 18 inches by 8 inches. Burr (2005) reported on a female emergency department nurse who suffered multiple trauma from a motorcycle accident, and then experienced chronic pain and persistent emotional issues after physical recovery had been completed. Upon completion of treatments over a period of months, she reported better sleep, relaxation, a quieting of her mind, feeling lighter, and a blunting of her chronic pain. Scandrett-Hibdon (2005) reported on a 49 year old woman with breast cancer post mastectomy and a later breast implant surgery, who felt the Healing Touch sessions helped her relax, cope and maintain a positive outlook, while physically her wound healed well and she required no opioid medications postoperatively. Guarneri and King (2005) reported on a young woman diagnosed with severe hypertension and anxiety who responded to one session of Healing Touch with reversal of her weak and pale presentation. Kissinger's narrative (2006) follows a 40 year old female attempting to conceive in the face of longstanding childhood fears of dying during childbirth, who went on to bear two children, despite a life-threatening post-partum haemorrhage with her first born.

Three other authors used the case study format, but presented a number of case studies within the same publication. Wardell, Rintala & Tan (2008) presented detailed and contrasting case studies from two of the patients in their quantitative study discussed later in this literature review. For these two spinal cord injured males with neuropathic pain, one of them found their series of 6 weekly Healing Touch treatments to be beneficial in pain relief, a sense of deep relaxation and improvement in sleep, while the other male did not perceive a benefit and was disappointed in his lack of pain relief. Umbreit (2000) reported on six different cases where patients in the acute care setting verbalized decreased anxiety; noted improved wound healing; decreased pain in conditions such as ruptured ovarian cyst, myasthenia gravis and status post lung cancer surgery; reduced leg cramps during sleep for an elderly man; reduced shortness of breath and anxiety in a patient with cor pulmonale, histiocytosis and pulmonary hypertension; and reduced agitation and restlessness in a case of a terminally ill patient with liver failure. Slater (2004) also reported on a number of clients she treated in her private practice following a severe tornado, outlining similarities in their presentations of being indecisive, unable to grasp and retain new information, unable to complete tasks, described as going around in circles, and an unstable gait and dizziness. They responded to their series of three Healing Touch treatments in similar ways, reporting "a balanced and steady walk, a mind able to grasp thoughts easily, stable emotions...." (Slater, 2004, p.91).

The repeated themes in these case study reports of beneficial effects regarding anxiety and pain reduction, onset of relaxation, as well as the variety of beneficial effects noted by patients with a wide range of physical conditions and situations informed the design of this present study in numerous ways. Firstly, in regards to treatment frequency, the decision was

made to include repeated treatments rather than a single session. Secondly, in regards to the choice of sample characteristics, the sample was not chosen based on any one particular disease state. And lastly, in regards to the choice of outcome measurements, a holistic approach representing multiple dimensions of health was selected.

### **Level V-3: Qualitative research**

Qualitative research in Healing Touch has focused both on the providers and recipients of the modality. Studies that focus on the practitioner's experience of learning Healing Touch and the impact their learning journey may have had on their own personal or professional development are beyond the scope of the literature review in this present study. Instead, the qualitative studies where the focus has been on the client receiving the modality of Healing Touch will be presented, again as brief summaries only, and in chronological order from oldest to most recent.

Moreland (1997) used a phenomenological approach to study six women with breast cancer receiving chemotherapy, who also received a Healing Touch technique (the chakra connection) with each treatment. The following three themes emerged:

The experience of receiving the chakra connection: 1. Is caring expressed as a partnership, a nurturing act and self care. 2. Creates altered consciousness of the passage of time, the surrounding environment, of thought and of the presence of the practitioner performing the care. 3. Is a holistic experience which involves physical, mental/emotional and spiritual dimensions. (p.4).

Cristiano (1997) used a phenomenological approach for her master's thesis and observed and interviewed three female cancer patients immediately after having a single Healing Touch session in their own homes. Participants reported a deep sense of relaxation, feeling safe and protected, trusting and feeling at one with the practitioner, and various physical sensations such as vibration, current, force and pulling. They also identified a spiritual aspect to the experience, by feeling a sense of something larger and more powerful than themselves, and deriving from that experience a sense of comfort and courage to face their own difficult situation with cancer.

Holbrook (1998) used phenomenology to study four women who described themselves as having a healing experience, which included receiving Healing Touch treatments. Six themes emerged: Life before healing; Reforming self; Healing is a process, a long slow process, a whole process; There are many paths to healing; Healing is becoming, accepting, being comfortable with self as one 'in process' and A prescription for healing.

Kelly (1999) also used phenomenology to study three females receiving one session of spiritual Healing Touch for her master's thesis, but she chose women over 65 experiencing chronic musculoskeletal pain, and delivered the treatment herself. Reported sensations and benefits were similar to Cristiano's participants (1997), but also included a transient increase in pain before the pain and other sensations dissipated. In addition, almost poetic descriptions of positive emotional and or spiritual experiences were mentioned by the participants, such as 'floating in air or on whipped cream,' and 'a feeling like sunshine' and 'a connection with the practitioner and the rest of the universe' (Kelly, 1999, p.82).

Wardell (2000) studied 12 participants with chronic pain who attended an advanced class to learn the specific advanced Healing Touch technique of Trauma Release, and experienced the

technique themselves during the class session. Immediately after completion of the treatment technique, the participants' comments included "nice, peace, balance, clear detail and feels good" (Wardell, 2000, p.25). When interviewed at least one month later, reports included variation from no change noted in chronic pain patterns for two participants; initial decrease in pain that later returned for another two participants; decrease in pain (2); and absence from pain (4).

Kopecki (2001) also used phenomenology to study three female breast cancer survivors regarding their experience of receiving Healing Touch as a woman diagnosed with breast cancer. Her study demonstrated similarities in methodology, and in the size and gender of her sample to the qualitative work by Cristiano (1997), Holbrook (1998) and Kelly (1999). Three essential themes emerged in Kopecki's study: "Unity/Connectedness/Belonging; Inner Wellness; and Getting Me Through/Keeping Me Going" (Kopecki, 2001, p.56).

Tatumura, Maskarinec, Shumay & Kakai (2003) interviewed 143 cancer patients two to three years after diagnosis regarding their use of conventional treatments, religious and spiritual resources (RSR) and of complementary and alternative medicine, including Healing Touch. Specific benefits attributed to Healing Touch included relaxation, reduction in nausea and boosting the immune system. CAMs in general were used by her substantial sample of participants for these purposes: to prevent cancer recurrence, as a substitute for conventional treatment and as a last resort.

In VanAken's doctoral dissertation (2004), she used grounded theory to study 15 clients with moderate depression who received a series of 6 Healing Touch treatments on a weekly basis. The following categories emerged as a four stage process: believing in the practitioner/self/future; integrating all aspects of self; accessing inner strength and resources; and engaging with life. The entire theory produced from her work elegantly captures many of the nuances of the process of healing and logically links the components together into intuitively congruent relationships, as seen in Figure 1 (VanAken & Taylor, 2010, p. 134), where the client is seen to be moving through the four stage process above from the initial sense of disconnection from others, environment and self, to the final process of emerging from depression.

Ka'opua, Gotay and Boehm (2007) used longitudinal interviews of 28 wives of long-term prostate cancer survivors for their qualitative study about the wives' use of spiritually-based resources (SBRs) for adaptation and coping. One of the four core areas identified was that of community connections and meaningful participations, which for some participants was expressed by being part of a community of other Healing Touch volunteers who provided Healing Touch treatments to cancer patients.

Peck (2007) studied 12 disabled adults or frail older adults receiving supportive care in the home, who received between 6 to 14 Healing Touch treatments. Participants noted onset of benefits such as improved functional ability with basic activities of daily living (ADLs) and Instrumental ADLs, improvements in sleeping and emotional well-being, and decreased pain, that occurred after their first treatment for four patients, after their third treatment (four patients), after their fifth treatment (two patients) and after their seventh treatment (two patients). When treatment was abruptly terminated due to loss of funding, only six of the 12 participants sustained their positive gains. Peck (2007) stressed the importance of planned closure, which had prevented adverse effects in prior pre-determined protocols with a known limit on number of treatments, and she also noted the paucity of research on dosing regimens

for Healing Touch treatments. Peck's work (2007) stimulated thinking for this present study, by suggesting both a population (frail older adults living in the community) and an outcome measure (functional ability), as well as highlighting the need for careful consideration of dosing decisions (number, frequency and duration of treatment sessions) and the sensitive management of closure when the treatment protocol has been completed.

## **Level V-2: Program Evaluation Reports**

Some of the literature located during database and hand searching were publications describing the implementation of an integrative therapy department or program in a health care service, with Healing Touch being one of the Complementary and Alternative Therapies (CATs) made available to clients. Descriptive textual data were the most common type provided. Program evaluation reports are classified as Level V evidence per the Hartford institute of Geriatric Nursing. Client responses were generally positive, with consumer demand often being the trigger for creating the integrative model (Blanchet, 2008; Pierce, 2007; Svendsen & Bolles, 2005). Two common strategies to overcome any resistance from colleagues unfamiliar with the modality was to provide sample Healing Touch sessions for staff and to provide overviews of the research base (King, 2005; Villaire, 1999). Most services were provided on a volunteer model, either by current health care facility employees (Umbreit, 2000), or by external volunteers, either health care professionals or lay persons. Sometimes Healing Touch sessions were provided by volunteers who were previous patients who had since recovered and were now eager to assist others with the same diagnosis to recuperate fully (Umbreit, 2000). These program evaluation reports highlighted some creative ways to continue to provide Healing Touch treatments upon cessation of a research protocol, to avoid concerns such as those noted by Peck above (2007). To that end, a patient-to-patient support group model was included as an option for participants in this present study in the final participant mail-out that also included results and group allocation disclosure.

## **Level V-1: Narrative Literature Review**

Wardell and Weymouth (2004) presented a review of research to date, and this publication was used for ancestry searching. Wardell and Weymouth sorted their review by populations and conditions (2004) rather than by study design or other aspects of methodological rigour, but they did note limitations, stating "the reviewer cannot determine whether studies were poorly designed, poorly conducted, or simply poorly reported" (p.153). Their inclusion criteria were broader than those used in the literature review to inform the design of this present study, as Wardell and Weymouth included many research projects where the only primary source of reporting was an abstract submitted to the Healing Touch International's self-published biennial research survey (2004). They noted the variety of conditions and populations for whom Healing Touch appeared to provide a beneficial effect, warranting further, more rigorous research, including replication of prior studies and more complete reporting of future research (2004). The conditions, effects and populations discussed included pain relief, cancer, immune disorders, cardiovascular disorders, post-operative recovery, undergraduate nursing students, paediatrics and the elderly.

Four studies of older adults were reviewed by Wardell and Weymouth (2004), two of which also met the inclusion criteria for this present study (Wang & Hermann, 1999 and Peck, Wypzynski and Hauser, 2001, as cited in Wardell & Weymouth, 2004, which was later

published as Peck et al, 2007). An additional two did not meet the criteria for inclusion in the literature review for this present study, due to lack of in depth primary source information: Gehlhaart & Dail, 2000, (as cited in Wardell & Weymouth, 2004), who found pain relief for five long term care residents; and Ostuni & Pietro, 2001, (as cited in Wardell & Weymouth, 2004), who studied 12 participants with Alzheimer's disease and found a statistically significant improvement in the Healing Touch group for all ten behaviours measured. These included appetite, sleep, orientation, compliance with daily routine, socialisation, emotional stability, nonverbal responses, conversational communication and freedom from jargon. Conversely, there were no improvements in any of the above areas for the control group. Similarly, composure scores and physical comfort scores also showed a statistically significant improvement for the Healing Touch group only, and not for the control group (Ostuni & Pietro, 2001, as cited in Wardell & Weymouth, 2004).

## **Level IV Evidence: Case Series**

### **Level IV-2: Case Series, Post Test Only**

Two studies were found that fit this tier of the evidence hierarchy, which represents the lowest level of quantitative evidence recognized by the NHMRC, and has been designated as a Level IV-3 in the synthesized framework being used for the literature review in this dissertation. The lack of a comparison group, the use of investigator-created instruments rather than established and well validated instruments, and the lack of homogeneity in the participants included in the sample were key limitations in both of these studies, and engendered a commitment to try to avoid these limitations in the design of this present study.

Collinge et al. (2005) worked with 25 clients of a mental health clinic with diagnoses of PTSD (10), depression (9) anxiety disorders (3) and dual diagnosis. They received an average of five treatment sessions of one CAT: 19 of whom received massage, three acupuncture, two Reiki and one Healing Touch (non-randomised). The group was evaluated as a whole and reported positive responses, rating their therapy as helpful at 8.6 on a range of 1 to 10. This perceived helpfulness was positively correlated with the number of sessions ( $r = 0.46$ ,  $p = 0.02$ , two tailed). Their psychotherapists reported concurrent breakthrough in therapy for previously non-progressive clients. Four investigator-created questions showed statistically significant improvements for issues like sensation of physical self and body shame, both particularly pertinent given that 10 of the clients had a history of sexual abuse.

Dowd et al.,(2006) also found correlations between measures on their investigator-created Healing Touch Comfort Questionnaire (HTCQ) and number of treatment sessions ( $p < 0.05$ ), but the correlation levelled off after 20 treatments. They used a convenience sample of 56 clients already under the care of a Certified Healing Touch Practitioner (CHTP), where the length and number of treatments were determined by the client and CHTP in a naturalistic context, rather than being dictated by a research protocol. Clients having had 1-4 sessions were compared to those having 5 or more sessions, with a difference of 13.7 points on their score on the HTCQ ( $p = 0.037$ ). The range of scores for their sample was 77 to 202, with strong internal consistency demonstrated by an alpha coefficient of 0.94. Clients had presented to the CHTP for diverse purposes such as pain relief, stress reduction, low energy, depression, emotional nurturance and increased focus.

## **Level IV-1: Case Series, Pre-test/Post-test, Single and Multiple Conditions**

### ***Case Series, Pre-test/Post-test: Single condition (Healing Touch)***

Three of the located studies used this design, which is also ranked as a Level IV in the NHMRC system (Darbonne & Fontenot, 1997; Kemper, Larrimore, Dozier & Woods, 2006; Maville, Bowen & Benham, 2008). While this study design is an improvement over a post-test only design as discussed above, the lack of a comparison or control group still renders this design vulnerable to numerous threats to internal validity, with any statistically significant changes from pre- to post-intervention being potentially attributable to the maturation effect, the Hawthorne effect, or the placebo effect, rather than due to the intervention. Small sample sizes may have lacked adequate power to detect beneficial effects, and the frequent use of investigator-created instruments rather than established and well-validated instruments also persisted at this level of evidence.

Darbonne & Fontenot (1997) studied 19 patients with chronic pain and used a single item VAS for chronic pain before and after each of 4 treatment sessions, but also used an established instrument, the Chronic Pain Experience Instrument, before and after the series of four treatments. A free text question also produced similar comments to those found by qualitative studies being done by her contemporaries (Cristiano, 1997; Holbrook, 1998; Kelly, 1999), such as relaxed, serene, peaceful, centred, balanced. All expected relationships showed statistical significance at  $p < 0.05$  or  $p < 0.01$ . Demonstrating greater methodological sophistication than most other quantitative studies at this time or later, Darbonne & Fontenot (1997) reported power and effect sizes as well: a power of 0.93 and effect size of 0.64 for the VAS, and a power of 0.93 and effect size of 0.58 for the CPEI. In this study, the shorter term and longer term measurements were congruent.

Kemper et al. (2006) studied eight medical students who participated in a semester-long course where they learned and practiced Healing Touch (among other) techniques on each other. The Maslach Burnout Inventory showed a statistically significant improvement over time on two subscales: Personal accomplishment and Optimism about future practice. Responses to the investigator-created Likert-style questions also showed significant improvement in indicators of holistic practice, such as their confidence in being peaceful, calming and reassuring during patient encounters in both noisy and quiet environments; and the use of centering, of intuition and of their hands to help the patient feel better.

Similarly, Maville, Bowen & Benham (2008) studied a convenience sample of 30 university students from the health care faculty who received one 30 minute Healing Touch session of two pre-determined techniques (Hands in Motion and Chakra Connection). The use of the well-established Spielberger State-Trait Anxiety Inventory and of objective physiological measurements improved the methodological rigour of this study. Both the State and Trait anxiety scales showed statistically significant decreases from pre- to post-treatment ( $p = .004$  and  $p < .001$  respectively), as did the systolic BP ( $p < .001$ ), and as did two of the four continuous physiological measurements (heart rate and skin temperature, in a direction indicative of decreased sympathetic tone). Skin conductance and surface electromyography did not show a statistically significant change.

### ***Case Series, Pre-test/Post-test, Multiple conditions***

Four more studies (Slater, 1996; Wilkinson et al., 2002; Wilkinson, 2004; Kemper, Fletch, Hamilton & McLean, 2009) also used the pre-experimental design of a single group with repeated measurements of the dependent variables of choice. However, in each of these next four studies, the researchers also added in the more methodologically complex feature of doing pre and post session measurements on sessions that were 'non-treatment' condition sessions, as well as doing them on the actual Healing Touch sessions. In two studies (Slater, 1996 and Wilkinson et al., 2002), sessions with other treatment modalities were administered as the comparative condition. Although no control or comparison group was used in these four studies, the participants were seen to operate as their own control in the non-treatment or alternative treatment conditions.

Slater (1996) compared 23 participants with chronic, non-malignant post-operative abdominal pain on their responses to a Healing Touch treatment, to a sham or mock version of a Healing Touch treatment, and to an interview regarding their experience of pain, as measured by the McGill Melzack Pain Questionnaire (MMPQ). All participants received all three conditions, but the sequence in which they received them was randomised. Participants showed a statistically significantly greater amount of reduction in pain for both the Healing Touch and sham treatments than they did for the interview treatment condition, for both the overall MMPQ and for most of its subscales. However, their responses were essentially similar between the real and the sham Healing Touch conditions, again for both the overall MMPQ and for most of its subscales. Slater (1996) noted that the sham treatments may not have been inert as intended, due to undisclosed prior energy therapy training and/or lack of adherence to the sham protocol by some of the sham providers.

Slater (1996) included a rich tapestry of qualitative findings presented in a case study matrix, which indicated that perceptions and sensations reported by both the recipients and the sham providers are surprisingly similar to those reported by the genuine Healing Touch providers and their recipients. Numerous implications for the provision of a placebo version of Healing Touch in this present study were gleaned from the rich methodological detail presented in the full dissertation obtained for Slater's landmark study (1996) and the discussion therein. The details of the execution of the sham Healing Touch intervention will be discussed in more detail in a later section in this literature review, as will issues of dosing for the intervention, which also were highlighted by Slater (1996) and continue as a prevailing methodological challenge in the body of evidence for Healing Touch.

Wilkinson et al. (2002) used a single group case series pre-test/post-test design, with exposure to multiple conditions in both her master's thesis (2002) and her doctoral dissertation (2004). For her master's thesis, 22 patients already under the care of a Healing Touch Practitioner (HTP) in private practice were exposed to three consecutive conditions: rest with the HTP sitting in the room (presence only condition); Healing Touch by the same HTP; and then Healing Touch with music and guided imagery. Each session was 30-45 minutes long, consisting of whatever Healing Touch techniques the HTP selected. Stress ratings and salivary secretory immunoglobulin A (IgA) levels were compared pre- to post-treatment. Comparisons were also made between participants receiving Healing Touch from more experienced versus less experienced providers, with a four-fold increase in the beneficial change in salivary IgA levels in the more experienced providers' clients ( $p < 0.0003$ ). Stress ratings improved in both the Healing Touch alone condition and the Healing Touch plus music and guided imagery

condition. Qualitative data for the Healing Touch conditions included changes in mood from a negative or neutral mood to a positive one, relaxation, a sense of connection with the practitioner and within self, and for half of the participants, pain relief. Both client and provider complaints were made regarding the constrained length of the session for the research protocol.

Wilkinson, Knox, Chatman, Johnson, Barbour, Myles and Reel (2002) extracted 11 items from the HEALTH tool (acronym not defined) previously developed and self-published by another Healing Touch researcher (Philby & Poznanski-Hutchison, 1997, as cited in Wilkinson et al, 2002). The 11 items were ones that Wilkinson felt represented a propensity towards being influenced by the placebo effect. In the findings, those participants that met their criteria as a positive responder to HT did not in fact differ on their scores on this abbreviated HEALTH tool, as compared to those participants who were non-responders. The conceptual justification for the excerpted 11 items is not well described, but they are listed and all pertain to self-care practices such as meditation, prayer, imagery, spiritual beliefs, having a spiritual director and spiritual development. This questionable use of the HEALTH tool items represents another attempt in what will come to be a series of predominantly failed attempts to address the placebo issue, either by prediction, measurement or design, in an ongoing attempt to address the difficulty of disproving a placebo effect for an intervention for which it is difficult to devise a credible yet inert placebo.

Wilkinson (2004) built on her earlier master's research for her doctoral study of 15 men with Human Immunodeficiency Virus (HIV), using a similar design of six sessions with three conditions: Condition 1: Rest for 30 minutes with a Research Assistant present in a quiet room at the university; Condition 2: Rest for 30 minutes with a Certified Healing Touch Practitioner (CHTP) sitting in her private practice room; Conditions 3, 4, 5, and 6: Healing Touch in CHTP's rooms for an unlimited time. Provider-patient dyads were maintained through the treatment series. No statistically significant differences were found on any of the outcome measures of salivary secretory IgA before and after each treatment or for the established instrument, the Functional Assessment of HIV Infection (FAHI), measured before and after the full series of Healing Touch treatments. The FAHI has sub-scales for physical well-being, emotional well-being, functional well-being, global well-being, social well-being and cognitive functioning, none of which demonstrated a statistically significant change from before to after the series of Healing Touch treatments. Wilkinson again (2004) attempts to overcome the pervasive critical claim of a mere placebo effect for any beneficial results from Healing Touch, by the use of an established instrument, the Working Alliance Inventory, which is completed both by the practitioner and the participant; and by the creation of the Health Practices and Beliefs Scale (HPBS). However, there were no clear patterns of prediction of placebo response by either instrument, with responders and non-responders scores falling across the full range of both instruments, defying a clear correlation.

The findings from the studies at this tier of the evidence hierarchy demonstrate a continued reliance on the visual analog scale (VAS) as an outcome measure, small sample sizes, and the lack of a control group, all of which are methodological features that limit the confidence that can be placed in the validity of the findings. In addition, beneficial findings from single-rating items such as a VAS collected immediately before and after the treatments can be seen at times to contrast with the lack of beneficial findings in the same study, when more sophisticated instruments are used to measure changes over a series of treatments. Perceived beneficial effects from Healing Touch may be more clearly identified by short term outcome

measurements rather than long term outcome measurements, and the collection of both is a methodological strength. To this end, the design of this present study included the use of outcome measurements taken immediately after treatment (vital signs and health ratings) as well as using established instruments to measure changes over the entire series of treatments.

### **Level III Evidence: Non-randomised experimental trials**

Two studies fit in to this tier of the evidence hierarchy, ranked as Level III-2 by NHMRC (Weymouth, 1999; Wang & Hermann, 2006). Methodological issues that become evident at this tier of the evidence hierarchy included appropriate statistical testing, responsible and complete reporting, and the careful choice of a control group. The use of an active comparator, such as chiropractic therapy in the first study below, will become a frequent issue during the progression up the evidence hierarchy in this literature review. The use of an active comparator can be seen as a strategy to address the Hawthorne effect, since both groups are receiving time and attention from a provider; and may also address the three key components of the placebo effect: contextual conditioning, expectation of benefit, and the therapeutic alliance (Murcott, 2005).

However, the use of an active comparator introduces another major methodological concern. Chiropractic treatment, or any chosen comparator, may not itself enjoy a solid evidence base yet, so having Healing Touch perform as well or better than chiropractic therapy does not appreciably advance our knowledge base. Perhaps both treatments are effective, but similarly so. Or perhaps both treatments are NOT effective, but similarly so. The ideal comparator is a placebo, where the client is blinded to group allocation, and thus believes they are receiving the active treatment, and therefore forms an expectation of benefit, with the powerful effect that such an expectation creates (Murcott, 2005).

Weymouth (1999) compared 16 participants with low back pain treated by chiropractic therapy versus Healing Touch in a pilot study for her master's thesis. Outcome measures included pain, range of motion, quality of life and orthopaedic tests, all of which were essentially similar between the two treatment groups. Both the Healing Touch group and the chiropractic group showed improvement after treatment. In a partial and modified crossover design, 4 of the 16 participants went on to receive the comparator treatment as well, and experienced further improvement, pointing to possible potentiating effects from concomitant multiple therapies.

Wang & Hermann (2006) separated their 14 male inpatients of a locked dementia unit according to their scores on the Cohen-Mansfield Agitation Inventory, an established instrument, rather than by randomisation. The shared inpatient setting provides an excellent control for numerous confounding variables, a clear methodological strength. The six higher scoring (more agitated) participants were assigned to receive daily 10 minute seated Healing Touch treatments for four weeks, using the techniques of Unruffling (later re-named to Hands in Motion) and Modified Mind Clearing, all delivered by the same practitioner with Level 4 training. The intervention group showed a statistically significant decline in agitation ( $p = 0.00104$ ), while the control group's scores slightly increased in that time frame. Reported statistical results only included the within group comparison for the intervention group, rather than comparisons of the change over treatment time for the intervention group versus the change for the control group. This omission was poorly justified in the report, with the illogical statement: "Because the control group was included in the study to allow for qualitative

comparison, only the results for the intervention group are tested.” (p.38). This omission defeats much of the purpose of this experimental design, essentially rendering it a case series pre-test/post-test Level IV-1 evidence. Whether due to statistical naivety or intentionally limited disclosure of results, it is disappointing that complementary therapy researchers give critics cause to distrust their scientific objectivity with this type of incomplete research reporting. While no qualitative comments from the comparison group are reported (contrary to their explanation above), participants in the intervention group reported similar comments as those noted in earlier qualitative research, with comments like “a blessing,” “wonderful” and “boy this feels good.”

The above two examples of Level III evidence mark a clear incremental stride forward in methodological strength from the single group before and after comparisons seen in the case series designs discussed above, albeit with other limitations remaining, as have been highlighted. Despite these limitations, the stronger between-group comparisons distinctive for the above two experimental designs that include a control group of any type, allow for greater confidence in findings, by removing key threats to internal validity. However, the pivotal strength of randomization in to treatment groups marks the dividing line between Level III evidence and the highest level available for a single study to achieve, that of Level II, the Randomised Controlled Trial (RCT).

## **Level II Evidence: Randomised Controlled Trials (RCTs)**

This section of Level II evidence represents the most robust evidence available for Healing Touch as an intervention. While the next 13 studies all qualify as RCTs, there are varying levels of adherence to other criteria of research quality besides study design, and these criteria will be addressed and critiqued. The methodology of this present study was informed by a careful appraisal of the existing body of evidence at the Level II tier of RCTs, with an intention to retain and duplicate methodological strengths displayed therein, while at the same time attempting to minimize or remove methodological shortcomings as they were noted in the RCTs located during the proposal stage of this dissertation.

### **Crossover RCTs (3 studies)**

Three studies used a randomised crossover design, where participants were randomised in to separate treatment groups at the beginning of the study, but then some of the participants (usually those randomised to the control group of standard care), then went on to receive a second (active) comparator treatment. The NHMRC (2009) still ranks these crossover designs as Level II RCTs, but caution in interpretation is necessary, given the lack of parallel progression through the study’s time frame, which can introduce a maturation effect or historical effect for the group being moved through two different comparison treatments. In addition, if participants are being crossed over from an active comparator to another active comparator, the residual effects of the first treatment may negate or potentiate the effects of the second treatment, as seen above in Weymouth’s study (1999) where non-randomised participants were crossed over from one treatment to another and continued to experience further improvement.

However, the crossover design also has a number of advantages. Firstly, it can be a way to increase the statistical power to detect a difference between treatments when the number of available and suitable individuals who meet the inclusion criteria may be limited. In addition,

this design allows the researcher to offer (eventually) some type of treatment to each participant. Due to that appealing feature, a crossover design can create good will for the study amongst the population being targeted for recruitment, and among referral sources such as industry partners; it can also stem some of the attrition commonly experienced in higher proportions amongst the standard care group members, who may be feeling disappointed and/or neglected upon notification of their allocation in to standard care; it can therefore increase the effective sample size available for data analysis; and it can ease the regrets of a research team that may be uncomfortable denying treatment to some participants.

Wheeler Robins (1999) was the first to use a pure crossover RCT design, although Slater's work (1996) did use randomisation to decide the sequences of treatment conditions, but all participants in her sample received all three conditions, as described above. In Wheeler Robins doctoral study (1999), half of her sample of 27 males with HIV disease were randomised in to the Healing Touch treatment group, while the others received standard care for 4 weeks as a wait list control group, before being progressed in to a four week treatment series of Healing Touch. The same Level 4 trained providers followed their clients through the entire 4 week series of weekly treatments. Each 20-30 minute session consisted of the Chakra Connection technique only and was performed in a standard private hospital room at the General Research Centre at the University hospital. Outcome measures pre/post each HT session consisted of a radial pulse and the FACES scale. Other outcome measures were done before and after the entire 4 week series of treatment, including physiological measurements (serum serotonin, salivary DHEA, salivary cortisol, and a battery of serum immunocompetence indicators including cytokines); and four psychological measures: the General Well-Being schedule, the short version of the Profile of Mood States (POMS), the Impact of Events Scale (IES), and the Human Field Image Metaphor Scale (HFIMS). Despite the multiple measures above, some of which also had sub-scales, there were no pertinent statistically significant findings and thus all of the null hypotheses were retained.

Post-White, Kinney, Savik, Gau, Wilcox and Lerner (2003) studied 164 predominantly female cancer patients receiving chemotherapy, who were randomised in to sequences first (either standard care followed by intervention, or intervention followed by standard care). They were then further randomised into either Healing Touch only, massage only, or presence only. The standard care group attended hospital for measurements, but did not wait for the 45 minutes treatment time to elapse; instead, pre-treatment measurements were taken as post-treatment measurements too. This assumption overlooks the effect of the passage of time, and represents a minor methodological concession in an otherwise robust study design. The Presence only group rested on a massage table for 45 minutes with a provider present, and occasional conversation occurred, again representing a potentially different active comparator than silent presence. The massage therapy (MT) group received 45 minutes of defined strokes of Swedish massage with a standard gel. The Healing Touch (HT) group received a 45 minutes session of any techniques from Levels 1 through 3 of the curriculum, chosen by the provider after an energetic assessment, in keeping with an authentic Healing Touch practice outside of a research protocol. Statistical techniques ruled out sequence effects for most outcome measures, and data were limited to the first allocated condition for the two measures where statistical modelling indicated that sequencing may have had an impact (ondanestron use and pain interference). Other outcome measures included vital signs, a numeric ranking of pain and of nausea, Profile of Mood States (POMS), a Brief Pain Index and a Brief Nausea Index.

For the immediate post-session effects in Post-White et al, (2003), both MT and HT, as compared to the standard care group, reduced respiratory rate and pulse rate, as well as reducing systolic and diastolic blood pressure and pain. In contrast, the Presence group only showed decreased pulse and respiratory rate when compared to the standard care group. For effects over the whole series of treatments, the combined group of all 3 interventions, as compared to the control group, showed a decreased total mood disturbance over time, as measured by the POMS. When each intervention group was individually compared to the standard care group, both HT and MT reduced total mood disturbance and fatigue, and MT also reduced anxiety.

Qualitative data for the HT participants in Post-White et al (2003) included comments such as "I believe it helped greatly with my symptoms for 2 or 3 days out." Positive reports of pain relief, nausea relief, improved sleep and reduced tension were also noted. These qualitative comments are again in contrast with the absence of statistically significant differences on the quantitative measures of nausea and pain, and the discrepancy is more perplexing in this reasonably sized sample where an under powered design is not as likely of an explanation. However, given that the participants were not blinded to treatment group allocation, the placebo response is a legitimate alternative explanation for their perceived benefits in the qualitative data. In summary, Post-White et al.'s study (2003) was well reported, demonstrated strong methodological rigour and supported the effectiveness of HT in lowering pulse, respiration, systolic and diastolic blood pressure; reducing pain; reducing mood disturbance and reducing fatigue.

Dowd, Kolcaba, Steiner & Fashinpaur, (2007) used a similar wait list control group as did Wheeler Robins (1999) for their randomised crossover study of 52 university students. They were randomised to receive either Healing Touch, stress management coaching, both or neither (the control group). The control group participants were later progressed in to either the coaching only or the Healing Touch only group, per their preference, which introduced a potential confounding variable of self-selection bias. The Healing Touch group received a 15 to 20 minute session each week for three weeks at the University health centre by the same nurse performing the coaching intervention, which controls an additional variable by stabilizing the constancy of providers. A numeric 1-10 rating of stress and another of comfort was done before and after each intervention session. In addition, a longer 32 item written survey instrument called The Stress Test (ST) and a 35 item written instrument entitled The Healing Touch Comfort Questionnaire (HTCQ) were also administered at baseline, before the first intervention, immediately before the third intervention and 1 week after completion of the 3 week treatment protocol.

All 3 intervention groups demonstrated statistically significant changes ( $p=0.0001$ ) in the expected directions for both stress and comfort, when comparing the numeric rating post-session scores to the pre-sessions scores. The incremental improvement was greater in the HT group than in the coaching group. All of the groups showed no statistically significant difference in their mean scores on either the HTCQ or the ST at baseline, but their mean scores on the HTCQ improved for all three intervention groups (as compared to the wait list control group), at the midpoint testing and remained elevated at the final measurement one week after treatment concluded, with both time points reaching statistical significance ( $p = .01$ ). None of the 3 interventions showed greater efficacy than any of the other intervention arms in increasing comfort as per the HTCQ. The results on the ST were in the expected direction but did not reach statistical significance.

### **Three parallel arms RCTs (6 studies)**

The next group of studies all used a design whereby HT was compared to other intervention(s), rather than compared only to a standard care group. These designs are in part a response to the criticism of the lack of a placebo group in HT research. The premise is that if the comparison group is offered another intervention whereby there is a provider present in the room, either just sitting with the patient (the “presence only” intervention already seen above) or present and delivering another intervention, then a statistically significantly better outcome for the HT participant is postulated to be less likely to be attributable to a placebo effect only, than if the HT group is compared to a “standard care only” group. The selection of the substitute placebo treatment varies widely. In some cases, the placebo substitute chosen is a bona fide intervention in its own right, leading to difficulties in interpretation of results.

While this design does help offset the Hawthorne effect, in that participants are getting some attention and a relationship with a provider; in all of these designs, the participant is not blinded to the intervention being provided, and thus is fully aware that they are not in fact receiving Healing Touch as their intervention. Therefore, the possibility of the placebo effect is still a viable argument as an alternative explanation for any beneficial outcomes found in the HT group in these studies. As discussed earlier, this introduces a logical conundrum, as Healing Touch may be similarly effective or similarly ineffective as the active comparator used in the design. In these studies, the active comparators were other complementary therapies, which do not enjoy a robust evidence base themselves, so gathering information about whether Healing Touch performs as well, better or worse than an unknown standard is of questionable usefulness in building the evidence base. The best way to design out the competing hypothesis of the placebo effect is to design the study to compare the intervention to a credible but inert placebo version of the intervention.

### ***Healing Touch versus two or more active comparators (1 study)***

Rexilius, Mundt, Megel and Agrawal (2002) used a three arm non-parallel (sequential) design to randomize 36 primary caregivers of patients receiving autologous hematopoietic stem cell transplants to either: a Healing Touch group, a massage group or a control group which received a supportive visit from the researchers. The massage and Healing Touch interventions were administered twice per week for 30 minutes per session for 3 weeks, while the supportive visit treatments followed the same schedule but only lasted 10 minutes. A coin toss determined the sequence of delivery of interventions, with the supportive visit group receiving their series of six interventions first, followed by the massage group, and finally the Healing Touch group.

This design decision to use sequential rather than parallel arms proved to greatly complicate the study, as contextual changes in the stem cell transplant program meant that by the time the Healing Touch group received their intervention, the model of care had changed from a supported inpatient setting to an unsupported outpatient model, greatly increasing the caregiver burden for the recipients of Healing Touch, and introducing a substantial confounding variable. This experience underscores the methodological superiority of the parallel design, which standardizes such historical influences across all intervention groups.

Despite this unfortunate limitation, strengths of this study included conducting sample size, effect size and power calculations; experience level and consistency of providers (one CHTP provided all HT sessions; one certified massage therapist provided all massage sessions); and

the use of established instruments: Beck Anxiety Inventory, Subjective Burden Scale, Centre of Epidemiological Studies-Depression, Multidimensional Fatigue Inventory with domains for reduced motivation, decreased activity and general, emotional and physical fatigue. The findings were encouraging for the group of 13 caregivers who received massage therapy, but did not reach statistical significance for the 10 caregivers in the HT group, despite a number of trends in the expected direction. Despite initial group sizes of 14-15 individuals per group, attrition reduced the numbers to below the required sample size needed to show a large effect size ( $f = 0.52$ ) with an estimated power of 0.82.

### ***Healing Touch versus standard care versus active comparator(s) (5 studies)***

The inclusion of a standard care comparison in addition to the active comparators conferred an additional strength to the next group of studies, although multiple arms necessitated larger sample sizes to achieve the same effect size. In only some of these studies were these appropriate sample size calculations performed and reported, and the target size was not always reached. Greater statistical sophistication in analyses of these more complex designs were required and usually employed. However, sample size ranged from five participants (Kaye et al, 2003) to 748 participants (Krucoff et al., 2005), while statistical sophistication ranged from no inferential testing between treatment groups (Kaye et al, 2003) to multiple complex statistical testing using a variety of distinct tests appropriate to the multiple research questions and the level of measurement of data (Krucoff, et al., 2005). Despite the similarity in level of evidence based on study design, other key quality features varied widely among the studies in this tier of the evidence hierarchy.

Silva (1996) randomised 60 post-operative elective abdominal hysterectomy patients in a 1,000 bed hospital to receive either standard care, 20 minutes of Healing Touch or 20 minutes of massage, administered daily for three days. Outcome measures were narcotic usage, bowel treatments required, vital signs and an investigator-created Recovery Index comprised of pulmonary, urinary, motor and gastrointestinal assessments. Both treatments and all data collected were completed by the author. Although the use of an investigator-created instrument is a limitation, its development and validation are described well in her dissertation (Silva, 1992). However, sample size calculations are either not performed or not reported. The HT group experienced a statistically significantly accelerated recovery for the pulmonary and gastrointestinal systems ( $p = 0.01$ ), evident after only one treatment and continuing that gain after the second treatment.

Kaye et al (2003) reported by abstract only a very small RCT meant to compare standard care, Healing Touch and acupuncture among 5 diabetic patients. The acupuncture intervention was never delivered, and that deficiency was unknown until the end of the study, due to blinding to co-providers of treatment allocation. Between-group comparisons using inferential statistics were not attempted due to the small sample size, greatly reducing the internal validity of this randomised trial. Neuropathic pain levels and use of pain medication decreased for 3 of the 4 patients who received an active treatment.

Krucoff, et al. (2001) reported a much stronger methodology and the main findings of the results for the Monitoring and Actualization of Noetic Training (MANTRA I) study, while Seskevich et al (2004) reported on additional outcome measures not discussed in the first publication. MANTRA I was a pilot feasibility study of 118 participants, followed by MANTRA II with 748 participants (Krucoff et al., 2005). This is a notable exception in the Healing Touch

research, where pilot studies are a common methodology, but rarely eventuate in to later, larger studies.

Krucoff et al., (2001) reports the main findings of MANTRA I, the pilot study, where 118 patients undergoing cardiac catheterization had one treatment prior to the procedure. Randomisation was used to allocate them in to five parallel arms: standard care, stress relaxation, imagery, prayer, and Healing Touch. No statistically significant differences were observed on the main outcome measures of the Spielberger State-Trait Anxiety Inventory, the Duke University Religion Index (DUREL), cardiac monitoring parameters and major adverse events during six months of follow- up, as reported in Krucoff et al. (2001); but there was a 25% to 30% absolute reduction in adverse peri-procedural outcomes in patients treated with any noetic therapy as compared with standard therapy (Krucoff et al., 2001). Seskevitch, Crater, Lane & Krucoff (2004) reported additional outcome measures from the same study, consisting of eight VAS for various emotional states. Of these, only the VAS for the descriptor “worried” showed a statistically significant difference when comparing the amount of improvement from pre to post treatment ratings of the control groups as compared to all the noetic interventions groups combined.

Krucoff et al., (2005) in the main MANTRA II study that built upon the above pilot study, used permuted 2x2 block randomization stratified by clinical site to allocate 748 participants from nine medical centres who were undergoing cardiac catheterization in to four groups: either a triple intervention of music, imagery and touch (MIT), off-site intercessory prayer alone, both prayer and MIT, or neither prayer or MIT (standard care). Allocation in to the prayer intervention was masked, while allocation in to the MIT was unmasked. The full MIT intervention occurred once, over 40 minutes at the bedside, including one undisclosed HT technique by a CHTP. Outcome measures were again the State-Trait Anxiety survey and the Duke religiosity survey, one VAS for ‘distress’ and six month follow up for major cardiovascular adverse events (myocardial infarction, new onset of heart failure, need for repeat percutaneous coronary intervention or coronary bypass, readmission, death). None of the above measures showed any statistically significant differences for any of the treatment groups.

The blending of three different interventions of music, imagery and Healing Touch greatly complicated any interpretive conclusions, as the modalities may have either potentiated or negated each other. If the MIT group had proven superior to the other comparators, it would be impossible to know what contribution, if any, that Healing Touch itself had made to the demonstrated efficacy of the triple intervention. The authors acknowledge this limitation. Sample size calculations and appropriate statistical testing for the study design were notable strengths however, as was the multi-site design and the largest sample size for a prospective study found in this literature review.

MacIntyre, Hamilton, Fricke, Ma, Mehle and Michel (2008) also studied cardiac patients, block randomizing their 237 elective coronary artery bypass patients into standard care, Healing Touch or a Visitor intervention. Both interventions followed the same schedule of 3 sessions, delivered as a 20-60 minute session the day before the operation; a 60-90 minute session the day of surgery, and a 20-60 minute session the day after surgery. Sessions were administered by a CHTP in the patient’s hospital bed or a treatment table, and comprised of techniques chosen at the CHTP’s discretion. Outcome measures were length of stay, use of narcotic and anti-emetic medication, State-Trait anxiety inventory, and the Health Status Questionnaire SF-

12 to measure functional status. Appropriate statistical testing compared changes over time between treatment groups for all participants and found a greater decrease in anxiety for the HT group versus either the standard care or Visitor group; and a shorter length of stay for both the HT group and the Visitor group as compared to standard care. They then stratified the analysis into outpatient and inpatient sub-groups, where no differences were seen between treatments for the inpatient group, but the outpatient group demonstrated a shorter length of stay for the HT intervention as compared to the Visitor and standard care interventions. The importance of stratification to clarify the characteristics of participants that will benefit from Healing Touch will become evident in this present study as well.

## **Two parallel arm RCTs (5 studies)**

### ***Healing Touch versus one active comparator (3 studies)***

Three studies used the design of Healing Touch as compared to an active comparator and they will be presented chronologically (Taylor, B., 2001; Dubrey, 2006; Wardell, Rintala, Duan & Tan, 2006). Comparing Healing Touch against an active comparator that is itself of an unknown efficacy standard, as discussed previously, presents some logical challenges of interpretation. In addition, the uneasy balance is again evident in these studies, between the control required by setting treatment protocol parameters in an RCT versus allowing greater latitude in treatment protocols based on provider discretion, as would occur with authentic practice conditions outside of the research context. The tension between recreating the fidelity of the modality, while also preserving the controlled conditions required in the positivist paradigm, are a recurring consideration in study design for Healing Touch and other CAMs, and contribute to concerns about dose in a research setting versus dose in reality.

Taylor, B. (2001) studied 51 first and third year Australian university nursing students, who were randomised to receive either a control condition of rest for 50 minutes once a week for 4 weeks on a padded massage table in a quiet university room with music playing, or a 50 minute (maximum) Healing Touch session in the same university room as the control condition, with the same music playing, again once per week for 4 weeks, delivered by a practitioner with undisclosed levels of training or experience, and not necessarily being able to maintain the same provider/patient dyads through the series. For the control condition, a research assistant welcomed them to the room and settled them in, but it appears she did not remain in the room with them, so this does not constitute the “presence” condition used by other researchers, but rather simply rest and music. The careful control of the similarity of setting and situational components addresses one key component of the placebo effect, that of contextual cues (Murcott, 2005). Healing Touch providers (HTPs) were able to vary the techniques used based on their energetic assessment, to maintain the fidelity of the intervention of Healing Touch, but were restricted to choosing from among three techniques only (Chakra Connection, Modified Mind Clearing and Magnetic Unruffling). Length of treatment was also allowed to vary as per practitioner discretion, but a maximum of 50 minutes of treatment time was set for the research protocol. As mentioned in other Healing Touch research (Slater, 1996; Wardell, Rintala, Duan & Tan, 2006), the practitioners found these treatment protocol limitations to be frustrating and atypical to their usual practice of Healing Touch.

Taylor’s outcome measures were Lazarus’ Coping Scale, Rosenberg’s Self-Esteem Scale and Goldberg’s General Health Questionnaire, administered before and after the series of

treatments (2001). Quantitative data were analysed for all students together, but were also stratified and analysed separately for the year one students and the year three students. Note that year three is the graduating year in Australian bachelor degrees, with a probable concomitant greater stress level regarding examination results potentially preventing graduation, and/or in preparation for transition in to their first year of practice as a registered nurse. Indeed protocol adherence was affected by some students choosing to reschedule their treatments in order to prepare for assignments.

No statistically significant differences between the control group and the HT group's changes over time were found for the student group as a whole or for the year one students on any of the above 3 instruments. However, when analysed separately, the year three students showed a statistically significant difference compared to the control group on three items: demonstrating less transient stress ( $p = 0.05$ ), less chronic stress ( $p = 0.05$ ), and coping by putting in more effort ( $p = 0.05$ ). This differential response to Healing Touch according to the participant's specific situation was seen above with inpatients versus outpatients (MacIntyre et al., 2008), and provides a cautionary note about both careful selection of appropriate and relevant samples and about close scrutiny of diversity of baseline characteristics of the sample, that may require stratified analyses to reveal findings that would be otherwise obscured by confounding variables in an overly heterogeneous sample.

Half of the students in the experimental group (Taylor, 2001) also participated in semi-structured interviews, with comments regarding relaxation; being better able to study and think; experiencing better sleep patterns and feeling more refreshed after sleep; feeling happier; and being in less of a hurry. They also noted differences between treatments received from different HTPs, which again raises a methodological caution for future study design to control for this potential confounding variable whenever possible.

Wardell, Rintala, Duan & Tan (2006) also reported provider frustration with treatment protocols, and also found minimal evidence of distinctions between the two treatment groups in their study of 12 spinal cord injury patients experiencing chronic neuropathic pain. They compared a series of six weekly sessions of Guided Progressive Relaxation (GPR) delivered by a Research Assistant trained in the GPR technique but naïve to energy healing modalities, against six weekly sessions of Healing Touch, delivered in the patients' homes by a geographically proximate CHTP, with patient/provider dyads maintained throughout the series. In contrast to the protocol above used by Taylor (2001), Wardell et al did not restrict the length of sessions or the particular Healing Touch techniques to be used. However, even the restriction of the number of sessions to six sessions frustrated the providers, who fed back their recommendation that a 10 session treatment series would have been more appropriate.

Outcome measures before and after each treatment session included a set of 3 Visual Analogue Scales for "current pain," "most severe pain," and "coping" as well as a number of written instruments administered before the first session, and after the 2<sup>nd</sup> and 6<sup>th</sup> sessions of a 6 week series of treatments: POMS (65 item version), Brief Pain Inventory, Centre for Epidemiological Studies-Depression Scale short form (CESD-10) and the Diener Satisfaction with Life Scale. The only statistically significant finding on these instruments was that the HT group reported less interference of pain, (a subscale of the BPI), than did the GPR group. Although specific  $p$  values for each comparison are not reported, within group comparisons for all 3 of the VAS are reported as a significant decrease in pain, but this decrease occurs in both treatment groups.

The fact that both interventions were effective, at least in the short term, highlights one of the disadvantages of using a potentially active intervention as a proxy placebo. If both interventions are equally effective, there will not be a statistically significant difference found when making comparisons between the two treatment groups' improvements over time. Whether this is true because both interventions are effective, or because both interventions are triggering a placebo response, or because one is effective and one is triggering a placebo response, is impossible to discern. If the proxy placebo is actually an effective intervention, and the HT intervention has to produce a statistically significantly greater effect on the dependent measures than that effect produced by the proxy placebo intervention, then an excessive burden of proof is being laid at the door of the HT intervention (or any other complementary therapy being tested in this way). In the best scenario, the active comparator being used as a placebo proxy is a treatment that enjoys a solid evidence base itself, and a comparable performance by the Healing Touch treatment group could be cited as evidence of equivalent efficacy as the validated active comparator. Unfortunately, active comparators with a pre-existing evidence base are rarely the ones chosen in these designs to date, with a tendency to instead use other complementary therapies that are also still at early stages of building up the support from higher-level evidence.

Qualitative data were also collected and summarized in their 2006 publication (Wardell et al, 2006), and then reported in greater detail for two of the HT participants using a case study narrative in Wardell, Rintala and Tan (2008), one of which reported an overall beneficial response, while the other reported an equivocal one. The participants in the GPR group reported relaxation, distraction from pain focus, and later use of GPR for self-care, but none stated a decrease in their pain, in contrast to the quantitative findings for the VAS results where both the GPR group and the HT group had a significant decrease in pain as measured by the three VASs.

One client expressed disappointment and even anger that the HT had not removed his pain (Wardell et al., 2008), which echoes the findings of disappointment reported in Kaye, Wollitzer and Jovanovic's study when the acupuncture intervention did not occur (2003). These are cautionary lessons to future complementary therapy providers, to not over-sell any therapy, as making promises can worsen a patient's emotional or physical distress when they are not able to be fulfilled. While this advice suits all therapies, conventional or complementary, it is particularly true for complementary therapies, since many of the patients who seek out CAM do so out of desperation and frustration with the failure of the conventional medical community to solve their health problems (Murcott, 2005). Similarly, Wardell et al (2008) discuss the possible distress that can be caused by setting a patient up to expect that a particular therapy will relieve their pain, when their experienced reality post treatment then fails to meet that expectation. The expectation of benefit is a key component in the placebo response (Murcott, 2005), and participants will form those expectations themselves, based on prior experiences or conversations with others, but also based on the information provided to them by the researchers about the goals of the research project. Ethical considerations require that false promises are avoided, and that researchers disclose the existing lack of current conclusive evidence, which has often formed part of the justification for conducting the new study for which participants are being recruited.

Dubrey (2006) is the final study comparing Healing Touch to a single active comparator, in her work with 148 patients admitted to an inpatient alcoholism unit. Sample size calculations were completed and targets reached. Randomisation resulted in 81 patients receiving a 25 minute

session of the Healing Touch techniques of Chakra Connection followed by Magnetic Clearing, on Days 8, 9 and 10 of their admission; while the 67 patients in the active comparator group had 25 minute sessions on Days 8 and 10 only, where an unpaid volunteer with no prior HT experience as either a client or a provider, and no alcohol counselling experience, read pre-selected chapters of the Big Book of Alcoholics Anonymous while the client lay supine. Ten VAS were completed and vital signs were measured before and after treatment sessions on Days 8 and 10. The ten VAS covered 4 positive mood descriptors (hopeful, happy, calm, satisfied) and four negative mood descriptors (worried, sad, upset, tense) as well as two unpleasant physical sensations (pain and shortness of breath). HT group participants had a greater reduction in heart rate after treatment sessions on both Day 8 and Day 10 ( $p = 0.02$ ) than the reduction experienced by the Big Book group. For Day 8 measurements, the HT group showed statistically significant changes from pre- to post-treatment, as compared to the Big Book group's changes ( $p = 0.04$ ). The HT group participants were happier, more satisfied and had a greater reduction in pain. For Day 10 measurements, the HT group again showed statistically significant changes from pre- to post-treatment, as compared to the control group's changes. The HT group had a greater reduction in feeling upset, greater reduction in pain, were less tense and were calmer ( $p < 0.04$ ).

In summary, there were methodological strengths noted in each of these three studies, and some mixed findings where a few scattered outcome measures demonstrated statistically significant distinctions between groups, while most outcome measures did not. Methodological issues raised were centred on the recurring logical paradox of comparing Healing Touch to an active comparator of unknown efficacy; the continued contradictions between beneficial qualitative comments and non-significant results on quantitative instruments purported to measure similar constructs to those being reported as benefits in the qualitative data; and balancing aspects of the fidelity of Healing Touch in relationship to provider discretion in number and length of session and diversity of techniques administered (issues of dose) against the need for control regarding parameters of the protocol in the environment of an RCT.

### ***Healing Touch versus standard care (1 study)***

Ziembroski, Gilbert, Bossarte and Guldberg (2003) randomly allocated 26 hospice patients in to a standard care group and 29 hospice patients in to the Healing Touch group, where they received three sessions from a CHTP, each of which consisted of the Mind Clearing technique followed by the Chakra Spread technique, occurring between their fifth to 25<sup>th</sup> day after entering the hospice program. Treatments were administered in the patient's home or in their nursing home residence, either seated in a chair or lying in bed. Outcome measures included the Missoula-VITAS Quality of Life Index for Hospice Patients, with numerous sub-scales, administered before and after the treatment series, and an investigator-created questionnaire with a focus on emotional and spiritual concerns. As in prior studies, a qualitative component for a portion of the respondents was also included in the design, with most participants in both treatment groups reporting positive experiences.

The Missoula-VITAS results were reported with descriptive statistics only for both groups, without an inferential statistical between- groups comparison being performed or reported, which is a disappointing omission. The authors describe a side-by-side comparison of individuals in each group, to their counterpart in the other group, in order of enrolment in to the study, but they do not detail the results of this analysis.

Instead, means of the change from pre treatment scores to post-treatments score of both groups are tabled and graphed, and the direction of change and magnitude of change are described. Of the five sub-scales on the instrument, the HT group improved for the interpersonal dimension and the symptoms dimension, while the control group's scores worsened over the same time frame for those two dimensions. In contrast, for the transcendent and well-being dimensions, the control group improved, while the HT group worsened. Both groups had worsening physical functioning over time, but the control group had a larger incremental decline than did the HT group. All of these changes may be trivial and spurious, as no tests of statistical significance were reported. However, the lesser amount of decline in physical functioning in the Healing Touch group as compared to the standard care group, while apparently not a statistically significant distinction, is an intriguing trend that directly relates to the research question in this present study.

In the qualitative data, the 21 HT participants indicate relaxation as the most commonly reported outcome (7 responses), while increased relief of pain, increased calmness, improved breathing and spiritual benefit are mentioned by 3-4 respondents each. The inclusion of spiritual benefit, in the face of the HT group's average scores declining on the Transcendent dimension of the Missoula-VITAS measure, is an interesting seeming contradiction, similar to the contradiction found between qualitative and quantitative data in other studies (Slater, 1996; Wardell, Rintala, Duen & Tan, 2006). It is possible that quantitative research is too 'blunt' an instrument to detect the subtle subjective changes that occur in response to Healing Touch sessions. However, one can argue that if the changes are that subtle, they may not be clinically significant enough to warrant further study or inclusion into practice. Another consideration for the mixed findings can again be due to the 'too little, too late' aspect of working with a terminally ill sample, as was seen in Wilkinson's 2004 study with HIV clients. Both her HIV sample and Ziembroski et al.'s hospice sample can be expected to have an inevitable decline at end of life due to disease progression, despite any non-curative intervention. Even symptomatic relief may not be obtained at later stages of the illness trajectory. These concerns about the illness trajectory may again be relevant in this present study of frail elders, and thus a measure of co-morbidity will be included, in hopes of teasing out the severity of physical illnesses as a potential confounding variable.

### ***Healing Touch versus placebo (1 study)***

Cook, Guerrerio and Slater (2004) conducted the only parallel RCT comparing Healing Touch to a placebo by their innovative design for a mock version of Healing Touch. Their sample of 62 female patients undergoing radiation treatment for breast or gynaecological cancer received six Healing Touch or placebo treatments, commencing when they had completed no more than one third of their radiation treatments, then weekly thereafter, except for a 4 week interval between the fifth and sixth (final) treatment. After each radiation treatment, participants had their HT or mock HT session in a designated room at the medical centre, lying fully clothed on a padded massage table, with a three foot by three foot opaque screen at their neckline, similar to one used in operating theatres during spinal anesthesia. Healing Touch providers with at least Level 2 training performed an energetic assessment before using whichever Healing Touch techniques they felt were appropriate for the client. Specific techniques used were not identified, but presumably those techniques involving movements around the head were not chosen, in order to preserve blinding. This would restrict the range of techniques substantially. Similarly, those techniques that use direct contact touch would

also have presumably been excluded to preserve blinding, although most HT techniques can be modified to instead work above the skin rather than directly on the skin. Placebo providers with no HT training walked around the table behind the screen, standing and moving as they would in a true Healing Touch session, but keeping their hands at their side and their minds pre-occupied with mental calculations. Ten randomly selected video recordings of both genuine and mock HT confirmed appropriate protocol adherence. Blinding was effective, with only 26% of the placebo participants correctly identifying themselves as such. There was no statistically significant difference between the two treatment groups regarding belief in group assignment.

Outcome measures included an investigator-created five question Likert scale to measure attitudes toward Healing Touch, and no between group differences were noted for this measure. A well-established instrument was used, the Medical Outcomes Study SF-36, which is comprised of nine sub-scales covering domains of health, including physical functioning and physical role functioning. Within group comparisons were reported, a lower level of analysis that is more commonly seen in simple case series pre-test/post-test designs. These comparisons showed statistically significant improvements occurring in both treatment groups. For the genuine HT group, the improvements were on the three sub-scales of emotional role functioning, mental health and health transition. For the mock HT group, the improvements were on the two sub-scales of physical role functioning and health transition.

More appropriately stringent between group statistical analyses were also conducted, based on the change over time in the HT group versus the change over time in the placebo group. The HT group outperformed the placebo group at a statistically significant level on three sub-scales: pain, vitality and physical functioning. In addition, the difference between treatment groups for the improvement in the overall SF-36 score nearly reached significance ( $p < 0.06$ ), with higher scores in the HT group indicating greater overall functional ability.

Again we see mixed results on the effectiveness of HT, but with stronger evidence here, and in the context of a more methodologically rigorous research design. It is possible that having to curtail the HT techniques used to avoid any positions around the head in order to maintain a credible placebo, is a trade-off that may have resulted in reducing the 'dose' or effectiveness of the HT intervention, thus suggesting that a method of blinding that does not impose this restriction would be preferable, as was accomplished in this present study through the use of a sleeping mask to accomplish participant blinding to treatment allocation. This study by Cook et al (2004) was the only randomised placebo-controlled trial of Healing Touch found during the initial literature review, and this glaring gap in the evidence base prompted the design of the present study.

## **Summary of the evidence to date**

The above comprehensive review of the literature to date upon the commencement of this present study indicates a number of intriguing and potentially promising areas of further exploration regarding the possible beneficial effects of Healing Touch. While the level of evidence provided varies greatly, with numerous methodological concerns as will be discussed below, the current body of evidence to date seems to indicate that Healing Touch may provide the following beneficial responses to selected populations. The summary of the evidence is presented according to three main categories: anecdotal evidence, qualitative evidence and

quantitative evidence. The three studies related to the selected primary outcome measure for this present study, physical functioning, are bolded for the reader's convenience .

### **Anecdotal evidence**

The anecdotal evidence describes the following beneficial effects of Healing Touch in selected case study examples:

- Relaxation (Burr, 2005; Ercums, 1998; Scandrett-Hibdon, 2005; Umbreit, 2000; Weber, 2003; Wetzal, 1993)
- Quietening of the mind (Burr, 2005)
- Wound healing (Umbreit, 2000; Weber, 2003; Wetzal, 1993)
- Infertility (Kissinger & Kaczmarek, 2006)
- Autoimmune disease (Ercums, 1998)
- Improved sleep (Burr, 2005; Umbreit, 2000)
- Decreased pain (Ercums, 1998; Umbreit, 2000; Weber, 2003)
- Decreased shortness of breath (Umbreit, 2000)
- Decreased agitation in end-stage liver failure (Umbreit, 2000)
- Spiritual connection (Ercums, 1998)

### **Qualitative evidence**

The Qualitative evidence describes the following beneficial effects of Healing Touch for selected populations, which have been further categorised according to physical, mental (cognitive), emotional and spiritual dimensions of health:

#### ***Physical benefits***

- Decreased pain (Peck, 2007)
- Improved sleep (Peck, 2007)
- **Improved functional ability with BADLs and IADLs (Peck, 2007)**

#### ***Mental benefits (Cognitive)***

- Increased mental clarity (Van Aken, 2004)

#### ***Emotional benefits***

- Improved emotional well being (Peck, 2007)
- Empowerment (Van Aken, 2004)
- Feeling safe & protected, trust in HTP (Christiano, 1997; Van Aken, 2004)
- Sense of 'oneness' between self & HTP (Christiano, 1997)
- Sense of 'oneness' within themselves (Christiano, 1997)
- Integrating all aspects of self (Van Aken, 2004)

### ***Spiritual benefits***

- Comfort & courage to face their cancer (Christiano, 1997)
- Accessing inner strength & resources (Van Aken, 2004)
- Spiritual connection to something larger than themselves (Christiano, 1997)
- Felt a sense of spirit (VanAken, 2004)

### **Quantitative evidence**

#### ***Single group repeated measures designs***

The quantitative evidence garnered from single group repeated measures designs have also been further categorised according to physical and emotional dimensions of health:

##### **Physical benefits:**

- Physiological parameters of relaxation: decreased pulse, respirations, blood pressure (Maville, Bowen & Benham, 2008)
- Decreased chronic pain (Darbonne & Fontenot, 1997; Slater, 1996)

##### **Emotional benefits:**

- Decreased agitation in patients with dementia (Wang & Hermann, 2006)
- Decreased anxiety (Maville, Bowen & Benham, 2008)
- Decrease in perceived stress (Wilkinson, 2002)

#### ***Randomised between group comparisons (RCTs)***

The quantitative evidence garnered from between group comparison designs have also been further categorised according to physical and emotional dimensions of health:

##### **Emotional benefits:**

- Decreased total mood disturbance (Post-White, Kinney, Savik, Gau, Wilcox & Lerner, 2003).
- Decrease in perceived stress (Dowd, Kolcaba, Steiner & Fashinpaur, 2007; Taylor, 2001)
- Increased comfort (Dowd, Kolcaba, Steiner & Fashinpaur, 2007)
- Increase in perceived happiness, calmness and satisfaction (Dubrey, 2006)
- Decrease in perceptions of feeling tense and feeling upset (Dubrey, 2006).

##### **Physical benefits:**

- Reduced pain ( Dubrey, 2006; Cook, Guerrerio & Slater, 2004; Post-White, Kinney, Savik, Gau, Wilcox & Lerner, 2003).
- Reduced heart and respiratory rate and blood pressure (Dubrey, 2006; Post-White et al, 2003)
- Improved post-operative recovery (Silva, 1996)

- Decreased worry pre-procedure for unstable coronary syndrome (Seskevich, Crater, Lane & Krucoff, 2004)
- Increased vitality (Cook et al, 2004)
- **Increased physical functioning (Cook et al, 2004)**

The above list of benefits reported in anecdotal, qualitative and quantitative research to date offer some intriguing potential outcome measures for further exploration. However, this review has also revealed a number of recurring methodological shortcomings within the current body of evidence, many of which may be possible to remedy by careful attention to the details of the design of this present study.

## **Methodological Issues:**

### **Sample size**

This comprehensive review of the literature has highlighted a number of methodological concerns in the body of quantitative research for Healing Touch as reviewed prior to the commencement of this present study. The first concern relates to a preponderance of small sample sizes. Very few quantitative studies reported performing sample size calculations (i.e. Dowd et al., 2007; MacIntyre et al., 2008) and many studies were pilot studies or feasibility studies that never progressed to adequately powered studies (i.e. Wardell, Rintala, Duan & Tan, 2006) which may be related to funding and/or to limitations identified during the pilot study. A large number of the studies reviewed above were master's theses or doctoral dissertations, with their concomitant restrictions on the duration of the study, and on the financial resources necessary to recruit and treat large sample sizes (Silva, 1996; Slater, 1996; Weymouth, 1999; Wheeler-Robins, 1999; Wilkinson et al., 2002; Wilkinson, 2004). Even non-student projects performed by clinician/researcher teams were often under-funded and under-powered (Cook et al., 2004; Taylor, B., 2001; Wang & Hermann, 2006; Ziembroski et al., 2003).

### **Treatment protocols**

A variety of dosing regimens have been noted in this literature review, with a variety of treatment times per session: 10 minutes (Wang & Hermann, 2006); 15-20 minutes (Dowd, et al., 2007; Silva, 1996), 20-30 minutes (Wheeler-Robins, 1999); 30 minutes (Cook et al., 2004; Dubrey, 2006; Krucoff, 2001; Maville et al., 2008; Slater, 1996; Taylor, B., 2001; Wardell et al., 2006); 45 minutes (Post-White et al., 2003; Wilkinson, 2002) or sessions of unlimited time frames (Wilkinson, 2004). The number of treatment sessions has also varied considerably, from a single session (Krucoff et al., 2001; Maville et al., 2008; Slater, 1996) to a series of two treatment sessions (Ziembroski, et al., 2003); three treatment sessions (Dowd, et al, 2007; Dubrey, 2006; Wilkinson et al., 2002); four treatment sessions (Darbonne & Fontenot, 1997; Post-White et al., 2003; Taylor, B., 2001; Wheeler-Robins, 1999; Wilkinson, 2004); six treatment sessions (Cook et al, 2004; Rexilius et al., 2002; Wardell et al., 2006); 12 treatment sessions (Kaye et al., 2003); and 28 sessions (Wang & Hermann, 2006).

Settings also varied greatly and included acute care inpatients (i.e. Kemper et al., 2006), ambulatory care outpatient clinics (i.e. Cook et al, 2004); residential aged care settings (Wang & Hermann, 2006); the private practice rooms of Certified Healing Touch Practitioners (i.e.

Wilkinson, 2004); participants' homes (i.e. Wardell et al., 2006; some of the participants in Ziembroski, et al., 2003), or in university settings (Dowd, et al., 2007; Maville et al, 2008; Taylor, 2001).

## **Providers of Healing Touch treatments and comparator treatments**

Varying levels of training and/or experience of the Healing Touch providers have also been seen throughout this literature review, making issues of the 'dose' of Healing Touch required to achieve an observable effect become a relevant concern. Protocols have ranged from using providers with undisclosed levels of training in some studies (i.e. Kaye et al., 2003; Krucoff et al., 2001; Taylor, 2001) to fully disclosed levels of training and/or years of experience, that represent the full continuum from providers with only Level One training (i.e. Dubrey, 2006); Level Two or higher training (i.e. Cook et al., 2004) Level Three or higher (i.e. Collinge, Wentworth & Sabo, 2005; Wilkinson, 2004); Level 4 or higher (i.e. Dowd, et al., 2006; Wheeler-Robins, 1999); up to providers that were Certified Healing Touch Practitioners, many with long-standing private practices (i.e. Post-White et al., 2003; Rexilius et al., 2002; Wardell et al., 2006; Ziembroski, et al., 2003).

The experience level of the Healing Touch provider is a salient aspect of dose, as shown in Wilkinson's first study (2002), where outcomes differed for clients treated by less experienced (Levels 1 to 3) versus more experienced (Levels 4, 5 or CHTP) providers. Similarly, some studies disclosed whether or not practitioner/client dyads were retained through the entire series (Wilkinson, 2002), or whether a multiplicity of providers or a single provider was used; while other studies did not disclose these aspects of the protocol. Ideally, a study design that stipulates a single provider for all treatment sessions, such as that accomplished by Wang and Hermann (2006) would reduce one source of variability. Similarly, having that provider be highly trained and experienced could maximise that aspect of 'dose' in order to provide the best possibility of observing a beneficial effect, should one be present. However, the limited availability of Healing Touch providers with higher levels of training in some areas may preclude overly restrictive protocols, particularly in less densely populated areas, such as the one where the present study was conducted. Issues of volunteer providers versus paid providers may also limit availability, depending on study funding and the intensity of the treatment protocols (i.e. daily versus weekly) and the volume of participants being treated at any one time.

Providers of sham treatments have also been representative of a range of approaches, with sham treatments provided by individuals who were intended to be naïve to energy therapies and later disclosed familiarity with other related energy therapies (Slater, 1996), or ones who began to function as energy therapy providers over the course of the study as they gained experience with successive participants (Slater, 1996). These irregularities led to concerns about both sham provider discomfort and about sham provider's adherence to a truly inert protocol (Slater, 1996). In contrast, sham providers in another study were uniformly trained and followed detailed and prescriptive protocols (Cook et al, 2004).

## Outcome measures

Outcome measures have ranged from investigator-created single item rankings (Collinge et al., 2005) or multi-item instruments (i.e. Dowd et al., 2006; Silva, 1996); to a preponderance of Visual Analogue Scales (i.e. Darbonne & Fontenot, 1997; Seskevitch et al, 2004; Wardell et al., 2006) and 1 to 10 numeric rating scales (i.e. Kaye et al., 2003; Wilkinson et al., 2002), through to a wide variety of formal and well-established self-report instruments with a track record of sound psychometric properties. Some of these are listed in the text box below:

Beck Anxiety Inventory (Rexilius et al., 2002;  
Brief Pain Inventory (Wardell et al., 2006)  
Center for Epidemiological Studies—Depression (Rexilius et al., 2002; Wardell, et al., 2006)  
Cohen-Mansfield Agitation Inventory (Wang & Hermann, 2006)  
Chronic Pain Experience Inventory (Darbonne & Fontenot, 1997)  
Deiner Satisfaction with Life (Wardell et al., 2006)  
Duke Religious Inventory (Krucoff et al., 2001)  
Goldberg’s general Health Questionnaire (Taylor, B., 2001)  
Lazarus’ coping Scale (Taylor, B., 2001)  
McGill-Melzack Pain Questionnaire (Slater, 1996)  
Missoula-VITAS Quality of Life index (Ziembroski, et al., 2003)  
Multidimensional Fatigue Inventory (Rexilius et al., 2002;  
Profile of Mood States (POMS) ( Post-White et al., 2003; Wheeler-Robbins, 1999; Wardell, et al., 2006)  
Rosenberg’s Self-Esteem Scale (Taylor, B., 2001)  
SF-36 (Cook et al., 2004)  
Spielberger State-Trait Anxiety Inventory (Krucoff, et al., 2001; Krucoff et al., 2005; Maville, Bowen & Benham , 2008; MacIntyre, Hamilton, Fricke, Ma, Mehle and Michel, 2008)

Besides these (mostly) self-report instruments, objective measures have also been used, including observations such as vital signs (i.e. Dubrey, 2006; Silva, 1996; Taylor, 2001) or agitation behaviours (Wang & Hermann, 2006) or biological markers like salivary cortisol (Wheeler-Robbins, 1999; Wilkinson et al, 2002; Wilkinson, 2004) or serum levels of immune globulins (Wheeler-Robbins, 1999) or of haemoglobin A1C (Kaye et al., 2003).

In the interest of providing a holistic picture of the participants’ response to treatment, numerous outcome measures are often utilised within one study, with mixed results that can make interpretation more difficult, and creating the limitation of multiplicity of testing that can create spurious statistically significant findings. The lack of consistency in instruments used to measure the effects of Healing Touch precludes the ability to conduct a meta-analysis for a systematic review (Anderson & Taylor, 2011).

## Data collectors

Often some or all of the data have been collected by the same person providing the treatment (i.e. Dowd et al., 2006; Wheeler-Robbins, 1999), for the sake of cost or convenience, and more often the person collecting the data has not been clearly reported. Even if separate data collectors are used, they are usually aware or become aware of the participant’s group allocation, since the participant themselves know their treatment allocation and tend to disclose it during data collection. Blinding of data collectors has only occurred in those designs where the participants themselves were also unaware of their treatment group allocation, such as when comparing Healing Touch to a placebo (Cook et al, 2004), or in Krucoff’s design

(2001) where standard care participants and off-site prayer recipients could both have assumed they were in the off-site prayer group and thus been unable to disclose to the data collectors if they were in the off-site prayer group or in the standard care group. However, they would have still been clearly aware that they were not in the Healing Touch group.

## **Methodological issues summarised**

Principles of robust research rigour for experimental designs require minimising variation by controlling as many confounding variables as possible within the chosen design and circumstances (Moher, et al., 2010). Careful selection of the appropriate outcome measures that will enable the researcher to observe a clinically relevant response to the intervention in the chosen population is another crucial step (Walach, Jonas & Lewith, 2002) and one that can be well informed by a review of prior credible qualitative research (DeCenso, Guyatt & Ciliska, 2005). Well-validated instruments, when available, are preferable to investigator-created tools (NHMRC, 2009). Statistical consultation to determine the sample size necessary to ensure the study is adequately powered to detect a clinically relevant response is also a crucial step (NHMRC, 2009). Further statistical consultation is also necessary to ensure the most appropriate statistical testing is used for the type of data collected, in order to observe accurate statistical principles and to answer the research question that has been posed (Moher et al., 2010). Questions regarding the efficacy of an intervention are best resolved through use of placebo-controlled randomised clinical trials, when such a design is practically feasible for the intervention whose efficacy is being scrutinised (Moher et al., 2010). If comparison to a placebo version of the intervention is not practically feasible, then alternative selections for the comparator group should be carefully considered. Inappropriate choice of a comparator may lead to introducing further confounding variables and/ or to limiting the contribution of the study by providing illogical comparisons to other comparator interventions which are also of unknown efficacy themselves (Anderson & Taylor, 2011). Treatment protocols also require careful consideration, to ensure the administration of a 'dose' of the intervention (Targ, 2002) that is sufficient to trigger a beneficial response for the outcome being measured. Treatment protocols also need to carefully balance the rigour and restrictions required in a controlled trial against the need for delivering an authentic intervention that maintains as much fidelity as possible when compared to the delivery of the intervention in non-research contexts (Anderson & Taylor, 2011). Finally, blinding of data collectors at the least, but also of participants and co-providers whenever possible, substantially improves the internal validity of the design, by removing these potent sources of possible bias (Walach, Jonas & Lewith, 2002).

## **Chapter Summary**

The collection of studies reviewed above represents a credible body of anecdotal evidence, and a less compelling body of qualitative and quantitative evidence. While some robust qualitative research has been done, showing generally positive participant responses to the experience of receiving the intervention of Healing Touch, the quantitative evidence has fallen short of providing an equally clear picture. Numerous methodological issues have contributed to these mixed findings, including small sample sizes, lack of randomization into group assignments, difficulties designing inert but credible placebo treatments, a lack of consistency

of instruments used to measure purported beneficial effects of HT on clients, and an equally inconsistent variety of patient conditions and populations.

Much of the published research consists of master's theses and doctoral dissertations, which represent the individual passion of a sole student researcher, who is usually poorly funded, resulting in small sample sizes. In addition, these student studies typically have not been disseminated widely through the usual channels in professional journals accessed by electronic databases. There is thus a 'patchy' and ad hoc approach to Healing Touch research, with very little sequential building of new research upon the foundation of prior research, as in the ideal programmatic approach to knowledge development.

Therefore, some recommendations for future quantitative research regarding Healing Touch can be gleaned from the experiences of the researchers who undertook the above studies and whenever possible, these recommendations have been integrated into the design of this present study:

1. Perform sample size calculations and recruit a sufficient sample size to cover high attrition rates.
2. Use a group to group comparison design whenever possible.
3. Randomise into groups whenever ethically possible.
4. Use as a comparator, a placebo version of the intervention, which convincingly simulates or mimics Healing Touch, rather than using an active comparator as a proxy for a placebo.
5. Focus on patient populations and/or conditions that prior quantitative and/or qualitative research implies may benefit from Healing Touch, to provide a more systematic program of research that builds a body of evidence over time specific for that population, condition, or outcome measure (i.e. pain relief in breast cancer patients; stress management in health care professionals).
6. Recognise that Healing Touch can impact on any/some/all of the participant's physical, emotional, mental and spiritual dimensions, and choose outcome measures accordingly.
7. Select those outcome measures that have been repeatedly reported by participant comments in qualitative data and have also shown indications of efficacy in quantitative data.
8. Measure outcomes with established instruments that have demonstrated appropriate psychometrics for the chosen population, rather than investigator-created tools with no established reliability and validity.
9. Obtain statistical consulting advice prior to the design of the study.
10. Perform the highest level of statistical analysis that is logically possible for the type of data collected, and then report those findings, even if they are not statistically significant, rather than not performing or not reporting group-to-group comparisons when two groups do exist.
11. Report all findings fully and accurately, with p values for both significant and non-significant findings, conforming to the CONSORT guidelines for reporting of randomised controlled trials.

The findings of current research to date in Healing Touch, and the methods by which those findings have been obtained, have all contributed to informing both the focus and the design of the present study, which will be discussed in greater detail in the following chapter entitled Methods. Given the presence of three prior studies where a beneficial response to Healing Touch was noted for physical functioning (Cook et al, 2004; Peck et al, 2007; Ziembroski et al, 2003), this present study focused on using the rigorous design of a placebo-controlled RCT to test the efficacy of Healing Touch as a nursing intervention for the outcome measure of functional ability in the population of older women living alone in the community.

Using the acronym of PICOS, where the P stands for population, the I for intervention, the C for comparator, the O for outcome measure and the S for study design from the PRISMA group (Liberati et al, 2009), the following components have been identified for this present study:

Population: Older women living alone in the community.

Intervention: A series of 7 treatments of the energy-based complementary therapy Healing Touch.

Comparator: A placebo version of Healing Touch.

Outcome: Functional health as measured by the ability to perform activities of daily living.

Study design: A two parallel arm randomised placebo-controlled trial.

## **Aim of the research**

This aim of this study is to observe the effect of Healing Touch on the holistic health of older women living alone in the community, including cognitive, physical, emotional, spiritual, and particularly their functional health, which is often determined by the interactive effect of the status of the above-stated health dimensions.

## **Research Question**

Will Healing Touch promote and maintain the health status of single older women in the community by preventing, delaying or minimizing functional decline?

## **Null Hypothesis**

The experimental group and the placebo group will experience the same level of functional decline over the course of the study.

## **Alternative Hypothesis**

The experimental group will experience a clinically significantly smaller amount of functional decline than the placebo group, by at least one unit on the scale of the chosen instrument for measuring functional ability to perform activities of daily living.

## **CHAPTER THREE: Methods**

## **Introduction**

Chapter Three will discuss the methods used to address the research question, beginning with the study design, the sample, the recruitment processes and the settings used for data collection and intervention. The method of randomisation and treatment allocation will be covered next, including allocation concealment issues (blinding). The intervention and the comparison treatment will then be outlined, including issues of dosing and providers, the similarity of the intervention to the control (placebo), and the similarity of the intervention protocol to Healing Touch treatments delivered outside of this research context. The key ethical considerations of working with a vulnerable population as well as using a placebo will be briefly covered. The primary and secondary outcome measures will be discussed next, with an introduction to the instruments used, including their suitability for the chosen sample and their psychometric properties. The chapter will conclude with a detailed discussion of the statistical analysis process that was undertaken to answer the primary and secondary research questions and to explore the ancillary analyses, thus leading in to the Results chapter to follow.

## **Study Design**

The study was a parallel two arm, randomised placebo-controlled trial, with data collection occurring pre-intervention (Week 0), post-intervention (Week 8) and six months following the conclusion of the intervention (Week 33). The intervention was a weekly treatment session in the participant's home, delivered by the Principal Investigator (PI) who has trained up to Level Four of the Colorado Center for Healing Touch Curriculum for Healing Touch. Treatment sessions occurred approximately weekly, for a series of 7 sessions. Participants were randomly allocated in blocks of ten to either the Healing Touch treatment group or the mimic healing touch (placebo) group as per the process outlined in a later section. Random allocation group status was unknown to the participants, to the two Research Assistants collecting the data, and to a third Research Assistant who entered the data into the SPSS statistical program, as well as to any referral sources/co-providers involved in the participant's care and/or in the recruitment process for the study. Also blinded was the statistical consultant who verified all statistical analyses performed by the PI, with treatment groups only identified as Group A and Group B.

## **Pilot study**

A small pilot study was conducted, beginning in September 2008, with 4 participants. The basic design of the study remained as proposed and described above. The pilot study led to minor changes broadening the eligibility criteria and the recruitment process after noting the slow pace of recruitment in the Pilot Study. These changes maximised potential for recruitment targets to be reached within the time constraints of the student research environment. Inclusion criteria were broadened by changing the age from over 75 years old to over 65 years old, and from receiving nursing support at home to receiving any type of assistance at home, as defined in the recruitment materials discussed below.

In addition, refinements were made to the timing of revelation of group allocation to the PI during the first treatment visit. Rather than opening the envelope immediately prior to arrival

at the client's home, which affected the interactions during the initial intake history, the timing was altered so that the envelope was not opened until the history and pre-treatment briefing had been completed, after the client had been settled onto the massage table with the sleeping mask and ear plugs applied.

Lastly, a refinement was made to the method of data collection by the Research Assistant (RA). During the pilot study, the RA recorded the amount of time the first two participants took to complete each instrument by reading and writing their responses, and then recorded the same information for the second two participants to complete each instrument by the RA verbally asking the question and then circling the response that the participant verbalised. The data confirmed that the spoken method took no longer to complete than the written method. The spoken method was also deemed by the PI, RA and primary supervisor to ensure higher reliability of data and consistency between participants, given that the spoken method would be a required adaptation anyway, for those participants with significant vision or dexterity problems, both of which are situations likely to occur in an older adult population.

## **Participants**

The eligibility criteria were established to target the most common demographic profile of potential future residents of aged care facilities, the single older woman (AIHW, 2007), by attempting to identify women living alone who were beginning to experience some early levels of functional decline. This population was appropriate given the main research hypothesis of determining if the intervention could prevent or delay further functional decline, which is often the precipitating factor for nursing home placement. A further necessary parameter was the participant's ability to provide a full and complete data set over the duration of the study (nine months for each participant).

With these considerations in mind, the inclusion criteria were:

- female;
- over 65 years old;
- no or minimal cognitive impairment;
- able to speak, read and write in English;
- living alone in the community; and
- receiving support services in the home.

This assistance could be from friends, family, volunteer or paid assistants to provide assistive services for house cleaning, home maintenance, yard service, hygiene, meals, shopping or transport.

Exclusion criteria were:

- males;
- cognitive impairment (defined as a score of 27 or lower out of a possible 30 on the Mini Mental Status Exam);
- women cohabitating with a roommate/significant other/caregiver;
- Indigenous Australians;

- any prior experience with Healing Touch; or frequent or recent experience with Therapeutic Touch, Reiki or other energy-based touch therapies.

Participants with recent experience with other similar energy modalities were excluded, to preserve participant blinding, which was also one of the rationales for only including single occupants. In addition, older adults with spouses, room-mates or an extended family member(s) cohabitating are less vulnerable to functional decline and residential care placement, given the available support at home. Indigenous Australians were excluded for a number of reasons. Firstly, their older adult status is defined by a different, lower age parameter, and a homogenous age-defined sample was required. Secondly, the extended family living arrangements that are culturally more common for Indigenous Australians would make them unlikely to meet the criteria of the vulnerable, at-risk single occupant in a residential dwelling, which was also necessary to preserve blinding of participants to their treatment group allocation in the study protocol. Lastly, the unfortunately poor survival statistics for Indigenous Australians over 65 years of age, coupled with the more commonly encountered and supportive extended family living arrangements, mean that fewer older Indigenous Australians comprise the demographic profile for residential care settings, which was the generally undesirable endpoint that the Healing Touch intervention was postulated to assist older adults to avoid or delay experiencing.

## Recruitment

The Principal Investigator (PI) presented the study proposal to programs within the local Queensland Health Townsville Health Service District (THSD) that provided nursing services for older adults and requested their assistance in identifying appropriate potential participants by giving them the Letter of Invitation (see Appendix F, for Revised version 3). A clear acrylic document holder and a supply of the Letter of Invitation (LOI) were provided to each relevant ward or service. In addition, an acrylic A5 sign holder was placed in front of each document holder, with a colourful feminine sign inserted, that included a picture of the PI to foster familiarity and reduce possible apprehension regarding a stranger entering their home (see Appendix G).

A key recruiting tool was the colourful Letter of Invitation (LOI), printed on pink paper and decorated at the top with the Queensland Health logo and a blue clip art picture of a nurse gently touching a patient, and another clip art picture of a cosy house complete with a picket fence. In the revised Letter of Invitation Version 3 (see appendix F) the broadened eligibility criteria discussed above were simplified to lay terms as below:

- Receiving some support or help at home???
- (This can be help with transport, meal preparation and/or home/yard maintenance; or help from nurses, personal carers, occupational or physiotherapists, or any other paid or volunteer caregivers who help you at home.)

In addition to the change in eligibility criteria after the Pilot Study, the actual process of recruitment was also widened to include additional modes of recruitment aimed directly at potential participants, rather than only through their health care providers. These changes were also approved by the THSD Human Research Ethics Committee (HREC). The new recruitment methods included a paid advertisement (see Appendix H), that was placed in the local commercial newspaper (Townsville Bulletin) and in the free newspaper (Townsville Sun)

and as a free advertisement in the Magnetic Times news website, the Magnetic Island printed community newsletter and a number of church bulletins across the greater Townsville Catholic diocese.

Another recruitment process used was snowball recruitment. Earlier study participants spontaneously asked for additional LOIs to hand out to their friends, neighbours and even siblings, to support them in discussing the study. These word-of-mouth referrals proved very effective, so later participants were given the LOIs to distribute to any appropriate contacts in their networks, if they were comfortable doing so.

In June 2010, the PI issued a media release (See Appendix I) which generated positive media attention, first by a short article in the Townsville Sun (Appendix J), and then by a short article with a large picture of the PI standing next to a massage table, basket of pillows, etc in the Townsville Bulletin (Appendix K). In addition, the local ABC radio station ran an interview that same month. In summary, a variety of methods were used, including recruiting through health service organizations, community organizations, newspaper advertisements and articles, radio interviews, and snowball recruitment.

All of the recruitment methods above directed any interested potential participant to contact the PI by telephone. She then described the study to the potential participant as per the Phone Screening Script (Appendix L). If the participant remained interested, the PI then went on to ask the screening questions to ascertain eligibility, as per the Phone Screening Form (Appendix M). After the description of the study and the eligibility screening process, if a potential participant was eligible and still interested, she was then enrolled, given a participant identification code and added to the patient register. Usually, appointments were also booked for the intervention treatment series during this initial 20-30 minute phone call, and the participant was told that the RA would be contacting them directly by phone to organize a mutually agreeable time for the Baseline pre-intervention (Week 0) data collection home visit by the RA, within 1-14 days prior to the first treatment visit by the PI. If time permitted, a mailing was also done to the newly enrolled participant, including the Letter of Invitation (Appendix F), the Patient Information/Consent (PIC) form (Appendix N), the PI's university lecturer's business card with her private mobile phone number hand-written on it, and a list of the intervention appointments that included three blank spaces to write in the three RA data collection appointments when they were finalized over the phone by the RA and participant directly. If the time between the booking and the first appointment was too short to allow a mail-out, then the above documents were provided in person instead, with the RA providing the PIC at the first data collection visit and the PI providing the rest of the documents at the first treatment session.

## **Losses and exclusions**

Potential participants were lost at each of the above steps, as shown in the Participant Flow Diagram in Chapter Four, Results, Figure 3. Decisions about cases to include or exclude for analysis will be described next, as these were made with consideration to missing data and to adherence to data collection timeline protocols and/or adherence to treatment protocols, as described below. The end result was a modified Intention-to Treat analysis, as defined by Polit and Gillespie (2008).

A stringent or pure Intention-to-Treat analysis, would require either no attrition, or would require imputation of missing data at the second and/or third data collection time points (Polit & Gillespie, 2008). These options were considered and discarded. The primary outcome measure was the difference between the participant's functional health at baseline and at conclusion of the study, requiring data from the six month Follow-up data collection time point (Week 33) in order to calculate the difference. Thus any participants for whom no Week 33 data were collected were removed from the analysis, rather than possibly introducing a systematic error by attempting to replace missing values for those participants with either their former values at the last completed data collection (Week 8, six months earlier) or by replacing missing values with the average of the values of other participants in the study, either as a whole or in their specific treatment arm. Neither of these options could be expected to result in accurate imputed data for the Week 33 data collection time point in this ageing population, so cases for whom no Week 33 data were collected were excluded from analysis.

The next consideration was adherence to the treatment protocol, including treatment timelines. Participants were included for analysis, regardless of whether they completed all 7 treatments in the series, and regardless of whether they completed their treatment series within the usual 42-60 days of the treatment series. Exclusion of these treatment non-compliers from analysis, would have resulted in a "per protocol" analysis, which has been shown to introduce a bias and overestimate treatment effect (Moher et al., 2010). By keeping these treatment non-compliers in the analysis, we have preserved the benefits of randomisation (Moher et al., 2010; Polit & Gillespie, 2008).

While *treatment protocol* adherence was not a reason for exclusion of cases, adherence to *data collection protocol* timelines was also considered and resulted in two exclusions. The two exceptions were two participants from the placebo group whose six month (Week 33) data were collected 11 and 13 months after their treatment series were completed. These two data sets were not included in the analysis, as the effect of the natural ageing process over the extended time period would possibly introduce a substantial contaminant and thus affect the results of these two participants. However, other minor variations from data collection timelines were not a cause for exclusion.

The above inclusions thus distinguish the analysis undertaken from a 'per protocol' analysis, where only those participants who are 'compliers' with all aspects of the study protocol are included for analysis. The aforementioned aspects of study protocol adherence were however evaluated from the data, and the results of that evaluation are included in the Results chapter. These above inclusion and exclusion decisions thus made this analysis a modified Intention to Treat Analysis, as defined by Polit and Gillespie (2008). This modified Intention to Treat analysis is in keeping with CONSORT recommendations (Moher et al., 2010) as an acceptable alternative to a pure ITT, as long as the investigators fully disclose their decision making process and the number of cases excluded from analysis, with the reasons for doing so, as has been described above and detailed in the accompanying participant flow diagram (Figure 3).

## Randomisation Process

The program Excel was used to generate multiple series of 10 numbers between 1 and 100. For each series, they were evaluated as to whether there was a balance between odd and even numbers. If the series was not balanced, it was discarded. If the series was balanced, it was copied and pasted onto the second Excel worksheet.

This process continued until 20 balanced series of ten randomly generated numbers were obtained. For each series, an even number was converted to an allocation of Healing Touch and an odd number was converted to an allocation of Mimic Healing Touch (placebo).

Then random numbers between 1 and 20 were generated, and used to allocate which of the 20 series would be used first, and which would be used second, etc. Any repetitions were skipped over and the next number that had not already been ordered would be used as the next one to occur in the series. For instance, the series number 11 came up again in the sixth position, but it had already been assigned earlier, so it was skipped over, as was the series number 10, which came up in the seventh position but had also already been used earlier.

The words "Healing Touch" were printed in large font on 4 lines spaced evenly on an A4 sheet of paper. The paper was cut in half and in quarters to achieve 4 allocations on an A4 width and a height that slid easily into the envelopes. The same process was repeated for the words "Mimic Healing Touch" to generate 100 of each allocation slip of paper.

The brown internal office envelopes were stuffed with the allocations in numeric order from series # 1-20 by the Principal Investigator, except for series 19 and series 11, (the two series that were randomised to be the first two series to be used for the January 2009 enrolments). These two series were stuffed by someone else, to avoid any potential inadvertent memorisation of the order of allocations by the PI. The series 1-20 were ordered in their randomised sequential order and kept in a lidded cardboard box in a locked office.

As the enrolment continued, the envelopes were removed from the box and inserted in to a new participant chart, maintaining the randomised order of the envelopes conforming to the process above. New participant charts were carefully kept in the randomised order in a locked briefcase on wheels used during the home visits, and were not allocated to a specific participant until the full enrolment process described below occurred.

Participants called in to enquire/enrol in response to various recruitment methods. If the PI was unavailable to answer the phone, the participant was invited to leave a voicemail message as per the outgoing announcement in the voicemail box. When the PI was next available, she returned phone calls in the order in which they had been received, leaving a message for the participant if she was not able to contact them directly, and also trying again at a later time. At the initial phone contact, if the participant was not available to speak for the 20-30 minutes required to complete the screening and enrolment process, then an alternative time to discuss the study was negotiated.

During the phone conversation, the participant was screened for eligibility as per all inclusion/exclusion criteria except the MMSE. If they met the eligibility requirements, they were assigned a participant code (i.e. A001) at this time. Their 7 appointments with the PI were then booked according to participant availability and preference (i.e. 'next week on Tuesdays at 10:00am' or 'two weeks from now on Thursdays at 5:00pm' etc.).

Once the participant was phone screened, given the next participant code and booked with the PI for the 7 intervention appointments, the RA was notified of the new enrollee and given contact details through a secured communication channel. The RA rang the participant directly and scheduled the Pre-intervention Week 0 data collection visit to occur prior to the first scheduled intervention visit by the PI. The RA contacted the PI after that baseline visit, to report if the participant had scored high enough on the MMSE to continue in the study. If the participant was not eligible due to a low score on the MMSE, the RA had deferred completing any of the other instruments in the questionnaire package and explained to the participant that they were not eligible to continue, and given them a previously prepared handwritten thank you card from the PI and the RA, expressing gratitude for their time and interest. If the participant did pass their MMSE at 28 or above, the PI moved them forward to the next step.

Shortly before each initial intervention home visit, the PI created new participant charts in the order of participant visits to occur. For instance, the Monday 8am participant was given the next new chart (with envelope of randomised treatment allocation) from the stack, the Monday 10am new participant was given the second chart (with envelope), the Monday 12pm new participant the third chart, etc. No allocation was made until close enough to the next new initial visit to be sure that there were no other potential timeslots into which another new initial visit could be scheduled to occur at an earlier time/date. This attention to detail ensured that the exact sequence of randomised allocations was maintained.

Once this treatment allocation envelope had been assigned to a particular participant and inserted in to their prepared new patient chart, then this pairing of treatment allocation and participant was maintained. If circumstances for either the participant, the RA or the PI required a postponement of their initial visit at the last minute, then the participant still continued with the same envelope/chart/allocation. This happened twice due to illness for the RA and once due to illness for the PI, and three times due to postponement by the participants.

At the time of the initial intervention visit by the PI, introductions and the intake interview (health history) were conducted without the PI being aware of the participant's allocation. Only after the participant had been settled comfortably onto the massage table or chair, and their ear plugs and sleep mask had been applied, did the PI open the envelope and discover if this participant had been randomly allocated to Healing Touch or to Mimic Healing Touch.

## **Study settings**

The study was conducted in the participant's home, with both the RA and the PI conducting home visits for the purposes of data collection and treatment. The PI brought all necessary equipment to the home and delivered the 7 treatment sessions there. A private setting was required, as an observer would probably be able to determine if the participant was receiving the actual Healing Touch treatment or the placebo treatment. The Research Assistant also visited the participants in their private residences for all three data collection events, unless the participant had temporarily relocated (i.e. been hospitalized, two participants) or permanently relocated (i.e. moved in to a residential aged care facility, one participant). The location of the data collection was recorded on the questionnaire.

On a few selected occasions, another person was present in the participant's home during a home visit. When this was unavoidable during a treatment session, the other person was

asked to remain in another room, without any visual contact with the PI and the participant. All other protocol setting requirements were maintained, although the sound of a television and/or inaudible levels of conversation in the next room were noted as background noise. Since the participant was provided with ear plugs during each treatment session anyway, these muted and distant noises were not considered a sufficient deviation from protocol to require the treatment session to be cancelled. However, in the rare situations where visual contact was unable to be shielded and/or if auditory distractions were loud enough to be considered detrimental to the participant's ability to relax and enjoy their session and/or to the PI's ability to concentrate and provide an appropriate treatment session, then the appointment was rescheduled.

Similarly, if another person was going to be present in the home during a data collection visit, the RA usually re-scheduled the home visit. If rescheduling was not possible or desirable, then the RA isolated the participant out of earshot from the other people in the home, to preserve privacy and to ensure there was no bias in response. In one instance early in the study (within the first 15 participants), a family member remained in the room, and both the RA and the participant herself felt that the data were not representative due to distraction and bias. In this instance, the RA came back a couple of days later to complete the questionnaire from the point of interruption onwards, and also repeated one instrument (Spiritual Well Being scale) for which the participant felt she had been unable to concentrate and respond accurately. In all other instances, the participant was alone in the room with the RA when data collection occurred, and was usually also alone in the house with the RA when data collection occurred.

The specifics of the home setting were collected as part of the data, and ranged over the following possibilities: residing in houses in ordinary residential neighbourhoods; in units (apartments or duplexes) in ordinary residential neighbourhoods; in villas in retirement villages (some attached, some detached); in a granny flat on a family or non-family members' property; in a room in a family member's home; in a hospital room; in a residential aged care facility room; and in a one-bedroom kitchenette-only unit in a retirement village where meals were served in a communal dining room, but no supervision or health care was provided (which was still considered independent living and did not qualify as a hostel or low-care bed).

The treatment series was either suspended or concluded early when participants entered the hospital or a residential aged care facility. Since ethics approval to conduct the treatment session was not feasible for every possible health care institution to which a participant might relocate during their 7 treatment sessions, and since conducting a treatment session in a health care facility would be more likely to result in observation and thus determination of the participant's allocation in to the treatment arm versus the placebo arm, then their treatment series was either temporarily suspended and resumed upon their hospital discharge and recovery (1 participant); or the treatment series was concluded early (1 participant after 6 sessions; another participant after 5 sessions). When possible, even if the full series of 7 treatments had not been completed, data collection for the post-intervention Week 8 time point and/or the six month Week 33 follow-up time point was still completed, in the setting in which the participant was currently residing, with appropriate considerations for privacy and data integrity, as described above.

## Challenges in the home setting

There were a number of challenges inherent in the use of the home setting while conducting an intervention according to an experimental protocol, including privacy, temperature, noise levels and interruptions, which will each be discussed in turn. Although the setting was different for each participant, in that each home was different from every other home, a number of precautions were taken to minimise variability and to adhere to the protocol. The environment was set up prior to the PI opening the envelope to reveal that participant's allocation in to the experimental or placebo group. Therefore, in all cases the environment needed to be controlled to be shielded from the view of others.

To that end, in each setting, the treatment was conducted in a private or semi-private area, where visual contact by others was impossible or highly unlikely. Due to the requirements of a large enough space to set up the massage table, and for the PI to move around all four sides of the table to reach various sections of the body for the techniques, then the treatment session often was conducted in the lounge or living room area. The front door was closed, and the front window drapes were pulled closed, unless naturally shielded from the foot path and/or road by distance or foliage. The participant was notified during the phone screening conversation that a private and quiet environment was required, and that any visiting house guests would need to be off the premises while the session was conducted. In a few instances, house guests visiting from out of town (or for one participant, her non-resident caregiver), remained on the premises, but the treatment session was conducted in a different room to avoid visual contact.

Temperature then became another consideration. In the warmer climate of the tropics during the extended summer season, closing doors, windows and/or drapes sometimes necessitated an alternative source of air flow, such as turning on an overhead fan and/or opening other windows; or using an air conditioner. Given the methods used in the Placebo Protocols (see Appendix O), an alternative explanation for a sensation of air movement over the body also served the function of assisting in preserving the blinding of the participant, so the use of fans in the room was encouraged for all participants. The treatment protocol also called for a lightweight sheet to be placed over the top of the participant (again to preserve blinding so the feel of the filled leather glove was not able to be distinguished from the skin of the PI's hand). Despite the light weight nature of the sheet, some participants in some sessions still found the sheet to be warm, so fans and/or air conditioning were encouraged. In many homes, fans and/or AC were already in use at the time of arrival anyway. One participant found the lightweight sheet provided by the PI to be so uncomfortably warm that she requested to use a cotton sheet of her own, and this accommodation was allowed to prevent attrition. Another participant had an allergic reaction to the material of the sleeping mask, and so a small hand towel of her own, carefully folded and draped over her eyes by the PI was used instead.

The last environmental control was in regard to noise levels. As per the script used in the Phone Screening conversation (see Appendix L), the participant had been advised in advance that ear plugs would be provided to screen out noise and allow them to fully enjoy the relaxation of their session. In residences with shared walls, the next door neighbour's television or radio might be a source of unwanted noise. Traffic noise, lawn mowers, school playgrounds or parks and other sources of external noise were also blocked by closing windows and the use of the ear plugs. Again however, the ear plugs also helped to preserve

the blinding of the participant to the sound of the stuffing moving around in the filled gloves as they were re-located to a new area of the body (see the Placebo Protocols, Appendix O). Lastly, the ringer on the participant's phone was turned off, or the phone unplugged from the wall, in order to avoid a startling response during deep relaxation. The participant was then reminded as the PI was packing up the equipment, to turn the phone back on again, or else the PI would do it for the participant if she so desired. The participant had been advised of these environmental controls during the Phone Screening conversation (see Appendix L).

Potential and actual interruptions were another source of variation in the environment. Participants were notified during the first session that it was best for them to not be interrupted while in a deep relaxation state, that the sequence of steps in the protocol needed to be maintained for a research study, and that the PI needed to spend fairly close to the same amount of time with each participant before moving promptly on to the next scheduled appointment. (See Pre-Treatment Session Briefings, Appendix D). Hence any unexpected visitors to the front (or back) door would be greeted by the PI, while the participant remained resting on the massage table with their ear plugs and sleeping mask intact. The PI would explain that the participant was having a relaxation session and could not be disturbed or interrupted, and that she would be available again in about an hour, and offer to take a message, and gently send the visitor away. In a few situations, the participant spoke briefly to the person at the door from their position lying on the massage table, but the visitor then promptly left without having had the opportunity of observing any treatment techniques in progress. Participants were understanding of this precaution and readily complied. In one session out of 1,142 home visits, the interruption was unavoidable, and the treatment session had to be suspended while the participant arose from the massage table and briefly dealt with the visitor.

Despite these precautions, a portion of two treatment sessions might have been observed by the unexpected entry in to the treatment area by a family member. The prompt awareness of the interruption by the PI in these cases, coupled with the screening precautions described above and/or the nature of the technique being used during that particular session, are believed to have been sufficient to avoid the observer from becoming aware of the participant's group allocation, (and potentially relaying that information to the participant). In addition, the unfamiliarity with the Healing Touch techniques would have made it difficult for these observers to be sure if what they had seen, (if they did in fact see anything), was a genuine Healing Touch technique or the simulated Healing Touch techniques from the placebo protocols.

Many participants, especially after enjoying the relaxation of their first session, came up with their own methods to avoid possible interruptions. Many participants reported notifying neighbours and family members of their weekly appointment times so they would not be disturbed and could fully enjoy the relaxation of their scheduled treatment session. A few created home-made handwritten "Do Not Disturb" signs for their front door or front veranda. After consideration, the PI did not create and use such a sign herself routinely for all participants, as it could be seen as a privacy violation for the participant and/or considered an overly restrictive part of the protocol. However, if the participant suggested the use of such a sign, it was allowed. Thus standardisation of the sign was not possible, but standardisation of no interruptions to the treatment session by visitors was achieved as described above for all but a few of the 1, 142 home visits.

## **Instruments /Outcome Measures**

Instruments were selected from a range of possible tools in order to achieve the goal of understanding health from a holistic perspective by measuring various health dimensions, with each dimension measured by an instrument specific to that health dimension. Instruments were generally limited in length to one page each, in order to minimise the response fatigue in an older adult sample. Instruments that are well-known, frequently used and widely available were chosen for ease of replication in future research on Healing Touch and other CAMs/CATs. Psychometric properties are presented in varying breadth and detail, depending on availability, as described by the original instrument developers, subsequent users, and/or authors of texts designed to compare and contrast the strengths and weaknesses of various instruments, such as McDowell (2006). Data regarding validity was not as prevalent as data regarding reliability.

### **Primary Outcome Measure**

#### ***Older Americans' Resources and Services Multidimensional Functional Assessment Questionnaire (OARS FMAQ)***

The OARS-FMAQ is a comprehensive survey initially developed to explore alternatives to institutionalisation of older adults (Fillenbaum & Smyer, 1981). Permission to use the instrument was obtained from the authors and a training video was purchased as well, that both RAs were given to watch prior to commencing data collection.

Only the sub-scales regarding functional health in relation to Basic and Instrumental Activities of Daily Living (ADL) were used in the present study. The Basic ADL sub-scale comprises eight questions regarding the participant's self-reported ability to eat, dress/undress themselves, groom, walk, get in and out of bed, take a bath or shower, continence ability, and whether or not they have someone who helps them perform these or other functions. The Instrumental ADL sub-scale comprises an additional seven questions regarding using the phone, transport, shopping, meal preparation, housework, money management and administration of medication. For all questions, the possible responses are 0 for unable, 1 for able to perform with assistance, and 2 for able to perform independently. Thus higher scores indicate more independent functioning. The Basic ADL scale ranges from 0 to 15, while the Instrumental ADL possible score ranges from 0 to 14. The two are summed to reach the Total ADL score, which ranges from 0 to 29. The scoring described above is the method of scoring commonly used in current research (McDowell, 2006), but the original OARS-FMAQ relied on the interviewer to make a global clinical judgment of the participant's overall classification of ADL functional ability, with a much narrower score range of 0 to 6, allowing less discrimination (Fillenbaum & Smyer, 1981). Hence the more common scoring described above was used in this present study, to enable more subtle discrimination of changes over time.

The instrument was initially developed and tested with elderly community residents (Fillenbaum & Smyer, 1981), and enjoys robust psychometrics. Duke University Center for the Study of Aging and Human Development, reported five week test-retest correlations for 30 elderly subjects of 0.82 for the Basic ADL sub-scale and 0.71 for the Instrumental ADL sub-scale (1978, as cited in McDowell, 2006, p.599). Fillenbaum conducted a factor analysis of the full OMFAQ instrument, and identified one factor each for the Basic ADL sub-scale and for the Instrumental ADL sub-scale (1988, as cited in McDowell, 2006, p.601). Both the full OARS

FMAQ and the ADL sub-scales have been widely utilized, with robust reliability coefficients reported (McDowell & Newell, 1996), presumably based on the rater scoring system intended by the instrument's developers, as described above. For instance, Reuben, Valle, Hays and Siu (1995, as cited in McDowell, 2006, p.599) reported an alpha internal consistency for the Instrumental ADL sub-scale of 0.68.

In this present study, the reliability coefficients were also generally robust. The lowest performing sub-scale was the Basic ADL sub-scale (Cronbach's alpha of 0.309 at Week 0; 0.276 at Week 8; and 0.424 at Week 33; n = 153 at all time points.) The Instrumental ADL sub-scale demonstrated a Cronbach's alpha reliability coefficient of 0.555 at Week 0; 0.678 at Week 8; and 0.661 at Week 33 (n = 153 at all time points). Lastly, the Total ADL sub-scale (the sum of the Basic ADL and the Instrumental ADL) showed Cronbach's alpha of 0.606 at Week 0, followed by 0.668 at Week 8 and 0.710 at Week 33 (n = 153 at all time points).

## **Secondary Outcome Measures**

### ***Social Support***

Social health was measured using the Medical Outcome Study Social Support Survey (MOS-SSS) developed by Sherbourne and Stewart (1991) with permission received from both authors to use the instrument in this present study. They developed the tool working with 2,987 participants drawn from an ambulatory sick population, all of whom had at least one of four medical conditions (hypertension, coronary heart disease, diabetes or depression). Their participant pool shares similar features to the chosen sample for this present study. The MOS-SSS is comprised of 19 statements with Likert style choices ranging from "none of the time" through to "all of the time." The main stem asks "how often is each of the following kinds of support available to you if you need it?" and then goes on to list statements such as: "Someone to help you if you were confined to bed" or "Someone whose advice you really want" or "Someone who hugs you." Although four sub-scales can be used, the focus for statistical analysis in this present study was the total score, which ranges from 0 to 100.

The internal consistency reliability coefficient, Cronbach's alpha, was 0.97 for the original instrument (Sherbourne & Stewart, 1991). The instrument has been previously validated in a number of populations, including older adults (McDowell & Newell, 1996), who were also included in the development of the questionnaire (Sherbourne & Stewart, 1991). Other older adult populations similar to the sample in this present study were studied with this instrument; these included patients with COPD, mean age of 67, receiving nursing care in the home (Coulter, Frederick, Barnett, Singh & Wludyka, 2005); Taiwanese elders with hip fractures (Shyu, Rang, Tsai, Liang & Chen, 2006); male and female post stroke patients, mean age 66 (Michael, Allen & Macko, 2006); older men aged 40-86, where the scale's internal consistency coefficient was 0.96 (Hill & Donatelle, 2005); and male and female cardiac patients with a mean age of 66, where the scale's internal consistency as measured by a Cronbach's alpha coefficient was 0.95 (Urizar & Sears, 2006). In this present study, Cronbach's alpha was similarly high as that originally reported by the instrument authors, at 0.948 for the Week 0 data; 0.961 for the Week 8 data and 0.946 for the Week 33 data.

## ***Psychological Well Being***

The original Psychological Well Being Scale (PWBS) was developed from qualitative research using a sample of 171 middle aged and older adults (Ryff, 1989a), and the original scale comprised of 120 items, with 20 items per each of six sub-scales (Ryff, 1989b). Items are scored across a Likert scale of strongly agree to strongly disagree, with higher scores representing higher levels of psychological well-being. The PWBS-short form of 18 items was used for this present study, with a scale range of of 18- 108. Six of the items are negatively worded and require reverse scoring.

Each sub-scale in the original instrument was theoretically derived to represent six different domains of psychological well-being, and the appropriateness of the six dimensions were confirmed through factor analysis (Ryff, 1989b; Ryff & Keyes, 1995). The PWBS-short form of 18 items was later developed (Ryff & Keyes, 1995) by sampling only three of the original 20 items in each dimension's sub-scale, and these three question items were chosen by the developers of the scale as ones that would provide the best representation of the full breadth of that sub-scale's dimension (Ryff & Keyes, 1995). This decision preserved the breadth of the dimensions and maximised content validity, but resulted in low Cronbach's alpha coefficients for the sub-scales, which ranged from the lowest coefficient of 0.33 for the "Purpose in Life" sub-scale to a maximum of 0.56 for the "Positive Relations with Others" sub-scale (Ryff & Keyes, 1995), which were confirmed as low in a later study as well (Keyes, Shmotkin & Ryff, 2002), where the "Purpose in Life" Cronbach's alpha coefficient was only 0.26.

However, the PWBS-short form is still widely used, particularly in time-limited contexts such as telephone surveys (Keyes, Shmotkin & Ryff, 2002) or in high volume large national surveys (Clarke, Marshall, Ryff & Wheaton, 2001). Therefore it was deemed adequate for the purposes of this present study, which was to obtain a robust measure of overall psychological well-being as one of a number of other discreet health domains, without inducing survey burden fatigue in a potentially frail sample.

This scale was also chosen for this present study because it was developed using age-stratified sampling and was sensitive enough to discriminate between age groups, even for some of the sub-scales of the PWBS-short form (Ryff & Keyes, 1995); and was also used in later studies with older adults (Clarke, Marshall, Ryff & Wheaton, 2001). Despite the above noted limitations in the use of the sub-scales of the PWBS-short form, the scale overall correlates well with the original 120 item scale (Ryff & Keyes, 1995) and each of the 18 items correlates strongly and positively with its own sub-scale (Clarke, Marshall, Ryff & Wheaton, 2001).

Permission was requested from Carol D. Ryff for use of the scale in this present study. Response from a member of her research team (Theresa Berrie, personal communication by email), identified a more recently developed 42 item version with stronger psychometrics that is their preferred version for situations when the original 120 item scale is considered too lengthy. She mentioned psychometric problems (see above) and noted that the 18 item instrument does not do as good of a job of covering the content of the six sub-scale constructs as does either the 42 item instrument or the original 120 item instrument.

However, given the premise in this present study of using a holistic, multidimensional battery of instruments, the need for each instrument to be contained to a one-page tool outweighed the superior psychometrics of the 42 question version, particularly given the concern for over-burdening a potentially frail older population. Therefore the 18 item version was retained, but

only the total PWBS-short form scores were used for statistical significance testing for differences between treatment groups in this present study, rather than an in-depth analysis of the six sub-scale constructs. In this present study, the total PWBS-short form demonstrated adequate internal consistency with a Cronbach's alphas of 0.844 for the Week 0 data, 0.843 for the Week 8 data, and 0.736 for the Week 33 data.

### ***Spiritual Well Being***

The Spiritual Well-Being Scale (SWBS) was developed by Raymond Paloutzian and Craig Ellison to fill a need for a quantitative measure of the influence of a spiritual dimension on quality of life (Paloutzian & Ellison, 1982). The scale has 20 items, and consists of two sub-scales: Religious Well-Being (RWB,) and Existential Well-Being (EWB), which are summed to achieve the total Spiritual Well-Being (SWB) score. Each of the 10 (odd numbered) items in the RWB sub-scale uses the term "God" while none of the 10 (even numbered) items in the EWB do so. For the purpose of this study, at the first mention of the term "God" the RA had a footnote to a potential modification where the participant was offered a list of alternative terms, or the option to insert a term of their own creation, in lieu of the word "God" for all the following items that contained that term. This suggestion was mentioned as a suitable option by the authors (Paloutzian, 2002) in response to requests asking to adapt the instrument by a substitution of terms such as "higher power" for the term "God". Adapting the instrument from a pen-and-paper tool to a verbally administered tool was also considered suitable (Paloutzian, 2002) for children, and was done in this present study for older adults in order to standardise data collection procedure while working around potentially high prevalence rates of vision or dexterity impairments in the chosen sample.

Each item of the SWBS is scored on a Likert scale with response choices ranging from strongly agree to strongly disagree, scored from 1 to 6, with higher scores indicating greater levels of well-being (Paloutzian & Ellison, 1991). Each sub-scale has a range of 10-60, and the total SWBS has a range of 20-120 (Paloutzian & Ellison, 1991). Half of the items in each sub-scale are negatively worded and reversely scored (Paloutzian & Ellison, 1991). The authors recommend examination of not just the total scale scores, but also the scores of each sub-scale, as high scores on one sub-scale do not always correlate with high scores on the other sub-scale (Paloutzian & Ellison, 1982). Psychometric properties reported by the authors (Paloutzian & Ellison, 1982) during development included robust test-re-test reliability coefficients of 0.93 for SWB, 0.96 for RWB and 0.86 for EWB, as well as high Cronbach's alpha coefficients for internal consistency of 0.89 for SWB, 0.87 for RWB and 0.78 for EWB. In this present study, the total Spiritual Well Being Scale demonstrated adequate internal consistency with a Cronbach's alphas of 0.933 for the Week 0 data, 0.941 for the Week 8 data, and 0.898 for the Week 33 data.

The instrument is recommended by the authors as suitable to evaluate the impact of nursing interventions in hospital and other nursing care settings by serial testing over a period of time (Ellison & Smith, 1991; Paloutzian, 2002). They go on to report that it has been used in multiple settings (".....universities, seminaries, hospitals, clinics and federal prisons") and with diverse samples, including "undergraduate and postgraduate students, housewives, professional women, servicemen, teenagers, nurses, the elderly, the hospitalized, evangelical believers, ethical/cultural Christians, and non-Christians" (Ellison & Smith, 1991, p.39), in both the authors' country of origin (USA) and numerous foreign countries such as Taiwan, Israel, Korea, Hong Kong and the Netherlands (Paloutzian, 2002). Twenty years after the tool's

development, one of the authors noted that more than half of the studies using the SWBS had been conducted within the discipline of nursing (Paloutzian, 2002), similar to this present study. In a description of norms obtained in a variety of populations and settings, the authors noted that age and gender do not appear to be related to SWBS, so the need for separate norms for age groups or gender groups is doubtful (Bufford, Paloutzian & Ellison, 1991). The norms reported in the above publication regarding a sample most similar to the sample in this present study are those reported by Sherman (1986, as cited in Bufford, Paloutzian & Ellison, 1991) for 56 medical outpatients: a mean(standard deviation) of 51.50(9.67) for RWB; 48.50 (8.38) for EWBS; and 99.89(16.01) for SWBS. The authors also report a known ceiling effect for this instrument, with scores highly skewed (Bufford, Paloutzian & Ellison, 1991). Permission to use the instrument was obtained and sufficient copies for this present study were purchased from Life Advance, Inc, 81 Front Street, Nyack, New York 10960 ([www.lifeadvance.com](http://www.lifeadvance.com)).

Given the similar response choices in the Spiritual Well-Being Scale and the Psychological Well-Being Scale of strongly agree to strongly disagree, these two instruments were purposefully separated in the sequencing of the instruments in the questionnaire package, to avoid participant's potential tendency towards choosing the same response for every item, and thus introducing a response bias.

### ***Duke Health Profile***

The Duke Health Profile was created as a "brief and practical measure to evaluate patient-reported functional health status in primary care settings" (McDowell, 2006, p. 591). This 17 item instrument (Parkerson, Broadhead & Tse, 1990) is a derivation from the original 63 item Duke-UNC Health Profile (Parkerson, Gelbach, Wagner, et al., 1981). The design of the original instrument was underpinned by the World Health Organisation's definition of health as multi-dimensional, and thus included sub-scales for physical, emotional and social function, as well as symptom status (McDowell, 2006). The shorter form 17 item Duke Health Profile used in this present study can be further divided in to 11 sub-scales, some of which measure function and some of which measure dysfunction. The 11 sub-scales are computed through use of 1 or more items per sub-scale, with many items then being used again in other sub-scales. The presence of shared items in multiple sub-scales prevents them from being seen as independent measures, another limiting feature for the use of the sub-scales for the purposes of the present study. Concern already existed for multiplicity of statistical significance testing in this present study, due to the decision to include multiple instruments described above to robustly measure each of several selected health domains to achieve a holistic picture of the participants' health status. Therefore, it was decided that the 11 sub-scales of the Duke would not be used, but rather only the total Duke score, as a measure of overall Quality of Life and functional health status. To that end, rather than using the complex sub-scale calculations provided by the authors, their less complex scoring option of a simple sum of the 17 items was used (McDowell, 2006, p. 593). Each item was separated into three choices per item, scored as 0, 1, or 2, with higher scores indicating better health status, and a scale range of 0 to 34.

The Duke Health Profile was also chosen because a number of the items queried within it reflected benefits mentioned by recipients of Healing Touch treatments in qualitative research, such as anxiety reduction (Krucoff et al., 2001), pain reduction (Slater, 1996; Wardell et al., 2006), or improvement of sleep (VanAken, 2004). Therefore the instrument appeared to have face validity. Lastly, the Duke included a question regarding self-esteem, another positive benefit noted in qualitative findings in prior HT research (Van Aken, 2004). In

addition, the instrument was developed with a study population of 683 primary care adult patients, similar in many respects to the sample chosen for this present study, with solid reliability as noted by Cronbach's alphas of 0.55 to 0.78 and test-retest correlation coefficients of 0.30 to 0.78 (Parkerson, Broadhead & Tse, 1990). In this present study, the Duke Health Profile demonstrated adequate internal consistency with a Cronbach's alphas of 0.659 for the Week 0 data, 0.751 for the Week 8 data, and 0.708 for the Week 33 data.

## **Ancillary Analyses**

### ***MMSE***

The Mini Mental State Examination (MMSE) was used primarily as a screening tool in this RCT, to exclude potential participants already demonstrating even mild cognitive impairment, and to ascertain reliability of self-report data. There are 11 items covering multiple cognitive functions such as orientation to time and place, registration, attention and calculation, recall, naming, repetition, comprehension, reading, writing and drawing. The items require the participant to follow written and verbal commands, write a sentence, draw a diagram, and verbally respond to questions.

This instrument was designed for use with older adults, and has been employed widely in both clinical and research applications since its creation (Folstein, Folstein & McHugh, 1975; McDowell, 2006). The MMSE enjoys robust psychometrics, as reported by Folstein (as cited in McDowell, 2006, p. 430) with a test-retest reliability of 0.89 and inter-rater reliability of 0.82. These findings were confirmed by numerous later researchers, with test-retest reliability ranging from 0.56 to 0.92 over 24 hours elapsed time between testing, but decreasing to ranges from 0.38 to 0.83 over 1 to 2 months between testing (Folstein, Folstein & Fanjiang, 2001).

Internal consistency is noted to be higher in clinical samples, with Cronbach's alpha coefficients ranging from 0.56 to 0.96, as compared to community samples, where alpha coefficients were ranging from 0.31 to 0.77 (Folstein, Folstein & Fanjiang, 2001). In this present study, the MMSE was hand scored during the home visit at the time of the Week 0 Baseline data collection, as an eligibility screening instrument, so only the total MMSE score was entered in to the data base, not each individual item score. Therefore, a Cronbach's alpha coefficient for the sample of this present study was unable to be calculated.

There are some potential variations in administering and scoring the MMSE, so the MMSE Clinical Guide written by the instrument authors (Folstein, Folstein & Fanjiang, 2001) was obtained, as well as a journal article detailing the potential variations in scoring and the rationale for each variation (Molloy & Standish, 1997). The RA and PI discussed each item and made decisions together how to score the items. For instance, given our location in tropical North Queensland, a correct identification of the wet versus dry season was accepted as accurate. The decisions were noted directly on the journal article, which the RA carried with her for reference in the field, as well as a copy of the second chapter of the Clinical Guide "Administration & Interpretation" (Folstein, Folstein & Fanjiang, 2001). These calibration decisions were reviewed with the second RA upon hiring, as part of her training, before commencing on joint data collection home visits with the first RA for training and for confirmation of inter-rater reliability.

The range of the MMSE scale is between 0 and 30 with higher scores indicating greater cognitive ability (Folstein, Folstein & Fanjiang, 2001). A change in score of 2 to 3 points across repeat administrations is considered clinically significant, while a sample diagnosed with Alzheimer's disease displayed annual declines of 3 to 4 points (Folstein, Folstein & Fanjiang, 2001). Permission to use the instrument was obtained, and the Clinical Guide written by the instrument authors was also purchased and consulted (Folstein, Folstein & Fanjiang (2001).

### ***Charlson Co-Morbidity Index (CCI)***

The Charlson Co-Morbidity Index (CCI) is a weighted index for 19 different diseases or categories of diseases, designed originally as a prognostic indicator for mortality based on chart review (Charlson, Pompei, Ales & MacKenzie, 1987). A later version based on participant self-report data per pen and paper questionnaire or verbal questioning was developed and used in this present study (Katz, Chang, Sangha, Fossel & Bates, 1996), although scoring was based on the weightings published for the original instrument (Charlson et al, 1987). A score of zero indicates the absence of any co-morbid conditions, while a score of 1 indicates one of the lower severity conditions, (i.e. myocardial infarct or diabetes), while increasingly higher scores are noted as additional and more serious co-morbid conditions are identified. Higher weighted conditions include for instance, leukaemia or diabetes with end organ damage (weighted as 2); moderate or severe liver disease (weighted as 3) and AIDS or metastatic solid tumour (weighted as 6). The CCI was used in this present study to identify a potential confounding variable of greater co-morbidity in one treatment group versus another at baseline. This scale was also used to assess for increasing co-morbidity over the course of the study period, in the sample as a whole. Reasonable Cronbach's alpha coefficients were obtained for the participants in this present study, with an alpha of 0.561 for the Week 0 data (n=116); an alpha coefficient of 0.504 for the Week 8 data (n = 133); and an alpha coefficient of 0.481 for the Week 33 data (n = 132).

### ***Vital Signs***

Given the setting in the participant's home, portable equipment that did not require a source of electrical power was chosen for vital sign measurements. Temperature was assessed using a digital oral thermometer. Blood pressures were obtained by use of a stethoscope and an analog sphygmomanometer on the left arm only. Pulse and respiratory rates were obtained by placement of a stethoscope on the participant's upper chest, counting for 30 seconds for pulse and then another 30 seconds for respirations, and then doubling the rates to obtain a rate per minute for charting. Participants were told their heartbeat was being counted, but were not told their breaths per minute were being counted, to avoid conscious alteration of respirations.

### ***Participant Self-ratings of health dimensions***

Before and after each treatment session, the PI asked participants to rank their perceived health status on a scale of 0 to 10, with 0 being the worst possible health imaginable, and 10 being the best possible health imaginable. The rating was obtained for physical health status, emotional health status, intellectual health status, and spiritual health status. A brief synopsis of possible definitions of spiritual health was provided at the first visit, but for subsequent visits, only the phrase "spiritual health as you define it" was used as the verbal prompt. As was noted in the literature review in Chapter Two, visual analogue scales have been used

successfully in a number of prior studies of Healing Touch, and so an adaptation of the 0-10 scale was included in this present study as a simple tool to monitor for immediate treatment effects in the four domains of health that energy therapies purport to influence (Bradford, 1993; Brennan, 1987; Gerber, 2001; Hover-Kramer, 2002; Hutchison, 1999; Mentgen, 2001; Oschman, 2000; Wardell & Mentgen, 1999). The PI indicated by use of her hand at the participant's waist level while seated on the massage table, the lower point for the zero mark while stating "the worst possible health you can imagine" and then raised her hand to the participant's eye level while stating "the best possible health you can imagine." Ratings of 0-10 are a common tool in clinical and research settings and despite their simplicity, enjoy adequate psychometric properties (Williamson & Hoggart, 2005).

### ***Demographics***

Conventional demographic information was obtained regarding age, income, education, religion and marital status (see Appendix P). Additional information was obtained as potential confounding variables regarding country of birth, English language skill and the use of other complementary and alternative therapies (CATs). Lastly, as a possible outcome effect of treatment, information was obtained regarding the most recent hospitalisation history and the current living arrangement from a choice of varying levels of dependent to independent settings. Collection and comparison between treatment groups of descriptive demographic information allows the researcher to check for the adequacy of the randomisation process in distributing demographic characteristics evenly between comparison treatment groups (Polit & Beck, 2006).

### ***Satisfaction with treatment series***

Additional information was collected regarding the participant's satisfaction with the length of each treatment and with the number of treatment sessions, both to enable comparisons between treatment groups and to further inform decision-making regarding dosage regimens and the length of treatment series for future research (see Appendix P). Participants' attitudes towards the therapy were also gauged, by asking their interest in future Healing Touch sessions at various costing levels (free, Medicare-subsidized or out-of-pocket) and if they would recommend Healing Touch to a friend or family member. Lastly, a semi-structured interview template was used to further gauge their perceptions of the experience of receiving Healing Touch or mimic Healing Touch (placebo), and to ascertain their belief regarding into which group they had been randomly allocated for the study.

## **Procedure and Timing of Contacts with Participants**

In the pilot study, the RA timed the duration for each instrument in the questionnaire for the Pre-intervention Week 0 data collection visit on all 4 participants. For the first two participants, they were given the questionnaire to read for themselves and to write in their responses themselves. For the second two participants, the RA verbally read out each question to them and then the RA circled/wrote in their responses. While there was no substantial difference in the amount of time taken for the two methods of data collection, the RA felt more confident that the participant understood the question and was giving an accurate response by using the verbal method of questioning. This method allowed for the participant to request clarification about the question and/or for the RA to request

clarification about the answers, as well as to observe for non-verbal cues indicating a lack of hearing and/or of comprehension for each question. Given that some participants would be unable to read/write their responses due to vision or fine motor coordination difficulties, and that this ability might decline over the 9 month course of data collection, the PI, the RA and the primary supervisor decided that all data collection for the main study would occur through verbal questioning by the RA. This allowed standardisation across data collection points for any one participant whose visual or fine motor coordination abilities might decline over their approximate 9 month duration in the study, and also allowed for standardisation across all participants. In addition, it gave the RA and PI more confidence that the data that was collected did in fact accurately represent the participant's intended response and the health status being described.

The first instrument on the questionnaire was the Mini Mental Status Exam (MMSE), for which the participant needed to reach a score of 28 or higher out of 30 to be eligible for this study. If they did not achieve that level of score, they were given a handwritten floral pink "Thank You" card, thanking them for their interest but declining their inclusion in to the study. If they did achieve that score, their pre-booked intervention series of appointments commenced as planned.

The intervention consisted of 7 home visits, spaced one week apart, beginning within 1-14 days of the RA's home visit for the Pre-Intervention Week 0 Data collection. As close as possible to the final intervention, but within 14 days of it, the RA returned for the Week 8 data collection home visit. At this time, she completed the same questionnaire again, supplemented by an additional 6 quantitative questions and an additional 5 qualitative questions (see Appendix Q). The qualitative questions were audio recorded and later transcribed by a professional transcription service. The RA then made approximately monthly phone calls to the participant, lasting 5-10 minutes, verifying that no change in address had occurred or was imminent, and thus maintaining contact with and interest by the participant. Six months after the final intervention appointment (within a 10% buffer of 18 days before or after the exact 6 month point), the RA again returned for a home visit to the participant's current residential location, and administered the same questionnaire for the third and final time. This marked the end of the data collection phase for the participant.

Once data collection had been completed for the required sample size, and some data entry and data analysis allowed for reporting of preliminary results, then all participants were contacted for a final time by regular Australian post. Participants had been advised of this final point of contact at the beginning of the study and then it was reinforced by the PI at the seventh and final intervention appointment, as per the Final Session end of Treatment series Script (Appendix Q) and then by the RA at the third and final data collection appointment. Included in this postal communication was a summary of preliminary results (Appendix R), notification of the participant's group allocation by randomisation in to either the experimental group or the placebo group (Appendix S), and a few options for future contact if desired (Appendix T). These options included the offer of one sample session of actual Healing Touch, limited to those participants who had been randomised into the placebo group; the offer to all participants of inclusion in an upcoming information evening or a full Level One weekend class by a Certified Healing Touch Instructor, at a discounted senior/pensioner rate; or inclusion on a list of potential volunteer clients for those students of Healing Touch who were looking for opportunities to further develop their skills in Healing Touch by delivering treatments to volunteer clients. Most importantly, the cover letter for the postal package

included the profuse gratitude of the research team for all the time and effort that the participants had contributed in order to bring the Healing Touch for Older Women at Home research study to a successful completion (Appendix U).

## **Blinding**

Only the PI knew the group allocation status of any one participant, until all participants were notified of their group status in July of 2012. The primary supervisor was advised of the group allocation status of selected participants only when the need arose for discussion and decisions about procedural or logistical matters. Similarly, the Healing Touch mentor nominated by the PI for the purposes of clinical supervision was advised of a (de-identified) participant's group allocation status for the purposes of advice and professional development during case study discussions. Once the participants themselves had been notified of their group allocation status, the research team members were also allowed to know which participants had been allocated to the experimental versus the placebo groups.

## **Intervention and Placebo**

The Intervention Protocol consisted of a series of 7 home visits by the Principal Investigator, who has been trained in Healing Touch techniques, which are described below. Home visits were done on a weekly basis. Each home visit was approximately 1.5 hours long, (including equipment unloading and assembling, multi-modal assessment, treatment, re-assessment, equipment disassembling and re-loading). Participants assigned to the experimental group received a 30 minute actual Healing Touch treatment. Participants assigned to the placebo group received a 30 minute mimic Healing Touch treatment (placebo). All participants had a multi-modal assessment which included a verbal assessment, their rating of their perceived health on 4 dimensions (physical, emotional, cognitive and spiritual) and had their vital signs taken by the PI, who is also a Registered Nurse. Vital sign measurements included oral temperature by digital thermometer, auscultated pulse on the upper chest wall for 30 seconds, visual observation of respirations for 30 seconds while the stethoscope head remained in position on the chest, and blood pressure by manual sphygmomanometer and stethoscope. This multi-modal assessment was done both before and after every treatment session for all participants in both the experimental and placebo groups.

The detailed breakdown of the sequence of events for each home visit is further described in brief steps in the text box below and the detailed steps for the PI to refer to in the field to maintain consistency of protocol are further described in Appendix V.

Healing Touch is a collection of 35 different techniques (see Appendix B), where the Healing Touch practitioner uses either gentle direct touch on the skin, or indirect touch above the skin, or both types of touch, in a prescribed sequence of steps moving through different locations in the body. Energy therapies like Healing Touch are purported to strengthen, balance, and support the energetic field surrounding and interpenetrating the physical body (Hover-Kramer, 2002). Providing this support to the energetic system is theorized to support and maintain physical, emotional, cognitive and spiritual health in the client (Hover-Kramer, 2002).

Some of the 35 techniques also have more specific applications. For instance, a direct touch technique entitled Modified Mind Clearing, uses the palms of the HTP's hands in different locations around the head, neck and shoulders, and is used for alleviating the pain of

headaches or for promoting mental clarity in clients who report feeling scattered in their thinking (Hover-Kramer, 2002). Another example is an indirect touch technique entitled Lymphatic Drain, which uses gentle sweeping motions above the skin, along the extremities and the torso, again in a prescribed sequence, to support the lymphatic system in clients needing repair or support for their immune system (Hover-Kramer, 2002).

In a typical Healing Touch session in private practice in the community setting, the practitioner would perform both a verbal assessment and an energy assessment to guide her selection of which technique to perform that day. Both of these elements were retained in the intervention protocol for this study, with the availability of all techniques not being curtailed. This was an important design feature, as previous research on Healing Touch had restricted the HTP's selection of techniques to be used in the study to only a subset of those available within the Healing Touch curriculum, leading the HTPs involved in those studies to criticize the research protocol as being unrepresentative of true Healing Touch practice (Wardell, et al., 2006).

However, in the interest of protocol consistency, the intervention was standardized to an average treatment time of 30 minutes, with variation not to extend beyond 20-40 minutes at most. In practice, less than a dozen treatment sessions out of 1, 142 home visits went beyond the 30 minute time frame. This limitation on treatment time meant that most participants only received one technique, although for some of the shorter techniques with less steps (i.e. less locations on the body for hand placement), there were some sessions where a 2<sup>nd</sup> technique could be included without running over the protocol's time limits. Rarely, for the same reasons, a 3<sup>rd</sup> technique was able to be included as well.

The 35 techniques within the Healing Touch collection are listed in Appendix B. The placebo group received one of the placebo techniques listed in the Placebo Protocols (see Appendix O). A number of pre-treatment and post-treatment steps were only simulated for the participants who were randomised in to the placebo group, and these differences will be discussed further in the next section.

The experimental group received 7 treatments of Healing Touch sessions, using one (or in a few instances, two) of the 35 techniques available for the Healing Touch Practitioner (HTP) to select among for use for a given client's condition and status at any particular session. Healing Touch as administered in the study was congruent with Healing Touch in non-research settings with a couple of minor modifications. Only one technique, the lymphatic drain, was modified, as it ideally is done with the client lying supine, and then repeated again with them prone; but this mid-session position change was not easily manageable given the sleeping mask, ear plugs, and the mobility levels of some of these older participants. Similarly, the client was placed prone for the full session for back work, rather than turning from supine to prone part way through the session. The other minor modification concerned just one step in the Scudder technique, that is usually performed after the client sits up, with the practitioner standing behind them, and a similar step in the Full Body Connection. The hand position with the client sitting was not included due to the positioning arrangements and the timing of the removal of the sleeping mask in the sequence of the treatment protocol. Other than these minor modifications, all of the other steps (sometimes as many as two dozen hand positions) within all of the other techniques, were still able to be performed as per an authentic Healing Touch session.

## Similarity of intervention to placebo

The mimic HT treatment session was carefully designed to preserve blinding of the study participants to their group allocation. The basic steps of each treatment session at the time of the home visit are listed in the text box below, and a further in-depth description of these steps can be found in Appendix V.

**Table 2. Comparison of sequence of steps for Healing Touch versus Placebo**

Healing Touch (Experimental group)	Mimic Healing Touch (Placebo group)
HTP assists client to sit on massage table	HTP assists client to sit on massage table
HTP asks client to rate P/E/M/S health 1-10	HTP asks client to rate P/E/M/S health 1-10
HTP takes vital signs: T/P/R/BP	HTP takes vital signs: T/P/R/BP
HTP applies ear plugs, sleep mask	HTP applies ear plugs, sleep mask
HTP does a brief protection affirmation	HTP does a brief protection affirmation
HTP grounds	HTP does NOT ground
HTP centers	HTP does NOT center
HTP sets healing intention	HTP does NOT set healing intention
HTP attunes to client	HTP does NOT attune to client
HTP does hand scan assessment	HTP does NOT do hand scan assessment
HTP performs selected <u>actual</u> Healing Touch technique	HTP performs selected <u>mimic</u> healing Touch (placebo) technique
HTP re-assesses by hand scan	HTP does NOT re-assess by hand scan
HTP documents on HT documentation form	HTP documents on HT documentation form
HTP does <u>actual</u> grounding of client	HTP does <u>mimic</u> grounding of client
HTP assists client to sit up on massage table	HTP assists client to sit up on massage table
HTP takes vital signs again	HTP takes vital signs again
HTP asks ratings P/E/M/S	HTP asks ratings P/E/M/S
HTP asks client their experience of the session & documents any comments made	HTP asks client their experience of the session & documents any comments made
HTP assists client off massage table	HTP assists client off massage table

## Similarity of the intervention as delivered in the study protocol to Healing Touch sessions delivered in non-research contexts.

The treatment sessions for the participants randomised in to the experimental group were designed to resemble a typical Healing Touch session performed in private practice in the community as much as possible, with a couple of exceptions described below, that were required to preserve blinding of the participants to their group allocation. In addition, the mimic Healing Touch sessions for the participants who were randomised in to the placebo group were designed to resemble the actual Healing Touch sessions done per the research protocol for this study, again as much as possible. The differences between the actual Healing Touch treatment sessions as per the research protocol for this study and Healing Touch as

practiced in the community are described below, as are the differences between the experimental group's treatment sessions and the placebo group's "treatment" sessions.

The Healing Touch sessions were performed in keeping with the usual practice of HTPs in private practice in the community, with a couple of exceptions. These two exceptions were that the HTP did not briefly discuss the results of the pre-treatment energy system assessment with the client prior to beginning treatment, and again did not briefly discuss the post-treatment energetic assessment results with the client. These two discussions did not occur for clients in either the placebo or the experimental group, to preserve blinding, but they would often occur in a private HT session in the community. Given that no actual energetic assessment was done for the participants in the placebo group, if these discussions had happened, it would have made it obvious which participants were receiving a true assessment and treatment sequence. Given the prevalence of snowball recruiting in this study, with next-door neighbours and siblings in the same study, this adaptation of usual community HT practice was required to preserve blinding of participants.

Although assessment results were not discussed, clients were informed as to which one of the techniques might be used in the session, and thus the relevant sensations they might experience (i.e. direct touch versus indirect touch techniques, or touch near a particular part of the body or for a particular purpose). This discussion was based on the verbal assessment done for all clients and on the practitioner's plans to use a particular technique (1 of 11 placebo techniques or 1 of 35 real techniques).

For the participants in the placebo group, these plans were executed, as no energetic assessment was actually performed, but was only simulated by slowing walking from the participant's feet to their head, first along the supine client's right side of the table and then along the left, and repeating this sequence a second time, before then writing 'the assessment' on the participant's chart. The same textual and diagrammatic charting of a simulated pre-treatment energy assessment was used for each session and each participant in the placebo group, and the same textual and diagrammatic charting of a simulated post-treatment energy assessment was done for each placebo session. This diagrammatic charting showed a modest improvement in the energetic flow within the major and minor chakras that are typically assessed (i.e. the circular symbol to represent each chakra was drawn in a slightly larger size on the post assessment diagram). The verbal assessment of how the client's week had gone, (i.e. any major events, changes in their health status, etc.) was actually performed and charted for all participants in both the experimental and placebo groups. Their verbal comments after the session were also documented as stated for both treatment groups.

For the participants in the true Healing Touch treatment group, the plans that were discussed with the client regarding which technique might be used, were sometimes modified, to take in to account the results of the actual energetic assessment, which normally guides the HTP in their selection of techniques in a private practice setting. The placebo techniques were all named with similar names as those techniques in the actual Healing Touch program. The name of the technique used was written down on the documentation form for each session for all participants, regardless of group allocation. (See Appendix W for a copy of the blank session documentation form). Clients were told the name of the technique that had been used if they asked about it, in order to allay suspicion as to their group allocation and also to preserve blinding. Similarly, if clients asked about either their pre-treatment or post-treatment assessment, they were all told only a vague and general statement to the effect

that their system seemed to be responding well to the treatment. In actuality, these conversations rarely happened, as instead most participants in both groups either spontaneously offered their own perception of how the treatment had gone, or did so in response to the general post-treatment question (asked of all participants who did not spontaneously volunteer a comment), that was phrased along the lines of “What was this session like for you?” and if further prompting was needed, a more specific question was asked: “Did any sensations, images, or ideas come to mind for you during the session?”

Other differences for the participants in the placebo group as compared to the experimental group included the lack of a centring, grounding or attuning step. These steps all occurred after the participant had been settled on to the massage table and their ear plugs and sleeping masks had been applied. At this point the HTP would step aside (having discussed this with the participant in the Pre-treatment Session Briefing, see Appendix D) and stand quietly for a few minutes. For the actual HT treatments, the HTP would use this time to ground and center, but for the placebo participants, she would only stand quietly, noting the time on her watch until at least 2 to 3 minutes had elapsed. However, for all participants from both groups, at the beginning of this quiet standing time, the HTP would state a brief two sentence protection affirmation (See Appendix X). Attunement is a conscious and deliberate process that occurs when the HTP first makes contact between her own hands and the client’s energy field (Hover-Kramer, 2002). As this step did not require tactile contact, and occurred while the participant was masked, participants were unaware of the absence of this step.

The treatment itself was simulated by two mechanisms, one to mimic direct touch, and the other to mimic indirect touch. Simulated direct touch occurred by the HTP placing light brown, soft leather gloves in her hand size, filled with a stuffing to mimic the shape, weight and flexibility of hands in a relaxed posture, on specific locations. The PI placed the gloves in locations on the participant’s body that were relatively inert from an energetic perspective (i.e. not on any major chakras on the torso, or on any minor chakras on the joints). The gloves were left in position for a timed 5 to 7 minute duration depending on the placebo technique being used. A picture of the filled gloves being held next to the HTP’s hand demonstrates the size and flexibility of the stuffed glove (See pictures in Appendix Y). The gloves were placed on the top of the lightweight top sheet used for all participants, so the client would be unable to discern the difference between the feel of actual skin versus the feel of the soft leather of the gloves. Again to preserve blinding, the top sheet was used for the actual HT treatments as well.

For some techniques on participants receiving actual HT treatments, the PI’s hand placement happened through the sheet, rather than with direct skin-to-skin tactile contact, depending on the technique being used and the required locations for that technique. For instance, hand placement on the torso always happened through the sheet, as was usually the case for hand placement on the participant’s legs. But of course hand placement was NOT through the sheet on the client’s head and was usually not through the sheet on the client’s hands and arms as well, with direct tactile contact occurring in those body locations, for participants receiving actual HT. In the usual practice of HT, the client also remains dressed and hand placement of the practitioner is often through clothing and sometimes a light covering. The use of a different technique each week for all participants, and the variety of circumstances of hand placement within each technique, was sufficiently distracting to preserve blinding of participants, even when they were sisters or next door neighbours and discussed their experiences of treatment sessions together.

To simulate indirect touch, a flat laminated A5 size booklet (See picture in Appendix Z) was used in a sweeping manner similar to a fan, near the participant's body. There are 3 such booklets published by Healing Touch Program, and these booklets were part of the books used as a reference during treatments. Thus their presence would not arouse suspicion, as they were always used in a session anyway, placed usually on a surface near the massage table, where the PI was charting, such as a table or kitchen counter. The booklet was waved gently over each body area 3 times, checking for movement of the top sheet to ensure the booklet was placed close enough to the body and moved forcibly enough to create a tangible sensation of faint air movement for the participant to experience. The PI would then stand still with no movement for approximately a 1 minute interval, and then repeat the sweeping motion a second time, pause again for a minute, and then repeat a final, third time. After three iterations, the PI would move to another location around the participant's body and repeat the process. The specific sequences and hand placements used for the Placebo Techniques are described in the Placebo Protocol in Appendix O.

## **Ethics**

### **Approvals**

In July 2008, ethical approval for the study was obtained via the process using the National Ethics Application Form (NEAF), which was lodged with the Human Research Ethics Committee (HREC) of the Townsville Health Service District (THSD). The THSD HREC responded with queries and a request for a meeting between the PI and her primary supervisor and the Chairperson of the HREC and one of the HREC's community members. Additional bibliographic information was provided, and in response to a query, the Patient Information Consent (PIC)/Letter of Invitation (LOI) form was altered to include the protocol aspect of the wearing of ear plugs during the session. Lastly, the NEAF was amended to include an additional exclusion criterion of the participant having experienced giving or receiving an energy modality, in addition to the pre-existing exclusion criterion of prior experience specifically with Healing Touch treatments. During the meeting, the specific details of the placebo protocols were discussed and approval was granted for the revised PIC/LOI form (Version 2, July 2008) to be used.

The THSD HREC approvals were then forwarded to James Cook University where the PI was enrolled, where two queries was made by the JCU School of Nursing Sciences ethics monitor, regarding a decline in MMSE scores over the course of the study and the opportunity to withdraw from the study in the middle of a treatment session. Both queries were addressed and clarified to her satisfaction and then the JCU HREC approved the study as well.

The pilot study occurred from September to December of 2008, but the target sample size of eight was not reached, as discussed above in the section on Recruitment and the section on Participants. Amendments were requested from the THSD HREC regarding the sample inclusion/exclusion criteria and the process of recruitment. Because of the necessity of widening the pool of participants beyond recruiting clients who were under the care of a registered nursing service coming in to the home, an additional point was added to the Patient Information/ Consent (PIC) form (Version 3, December 2008, see Appendix N) to provide a substitute safety net. Point # 8 stated: "I consent to the Researcher(s) contacting either a nominated family member or my General Practitioner, if they arrive for a home visit and find

me unwell and in need of assistance.” Names and contact details of a family member and GP were added as line items to the phone screening form (see Appendix M) and were obtained at that initial contact. Based on this addition of Point # 8 to the Consent form, and after further email consultation with the new Chairperson of the THSD HREC, each participant’s General Practitioner (GP) was notified by letter (see Appendix AA) for any MMSE scores of 26 or lower, in keeping with the MMSE authors’ published norms and suggested thresholds for potential cognitive impairment with this instrument being used for its intended purpose of screening, not diagnosing (Folstein, Folstein, Fanjiang, 2001). This procedural step also served to more explicitly address the original concern voiced by the JCU Ethics Monitor. The above amendments and their approval from the THSD HREC were then forwarded to the JCU HREC and accepted in full.

The pilot study experience also identified that retirement village residents who frequently socialize together would be comparing notes on their experiences in the study, so the original intention of the same placebo techniques in the same sequence for each placebo participant needed to be varied, in order to prevent detection of the placebo amongst the participants who were close friends or neighbours. This effect was also intensified due to the addition of snowball recruiting. Therefore, additional placebo techniques were designed, which also allowed the original intention of a different technique to occur each week, without requiring the use of placebo techniques in the prone position, as some participants were not comfortable and/or sufficiently mobile to assume that position on the massage table. The revised Placebo Protocols were submitted to the THSD HREC as part of the amendments, and approved.

Lastly, in 2010, in an effort to further improve and hasten recruitment, the local Spiritus home care service was contacted and expressed an interest in learning more about the study and assisting in identifying potential suitable participants from amongst their client base. The above documents were forwarded to the Spiritus national HREC. The PI and her primary supervisor met with the HREC via teleconference and discussed the study further, and approval was granted from the Spiritus HREC to recruit through their nursing staff. However, the condition was placed that any potential participants who had been identified through the Spiritus nursing staff be consented with a fourth version of the PIC, with no content changes, but simply with the Spiritus name and logo added in the footer. This model of recruitment resembled the original recruitment process through the public sector via the various THSD community nursing services for older adults, and unfortunately was equally ineffective, only resulting in an additional three participants being recruited into the study.

Annual progress reports were submitted to the THSD HREC and to the JCU HREC, while the Spiritus HREC required progress reports every six months. All three HRECs were sent a copy of each of the documents in the packages mailed out to participants upon completion of data analysis in March 2012, including a Cover Letter (Appendix U); the Summary of Results for Participants (Appendix R), notification of their randomised group allocation (see Appendix S), and a green Options Sheet to mail back to the PI if they so desired, regarding any interest in future contact to receive a sample session, a copy of publications, etc. (Appendix T).

## Statistical methods

### Sample Size Calculations:

Sample size calculations were performed based on the primary outcome measure of functional health as measured by the OARS-ADL, but power testing indicated that the adequate sample size required to detect a clinically relevant difference of 1.0 between the two groups on the ADL instrument was also sufficient power to detect clinically relevant differences between treatment groups on two of the secondary outcome measures, the Spiritual Well Being Scale and the Psychological Well Being scale.

Sample size calculations were performed by a consulting biostatistician within the Faculty of Health, Medicine and Molecular Sciences (FMHMS), prior to the later inclusion of another biostatistician from the FMHMS as a member of the advisory team for this project. The following hypothesis was used to guide the sample size calculations.

### ***Main alternative hypothesis:***

The control group deteriorates by at least one unit more on the Activities of Daily Living (ADLs) scale (2-sided test) than the intervention group over the 6 months follow-up period.

### ***Main Null hypothesis:***

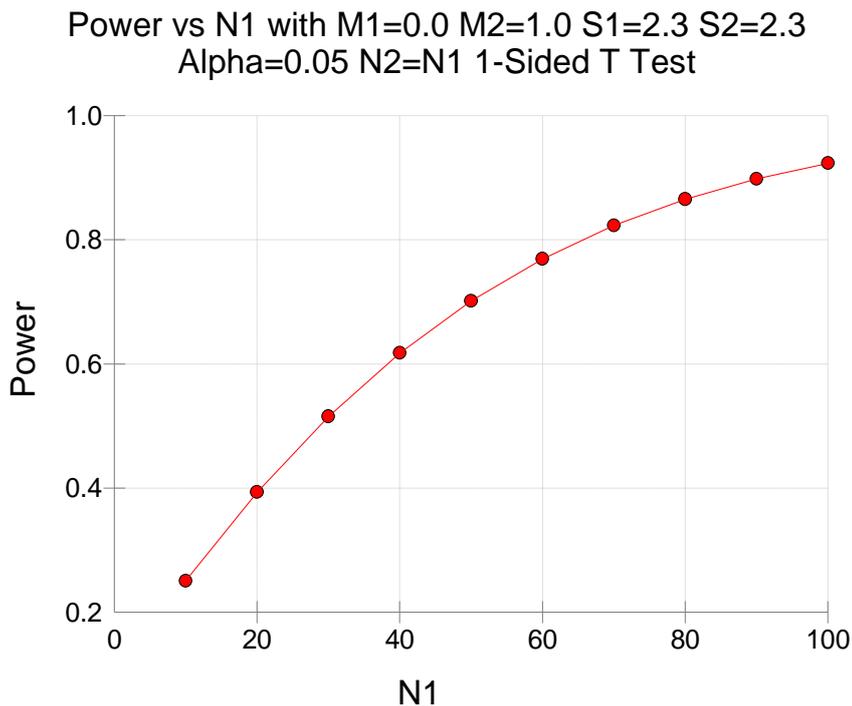
The control group deteriorates by less than one unit more on the ADL scale when compared to the intervention group or even performs better than the intervention group.

### ***Sample size calculations:***

#### **Functional Health**

Sample size calculations were based on the assumption that randomisation would be successful (i.e. no differences on the ADL scales at the start of the trial) and that the goal was to detect a minimal clinically relevant difference of 1 in the changes of the two groups over the study period as significant at an alpha level of 0.05 with a power in excess of 0.8. The difference of the temporal changes between the groups was therefore hypothesized to be at least 1 unit on the ADL scale in favour of the intervention group, thus requiring the conduct of a two-sided unpaired t-test on the changes between the two groups. Mathematically, the distribution of these changes was expected to have a standard deviation (SD) of maximally 2.3 (Cole, McCusker, Elie, Dendukuri, Latimer & Belzile, 2006; Royall, Palmer, Chiodo & Polk, 2004). A further assumption was that 20% of the enrolled participants would be lost to follow-up for various reasons, thus requiring enrolment of around 90 participants per group to achieve a final sample size of around 70 participants per group, which in turn would achieve a power of at least 80% to find the hypothesized difference in change as significant at an alpha level of 0.05.

The exact situation is detailed in the following graph, Figure 2:



**Figure 2. Power and Sample Size Requirements (with acknowledgements to Associate Professor Rheinhold Mueller)**

### **Spiritual Well-being:**

The study will be able to find a difference of change between the intervention and control group of around 5 units on the scale as significant with a power in the excess of 80% at an alpha level of 0.05.

### **Psychological Well Being:**

The situation for the PWB subscales is - in statistical terms - nearly identical to the ADL subscales and consequently the study also has enough statistical power to detect a clinically relevant change of 1 unit on this scale.

### **Conclusions of sample size calculations:**

A sample size of 90 participants in each group is expected to result in 70 observations available for analysis per group at the end of the follow-up period which in turn provides enough statistical power for the three most important outcome measures (the main outcome plus the two most important additional outcomes) to detect a clinically relevant difference as significant, if it really is there.

### ***Interim analyses and stopping guidelines***

Data collection continued until the calculated sample size was reached. Interim analysis was not performed and no pre-set stopping guidelines were generated. The literature review indicated a very low likelihood of any adverse reactions, and the clinical experiences of the HTP both prior to and during the study supported this low risk estimation. On the other hand,

a potential benefit to the experimental group was not expected to be of such magnitude that it would ethically require that blinding be removed and that participants receiving the placebo treatment would be offered the actual experimental treatment instead.

### **Data Entry:**

All data were entered by a Registered Nurse Research Assistant who was blinded to participant identity and to group allocation. The data were entered into the statistical analysis program SPSS (IBM SPSS, PASW version 18.0, Chicago, Illinois), in to a template created by the PI with consultation from her supervisory committee. Naming conventions for all variables were established by the PI in accordance with expert advice from the primary and co-supervisors. The PI undertook a basic statistical course during her Master's studies, and another 2 week intensive statistical post-graduate course at the commencement of the PhD. These studies informed the design of the research, the instruments chosen for outcome measures, and the plans for data analysis, again after consultation with statistical experts.

### **Ambiguous data:**

During data entry, if ambiguously worded or recorded data were encountered, the Data Entry Research Assistant (DERA) flagged the case to show and discuss with the PI. If appropriate for the question item missing, the PI cross referenced the missing question item to the participant's responses on the same item at the other two data collection time points; and/or to their response on other related items on the OARS; and/or to the PI's chart notes at the time of the Intake Health History (see Appendix BB) (for missing baseline Week 0 data); and/or to the final treatment session (for missing post-intervention treatment series data at Week 8); and/or to the HTP's observation of the participant's status during the seven treatment sessions. If these processes could not reasonably ascertain the intended response, or if there was no response at all recorded on the RA questionnaire, then the data field for that question item was left blank.

These sources and processes were used during the data entry phase, to clarify ambiguous or missing answers regarding the identity and/or relationship of the 1-2 helpers identified on the OARS (Q15a and Q15b), the frequency of incontinence on the OARS (Q14a); unanswered or ambiguously recorded items in the Charlson Co-Morbidity Index, and unanswered or ambiguously recorded items on the demographic questionnaire (i.e. living arrangement, time since last hospitalisation, since widowhood or since divorce).

### **Cleaning the data**

Data cleaning was accomplished through running frequency analyses in SPSS for all variables, and locating erroneous or missing values. In addition, 10% of the participant data collection sets (questionnaires administered by the RAs) were randomly selected and cross referenced to the data entry performed in SPSS to calculate an error rate below 1%. Similar processes were used for the data collected and entered by the PI for vital signs and participant self-ratings on health dimensions, again with 10% of the treatment charts being randomly selected and cross-referenced to data entry within SPSS, for an acceptable error rate less than 5%.

### **Missing values:**

After the above data entry and data cleaning processes were completed, it was noted that there were still missing values for eight participants for one or more items on the OARS

instrument, which was the primary outcome measure. These missing values prevented calculation of sub-scale and/or total OARS scores. A similar process as described above during data entry was again implemented during the data analysis phase. First the PI returned to source data (the hard copy of the questionnaires, or to the RA who completed the questionnaire during the data collection interview), which resulted in completing the data for most of the instances that were encountered. If appropriate for the question item missing, the PI cross referenced the missing question item to the PI's chart notes at the time of the Intake Health History (for missing baseline data) and/or the final treatment session (for missing Week 8 data) and/or to the PI's observation of the participant's status during the seven treatment sessions; and/or to their response on other related items on the OARS.

***Characteristics of the sample at Baseline: demographics, outcome measures, full sample, Group A vs B.***

Descriptive statistics were performed for the 153 participants included in the analyses. Demographic information collected and analysed included date of birth; country of birth; year migrated to Australia if applicable; whether English was their first or later language; religion; level of education; current income; current living arrangement; time since their last hospitalisation and the setting of that hospitalisation; previous and current experience with Complementary or Alternative Therapies (CATs). For continuous data, measures of central tendency and dispersion were calculated in SPSS using the Frequencies function. For approximately normally distributed variables, means and standard deviations were calculated and reported. For skewed distributions, medians and inter-quartile ranges (IQRs) were calculated and reported, with the selective addition of full ranges (minimum and maximum values) when appropriate. For categorical variables, both counts and percentages were calculated and reported.

The sample was then characterised according to baseline values on the primary outcome measure of functional health, as measured by the Older Americans Resources Survey (OARS) Activities of Daily Living (ADL) instrument. The total instrument score is reached by summing the two sub-scales of Basic ADLs (BADLs) and Instrumental ADLs (IADLs), and so these sub-scale scores at baseline were also reported.

The secondary outcome measures were other dimensions of health, including social health, spiritual health, psychological health and overall quality of life. In addition, cognitive health and co-morbidities were also measured and reported as potential confounders and as an indication of the reliability of the self-report data obtained by the blinded Research Assistant at each data collection time point. Each of the instruments used, the health dimensions they measured, the abbreviation used for each instrument in the reporting of results in subsequent tables and graphs, the number of questions within the instrument and their possible range of scores are detailed in Table 3.

**Table 3. Overview of Instruments used**

Health Dimension	Name of Instrument	Abbreviation used for reporting	Number of Items (Questions)	Lowest possible score	Highest possible score
1a. Functional Health-- Basic Activities of Daily Living	Older Americans Resources Survey (OARS)-Basic ADLs	BADL	8	0	15
1b. Functional Health-- Instrumental Activities of Daily Living	OARS-Instrumental ADLs	IADL	7	0	14
1. Functional Health--All Activities of Daily Living combined	Sum of BADL and IADL =OARS-Total	Total ADL	15	0	29
2. Social Health	Medical Outcomes Study Social Support Survey	MOS-SSS	20	0	100
3. Psychological Well Being	Ryff's Psychological Well Being Scale	PWB	18	18	108
4. Spiritual Well Being	Paloutzian & Ellis Spiritual Well Being Scale	SWB	20	20	120
5. Quality of Life	Duke Health Profile	Duke	17	0	34
6. Cognitive Health	Mini Mental Status Exam	MMSE	11	0	30
7. Co-morbidities	Charlson Co-Morbidity Index	CCI	11 (7 of which have nested sub-questions)	0 (0= Absence of any of the diseases in the CCI)	Not applicable (each possible disease worth 1, 2, 3 or 6 points, depending on severity & likelihood of mortality)

The procedures used to score each instrument are described in the following section. Once the instruments were scored, measures of central tendency and dispersion were calculated in SPSS using the Frequencies function. As for demographic characteristics above, for instrument scores that were approximately normally distributed, means and standard deviations were calculated and reported. For skewed distributions, medians and inter-quartile ranges (IQRs)

were calculated and reported, with the selective addition of full ranges (minimum and maximum values) when appropriate. Criteria used to establish distribution status included: a.) no more than a 10% difference between mean and median; b.) standard deviation no more than 1/3 the value of the mean; and c.) histogram of frequencies appeared roughly symmetrical.

These baseline demographic and outcome measures, were calculated and reported for the full 153 cases analysed, and then separately for the Healing Touch Group and the Placebo Group. Comparisons were then made to evaluate whether the two groups showed large differences at Baseline, as an indirect measure of the successfulness of the randomisation process for allocation in to the two treatment arms. Inferential statistical testing was not used to compare the differences between the groups at baseline, as it was already established by the nature of the randomisation process, that any differences present at this point were merely due to chance. However, some disparity between the Placebo Group and the Healing Touch Group existed on income and on living arrangements. To further exclude the possible influence of these two potential confounding characteristics on the two treatment groups' responses to the intervention, the analysis of the differences over time on the main outcome measures were stratified according to both income and to living arrangement.

**Primary analysis: Hypothesis testing of the differences between the Healing Touch Group's and the Placebo Group's responses as measured by their change over time on the selected outcome measures (Between Groups comparison).**

For each of the primary and secondary outcome measures, each participant's score at the baseline data collection point, Pre-Intervention, or Week 0 was subtracted from their score at the six month follow-up data collection time point, Week 33, using the "Compute variable" function from the "Transform" menu in SPSS. This resulted in the creation of a new difference variable for each instrument

For all instruments except the CCI, a higher score indicates a higher or better health status. Therefore subtracting the baseline value from the follow-up value resulted in a negative number if the participant's health status as per that instrument had declined or deteriorated. Conversely, a positive value indicated an improvement in their score on that health dimension as measured by that particular instrument.

For the CCI instrument, a higher value indicates a higher number of chronic diseases. At baseline, the participant might have only one, relatively minor chronic disease, resulting in a score of 1. At Week 8 and Week 33, the participant might have been diagnosed with a second, more serious disease, weighted to be worth 2 points on the CCI. Adding this disease to her previous ongoing chronic disease, she now achieves a score of  $1 + 2 = 3$  for her CCI at Week 33.

Again the "Compute variable" function in SPSS was used to create a new difference variable. A higher score on the CCI at follow-up than at baseline indicates the presence of additional disease(s) since baseline, which is equivalent to a deterioration in health status, contrary to all the other instruments. Therefore the equation for computing the difference variable for the CCI was reversed from that described above for all the other instruments. This alteration enabled greater consistency and ease of reporting and interpretation of results, by retaining the meaning of a positive/negative number across all of the difference variables.

Once the difference variables had been computed for each instrument, the database file was split according to the "Split file" function to create Group A and Group B. The groups were not

titled as to their status as Healing Touch or Placebo until the end of the data analysis, enabling the biostatistician member of the advisory committee to remain blinded when she double checked all statistical testing performed by the PI. Frequencies were run for each group, and measures of central tendency and dispersion were reported. Means and standard deviations were reported for approximately normally distributed difference variables, or medians and IQRs for those that were not normally distributed. Minimum and maximum ranges were again included when they further illuminated the data. Criteria used to establish approximate normality of numerical distributions were as above.

However, since the average values of these difference variables were usually quite small, the second rule regarding the standard deviation being no more than 1/3 of the mean was not possible to fulfil, and the other two criteria had to be relied upon instead. In addition, for many of the difference variables, the medians were zero, making it impossible for the difference between the median and the mean to be less than 10%. In light of the above considerations, most of the between group testing on the difference variables required the use of non-parametric tests for statistical significance. Since only two groups were being compared, the Mann Whitney U test statistic was calculated and reported. In the few cases where approximate normality assumptions were given, unpaired t-tests were applied. The significance level was set at less than 0.05.

### ***Stratification***

Recoding the data in to collapsed categories (visual binning)

As mentioned earlier, a disparity between both the income level and the living arrangement frequencies in the Healing Touch as compared to the Placebo group was further explored through stratification. Firstly for income, the participants were split into two groups, the first with an annual income of less than \$20,000; and the second with an annual income of greater than or equal to \$20,000. Within the 'poorer' group, the treatment group comparisons, again using the Mann Whitney testing or unpaired t-tests, were repeated. Similarly, within the 'richer' group, the treatment group comparisons were repeated.

There was also a disparity at baseline between Healing Touch and Placebo group regarding the percentage of participants living in their own homes in an ordinary residential neighbourhood, versus the percentage living in a retirement village. Stratification was again used to compare treatment groups within the stratum of "Ordinary Neighbourhood" and to compare treatment groups within the stratum of all other living arrangements. This latter category mostly consisted of retirement village living, although 6 participants in this "All Other" category were in a granny flat, a family member's home, assisted living facility or the low-care wing of a residential care facility, at the time of Week 33 follow-up.

Although careful randomisation occurred for all participants entering the study, the participants within each of the individual strata were not randomised, since stratification occurred post-randomisation. Therefore, the allocation into treatment groups within any given stratum was based on the initial randomisation allocation of each participant within the sample as a whole, followed later by stratification during data analysis. The two treatment groups at baseline within each stratum were compared as well, to ensure that the stratification process had not resulted in disproportionate representation on demographic or outcome variables in one treatment arm versus the other, within each stratum. Within both the low income stratum and the high income stratum, the treatment groups were comparable

at baseline for age, education, marital status, religion, and their scores on the MMSE, the CCI, the Duke health profile, the ADL scales, the Spiritual Well Being Scale, the Psychological Well-being Scale and the Social Support Survey. Similarly, for the two living arrangement strata, again the treatment groups within each stratum were comparable at baseline for the same demographic and outcome measures listed above.

### ***Secondary Analyses***

In addition to the hypothesis testing discussed above to compare between the Healing Touch Group and the Placebo Group on the main outcome measures, some additional secondary analyses were also undertaken. The first of these additional analyses investigated the Within Group changes over time, using non-parametric Friedman tests on both the sample as a whole and on the Healing Touch Group and the Placebo Group separately. Given the small values of most of the difference variables, the concern was that the sample may have been too stable during the study period to experience any substantial functional decline in either treatment arm, making statistical testing comparing the amount of functional decline in each group an unreasonable proposition. Stability in cognitive status over time was of particular interest, as substantial deterioration of cognitive status during the course of the study may have called in to question the reliability of the self-report nature of the participants' responses to all other questions in the remaining instruments used for data collection.

The next area for secondary analyses focused on the amount of time since hospitalisation, and whether hospitalisation occurred for each participant during their time under observation in the study. The amount of time since the last hospitalisation, as asked at the Week 33 follow-up data collection time point, was converted into days. When the participant's recollection was in months or years, the maximum number of days in a month and/or the maximum number of months in a year were used to convert the time since the last hospitalisation into the same unit of measurement for all participants: days. The average number of days since last hospitalisation in the Healing Touch Group was then compared to the average number of days since last hospitalisation in the Placebo Group, using the Mann Whitney U test. The number of days during which the participant was involved in the study were compared to the number of days since last hospitalisation, to yield a categorical variable of yes/no in regards to whether the participant had a hospitalisation during their time in the study. These proportions within each treatment group were compared using Fisher's exact test, to determine if a higher proportion of participants in the Healing Touch versus the Placebo group avoided hospitalisation during the study.

Functional decline can result in the necessity to change living arrangements from one of full independence, to one of varying degrees of dependence. The proportion of participants within each treatment group who maintained their current level of independence, versus changing to a lower level of independence in their living arrangements, was also compared using Fisher's exact test.

### **Session Data collected by the PI**

All of the comparisons described thus far were based on the data collected by the Research Assistants during their home visit interviews. These data have the advantage of being collected by a blinded data collector who is unaware of the participant's group allocation, but

also has the disadvantage of being collected subjectively, as it is all based on the participant's self-report, dependent on their memory and assessment of their own health status.

Additional data were collected during each treatment session visit by the PI immediately prior to beginning the treatment (regardless of whether it was the Placebo or the actual Healing Touch), and immediately after the treatment concluded and the participant was assisted to a sitting position on the massage table. These assessments consisted of both objective (vital signs) and subjective (health ratings) data. The PI took an oral temperature using a digital thermometer, a respiratory rate and pulse rate using a stethoscope applied to the upper chest, and a blood pressure with a stethoscope and sphygmomanometer. In addition, the participant was asked to rate their own assessment of their health status on a scale of 0 to 10, where 0 was the worst possible health status, and 10 was the best possible health status. These self-perceived health ratings were done for physical health, emotional health, intellectual health and spiritual health, and were recorded on the PI's session chart, along with the vital signs obtained.

These data were entered in to SPSS by the PI, with first and second round data cleaning performed as described earlier. For each session's data, the differences were calculated between the before and after treatment values, using the "compute variable" function in SPSS. For example, these new variables included the difference in values between the Before treatment systolic blood pressure and the After treatment systolic blood pressure for treatment Session One, and again for each of the subsequent treatment Sessions Two through Seven.

Once all of the difference variables were computed, then their average values were compared between the Experimental and Comparison groups, for each type of data at each session. Non-parametric Mann Whitney U tests were used, as the median for the differences variables was often zero and/or histograms were not symmetrical. For example, the average value of the difference of the systolic blood pressure before and after treatment at Session One in the Healing Touch Group was compared to the average value of the difference of the systolic blood pressure before and after treatment at Session One in the Placebo group. It was reasoned that a change in vital signs or health ratings might not occur in all sessions, and might be a finding only in a later session, as the participant became more familiar and comfortable with the treatment procedure and the PI's presence in her home.

### **Data specific to the Week 8 data collection visit: Satisfaction with treatment and beliefs about group allocation to placebo or actual Healing Touch treatment protocols.**

At the time of the RA's visit to the participant's home to collect the data after the series of 7 treatment sessions had been completed (Week 8), some additional questions were asked beyond those of the instruments used for all 3 data collection points. These consisted of seven forced choice questions that were recorded by the RA in writing, and five semi-structured interview questions that were verbally asked by the RA and then audio-recorded and later transcribed.

The seven forced choice questions included the participant's opinion regarding the length of the treatment sessions, the number of treatment sessions, their interest in further treatments if they were free, their interest if they were an out-of-pocket cost to them, the amount they would be willing to pay for a treatment out-of-pocket, if they would support a change in

Medicare reimbursement so that they can receive Healing Touch at a free or reduced cost, and whether or not they would recommend HT to a friend/family member.

The percentages of participants who chose the optioned answers to the above questions were compared between the Experimental and Treatment groups, using Fisher's exact test, to determine if more/less participants responded in a particular way in one treatment group versus the other.

The five semi-structured interview questions were analysed according to the type of data generated. The first, second and third questions were open ended, asking participants to describe their experiences in receiving Healing Touch, including any noted sensations and benefits. The resulting qualitative data from these questions will be analysed at a later point using thematic content analysis, and that analysis is not included in this dissertation. The responses do not lend themselves to categorical quantitative analysis.

However, a quantitative categorical analysis was used for the participants' responses to the 4th and 5<sup>th</sup> questions on the audio taped semi-structured interview, similar to the analyses described above for the seven force choice questions. The fourth semi-structured interview question asked the participants their opinion as to whether the treatment they received was the mimic Healing Touch (placebo) or the actual Healing Touch. The kappa statistic was used to assess agreement between perceived and actual group allocation.

The fifth semi-structured interview question asked them to consider that if it does turn out that they were in the placebo group for this current study, would they want future participation in a follow-on study, if they were guaranteed to be given the actual Healing Touch treatment in the future study. A Fisher's exact test was used to test for difference between the Healing Touch and Placebo groups on their response to question five. Participants at times elaborated on their reasons for their affirmative or negative answers to the fourth and fifth semi-structured interview questions, and these elaborations will also be analysed qualitatively at a later point in time, as described above for the first, second and third qualitative questions.

**Hypothesis testing of the differences between the Healing Touch Group's and the Placebo Group's response to the intervention, as measured by their change over time from Week 0 to Week 8, on the selected outcome measures (Between Groups comparison).**

Previous studies of Healing Touch have not clearly determined the duration of the perceived benefits of treatments, but some studies (i.e. Wardell, et al, 2006) indicated that the beneficial effects of treatment may 'wear off' over time. Given that possibility, difference variables were also calculated between the participant's scores on the outcome measures at Week 8 minus their scores on the same outcome measures at Week 0 baseline. The same methods and processes were used as described above when baseline Week 0 to Week 33 differences were calculated and then compared across treatment groups.

### **Analysis of Intervention “dosage” in Healing Touch group vs Placebo group**

The total treatment time in minutes was recorded for each of the seven treatment sessions, for both treatment groups. Using the “compute variable” function in SPSS, a new variable was created to sum the treatment time in minutes of each session, to achieve the series total treatment minutes for each participant. Frequency analysis was performed for each treatment group, and then the treatment times for the Healing Touch group were compared to those of the Placebo group, using a Mann Whitney U test.

Similarly, the total days over which the treatment series occurred for each participant was calculated within SPSS using the “Date Wizard” to create a new variable of number of days under treatment. In this instance, a longer span of time over which the full series of seven treatments occurred, would indicate a less intense “dose” of therapy. Again the Mann Whitney U testing was performed to ascertain if there was a statistically significant difference between the Healing Touch and Experimental groups in regards to the duration of treatment.

### **Adherence to Protocol: Treatment and Data Collection Protocols and Timelines**

Given that a modified Intention-to-Treat analysis was used, rather than a ‘per protocol’ analysis, another concern for the internal validity of the study design relates to adherence to protocol. If there were more ‘protocol violations’ in regards to the delivery of the intervention and/or the collection of the outcome measures in one treatment arm versus the other, the ability of the study design to detect substantial differences in outcome measures over time between the two groups could be adversely affected.

The treatment protocol adherence was primarily evaluated as per the above section’s description. In addition, the total number of treatments completed for each treatment group was compared between the two treatment arms, using the Mann Whitney U test.

To evaluate the timing of data collection, again the “date wizard” was used to calculate new variables for the time between the RA’s first visit to collect baseline data, and the first treatment session delivered by the PI. Similarly, a new variable was also calculated for the time from the seventh treatment session by the PI to the RA’s visit for the Week 8 post treatment series data collection. Lastly, a third new variable was calculated for the time from the seventh treatment session to the six month follow-up data collection at Week 33. The two treatment groups were compared against each other for their central tendencies and distribution on the three new variables. These results were then compared to the protocol set for the timing of data collection at the outset of the study, to determine the number and severity of protocol violations. The number and percentage of total protocol violations for data collection timing in each group was then compared using Fisher’s exact test.

Of note, two participants, both from the placebo group, were excluded from all analyses, including the above processes, due to their “6 month” follow-up visit occurring 11 and 13 months after the final treatment session. Both participants re-located, one temporarily, and one permanently, and thus data collection did not occur until they happened to make a return visit to the original location of the study. In consultations with the supervisory team, it was concluded that this severe protocol deviation did not fit the overall study design closely enough to be included, particularly since both outliers were in the same treatment arm.

## Chapter Summary

The methods chapter discussed each phase of the study, from planning, recruitment and intervention through to data analysis. The planning stage included sample size calculations, selection and description of instruments, and consideration of ethical concerns resulting in approval from three relevant Human Research Ethics committees. The recruitment phase was detailed as to the original methods and the later modified recruitment methods, based upon slow recruitment during the pilot study. Decisions for exclusion of data sets from selected participants were described next, representing a modified Intention-to-Treat analysis. The intervention phase was then fully discussed, detailing the participants, settings, sequence of steps and the similarity between the intervention of Healing Touch and the comparator of a placebo that mimicked Healing Touch. The statistical analysis was outlined next, beginning with descriptive statistics profiling the sample as a whole and the two treatment groups at baseline, for both demographic characteristics and for primary and secondary outcome measures. The description of the analysis moved on to a comparison of the change over time for both treatment groups on primary and secondary outcomes, as a full sample and also stratified according to living arrangements and according to income levels. The procedures undertaken for ancillary analyses of the sample as a whole were then presented. Finally, methods of data analysis for satisfaction with treatment, belief regarding treatment group allocation and adherence to treatment and data collection protocols were highlighted. Building upon this firm foundation of a full description of the methods for conducting the intervention, and for collecting and analysing the data, the following chapter will go on to present the results for each of these levels of data analyses.

## **CHAPTER FOUR: Results**

## Introduction

This chapter will commence with a description of the flow of participants through the study, highlighting losses and exclusions in order to arrive at the final number of data sets used for analysis. The next section will present a description of the demographic features of the sample as a whole, as well as comparing the demographic features of the two treatment groups. The primary and secondary outcome measurements at baseline (Week 0) will be detailed next, again as a whole as well as by treatment group.

The chapter will then move on to address the main hypotheses of the study: the primary analysis of a comparison of the two treatment groups' response to the intervention, as measured by a calculation of the changes in their scores measured at the final data collection point in the study (Week 33) minus their baseline scores. This information on changes in scores over the time of the study by treatment group will be presented for the primary outcome measure of functional health as measured by the OARS Total Activities of Daily Living instrument, followed by the secondary outcomes of the other dimensions of health: emotional health, spiritual health, social support and overall quality of life. The information on the response of the two treatment groups to the intervention as measured by the primary and secondary outcomes will then be presented in a stratified analysis. Results will be stratified by living arrangement, and then by income because at baseline participants of the intervention and the placebo groups differed for these two characteristics.

The final section of the chapter presents results of secondary analyses that were undertaken. Firstly, within group comparisons over time were made on the sample as a whole and on each treatment group, for the Mini Mental Status Exam MMSE data, as a significant decline in cognitive health during the course of the study might invalidate the reliability of self-report data used for the primary and secondary outcome measurements. Similarly, the changes over time in the Charlson Co-morbidity Index will also be presented, as a potential confounding variable.

The presentation of the within group comparisons over time will then continue, to include the primary and secondary outcome measurements of the various health dimensions. The absence or presence of any statistically significant and/or clinically relevant changes between the Week 0 and Week 33 scores on the health dimensions of the participants will be detailed. The absence of *any substantial change* in this sample over this period of time may have complicated the intended comparison of *the amount of change* between the two treatment groups, which was the primary analysis intended to answer the main research question.

Further secondary analysis will focus on differences between the two treatment groups in regards to recent hospitalization patterns and changes in living arrangements from higher to lower levels of independence. Next a comparison will be presented between the two treatment groups on their changes in vital signs and their changes in their self-ratings of perceived health, based upon data collected immediately before and after each of their seven treatment sessions. Lastly, the satisfaction of both groups with the treatment received will also be compared, as elicited by additional questions asked by the blinded Research Assistant (RA) at the Week 8 data collection point. This analysis will include a comparison between the two treatment groups in regards to their members' beliefs about which treatment they were randomly allocated to receive, either placebo or Healing Touch. The treatment groups will be

referred to as Healing Touch (for the experimental group) and Placebo (for the comparison group who received the Mimic Healing Touch ‘treatment’).

## **Decisions about who to include in the Modified Intention to Treat analysis**

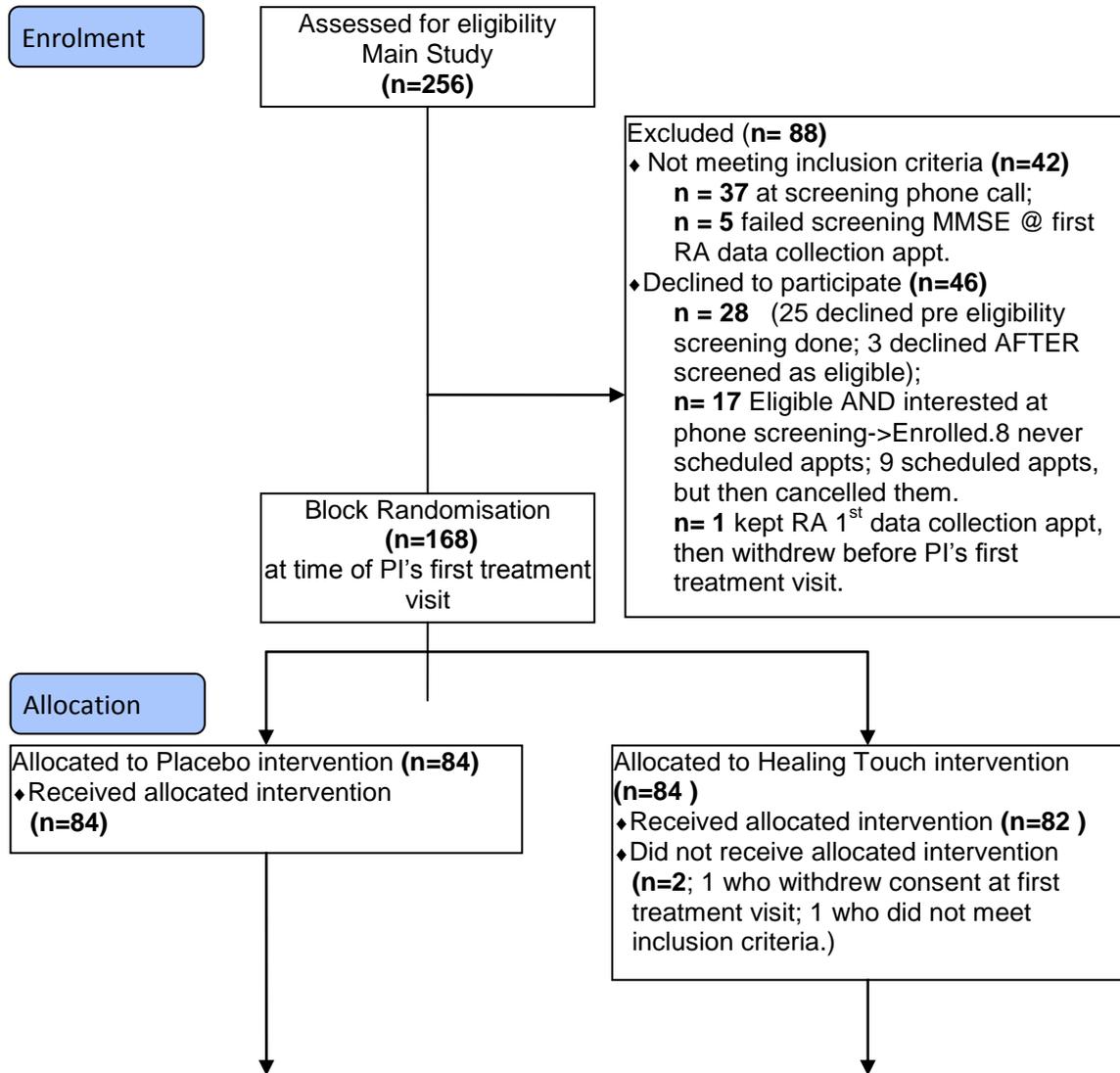
### **Recruitment, Losses and Exclusions**

Potential participants were lost at various stages, as shown in the Participant Flow Diagram below (Figure 3). As detailed in Figure 3, some cases were excluded from analyses. The primary outcome measure was the change between the participant’s functional health at Week 0 and at the conclusion of the study, requiring data from the six month follow-up (Week 33) data collection time point in order to calculate the change. Therefore, included for analysis were all patients who had been randomised and for whom six month follow-up data were collected within protocol timelines, regardless of whether they completed all 7 treatments in the series, and regardless of whether they did so within the usual 42-60 days of the treatment series, resulting in a Modified Intention to Treat (ITT) Analysis.

### **Numbers analysed**

The data were analysed using a modified intention to treat analysis, as diagrammed in Figure 3. Data analysis for the sample as a whole was thus performed on 153 cases, with 78 in the Healing Touch (experimental) group and 75 in the Placebo (Mimic Healing Touch comparison) group.

## Participant Flow Diagram



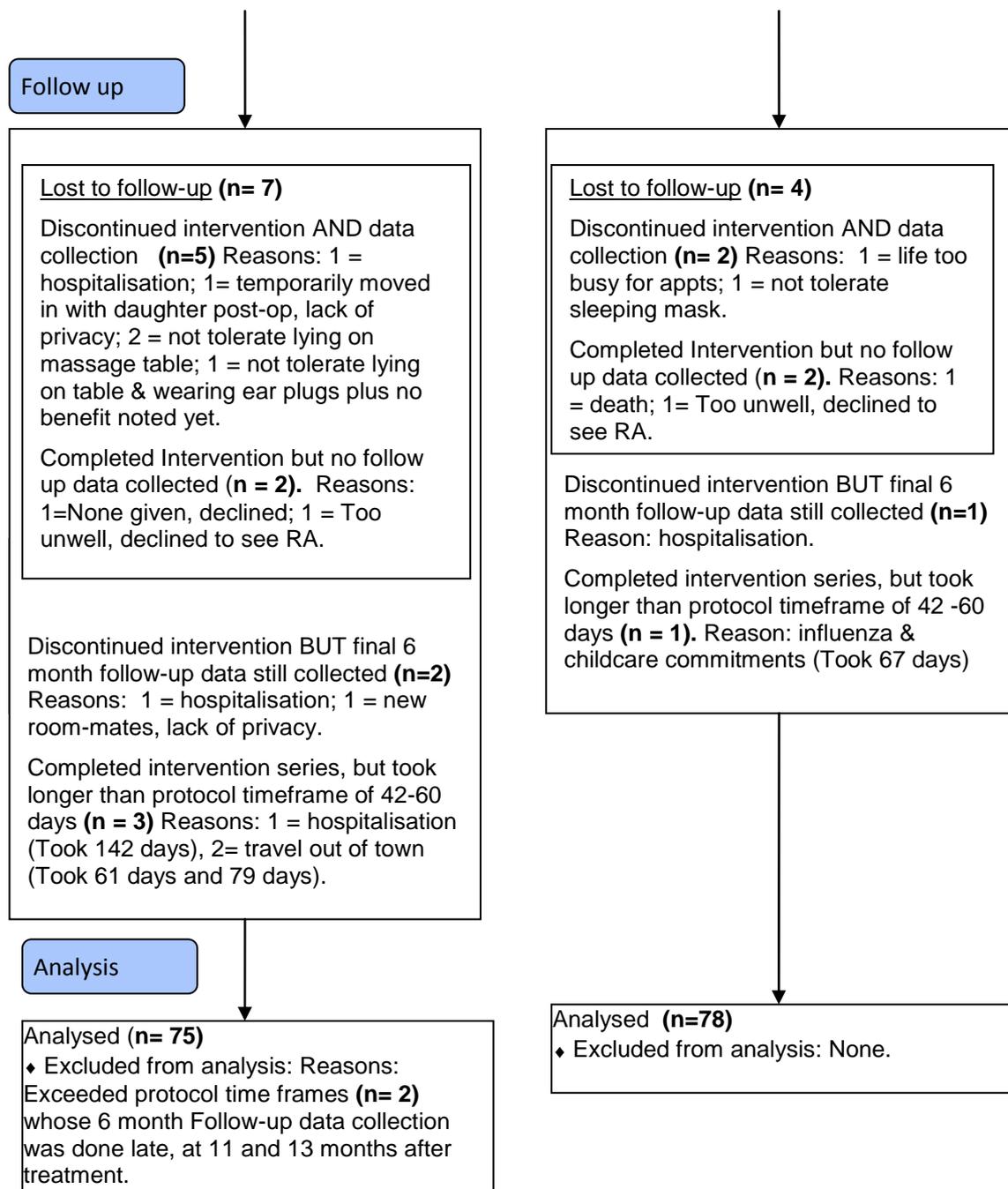


Figure 3. Participant Flow Diagram

## Description of Sample at Baseline (Week 0)

### Demographics

The sample used for analysis consisted of 153 cases, as detailed in the above Figure 3. The mean age was 75.5 years (SD6.3; Range 64 to 94) at the Week 0 data collection time point, prior to beginning the series of intervention treatments. The most common current marital status reported by participants was that of being widowed (71.2%), with the median number of years since becoming widowed being eight (8.0) years (IQR 4.8, 17.0).

Most participants (84.3%) were born in Australia. Those who immigrated to Australia came from a variety of 12 different countries, as detailed in Table 4 with the mean number of years since immigration being 42.4 years (SD 11.2). Accordingly, 95.4% of the participants cited English as their first language.

**Table 4. Country of birth for participants at Baseline (Week 0)**

	<b>Total sample n=153</b>	<b>Placebo Group n=75</b>	<b>Healing Touch Group n=78</b>
Born in Australia:	n (%)	n (%)	n (%)
Yes	129 (84.3%)	64 (85.3%)	65 (83.3%)
No	24 (15.7%)	11 (14.7%)	13 (16.7%)
Other countries of birth:			
England	7 (4.6%)	4 (5.3%)	3 (3.8%)
Scotland	3 (2.0%)	0	3 (3.8%)
Wales	1(0.7%)	1(1.3%)	0
Ireland	1(0.7%)	0	1(1.3%)
Netherlands	1(0.7%)	1(1.3%)	0
New Zealand	4 (2.6%)	3 (4.0%)	1 (1.3%)
Germany	2 (1.3%)	2 (2.7%)	0
USA	1(0.7%)	0	1 (1.3%)
Egypt	1(0.7%)	0	1 (1.3%)
Malaysia	1(0.7%)	0	1 (1.3%)
Indonesia	1(0.7%)	0	1 (1.3%)
Singapore	1(0.7%)	0	1 (1.3%)

A variety of religious faiths were represented, with the five most common ones being different denominations of Christianity, as displayed in Table 5. However, other religions were mentioned, and a number of statements regarding the absence of a formalised religion were also offered as a response to this demographic question.

**Table 5. Religion at Baseline (Week 0)**

	<b>Total Sample n=153</b>	<b>Placebo Group n=75</b>	<b>Healing Touch Group n=78</b>
Religion/Faith:	n (%)	n (%)	n (%)
Catholic	57 (37.3%)	31 (41.3%)	26(33.3%)
Anglican	38 (24.8%)	20 (26.7%)	18(23.1%)
Presbyterian	13 (8.5%)	3 (4.0%)	10(12.8%)
Methodist	9 (5.9%)	3 (4.0%)	6(7.7%)
Uniting	8 (5.2%)	3 (4.0%)	5(6.4%)
Baptist	2(1.3%)	0(0%)	2(2.6%)

	<b>Total Sample n=153</b>	<b>Placebo Group n=75</b>	<b>Healing Touch Group n=78</b>
Salvation Army	2(1.3%)	1(1.3%)	1(1.3%)
Other Christian religions (combined)	7(4.6%)	4(5.3%)	3(3.8%)
Buddhist	1(0.7%)	1(1.3%)	0(0%)
Pagan	1(0.7%)	0(0%)	1(1.3%)
My own religion	1(0.7%)	1(0.3%)	0(0%)
Agnostic	3(2.0%)	2(2.6%)	1(1.3%)
Non-practicing	2(1.3%)	1(1.3%)	1(1.3%)
States has no religion	3(2.0%)	1(1.3%)	2(2.6%)
Refused to name one	5(3.3%)	3(4.0%)	2(2.6%)

Education levels ranged widely, with a few participants having reported reaching less than Year 6 in their schooling (2.6%), while at the other end of the educational spectrum, 13% reported participation in tertiary education at TAFE or University. However, most participants (72.5%) cited a schooling level between Year 6 and Year 10 (Table 6).

**Table 6. Education at Baseline (Week 0)**

	<b>Total Sample</b>	<b>Placebo Group</b>	<b>Healing Touch Group</b>
	(n=153)	(n=75)	(n=78)
	n(%)	n(%)	n(%)
Year 6 or less	4(2.6%)	2(2.7%)	2(2.6%)
year 10 or less	111(72.5%)	55(73.3%)	56(71.8%)
Year 12 or less	15(9.8%)	5(6.7%)	10(12.8%)
Completed high school	3(2.0%)	0(0%)	3(3.8%)
TAFE or vocational	8(5.2%)	5(6.7%)	3(3.8%)
Bachelor's	8(5.2%)	5(6.7%)	3(3.8%)
Master's	4(2.6%)	3(4.0%)	1(1.3%)

The reported annual income clustered heavily around the \$20,000 per year mark, with 49% reporting between \$10,000 to \$19,999 per year, and another 47.6% reporting \$20,000 to \$30,000 per year (Table 7). The two treatment groups were dissimilar at Baseline (Week 0) regarding their income, with a higher proportion of wealthier participants in the Healing Touch group, so income was identified to be a potential confounding variable. Given this discrepancy in income at baseline, a stratified analysis will be undertaken later for this key demographic variable, with the participants in the below \$20,000 per year income bracket (“poorer”) being analysed separately from the participants in the above \$20,000 per year income bracket (“richer”).

**Table 7. Income at Baseline (Week 0)**

n(%)	Total Sample	Placebo Group	Healing Touch Group
	*(n=145)	(n=74)	(n=71)
Less than \$10,000 per yr	1(0.7%)	0(0%)	1(1.4%)
\$10-19,999/yr	71(49.0%)	40(54.1%)	31(43.7 %)
\$20-30,000/yr	69(47.6%)	32(43.2%)	37(52.1%)
\$30-40,000/yr	1(0.7%)	0	1(1.4%)
\$40-50,000/yr	1(0.7%)	1(1.4%)	0
\$50-75,000/yr	2(1.4%)	1(1.4%)	1(1.4%)

\*8 participants did not disclose their income.

The two treatment groups were dissimilar at Baseline (Week 0) regarding their living arrangements, a second potential confounding variable. The Healing Touch group had substantially more participants already living in the more structured accommodation setting of retirement villages rather than in houses or units in the community, as compared to the placebo group (Table 8). Functional decline, whether it is perceived or actual, and whether it is existing or potential, can precipitate relocation into these more structured accommodation settings, to avoid the extra burden of home repairs and yard maintenance that are shifted to the body corporate in a retirement village arrangement. Given this discrepancy in living arrangements at Week 0, a stratified analysis will be undertaken later for this key demographic characteristic, with participants living in their own homes or units in the community being analysed separately from participants living in retirement villages or other forms of structured accommodation.

**Table 8. Living Arrangements at Baseline (Week 0)**

	Total Sample	Placebo Group	Healing Touch Group
	n=153	n=75	n=78
Home/unit in normal residential neighbourhood	101(66.0%)	54(72.0%)	47(60.3%)
Retirement village	50(32.7%)	20(26.7%)	30(38.5%)
Granny flat on family's lot	2(1.3%)	1(1.3%)	1(1.3%)

Many of the participants reported use of another Complementary/Alternative Therapy (CAT) either currently or in the past. Information about specific types of modalities and in what time frames they had been utilised by participants was elicited as per the Data Collection Questionnaire (Appendix P). However, many of the available detailed options were not chosen by any participants, resulting in numerous cells with a value of zero that prevented robust statistical analysis. To enable further statistical analysis, the numerous therapies were collapsed into two categories of CAT: Tactile therapies and Energy-based therapies; and collapsed into two time frames: currently using or never used/only used in the past. The results are shown in Table 9 below, and reflect similar usage patterns at Week 0.

**Table 9. Comparison between groups of CAT usage at Baseline (Week 0)**

Current CAT usage at Week 0	Placebo	Healing Touch	Test Statistic
	(n=75)	(n=78)	
	n(%)	n(%)	
Tactile CATs	9 (12%)	15 (19.2%)	Fisher's Exact Test
	*(n=74)	(n=78)	
Energy CATs	2 (2.7%)	1 (1.3%)	Fisher's Exact Test

\*1 person did not answer this question

**Cognition, Co-morbidities and Hospitalisation History at Baseline (Week 0):**

The Mini Mental Status Exam (MMSE) was used as a screening measure, and an exclusion criterion was set for a score of 27 or less. The highest possible score on the MMSE is 30. The median MMSE for this sample at Week 0 was 29.0 (IQR 29.0, 30.0). The Charlson Co-Morbidity Index (CCI) was also included in the study as a descriptive measure to assess a potential confounding variable. Higher scores on this instrument indicate a greater number/severity of chronic conditions, with one mild condition resulting in a score of 1, and higher weighted scores of 2, 3 or 6 being allocated for additional conditions, depending on their severity. The median CCI for the full sample of 153 participants was 4.0(IQR 3.0, 5.0) with a minimum of 3.0 and a maximum of 11.0 (Table 10). Participants reported a median time since their last hospitalisation of 2.0 years (IQR 1.0, 9.6), with most hospital visits being at least an overnight stay (82.8%), as compared to an Accident and Emergency room visit only (13.1%) or a day surgery visit only (4.1%).

**Table 10. Health status at Baseline (Week 0)**

	Total Sample	Placebo Group	Healing Touch Group
	Median *(IQR) Range	Median (IQR) Range	Median (IQR) Range
	(n=153)	(n=75)	(n=78)
Mini Mental Status Exam (MMSE)	29.0 (29.0-30.0) 27 to 30	29.0 (29.0-30.0) 27 to 30	29.0 (29.0-30.0) 29 to 30
	(n=133)	(n=66)	(n=67)
Charlson Co-Morbidity Index (CCI)	4.0 (3.0, 5.0); 3.0 to 11.0	4.0 (3.0, 5.0); 3.0 to 11.0	4.0 (3.0, 5.0); 3.0 to 10.0

\*IQR = inter-quartile range

## Outcome Measures at Baseline (Week 0)

### **Primary Outcome Measure of Functional Health:**

The Older American Resource Survey (*OARS*) measures the primary outcome measure of functional health, i.e. the ability of the older person to perform both basic activities of daily living (Basic ADLs) and Instrumental Activities of Daily Living (Instrumental ADLs). An analysis of frequencies, central tendency and variation was performed for the Basic ADL and Instrumental ADL sub-scales and for the Total ADL scale firstly for the full sample of 153 participants and repeated with the participants separated in to the Placebo group and the Healing Touch group. None of these measures were approximately normally distributed, so they are reported as medians and inter quartile ranges in Table 11. The sub-scale scores showed a one point change between the two treatment groups at Week 0 in the medians, with the Healing Touch group at a higher functional health level at Week 0 on both Basic ADLs and Instrumental ADLs. However, the Total ADL score was the same for both treatment groups at Week 0. With average scores of 28 out of a possible 29 point scale, the sample enjoyed a high level of functional health at Week 0.

**Table 11. Functional Health at Baseline (Week 0)**

	<b>Total Sample</b>	<b>Placebo</b>	<b>Healing Touch</b>
	Median *(IQR) Range	Median (IQR) Range	Median (IQR) Range
	(n=153)	(n=75)	(n=78)
Basic ADLs subscale Scale range is 0-15	14.00 (14.0-15.0) 10 to 15	14.00 (14.0-15.0) 10 to 15	15.00 (13.0-15.0) 10 to 15
	(n=153)	(n=75)	(n=78)
Instrumental ADLs subscale Scale range is 0-14	13.00 (13.0-14.0) 8 to 14	13.00 (12.0-14.0) 8 to 14	14.00 (13.0-14.0) 9 to 14
	(n=153)	(n=75)	(n=78)
Total ADLs Scale range is 0-29	28.00 (27.0-29.0) 20 to 29	28.00 (26.0-29.0) 20 to 29	28.00 (27.0-29.0) 21 to 29

\*IQR = inter-quartile range

### **Secondary Outcome Measure of Social Health:**

The Medical Outcomes Study Social Support Survey (MOS-SSS) was used to measure a key dimension of social health, that of social support. An analysis of frequencies, central tendency and variation was performed for the total score and the four sub-scales. The MOS-SSS total score is an average of the four sub-scales scores, all of which are displayed in Table 12 below.

The sample's average scores on the total Social Support Survey and 3 of its 4 sub-scales were reasonably high, ranging from 75 to nearly 78 on a 100 point scale. For the sub-scale of

Affectionate Support, scores were even higher at nearly 92 out of a possible 100 for the sample as a whole.

The total MOS score was very similar between the two treatment groups at Week 0. A greater difference existed between the sub-scale scores, with the Healing Touch group reporting slightly higher scores on the two sub-scales of Tangible Support and Positive Social Interaction, while the Placebo group scored higher on Affectionate Support and Emotional/Informational Support. Even on the sub-scales, the largest difference between the two treatment groups was only 12.5 points on a 0-100 scale for Positive Social Interaction, so the groups were deemed as similar at Week 0 for the purposes of further statistical analysis, particularly since the between group comparisons would be based on the Total Social Support Survey scores, not the sub-scale scores.

**Table 12. Social Support at Baseline (Week 0)**

	<b>Full sample</b>	<b>Placebo</b>	<b>Healing Touch</b>
	Median *(IQR) Range	Median (IQR) Range	Median (IQR) Range
	** (n=152)	(n=75)	(n=77)
Social Support Survey Total Scale range is 0-100	77.6 (60.0,93.8) 3.1 to 100	79.69 (59.9,93.8) 19.5 to 100	77.60 (60.2,94.9) 3.1 to 100
	(n=153)	(n=75)	(n=78)
Subscale: Tangible Support Scale range is 0-100	75.00 (50,93.8) 0.0 to 100	75.00 (56.3, 93.8) 6.3 to 100	78.13 (50.0,95.3) 0.0 to 100
	(n=153)	(n=75)	(n=78)
Subscale: Affectionate Support Scale range is 0-100	91.67 (66.7,100) 0.0 to 100	91.67 (66.7,100) 0.0 to 100	83.33 (66.7,100) 0.0 to 100
	(n=153)	(n=75)	(n=78)
Subscale: Positive Social Interaction Scale range is 0-100	75.00 (50,100) 0.0 to 100	75.0 (50.0,100) 12.5 to 100	87.5 (50.0,100) 0.0 to 100
	(n=152)	(n=75)	(n=77)
Subscale: Emotional / Informational Support Scale range is 0-100	76.56 (60.2, 96.9) 9.4 to 100	81.25 (65.6,96.9) 9.4 to 100	75.0 (59.4,96.8) 9.4 to 100

\*IQR = inter-quartile range

\*\*1 person did not answer all questions of the MOS-SS.

### Secondary Outcome Measure of Psychological Health at Baseline (Week 0):

This instrument also relies on sub-scales to arrive at the total scale score, so central tendencies and variation for both the total scale and the sub-scales are presented below. The sample once again enjoys a relatively high level of health in this dimension of psychological well being, with Total PWB scores in the high 70s out of a possible 108, and with all sub-scales ranging from 12 to 14 out of a possible 18 (Table 13). The medians of the two treatment groups were nearly identical at Week 0 on their total Psychological Well-Being score, and on four of the six sub-scales. The placebo group scored 1-2 points higher on the other two sub-scales, Positive Relations and Personal Growth.

**Table 13. Psychological Well Being at Baseline (Week 0)**

	<b>Full sample</b>	<b>Placebo</b>	<b>Healing Touch</b>
	Median *(IQR) Range	Median (IQR) Range	Median (IQR) Range
	(n=153)	(n=75)	(n=78)
Psychological Well-Being Total Higher score = healthier; possible range 18 to 108. 6 subscales	78.0 (70.0,87.0) 57 to 108	78.0 (70.0,89.0) 57 to 108	78.0 (69.0,84.3) 62 to 104
	(n=153)	(n=75)	(n=78)
Autonomy (scale ranges from 3 to 18)	14.0 (12.0,16.0) 6 to 18	14.0 (12.0,16.0) 6 to 18	14.0 (12.0,16.0) 7 to 18
	(n=153)	(n=75)	(n=78)
Self Acceptance (scale ranges from 3 to 18)	12.0 (11.0,14.0) 6 to 18	12.0 (11.0,14.0) 6 to 18	12.0 (11.0,14.0) 6 to 18
	(n=153)	(n=75)	(n=78)
Positive Relations (scale ranges from 3 to 18)	13.0 (11.5,16.0) 7 to 18	13.0 (12.0,16.0) 7 to 18	12.0 (11.0,15.3) 7 to 18
	(n=153)	(n=75)	(n=78)
Environmental mastery (scale ranges from 3 to 18)	14.0 (12.0,16.0) 8 to 18	14.0 (12.0,16.0) 10 to 18	14.0 (12.0,16.0) 8 to 18
	(n=153)	(n=75)	(n=78)
Personal Growth (scale ranges from 3 to 18)	13.0 (12.0,16.0) 7 to 18	14.0 (12.0,16.0) 7 to 18	12.0 (11.0,15.0) 9 to 18
	(n=153)	(n=75)	(n=78)

	Full sample	Placebo	Healing Touch
Purpose in Life (scale ranges from 3 to 18)	12.0 (11.0,14.0) 5 to 18	12.0 (10.0,14.0) 5 to 18	12.0 (11.0,14.0) 7 to 18

\*IQR = inter-quartile range

### Secondary Outcome Measure of Spiritual Health at Baseline (Week 0):

The Spiritual Well Being (SWB) scale is also comprised of sub-scales, so again both the total and the sub-scale results for central tendency and variation are reported below. Three participants neglected to answer 1 or more questions needed to compute the Religious Well Being sub-scale score, and both sub-scales are required to be summed to arrive at the Total SWB score. This omission has resulted in varying sample sizes, as reflected in the differing n values in the cells of Table 14 below.

The sample overall scored reasonably well on this health dimension also, although their scores for the Existential sub-scale were slightly higher than their scores for the Religious Well Being sub-scale. For both of the sub-scales and for the total scale, the placebo and Healing Touch group's scores were again nearly identical.

**Table 14. Spiritual Well-Being at Baseline (Week 0)**

	Full sample	Placebo	Healing Touch
	Median *(IQR) Range	Median (IQR) Range	Median (IQR) Range
	** (n=150)	(n=73)	(n=77)
Spiritual Well-Being (SWB) Total Scale's possible score: 20-120	80.0 (70.0,92.0) 27 to 120	81.0 (70.0,93.5) 49 to 120	80.0 (71.0,92.0) 27 to 120
	(n=150)	(n=73)	(n=77)
Religious Well-Being sub-scale Sub-scale's possible score: 10-60	40.0 (30.0,48.0) 10 to 60	39.0 (30.0,50.0) 10 to 60	40.0 (30.0,46.5) 10 to 60
	(n=153)	(n=75)	(n=78)
Existential Well-Being sub-scale Sub-scale's possible score: 10-60	42.0 (39.0,48.0) 13 to 60	42.0 (39.0,48.0) 25 to 60	42.0 (39.0,48.0) 13 to 60

\*IQR = inter-quartile range

\*\*3 people did not answer all questions on the SWB.

### Secondary Outcome Measure of Quality of Life at Baseline (Week 0):

The Duke Health Profile was used as a measure of overall quality of life. Sub-scale calculations are not necessary to compute the total score for the Duke, and only the total quality of life score was of interest for the purposes of this study, and it is reported below. Again both treatment groups are very similar in their scores on this outcome measure (Table 15).

**Table 15. Duke Health Profile (Quality of Life) at Baseline (Week 0)**

	Full sample	Placebo	Healing Touch
	(n=153)	(n=75)	(n=78)
	Mean *(SD) Range	Mean (SD) Range	Mean (SD) Range
Duke Health Profile Higher score = better health, Scale range 0 to 34	23.86 (4.18) 12.0 to 33.0	23.50 (4.05) 14.0 to 33.0	24.22 (4.30) 12.0 to 33.0

\*SD = standard deviation

## Outcomes

### Primary Outcome Measure: Functional Health as measured by the OARS instrument.

The null hypothesis is that the amount of change (expected to be a negative change, due to the natural decline related to the ageing process) would be the same in both groups: the treatment group who received Healing Touch and the comparison group who received a mimic Healing Touch treatment as a placebo. The primary alternative hypothesis refers to the total decline from Week 0 to the follow up data collection point, Week 33, six months after the completion of the entire series of 7 weekly treatment sessions. Hence the change variable was set to be computed as the score at Week 33 minus the score at Week 0, meaning that a decline in the score would result in a negative number for the value of the change variable, and an improvement or an increase in the score would result in a positive value for the change variable.

For both of the subscale scores, and for the total ADL score, the change variables were computed and then compared between the Healing Touch group and the Placebo group using the Mann Whitney test, but the change variables did not reach statistical significance, so the null hypotheses were retained. However it is useful to note that for all three scores (Total, Basic and Instrumental ADL), the Healing Touch group showed a slightly smaller amount of functional decline than that experienced by the Placebo group. However, the difference between the amount of decline the Healing Touch group experienced is more likely to be due to a chance variation than to any true distinction between the two treatment groups, given a high p value of 0.557, which is neither near or even approaching the designated statistical significance level of 0.05; and given that the power analysis and sample size calculations were computer based on this instrument.

The relevant values are displayed in Tables 16 through Table 18. The distribution of each of these change variables was not normal, so the medians and IQRs were the most appropriate method of reporting the central tendency and distribution of the data and were featured first in the table below.

**Table 16. Functional Health, Total Activities of Daily Living (ADLs), Comparison of Treatment groups**

Median *(IQR) Range	n	Sample as a whole	n	Placebo	n	Healing Touch	Statistical test	p value
Week 0	153	28.00 (27.0-29.0) 20 to 29	75	28.00 (26.0-29.0) 20 to 29	78	28.00 (27.0-29.0) 21 to 29		
**Week 8	153	28.00 (26.0-29.0) 18 to 29	75	28.00 (25.0-29.0) 20 to 29	78	28.00 (27.0-29.0) 18 to 29		
Week 33	153	27.00 (26.0-29.0) 19 to 29	75	27.00 (25.0-29.0) 19 to 29	78	28.00 (26.0-29.0) 21 to 29		
***Change = Week 8-Week 0	153	0 (0,0.5) -5 to +4	75	0 (0,0) -5 to +4	78	0 (0,+1.0) -4 to +3	Mann Whitney 2732.0	0.443
***Change = Week 33-Week 0	153	0 (-1,0) -9 to +3	75	0 (-1,0) -9 to +2	78	0 (-1,0) -5 to +3	Mann Whitney 2770.5	0.557

\*IQR = inter-quartile range.

\*\*Intervention series occurred during Weeks 1 through 7.

\*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

**Table 17. Functional Health, Basic Activities of Daily Living (Basic ADLs) Sub-scale, Comparison of Treatment groups**

Median *(IQR) Range	n	Sample as a whole	n	Placebo	n	Healing Touch	Statistical test	p value
Week 0	153	14.00 (14.0-15.0) 10 to 15	75	14.00 (14.0-15.0) 10 to 15	78	15.00 (13.0-15.0) 10 to 15		
**Week 8	153	15.00 (13.5-15.0) 10 to 15	75	14.00 (13.0-15.0) 10 to 15	78	15.00 (14.0-15.0) 11 to 15		
Week 33	153	14.00 (13.0-15.0) 9 to 15	75	14.00 (13.0-15.0) 9 to 15	78	14.50 (13.0-15.0) 11 to 15		
***Change = Week 8-Week 0	153	0 (0,0) -3 to +3	75	0 (0,0) -3 to +3	78	0 (0,+0.25) -2 to +3	Mann Whitney 2678.5	0.305

Median *(IQR) Range	n	Sample as a whole	n	Placebo	n	Healing Touch	Statistical test	p value
***Change = Week 33- Week 0	153	0 (-1, 0) -4 to +3	75	0 (-1, 0) -4 to +2	78	0 (-1, 0) -2 to +3	Mann Whitney 2728.00	0.436

\*IQR = inter-quartile range.

\*\*Intervention series occurred during Weeks 1 through 7.

\*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

The Basic ADL sub-scale shows a non-significant trend towards improvement noted from Week 0 to Week 8 in the Inter Quartile Ranges (IQRs), and this improvement is only seen in the Healing Touch group, not the Placebo group. But again, this trend towards improvement in the Basic ADL score is not sufficient to distinguish the Healing Touch group from the Placebo group at the level of statistical significance, indicating that this difference between the two treatment groups is far more likely to be due to a chance variation rather than to any actual treatment effect. There is no corresponding pattern in the Instrumental ADL sub-scale scores, where the median value of the change for both treatment groups at both time points is zero.

**Table 18. Functional Health, Instrumental Activities of Daily Living (Instrumental ADLs) Sub-scale, Comparison of Treatment groups**

	n	Total Sample	n	Placebo	n	Healing Touch	Statistical test	p value
		Median *(IQR) Range		Median (IQR) Range		Median (IQR) Range		
Week 0	153	13.00 (13.0-14.0) 8 to 14	75	13.00 (12.0-14.0) 8 to 14	78	14.00 (13.0-14.0) 9 to 14		
**Week 8	153	13.00 (13.0-14.0) 5 to 14	75	13.00 (12.0-14.0) 9 to 14	78	13.00 (13.0-14.0) 5 to 14		
Week 33	153	13.00 (12.0-14.0) 8 to 14	75	13.00 (12.0-14.0) 8 to 14	78	13.00 (13.0-14.0) 10 to 14		
**Change = Week 8- Week 0	153	0 (0,0) -7 to +3	75	0 (0,0) -4 to +3	78	0 (0,0) -7 to +2	Mann Whitney 2923.5	0.994
**Change = Week 33- Week 0	153	0 (-1,0) -5 to +2	75	0 (-1,0) -5 to +2	78	0 (-0.25,0) -3 to +2	Mann Whitney 2920	0.985

\*IQR = inter-quartile range.

\*\*Intervention series occurred during Weeks 1 through 7.

\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

## Social Support

This is the only outcome measure that demonstrated a statistically significant difference between the two treatment groups, with the level of social support declining from Week 0 to Week 33 after completion of treatment in the Placebo group, while the level of social support improved over that same time frame for the Healing Touch group (Table 19). Of note, this divergence in direction of change was becoming visible at the Week 8 data collection as well, with the Healing Touch group remaining stable while the Placebo group declined, but the two treatment groups did not reach a statistically significant divergence in their pattern of change until the Week 33 data collection point.

**Table 19. Social Support: Comparison of Treatment Groups**

	n	Total Sample	n	Placebo	n	Healing Touch	Test Statistic	p value
		Median *(IQR) Range		Median (IQR) Range		Median (IQR) Range		
Week 0	**15 2	77.60 (60.0,93.8) 3.13 to 100.0	75	79.69 (59.9,93.8) 19.53 to 100.0	77	77.60 (60.2,94.9) 3.13 to 100.0		
***Week 8	151	78.39 (59.4, 94.5) 2.34 to 100.0	75	79.17 (58.9, 93.8) 7.03 to 100.0	76	76.69 (59.9, 96.3) 2.34 to 100.0		
Week 33	152	76.43 (61.5,92.19) 13.54 to 100.0	75	76.56 (57.55, 90.63) 13.54 to 100.0	77	76.30 (63.02, 93.49) 24.74 to 100.0		
****Change = Week 8- Week 0	150	0.0 (-8.66, +6.25) -35.42 to +46.88	75	-1.04 (-9.11, +6.25) -29.17 to +36.46	75	0.0 (-8.59, +6.25) -35.42 to +46.88	Mann Whit- ney 2728.5	0.75 2
****Change = Week 33- Week 0	151	0.0 (-8.07, +6.25) -34.90 to +45.31	75	-2.34 (-10.94, +4.95) -34.90 to +30.73	76	+1.82 (-4.69, +9.96) -30.47 to +45.31	Mann Whit- ney 2293.0	0.03 8

\*IQR = inter-quartile range.

\*\*Not all participants answered all questions

\* \*\*Intervention series occurred during Weeks 1 through 7.

\*\*\* \*A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

## Psychological Well Being

Both treatment groups experienced an incremental decline in their psychological well being at each data collection point (Table 20). Once again the Healing Touch group experienced less of a decline, but the difference between the amount of decline in each treatment group did not reach statistical significance.

**Table 20. Psychological Well Being: Comparison of Treatment Groups**

	n	Total Sample	n	Placebo	n	Healing Touch	Test Statistic	p value
		Median *(IQR) Range		Median (IQR) Range		Median (IQR) Range		
Week 0	153	78.0 (70.0,87.0) 57 to 108	75	78.0 (70.0,89.0) 57 to 108	78	78.0 (69.0, 84.3) 62 to 104		
**Week 8	***152	75.0 (70.0,84.0) 59 to 104	75	75.0 (70.0,85.0) 62 to 102	77	75.0 (69.0,84.0) 59 to 104		
Week 33	153	72.0 (68.0,78.0) 62 to 99	75	72.0 (68.0,79.0) 62 to 99	78	72.0 (68.8,78.0) 64 to 91		
****Change = Week 8- Week 0	152	-1.00 (-7.0, +3.0) -26.0 to +46.0	75	-2.00 (-8.0, +3.0) -25.0 to +15.0	77	-1.00 (-6.0, +3.0) -26.0 to +20.0	Mann Whitney 2682.0	0.448
****Change = Week 33- Week 0	153	-4.00 (-10.5, +2.0) -34.0 to + 17.0	75	-4.00 (-11.0,+2.0) -34.0 to +14.0	78	-3.00 (-10.0, +1.3) -31.0 to +17.0	Mann Whitney 2840.0	0.756

\*IQR = inter-quartile range.

\*\*Intervention series occurred during Weeks 1 through 7

\*\*\*Not all participants answered all questions

\*\*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

## Spiritual Well Being

This was an outcome measure that had an approximate normal distribution for all 3 time points, for the whole sample and for both treatment groups, so means and standard deviations (SD) were reported for the Spiritual Well Being scale scores (Table 21). However, the change variables were NOT normally distributed, so they are reported by median, inter quartile range (IQR) and range.

The two treatment groups showed a different pattern of change over time, but the differences between the two treatment groups did not reach statistical significance. For the change between Week 8 minus Week 0, the Healing Touch group showed a positive value, indicating an improvement of nearly two points on this 0-120 scale, while the Placebo group showed a change of -1.5 points, indicating a decline of nearly the same magnitude as the improvement demonstrated by the Healing Touch group. However, when comparing the Week 8 minus Week 0 change variable computed for the two treatment groups, the p value only reached 0.066, thus approaching but not reaching the set threshold for statistical significance of  $p < 0.05$ .

Interestingly, by the time of the Week 33 data collection, this pattern of response had changed direction, with the value of the change variables for both treatment groups now showing a decline, and a larger decline in the Healing Touch group, but not a statistically significantly larger decline. However, these variations in the amount of decline were clearly not statistically significant, with a p value of 0.772 that was far from the set threshold.

**Table 21. Spiritual Well Being (SWB): Comparison of treatment groups.**

SWB scale range: 20-120	n	Total Sample	n	Placebo	n	Healing Touch	Test Statistic	p value
		Mean(SD)* Range		Mean(SD) Range		Mean(SD) Range		
Week 0	**150	82.29(17.61) 27 to 120	73	82.44 (16.89) 49 to 120	77	82.14 (18.37) 27 to 120		
***Week 8	150	82.52 (17.21) 44 to 120	72	80.83 (17.09) 46 to 116	78	84.08 (17.28) 44 to 120		
Week 33	148	78.68 (12.82) 47 to 110	72	79.24 (13.28) 58 to 110	76	78.16 (12.44) 47 to 110		
		Median ****(IQR) Range		Median (IQR) Range		Median (IQR) Range		
***** Change = Week 8- Week 0	147	0.0 (-4.0, +5.0) -25.0 to +39.0	70	-1.5 (-5.3, +3.3) -25.0 to +25.0	77	+1.0 (-3.0, +6.5) -25.0 to +39.0	Mann Whit- ney 2221.5	0.066
***** Change = Week 33- Week 0	145	-2.0 (-8.0, +2.5) -36.0 to +36.0	70	-1.0 (-6.3, +2.0) -29.0 to +27.0	75	-2.0 (-12.0, +3.0) -36.0 to +36.0	Mann Whit- ney 2552.0	0.772

\*SD – Standard Deviation

\*\*Not all participants answered all questions

\*\*\*Intervention series occurred during Weeks 1 through 7

\*\*\*\*IQR = inter-quartile range

\*\* \*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

## Quality of life

This was an outcome measure that had an approximate normal distribution for all 3 time points, for the whole sample and for both treatment groups, so means and standard deviations are reported for the Duke Quality of Life scale scores. However, the change variables were not normally distributed for both groups, so they are reported by median, inter quartile (IQR) and range for treatment groups and the sample as a whole.

Duke Quality of life changes over time were essentially similar in both treatment groups, with both of the two change variables showing no statistically significant variation between the

treatment groups. The values of the two change variable were either neutral or improved for both treatment groups.

**Table 22. Quality of Life: Comparison of treatment groups**

	n	Total Sample	n	Placebo	n	Healing Touch	Test Statistic	p value
		Mean (SD)* Range		Mean (SD) Range		Mean (SD) Range		
Week 0	153	23.86 (4.18) 21.0 to 33.0	75	23.49 (4.05) 14.0 to 33.0	78	24.22 (4.30) 12.0 to 33.0		
**Week 8	153	24.92 (4.51) 12.0 to 33.0	75	24.73 (4.29) 14.0 to 33.0	78	25.09 (4.73) 12.0 to 33.0		
Week 33	153	24.37 (4.23) 13.0 to 33.0	75	24.13 (4.08) 14.0 to 31.0	78	24.60 (4.38) 13.0 to 33.0		
		Median *** (IQR) Range		Median (IQR) Range		Median (IQR) Range		
****Change = Week 8 – Week 0	153	+1.0 (-1.0, +3.0) -6.0 to +8.0	75	+1.0 (0.0, +4.0) -6.0 to +8.0	78	+1.0 (-1.0, +3.0) -5.0 to +7.0	Mann Whitney 2661.5	0.334
****Change= Week 33 - Week 0	153	0.0 (-2.0,+3.0) -12.0 to +11.0	75	+1.0 (-2.0, +3.0) -12.0 to +11.0	78	0.0 (-1.3,+2.0) -7.0 to +7.0	Mann Whitney 2862.0	0.717

\*SD= Standard Deviation

\*\*Intervention series occurred during Weeks 1 through 7

\*\*\* IQR = inter-quartile range

\*\*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

## Stratified Analysis

There were two particularly relevant demographic variables for which the two treatment groups differed substantially at baseline, despite the use of a randomisation process for allocation in to treatment groups. Given the expected potential influence of these two variables of income and living arrangements on the primary and secondary outcome measures, a stratified analysis based on these two variables was undertaken and will be presented next. The original Week 0 comparison tables are re-presented here for the reader's convenience.

### Living Arrangement

A stratification was undertaken to explore the potential impact of living arrangement, as a higher proportion of the Healing Touch group's participants were already living in a retirement village at Week 0 (Table 23). Living arrangements are an indirect measure of in/dependence of functional health, as they differ according to the level of support on offer, with a retirement village maintaining the grounds, the communal facilities, and the living units. Two strata were

created based on living arrangements at Week 0, and the treatment groups were compared within each stratum, and the results are presented below and the area of disproportion is bolded.

**Table 23. Living Arrangements at Baseline (Week 0): Comparison of treatment groups.**

n(%)	Total Sample	Placebo Group	Healing Touch Group
	n=153	n=75	n=78
Home/unit in ordinary residential neighbourhood	101(66.0%)	<b>54(72.0%)</b>	<b>47(60.3%)</b>
Retirement village	50(32.7%)	<b>20(26.7%)</b>	<b>30(38.5%)</b>
Granny flat on family's lot	2(1.3%)	1(1.3%)	1(1.3%)

### **Stratification by Living Arrangement: Comparison of the two treatment groups on the primary Outcome Measure of Functional Health**

The stratified results for the primary outcome measure are presented first, for both the sub-scales and the total scale. In the un-stratified results, there were no statistically significant results in the variation in functional decline experienced by the two treatment groups. However, in the stratified results, specifically for the stratum of participants already living in a retirement village, the amount of functional decline experienced by the two treatment groups differed at a statistically significant level of  $p=0.025$  for the sub-scale of Basic Activities of Daily Living (Basic ADLs). The Healing Touch group experienced statistically significantly less functional decline in their ability to perform Basic ADLs than the amount of Basic ADL functional decline experienced by the Placebo group (Table 24 and Figure 4). These changes support the alternative hypothesis.

**Table 24. Stratification by Living Arrangement at Baseline (Week 0): Comparison of Two Treatment Groups on the Primary Outcome Measure of Functional Health: Basic Activities of Daily Living (Basic ADLs)**

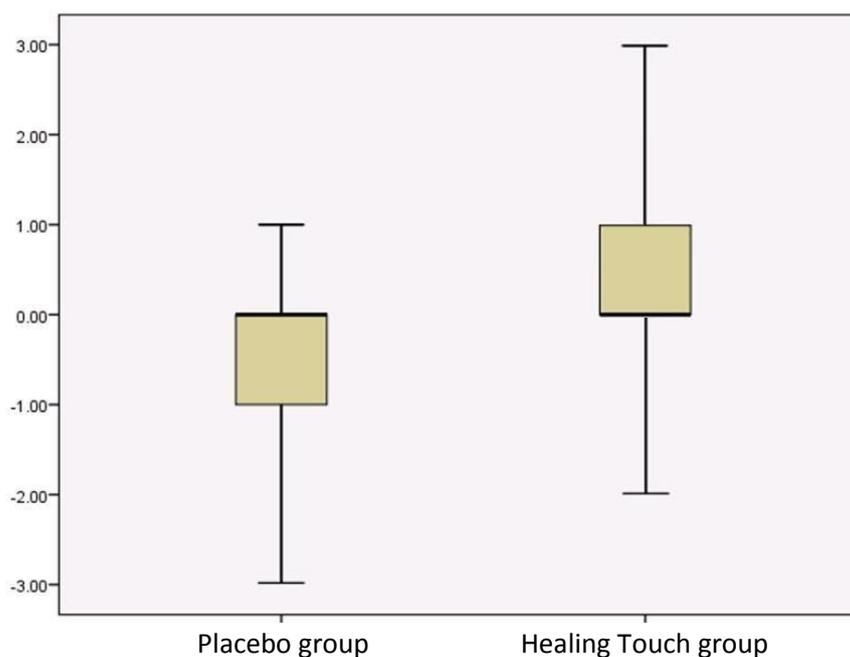
Outcome Measures	Living in own home/unit in ordinary residential neighbourhood At Week 0 (n=101)			Retirement village At Week 0 (n=52)		
	Placebo	Healing Touch	Test Statistic p value	Placebo	Healing Touch	Test Statistic p value
Median *(IQR) Range	(n=54)	(n=47)		(n=21)	(n=31)	
Week 0 Basic ADLs	14.0 (14,15) 10 to 15	15.0 (13,15) 12 to 15		15.0 (13, 15) 11 to 15	15.0 (13, 15) 10 to 15	
**Week 8 Basic ADLs	14.0 (13,15) 10 to 15	15.0 (14, 15) 11 to 15		14.0 (13, 15) 11 to 15	15.0 (14, 15) 11 to 15	

Outcome Measures	Living in own home/unit in ordinary residential neighbourhood			Retirement village		
	At Week 0 (n=101)			At Week 0 (n=52)		
Week 33 Basic ADLs	14.0 (13, 15) 9 to 15	14.0 (13,15) 11 to 15		14.0 (13,15) 10 to 15	15.0 (13,15) 12 to 15	
***Change Basic ADLs = Week 8 - Week 0	0.0 (0, 0) -3.0 to +3.0	0.0 (0,0) -2.0 to +2.0	Mann Whitney 1220 p = 0.702	0.0 (-0.5, 0.0) -3.0 to +1.0	0.0 (0.0, +1.0) -2.0 to +3.0	Mann Whitney 264.5 p = 0.199
***Change Basic ADLs = Week 33 - Week 0	0.0 (-1.00,+0.25) -4.0 to +2.0	0.0 (-1.0,0.0) -2.0 to +2.0	Mann Whitney 1186.5 p = 0.543	0.0 (-1.0,0.0) -3.0 to +1.0	0.0 (0.0,+1.0) -2.0 to +3.0	Mann Whitney 215.0 p = 0.025

\*IQR = inter-quartile range

\*\*Intervention series occurred during Weeks 1 through 7.

\*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.



**Figure 4. Change in Basic Activities of Daily Living from Week 0 to Week 33 for stratum of retirement village participants**

The stratified analysis was repeated for the other sub-scale of Instrumental Activities of Daily Living, as per Table 25 below. The two treatment groups were essentially similar for Instrumental ADLs, in both strata. Lastly, the stratified analysis was repeated for the Total ADL scale for Activities of Daily Living, as per Table 26 below. The two treatment groups were essentially similar for Total ADLs, again for both strata.

**Table 25. Stratification by Living Arrangement at Baseline (Week 0): Comparison of Two Treatment Groups on the Primary Outcome Measure of Functional Health: Instrumental Activities of Daily Living (Instrumental ADLs)**

Outcome Measures	Living in own home/unit in ordinary residential neighbourhood At Week 0 (n=101)			Retirement village At Week 0 (n=52)		
	Placebo	Healing Touch	Test Statistic (p value)	Placebo	Healing Touch	Test Statistic (p value)
	(n=54)	(n=47)		(n=21)	(n=31)	
Week 0 Instrumental ADLs	14.0 (13,14) 8 to 14	14.0 (13,14) 9 to 14		13.0 (11.5, 14.0) 10 to 14	13.0 (13.0, 14.0) 12 to 14	
**Week 8 Instrumental ADLs	13.0 (13, 14) 9 to 14	14.0 (13, 14) 10 to 14		13.0 (11,14) 9 to 14	13.0 (13, 14) 5 to 14	
Week 33 Instrumental ADLs	13.0 (12,14) 8 to 14	14.0 (13,14) 10 to 14		13.0 (11.5, 14.0) 8 to 14	13.0 (12,14) 10 to 14	
***Change Instrumental ADLs = Week 8 - Week 0	0.0 (0.0,0.0) -4.0 to +3.0	0.0 (0.0,0.0) -1.0 to +2.0	Mann Whitney 1257.0 p = 0.914	0.0 (0.0,0.0) -2.0 to +1.0	0.0 (0.0,0.0) -7.0 to +1.0	Mann Whitney 317.0 p = 0.846
***Change Instrumental ADLs = Week 33 - Week 0	0.0 (-1.0,0.0) -5.0 to +2.0	0.0 (0.0,0.0) -3.0 to +2.0	Mann Whitney 1173.0 p = 0.463	0.0 (0.0,0.0) -3.0 to +2.0	0.0 (-1.0,0.0) -2.0 to +2.0	Mann Whitney 271.0 p = 0.222

\*IQR = inter-quartile range

\*\*Intervention series occurred during Weeks 1 through 7.

\*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

**Table 26. Stratification by Living Arrangement at Baseline (Week 0): Comparison of Two Treatment Groups on the Primary Outcome Measure of Functional Health: Total Activities of Daily Living (Basic ADLs and Instrumental ADLs summed)**

Outcome Measures	Living in own home/unit in ordinary residential neighbourhood			Retirement village		
	At Week 0 (n=101)			At Week 0 (n=52)		
Median *(IQR) Range	Placebo	Healing Touch	Test Statistic (p value)	Placebo	Healing Touch	Test Statistic (p value)
	(n=54)	(n=47)		(n=21)	(n=31)	
Week 0 Total ADLs	28.0 27,29) 20 to 29	28.0 (27,29) 21 to 29		28.0 (25.0, 29.0) 22 to 29	27.0 (26, 29) 22 to 29	
**Week 8 Total ADLs	28.0 (26, 28) 20 to 29	28.0 (27, 29) 22 to 29		27.0 (24.5, 29) 20 to 29	28.0 (26, 29) 18 to 29	
Week 33 Total ADLs	27.0 (25.75, 29) 19 to 29	28.0 (26,29) 21 to 29		27.0 (25, 28.5) 19 to 29	28.0 (26,29) 23 to 29	
***Change Total ADLs = Week 8 - Week 0	0.0 (0, +1.0) -4.0 to +4.0	0.0 (0, +1.0) -2.0 to +2.0	Mann Whitney 1233.5 p = 0.791	0.0 (-1.0,0.0) -5.0 to +1.0	0.0 (-1.0,+1.0) -4.0 to +3.0	Mann Whitney 272.50 p = 0.288
***Change Total ADLs = Week 33 - Week 0	0.0 (-1.0,+1.0) -9.0 to +2.0	0.0 (-1.0,0.0) -5.0 to +2.0	Mann- Whitney 1256.0 p=0.927	0.0 (-1.0,0.0) -6.0 to +2.0	0.0 (-1.0,0.0) -4.0 to +3.0	Mann Whitney 267.0 p = 0.246

\*IQR = inter-quartile range

\*\*Intervention series occurred during Weeks 1 through 7.

\*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

### **Stratification by Living Arrangement: Comparison of the two treatment groups on secondary Outcome Measure of Social Support**

This is the only secondary outcome measure where the un-stratified results differed from the results stratified by living arrangement. In the un-stratified results presented above (Table 19), where all participants were examined together, the change from Week 0 to Week 33 on Social Support showed a statistically significant variation between treatment groups, with the Placebo group reporting a declining level of social support over time, while the Healing Touch improved over time. It appears that this distinction between treatment groups in the combined data was due to the influence of the sub-group of the 101 participants living in their own home or unit in an ordinary residential neighbourhood, for whom the between group comparison again reaches statistical significance ( $p = 0.012$ ) but within their stratum only (Table 27). For the other stratum, that of participants living in a retirement village or other

supported accommodation at Week 0, there is no statistically significant difference between the two treatment groups, with both treatment groups reporting a decrease in social support from Week 0 to the Week 33 data collection time point.

**Table 27. Stratification by Living Arrangement: Comparison of the two treatment groups on the secondary outcome measure of Social Support**

	Living in own home in ordinary residential neighbourhood At Week 0 *(n=100)			Retirement village At Week 0 (n=51)*		
	Placebo	Healing Touch		Placebo	Healing Touch	
	Median **(IQR) Range	Median (IQR) Range	Test statistic p value	Median (IQR) Range	Median (IQR) Range	Test statistic p value
	(n=54)	(n=47)		(n=21)	(n=30)	
Week 0	75.8 (59.4, 93.2) 19.5 to 100	70.6 (54.4, 70.6) 3.1 to 100		84.38 (64.6, 94.7) 41.9 to 100	87.1 (66.0, 98.0) 39.6 to 100	
	(n=54)	(n=45)		(n=21)	(n=31)	
***Week 8	78.6 (58.5, 91.5) 7.0 to 100	69.3 (62.2, 90.2) 2.3 to 100		81.25 (61.2, 99.6) 37.2 to 100	82.0 (57.3, 100.0) 24.2 to 100	
	(n=54)	(n=46)		(n=21)	(n=31)	
Week 33	74.7 (55.6, 90.6) 13.5 to 100	76.7 (64.3, 86.1) 24.7 to 100		78.13 (63.0, 93.0) 44.5 to 100	75.3 (61.7, 97.7) 44.8 to 100	
	(n=54)	(n=45)		(n=21)	(n=30)	
**** Change = Week 8 – Week 0	-1.04 (-8.72, +5.66) -29.17 to +36.46	0.00 (-7.68, +10.42) -32.29 to +46.88	Mann Whitney 1104.5 p = 0.437	-1.82 (-9.90, +7.42) -19.79 to +30.73	-0.91 (-8.98, +2.15) -35.42 to +31.25	Mann Whitney 301.5 p = 0.796
	(n=54)	(n=46)		(n=21)	(n=30)	
**** Change = Week 33 – Week 0	-2.47 (-14.78, +5.27) -34.90 to +27.08	+3.13 (-3.51, +14.65) -28.65 to +45.31	Mann Whitney 878.5 p = 0.012	-2.34 (-8.33, +5.21) -27.86 to +30.73	-1.04 (-7.36, +2.47) -30.47 to +32.03	Mann Whitney 304.0 p = 0.833

\*Not all participants answered all questions

\*\* IQR = inter-quartile range

\*\*\*Intervention series occurred during Weeks 1 through 7

\*\*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

**Stratification by Living Arrangement: Comparison of the two treatment groups on secondary Outcome Measures of Quality of Life, Spiritual Well Being and Psychological Well Being**

The stratified results for the secondary outcome measures are presented next (Tables 28 through 30). Within both Living Arrangement strata, the two treatment groups were again similar in their amount of decline or improvement over time for overall Quality of Life, Spiritual well-being and Psychological well-being. So the stratified results were similar to the un-stratified results for these three secondary outcome measures, with the notable exception of Spiritual Well Being.

**Table 28. Stratification by Living Arrangement: Comparison of the two treatment groups on secondary Outcome Measure of Duke overall Quality of life.**

	Living in own home in ordinary residential neighbourhood At Week 0 (n=101)			Retirement village At Week 0 (n=52)		
	Placebo	Healing Touch		Placebo	Healing Touch	
	Median *(IQR) Range	Median (IQR) Range	Test statistic p value	Median (IQR) Range	Median (IQR) Range	Test statistic p value
	(n=54)	(n=47)		(n=21)	(n=31)	
Week 0	23.5 (20.8, 26.3) 14.0 to 33.0	24.0 (21.0, 27.0) 12.0 to 32.0		24.0 (21.5, 26.5) 15.0 to 31.0	25.0 (21.0, 27.0) 16.0 to 33.0	
	(n=54)	(n=47)		(n=21)	(n=31)	
**Week 8	25.0 (21.0, 28.0) 14.0 to 33.0	26.0 (22.0, 28.0) 13.0 to 32.0		25.0 (22.5, 28.0) 20.0 to 31.0	26.0 (22.0, 29.0) 12.0 to 33.0	
	(n=54)	(n=47)		(n=21)	(n=31)	
Week 33	24.0 (20.0, 27.0) 14.0 to 30.0	25.0 (22.0, 27.0) 13.0 to 30.0		25.0 (23.5, 28.0) 18.0 to 31.0	26.0 (22.0, 28.0) 16.0 to 33.0	
	(n=54)	(n=47)		(n=21)	(n=31)	
***Change = Week 8 – Week 0	+1.00 (-1.0, +3.0) -6.0 to +7.0	0.00 (-1.0, +3.0) -5.0 to +7.0	Mann Whitney 1181.0 p = 0.547	+1.00 (0.0, +4.5) -6.0 to +8.0	+1.00 (-2.0, +3.0) -4.0 to +7.0	Mann Whitney 274.5 p = 0.338
	(n=54)	(n=47)		(n=21)	(n=31)	

	Living in own home in ordinary residential neighbourhood At Week 0 (n=101)			Retirement village At Week 0 (n=52)		
***Change = Week 33 – Week 0	+1.00 (-3.0,+3.0) -12.0 to +11.0	0.00 (-2.0,+2.0) -7.0 to +7.0	Mann Whitney 1267.5  p = 0.992	+1.00 (-0.5, +4.0) -4.0 to +10.0	+1.00 (-1.0, +2.0) -5.0 to +6.0	Mann Whitney 274.5  p = 0.338

\*IQR = inter-quartile range

\*\*Intervention series occurred during Weeks 1 through 7.

\*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

The results for spiritual well-being demonstrated a different pattern of change in the two different strata by living arrangement. Firstly, for the participants living in their own neighbourhood, the results showed a statistically significant difference in the amount and direction of change from Week 0 to Week 8 between treatment groups, with the Healing Touch group improving and the Placebo group declining in their reported levels of spiritual well-being. By Week 33, although the trend of a better response in the Healing Touch group persisted, the differences in the amount of change from Week 0 to Week 33 between the two treatment groups no longer reached or approached statistical significance.

In a marked contrast, for participants living in retirement villages, there were no statistically significant differences between the amount and direction of change from Week 0 to Week 8 in the two treatment groups, but the difference between treatment groups for the amount and direction of change from Week 0 to Week 33 was approaching statistical significance with a p value of 0.089. However, in this stratum of retirement village residents, the nearly significant trend showed the Healing Touch group declining in spiritual well being while the Placebo group was holding even by the Week 33 measurement.

**Table 29. Stratification by Living Arrangement: Comparison of the two treatment groups on secondary Outcome Measure of Spiritual Well Being**

Median *(IQR) Range	Living in own home in ordinary residential neighbourhood At Week 0			Retirement village At Week 0		
	Placebo	Healing Touch	Test Statistic	Placebo	Healing Touch	Test Statistic
			p value			p value
	** (n=53)	(n=46)		(n=20)	(n=31)	
Week 0	79.0 (69.0, 95.0) 49.0 to 120.0	80.0 (70.5, 92.0) 27.0 to 120.0		82.0 (75.0, 92.5) 69.0 to 120.0	81.0 (73.0, 100.0) 58.0 to 120.0	
	(n=52)	(n=47)		(n=20)	(n=31)	

Median *(IQR) Range	Living in own home in ordinary residential neighbourhood At Week 0			Retirement village At Week 0		
	***Week 8	74.0 (67,93.3) 46.0 to 116.0  (n=52)	81.0 (70.0,92.0) 44.0 to 120.0  (n=45)		83.0 (78.0, 93.5) 66.0 to 113.0  (n=20)	81.0 (71.0, 99.0) 60.0 to 118.0  (n=31)
Week 33	76.5 (66.3, 85.8) 58.0 to 109.0  (n=51)	79.0 (70.0, 85.5) 47.0 to 109.0  (n=46)		79.0 (75.0, 90.8) 66.0 to 110.0  (n=19)	77.0 (68.0, 84.0) 52.0 to 110.0  (n=31)	
**** Change = Week 8 – Week 0	-1.12 (-5.0,+2.0) -25.0 to +25.0  (n=51)	+1.00 (-2.0, +8.8) -25.0 to +39.0  (n=44)	Mann Whitney 852.0 p = 0.020	+2.00 (-7.0, +6.0) -21.0 to +14.0  (n=19)	0.00 (-4.0, +6.0) -18.0 to +26.0  (n=31)	Mann Whitney 293.5 p = 0.984
**** Change = Week 33 – Week 0	-2.00 (-6.00,+1.00) -29.0 to +18.0  (n=51)	0.0 (-8.75, +5.00) -32.0 to +36.0  (n=44)	Mann Whitney 967.5 p = 0.248	0.0 (-7.00,+5.00) -18.0 to +27.0  (n=19)	-4.00 (-14.0, 0.0) -36.0 to +20.0  (n=31)	Mann Whitney 209.5 p = 0.089

\*IQR = inter-quartile range

\*\*Not all participants answered all questions

\*\*\*Intervention series occurred during Weeks 1 through 7.

\*\*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

**Table 30. Stratification by Living Arrangement: Comparison of the two treatment groups on secondary Outcome Measure of Psychological Well being.**

	Living in own home in ordinary residential neighbourhood At Week 0 (n=101)			Retirement village At Week 0 (n=52)		
	Placebo	Healing Touch		Placebo	Healing Touch	
	Median *(IQR) Range  (n=54)	Median (IQR) Range  (n=47)	Test statistic p value	Median (IQR) Range  (n=21)	Median (IQR) Range  (n=31)	Test statistic p value
Week 0	79.0 (70.0, 88.3) 57.0 to 108.0	75.0 (68.0, 86.0) 62.0 to 103.0		75.0 (70.5, 89.0) 6.0 to 101.0	79.0 (70.0, 83.0) 67.0 to 104.0	

	Living in own home in ordinary residential neighbourhood At Week 0 (n=101)			Retirement village At Week 0 (n=52)		
	(n=54)	** (n=46)		(n=21)	(n=31)	
***Week 8	76.0 (70.0, 85.0) 62. to 99.0	73.0 (69.0, 85.0) 63.0 to 104.0		74.0 (68.0, 83.5) 64.0 to 102.0	76.0 (70.0, 84.0) 59.0 to 98.0	
	(n=54)	(n=47)		(n=21)	(n=31)	
Week 33	72.0 (68.0, 79.3) 62.0 to 99.0	72.0 (68.0, 79.0) 64.0 to 91.0		72.0 (68.5, 78.5) 66.0 to 94.0	72.0 (69.0, 76.0) 66.0 to 86.0	
	(n=54)	(n=46)		(n=21)	(n=31)	
****Change = Week 8 – Week 0	-1.50 (-8.3, +3.3) -25.0 to +15.0	-5.00 (-6.0, +3.3) -26.0 to +20.0	Mann Whitney 1144.5 p = 0.500	-2.00 (-6.00, +1.5) -13.0 to +9.0	-2.00 (-7.0, +3.0) -26.0 to +15.0	Mann Whitney 300.5 p = 0.640
	(n=54)	(n=47)		(n=21)	(n=31)	
****Change = Week 33 – Week 0	-5.00 (-12.0,+2.0) -34.0 to +14.0	-3.00 (-10.0,+2.0) -30.0 to +17.0	Mann Whitney 1174.5 p = 0.519	-3.00 (-7.5, +0.50) -24.0 to +9.0	-5.00 (-10.0,+1.0) -31.0 to +9.0	Mann Whitney 308.0 p = 0.744

\*IQR = inter-quartile range

\*\*Not all participants answered all questions

\*\*\*Intervention series occurred during Weeks 1 through 7.

\*\*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

## Income

The stratification by Income will be presented next, in summary form, with a focus on the key measure of interest in the main hypothesis, i.e. if the change in score from Week 0 to Week 33 differs between treatment groups at a statistically significant level. For the reader's convenience, the distribution of income levels at baseline is re-presented here, and the area of disproportion is bolded.

**Table 31. Income at Baseline (Week 0): Comparison of treatment groups**

n(%)	Total Sample	Placebo Group	Healing Touch Group
	(n=145)	(n=74)	(n=71)
Less than \$10,000 per yr	1(0.7%)	0(0%)	1(1.4%)
\$10-19,999/yr	71(49%)	<b>40(54.1%)</b>	<b>31(43.7%)</b>
\$20-30,000	69(47.6%)	<b>32(43.2%)</b>	<b>37(52.1%)</b>
\$30-40,000	1(0.7%)	0	1(1.4%)
\$40-50,000	1(0.7%)	1(1.4%)	0

n(%)	Total Sample	Placebo Group	Healing Touch Group
\$50-75,000	2(1.4%)	1(1.4%)	1(1.4%)

### Stratification by Income: Comparison of the two treatment groups on Primary Outcome Measure of Functional Health

The income stratification analysis did not reveal further distinctions as compared to the un-stratified results, with one exception. Therefore, the income stratified results will be summarised rather than presented in detail. To begin with, the change from Week 0 to Week 33 for the primary outcome measure of functional health is presented, for both the sub-scales and the total scale (Table 32). There are no statistically significant results in the variation in functional decline experienced by the two treatment groups, within either strata of income. So the income-stratified results show similar results to the un-stratified results for the primary outcome measure of functional health as measured by Basic Activities of Daily Living, Instrumental Activities of Daily Living, and Total ADLs.

**Table 32. Stratification by Income: Comparison of Two Treatment Groups on Change from Week 0 to Week 33 on the Primary Outcome Measure of Functional Health: Total Activities of Daily Living (ADLs), Basic ADLs and Instrumental ADLs.**

	“Poorer” Less than \$20,000 per year income at Week 0 *(n=72)			“Richer” \$20,000 or more per year income at Week 0 (n=73)*		
	Placebo	Healing Touch		Placebo	Healing Touch	
	(n=40)	(n=32)		(n=34)	(n=39)	
	Median **(IQR) Range	Median (IQR) Range	Test statistic p value	Median (IQR) Range	Median (IQR) Range	Test statistic p value
***Change = Week 33 – Week 0 Total ADLs (scale range from 0 to 29)	0.0 (-1.0, +0.75) -9.0 to +2.0	0.0 (-1.0, +1.0) -5.0 to +2.0	Mann Whitney 575.0	0.0 (-2.0, 0.0) -6.0 to +2.0	0.0 (-1.0, 0.0) -4.0 to +3.0	Mann Whitney 643.5
	(n=40)	(n=32)	p = 0.444	(n=34)	(n=39)	p = 0.823
***Change = Week 33 – Week 0 Basic ADLs (scale range from 0-15)	0.0 (-0.75, +1.0) -4.0 to +2.0	0.0 (-0.75, 0.0) -2.0 to +2.0	Mann Whitney 618.5	0.0 (-1.0, 0.0) -3.0 to +2.0	0.0 (-1.0, 0.0) -2.0 to +3.0	Mann Whitney 546.0
	(n=40)	(n=32)	p = 0.794	(n=34)	(n=39)	p = 0.158

	“Poorer” Less than \$20,000 per year income at Week 0 *(n=72)			“Richer” \$20,000 or more per year income at Week 0 (n=73)*		
***Change = Week 33 – Week 0 Instrumental ADLs (scale range from 0-14)	0.0 (-1.0, 0.0) -5.0 to +1.0	0.0 (0.0, 0.0) -3.0 to +2.0	Mann Whitney 538.0	0.0 (-1.0, 0.0) -3.0 to +2.0	0.0 (-1.0, 0.0) -2.0 to +2.0	Mann Whitney 581.0
			p = 0.172			p = 0.318

\*Not all participants answered the question about their income

\*\* IQR = inter-quartile range

\*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

### Stratification by Income: Comparison of the two treatment groups on secondary Outcome Measure of Social Support

This is the only outcome measure where the un-stratified results differed from the income-stratified results. The change from Week 0 to Week 33 on Social Support showed a statistically significant difference between the two treatment groups in the un-stratified results presented above, with the Placebo group declining over time, while the Healing Touch group improved over time. This finding is now seen more clearly to occur only for the lower income stratum, in which it approaches but does not reach statistical significance, with a p value of 0.087. For the higher income stratum, again the Healing Touch group improves while the Placebo group declines, but the variation in their response to the treatment over time is not as marked as it was in the lower income stratum, and it neither reaches nor approaches statistical significance.

**Table 33. Stratification by Income: Comparison of the two treatment groups on Change from Week 0 to Week 33 on secondary Outcome Measure of Social Support**

Median *(IQR) Range	“Poorer” Less than \$20,000 per year income at Week 0 ** (n=71)			“Richer” \$20,000 or more per year income at Week 0 (n=73)*		
	Placebo	Healing Touch	Test Statistic	Placebo	Healing Touch	Test Statistic
	(n=40)	(n=31)	p value	(n=34)	(n=39)	p value
*** Change = Week 33 – Week 0	-2.60 (-10.22, +3.58) -34.9 to +30.7	+1.56 (-3.13, +9.38) -30.5 to +45.3	Mann Whitney 472.5	-1.56 (-12.82, +7.42) -25.3 to + 23.2	+1.56 (-5.47, +9.11) -29.7 to +34.1	Mann Whitney 585.0
			p = 0.087			p = 0.388

\*IQR = inter-quartile range

\*\*Not all participants answered all questions

\* \*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

### Stratification by Income: Comparison of the two treatment groups on secondary Outcome Measures of Quality of Life, Spiritual Well Being and Psychological Well Being

The stratified results for the rest of the secondary outcome measures are summarised next. Within both income strata, the two treatment groups were again similar in their amount of decline or improvement over time for overall Quality of Life, Spiritual Well-Being and Psychological Well-Being. For these three secondary outcome measures, the stratified results were similar to the un-stratified results, and they are presented together in the table below. Of note, the decline in Psychological Well Being was more pronounced in the Poorer stratum than it was in the Richer stratum, regardless of treatment group allocation, with values of decline of 5 points in both treatment groups in the Poorer stratum, as compared to values of decline of only 1-2 points in the Richer stratum.

**Table 34. Stratification by Income: Comparison of the two treatment groups on Change from Week 0 to Week 33 on secondary outcome measures of overall Quality of life, Spiritual Well-Being and Psychological Well Being.**

	“Poorer” Less than \$20,000 per year income at Week 0 *(n=72)			“Richer” \$20,000 or more per year income at Week 0 (n=73)*		
	Placebo	Healing Touch		Placebo	Healing Touch	
	Median **(IQR) Range	Median (IQR) Range	Test statistic p value	Median (IQR) Range	Median (IQR) Range	Test statistic p value
Duke Quality of Life	(n=40)	(n=32)		(n=34)	(n=39)	
***Change = Week 33 – Week 0	+1.00 (-1.75, +3.75) -6.0 to +10.0	0.00 (-2.0, +2.75) -6.0 to +5.0	Mann Whitney 553.5 p = 0.324	+0.5 (-3.0, +3.0) -12.0 to +11.0	0.00 (-1.0, +2.0) -7.0 to +7.0	Mann Whitney 637.0 p = 0.773
Spiritual Well-being	(n=36)	(n=31)		(n=33)	(n=37)	
*** Change = Week 33 – Week0	-1.50 (-9.0, +1.0) -29.0 to +8.0	-2.00 (-13.0, +4.0) -36.0 to + 36.0	Mann Whitney 520.5 p = 0.637	-1.00 (-5.0, +4.5) -29.0 to +27.0	-1.00 (-12.0, +3.5) -32.0 to +15.0	Mann Whitney 562.0 p = 0.568
Psycho- logical Well Being	(n=40)	(n=32)		(n=34)	(n=39)	

	“Poorer” Less than \$20,000 per year income at Week 0 *(n=72)			“Richer” \$20,000 or more per year income at Week 0 (n=73)*		
***Change = Week 33 -Week 0	-5.00 (-15.75, +0.75) -33.0 to +14.0	-5.00 (-14.00, +1.00) -31.0 to +10.0	Mann Whitney 611.5 p = 0.746	-1.00 (-8.50, +2.25) -34.0 to +12..0	-2.00 (-8.0, +2.0) -22.0 to +17.0	Mann Whitney 603.5 p = 0.631

\*Not all participants answered the questions concerning their income

\*\*IQR = inter-quartile range

\*\*\* A negative number for the change in score indicates a decline in health status, whereas a positive number for the change in score indicates an improvement in health status.

## Ancillary analyses

### Introduction

This section will present a number of secondary analyses, the first of which will be within group comparisons for the MMSE, the CCI, and the primary and secondary outcome measures. In the next section, indirect outcome measurements, such as the amount of time since last hospitalisation, and changes in living arrangements from independent to dependent living units will be presented, followed by vital signs and self-ratings of four dimensions of health. Lastly, the participant’s responses to additional questions about their satisfaction with the treatments they received will be reviewed.

### Within Group comparisons over time

#### *Mini Mental Status Exam*

The medians were compared for the average scores on the MMSE at the three different data collection time points of Week 0, Week 8 and Week 33 using the Friedman test, which compares three or more paired medians to determine if they are different.

This testing was done to ascertain if any statistically significant changes occurred in the participants’ cognitive status over the course of the study. These comparisons were made for the sample as a whole, and then repeated for each of the treatment groups. In all comparisons, the changes were not statistically significant, indicating that the scores at Week 0, Week 8 and Week 33, on average, were similar and any observed changes were likely to have happened by chance. Of interest, the Healing Touch group showed a slight trend of improvement in their median MMSE score during the time of treatment (from 29.0 at Week 0 to 30.0 at Week 8), but the changes between scores at each of the three time points did not reach statistical significance (p = 0.084).

**Table 35. Within group comparisons over time for MMSE**

Median *(IQR) Range	Total Sample	Placebo	Healing Touch
	Median (IQR) Range	Median (IQR) Range	Median (IQR) Range
	n=153	n=75	n=78
Week 0	29.0 (29.0,30.0) 27 to 30	29.0 (29.0,30.0) 27 to 30	29.0 (29.0,30.0) 28 to 30
	n=153	n=75	n=78
**Week 8	29.0 (29.0,30.0) 24 to 30	29.0 (28.0,30.0) 25 to 30	30.0 (29.0,30.0) 24 to 30
	n=153	n=75	n=78
Week 33	29.0 (29.0,30.0) 23 to 30	29.0 (28.0,30.0) 23 to 30	29.0 (29.0,30.0) 25 to 30
Test Statistic	Chi-square 4.454	Chi-square 2.272	Chi-square 4.965
p value	0.108	0.321	0.084

\*IQR= inter-quartile range

\*\*Intervention series occurred during Weeks 1 through 7.

### ***Charlson Co-Morbidity Index (CCI)***

The CCI score represents the number and severity of chronic diseases present for the participant at each data collection time point. Friedman testing was again used to compare the within group changes over time on these 3 scores at Week 0 , Week 8 and Week 33, for the sample as a whole, and for both treatment groups separately. The absence of any statistically significant p values indicated a stable level of co-morbidity over time in this total sample, and in both treatment groups.

**Table 36. Within group comparisons over time for Charlson Co-morbidity Index**

Median (IQR) Range	Total sample	Placebo	Healing Touch
	(n=124)	(n=62)	(n=62)
Week 0	4.00 (3.0, 5.0) 3.0 to 11.0	4.00 (3.0, 5.0) 3.0 to 11.0	4.00 (3.0, 5.0) 3.0 to 10.0
	(n=124)	(n=62)	(n=62)
*Week 8	4.00 (3.0, 5.0) 3.0 to 12.0	4.00 (3.0, 5.0) 3.0 to 12.0	4.00 (3.0, 5.0) 3.0 to 10.0
	(n=124)	(n=62)	(n=62)

Median (IQR) Range	Total sample	Placebo	Healing Touch
Week 33	4.00 (3.0, 5.0) 3.0 to 11.0	4.00 (3.0, 5.0) 3.0 to 11.0	4.00 (3.0, 5.0) 3.0 to 10.0
Test Statistic	Chi square 4.374	Chi square 3.440	Chi square 2.265
p value	p=0.112	p=0.179	p=0.322

\*IQR = inter-quartile range

\*\*Intervention series occurred during Weeks 1 through 7.

## Outcome Measures

### Functional Health

#### Total ADL

Friedman testing indicated a statistically significant change between the three scores at Week 0, Week 8 and Week 33 for Total Activities of Daily Living (ADLs) for the sample as a whole. Post hoc comparisons using Wilcoxon testing of the possible pairs of scores revealed that the statistically significant changes were not between the Week 0 and Week 8 scores, but only between the Week 0 score as compared to the Week 33 score ( $p= 0.001$ ), and the Week 8 score as compared to the Week 33 score ( $p= 0.001$ ). This pattern of statistical significance indicates functional decline only occurred in the long term, not the short term.

The Friedman testing was repeated on the Placebo group and the Healing Touch group separately, with similar results as those found for the sample as a whole, although the changes between the three scores for Week 0, Week 8 and Week 33 did not quite reach statistical significance for the Placebo group ( $p = 0.053$ ). As for the sample as a whole, for each treatment group, the post hoc comparisons by Wilcoxon testing of pairs revealed that the statistically significant changes were again not between the Week 0 and Week 8 scores, but only between the Week 0 score as compared to the Week 33 score (Placebo  $p = 0.007$ ; Healing Touch  $p = 0.041$ ), and the Week 8 score as compared to the Week 33 score (Placebo  $p = 0.020$ ; Healing Touch  $p = 0.010$ ). This pattern of statistical significance again indicated that functional decline only occurred in the long term, not the short term, for the two treatment groups as well as for the sample as a whole. Of note, the median values were nearly identical, both between treatment groups and across time points, with the maximum change in median value of 1 unit on this scale ranging from 0-29 for Total ADL. Examination of the inter-quartile ranges and minimum to maximum ranges is necessary to distinguish patterns of change. Overall the picture is of a high functioning sample who maintained their high scores over the duration of the study, representing a ceiling effect for this instrument with this sample.

**Table 37. Friedman testing for changes in Total ADL scores at Week 0, Week 8 and Week 33**

	Total Sample	Placebo	Healing Touch
	Median	Median	Median
	*(IQR)	(IQR)	(IQR)
	Range	Range	Range
	(n=153)	(n=75)	(n=78)

	Total Sample	Placebo	Healing Touch
Week 0	28.00 (27.0-29.0) 20 to 29	28.00 (26.0-29.0) 20 to 29	28.00 (27.0-29.0) 21 to 29
	(n=153)	(n=75)	(n=78)
**Week 8	28.00 (26.0-29.0) 18 to 29	28.00 (25.0-29.0) 20 to 29	28.00 (27.0-29.0) 18 to 29
	(n=153)	(n=75)	(n=78)
Week 33	27.00 (26.0-29.0) 19 to 29	27.00 (25.0-29.0) 19 to 29	28.00 (26.0-29.0) 21 to 29
Test Statistic	Chi-square 12.926	Chi-square 5.872	Chi-square 7.321
p value	0.002	0.053	0.026

\*IQR = inter-quartile range

\*\*Intervention series occurred during Weeks 1 through 7.

### **Basic ADLs**

For the sub-scale of Basic ADLs only, a similar pattern of a statistically significant change was demonstrated for the sample as a whole and again only occurred in the long term, not the short term. The change between Week 0 and Week 8 scores did not reach statistical significance when the post hoc comparisons of pairs were done by Wilcoxon testing. However, the Week 8 to Week 33 comparison demonstrated a statistically significant decline ( $p= 0.003$ ), as did the Week 0 to Week 33 comparison ( $p= 0.022$ ).

When the Friedman testing for a change between scores at Week 0, Week 8 and Week 33 was repeated on each of the treatment groups, there were no statistically significant changes noted. Therefore, post hoc comparisons of pairs using Wilcoxon testing did not need to be performed to ascertain where these minimal changes occurred.

Of note, the median values were nearly identical, both between treatment groups and across time points, with the maximum change in median value of 1 unit on this scale ranging from 0-15 for Basic ADLs. Examination of the inter-quartile ranges and minimum to maximum ranges is necessary to distinguish patterns of change. As for Total ADLs above, here again for Basic ADLs, the overall the picture is of a predominantly high functioning sample who maintained their high scores over the duration of the study, representing a ceiling effect for this instrument with this sample.

**Table 38. Friedman testing for changes in Basic ADL scores at Week 0 , Week 8 and Week 33**

	Total Sample	Placebo	Healing Touch
0-15	Median *(IQR) Range	Median (IQR) Range	Median (IQR) Range
	(n=153)	(n=75)	(n=78)

	Total Sample	Placebo	Healing Touch
Week 0	14.00 (14.0-15.0) 10 to 15	14.00 (14.0-15.0) 10 to 15	15.00 (13.0-15.0) 10 to 15
	(n=153)	(n=75)	(n=78)
**Week 8	15.00 (13.5-15.0) 10 to 15	14.00 (13.0-15.0) 10 to 15	15.00 (14.0-15.0) 11 to 15
	(n=153)	(n=75)	(n=78)
Week 33	14.00 (13.0-15.0) 9 to 15	14.00 (13.0-15.0) 9 to 15	14.50 (13.0-15.0) 11 to 15
Test Statistic	Chi-square 6.629	Chi-square 2.539	Chi-square 5.119
p value	0.036	0.281	0.077

\*IQR = inter-quartile range

\*\*Intervention series occurred during Weeks 1 through 7.

### ***Instrumental ADLs***

For the sub-scale of Instrumental ADLs only, a similar pattern to the Total ADL results was found: a statistically significant decline for the sample as a whole, which again only occurred in the long term, not the short term. The decline is again seen most clearly in the Instrumental ADL sub-scale scores by examining the inter-quartile range.

For the sample as a whole, the post hoc comparisons using Wilcoxon testing of pairs revealed that the statistically significant changes were again not found between the Week 0 and Week 8 scores, but only between the Week 0 score as compared to the Week 33 score ( $p= 0.001$ ), and the Week 8 score as compared to the Week 33 score ( $p= 0.005$ ). This pattern of statistical significance indicates Instrumental ADL functional decline only occurred in the long term, not the short term, as seen in the other sub-scale for Basic ADLs, and as seen in the Total ADL scale.

Of note once again, the median values were nearly identical, both between treatment groups and across time points, with the maximum change in median value of 1 unit on this scale ranging from 0-14 for Instrumental ADLs. Examination of the inter-quartile ranges and minimum to maximum ranges is again necessary to distinguish patterns of change. As for Total ADLs and Basic ADLs above, here again for Instrumental ADLs, the overall picture is of a high functioning sample who maintained their high scores over the duration of the study, representing a ceiling effect for this instrument with this sample. Again the decline was minimal for the Instrumental ADL sub-scale, as it was for the Basic ADL sub-scale and the Total ADL scale.

**Table 39. Friedman testing for changes in Instrumental ADL scores at Week 0 , Week 8 and Week 33**

IADL 0-14	Total Sample	Placebo	Healing Touch
	Median *(IQR) Range	Median (IQR) Range	Median (IQR) Range
	(n=153)	(n=75)	(n=78)
Week 0	13.00 (13.0-14.0) 8 to 14	13.00 (12.0-14.0) 8 to 14	14.00 (13.0-14.0) 9 to 14
	(n=153)	(n=75)	(n=78)
**Week 8	13.00 (13.0-14.0) 5 to 14	13.00 (12.0-14.0) 9 to 14	13.00 (13.0-14.0) 5 to 14
	(n=153)	(n=75)	(n=78)
Week 33	13.00 (12.0-14.0) 8 to 14	13.00 (12.0-14.0) 8 to 14	13.00 (13.0-14.0) 10 to 14
Test Statistic	Chi-square 13.782	Chi-square 5.225	Chi-square 9.385
p value	0.001	0.073	0.009

\*IQR = inter-quartile range

\*\*Intervention series occurred during Weeks 1 through 7.

When the Friedman testing for a change between scores at Week 0, Week 8 and Week 33 was repeated on each of the treatment groups, there were no statistically significant changes noted for the Placebo group. Therefore, post hoc comparisons of pairs using Wilcoxon testing were not performed for the Placebo group. However, the Healing Touch treatment group did show a statistically significant change between the three scores across time, so post hoc comparison of pairs by Wilcoxon testing was performed for both treatment groups, to allow further comparison between treatment groups.

As for the sample as a whole, for each treatment group, the post hoc comparisons by Wilcoxon testing of pairs revealed that the statistically significant changes were again not found between the Week 0 and Week 8 scores, but only found between the Week 0 score as compared to the Week 33 score (Placebo  $p = 0.017$ ; Healing Touch  $p = 0.012$ ), and the Week 8 score as compared to the Week 33 score (Placebo  $p = 0.044$ ; Healing Touch  $p = 0.048$ ).

In summary, for the primary outcome measure of functional health , a statistically significant decline occurred for the sample as a whole, on the Total ADL scale and on both the Basic ADL and the Instrumental ADL sub-scales.

### Secondary Outcome Measures

Within group comparisons were also conducted on the total sample for the four secondary outcome measures, and those results are presented in Table 40 below. Spiritual Well-Being and Psychological Well Being both showed a statistically significant change among the three

means for Week 0, Week 8 and Week 33 for the sample as a whole, with a net result of a decline in status over the full course of the study. Thus the results for spiritual and psychological health were similar to those seen above for functional health.

The within group comparison of the means for the Week 0, Week 8 and Week 33 results for the scores on Social Support did not reach statistical significance, despite a trend that was also a net decline over the full course of the study for this health dimension. This is probably related to the improvement in Social support noted by the stratum of participants living in ordinary neighbourhoods, who comprised nearly two thirds of the sample. Lastly, the Duke Health Profile, measuring overall Quality of Life, showed a statistically significant change among the three means for Week 0, Week 8 and Week 33 for the sample as a whole, but in this health dimension, the net result was an improvement in status.

**Table 40. Within Group Comparisons over time on total sample for Secondary Outcome Measures**

	<b>Spiritual Well Being</b>	<b>Psychological Well Being</b>	<b>Social Support</b>	<b>Duke Profile Quality of Life</b>
<b>*N</b>	142	152	149	153
<b>Test Performed</b>	Repeated Measures ANOVA	Friedman	Friedman	Friedman
<b>Scores reported</b>	Mean(SD)**	Median (IQR)***	Median (IQR)	Median (IQR)
<b>Scale range</b>	0-120	18-108	0-100	0-34
<b>Week 0</b>	81.76 (17.24) 27 to 120	78.0 (70.0,87.0) 57 to 108	78.39 (60.16,93.75) 7.6 to 100	24.0 (21.0,27.0) 12 to 33
<b>****Week 8</b>	82.39 (17.02) 44 to 120	75.0 (70.0,84.0) 59 to 104	78.65 (61.71, 94.53) 7.0 to 100	26.0 (22.0,28.0) 12 to 33
<b>Week 33</b>	78.53 (12.80) 47 to 110	72.0 (68.0,78.0) 62 to 99	76.56 (61.3,92.19) 13.5 to 100	25.0 (21.0,28.0) 13 to 33
<b>Trend</b>	Net Decline	Net Decline	Net Decline	Net Improvement
<b>Test statistic</b>	Wilk's Lambda 0.875	Chi-square 14.260	Chi-square 0.558	Chi-square 17.114
<b>p value</b>	< 0.001	= 0.001	= 0.756	< 0.001

\*Not all participants answered all questions

\*\*SD = standard deviation

\*\*\*IQR = inter-quartile range

\*\*\*\*Intervention series occurred during Weeks 1 through 7.

Post hoc comparisons of pairs were conducted using the Wilcoxon test for those secondary outcome measures that reached statistical significance in the within group comparisons done by Friedman or repeated measures ANOVA testing.

Similar to the findings for Functional Health in the previous section, the pairs showing statistically significant changes during post hoc comparisons using Wilcoxon testing for the

secondary outcome measures of Spiritual Well Being (SWB) and Psychological Well Being (PWB) again occurred in the Week 0 to Week 33 comparisons ( $p = 0.003$  for SWB;  $p < 0.001$  for PWB); and in the Week 8 to Week 33 comparisons ( $p < 0.001$  for SWB;  $p < 0.001$  for PWB). No statistically significant change was demonstrated in the Week 0 to Week 8 comparison for the SWB ( $p = 1.00$ ), but one was found for Psychological WB ( $p=0.026$ ). This pattern indicated that for the sample as a whole, spiritual health declined in the long term, rather than in the short term, similar to the findings above for functional health; whereas psychological health declined by a statistically significant increment even during the series of 7 weekly treatments, from Week 0 to Week 8 and then declined yet again another statistically significant increment between Week 8 to Week 33.

The final secondary outcome measure, the Duke Health Profile measure of Quality of Life showed yet again a different pattern than any of the other outcome measures. There was a statistically significant net improvement as per the Friedman testing shown in the table above. Post hoc comparisons of pairs using Wilcoxon testing were done next, and these further demonstrated that two pairs showed statistically significant changes: Week 0 to Week 8 ( $p < 0.001$ ) and Week 8 to Week 33 ( $p = 0.019$ ), while the Week 0 to Week 33 comparison approached, but did not quite reach statistical significance ( $p= 0.058$ ). This pattern indicated that Quality of Life improved by a statistically significant increment even during the series of 7 weekly treatments, from Week 0 to Week 8; but then declined by a statistically significant increment between Week 8 to Week 33, resulting in a small net improvement from Week 0 to Week 33 that did not reach statistical significance.

### ***Summary of Within Group Comparisons of Outcome Measures***

Most of the outcome measures did show a statistically significant change between the scores for Week 0, Week 8 and Week 33 using non-parametric Friedman or parametric repeated measurements ANOVA testing. These findings indicated that the instruments used to measure these health dimensions were sensitive enough to detect changes occurring during the time span of the study, and that the participants were observed for a sufficient length of time for naturally occurring age-related decline to become apparent using these instruments.

## **Comparison of treatment groups on hospitalisation history**

The reported data regarding the amount of time that had elapsed since the participant last visited the hospital was very similar for both treatment groups at Week 0, but their response to this question at Week 33 showed more divergence. However, the difference between the two treatment groups did not reach the statistical significance threshold, even at Week 33.

**Table 41. Time in days since last hospitalization as reported at Week 33**

<b>Median *(IQR) Range</b>	<b>Placebo (n=75)</b>	<b>Healing Touch (n=78)</b>	<b>Mann Whitney</b>	<b>p value</b>
Time since last hospitalisation [days]	330 (150.0,1825.0) 11 to 18,250	730 (210.0,2190.0) 7 to 14,600	2645.0	0.306

\*IQR = inter-quartile range

The data on elapsed time since hospitalization was converted to a categorical variable to reflect whether or not each participant had a hospital visit during the time span of the study (between the Week 0 data collection and the Week 33 data collection). The results are displayed in Table 42 below, and again the difference between the two treatment groups did not reach statistical significance, despite a trend towards less hospitalisations in the Healing Touch group.

**Table 42. Incidence of hospitalization during the time span of the study: comparison of the two treatment groups**

n(%)	Placebo (n=75)	Healing Touch (n=78)	Test Statistic	p value
Hospital visit during study	29 (38.7%)	21 (26.9%)		
No hospital visit during study	46 (61.3%)	57 (73.1%)	Fisher's Exact test	0.168

In addition to asking participants about the elapsed time since their last hospital visit, data were also collected regarding the type of setting or service used during the last hospital visit. As above for time since last hospitalization, the two treatment groups were also very similar at the Week 0 data collection point for their pattern of the type of setting or service utilized. That Table has been re-presented for the reader's convenience.

**Table 43. Setting of last hospitalisation at Baseline (Week 0)**

n(%)	Placebo (n=73)*	Healing Touch (n=72)*
Day surgery only	3(4.1%)	3(4.2%)
A&E only, not admitted	10 (13.7%)	9(12.5%)
Overnight stay	60(82.2%)	60(83.3%)

\*Not all participants answered this question

There was greater divergence reported in their pattern of hospital settings used at the Week 33 data collection, with the Healing Touch group showing a slightly larger percentage of overnight admissions, but the difference between the two treatment groups was again not of a sufficient magnitude to reach statistical significance.

**Table 44. Setting of last hospitalisation at Week 33**

n(%)	Placebo (n=72)*	Healing Touch (n=73)*	Test Statistic	p value
Day surgery only	6(8.3%)	8(11.0%)		
A&E only, not admitted	17(23.6%)	8(11.0%)	Pearson Chi-Square 4.123	0.132
Overnight stay	49(68.1%)	57(78.1%)		

\*Not all participants answered this question

## Comparison of treatment groups on living arrangements at Week 33

There was already a difference noted between the two treatment groups at Week 0, as described earlier, regarding the relative distribution among varying levels of independence in living arrangements. At Week 0, there were more participants in the Healing Touch group who were already residing in the more structured accommodation setting of a retirement village, where yard work and building maintenance services were provided by the retirement village. The results as reported at the Week 33 data collection point are described in Table 45 below, where the above trend is still visible. In addition, some of the other more dependent options for living arrangements were newly reported at Week 33, representing some incidences of participants changing from their Week 0 living arrangement in to a more dependent living arrangement i.e. having moved in with a family member or in to a Residential Aged Care Facility (RACF).

**Table 45. Comparison between treatment groups: living arrangements at Week 33**

	Total Sample (n=153)	Placebo (n=75)	Healing Touch (n=78)
	n(%)	n(%)	n(%)
Home/unit in normal residential neighbourhood	95(62.1%)	50(66.7%)	45(57.7%)
Retirement village	52(34.0%)	21(28.0%)	31(39.7%)
Granny flat on family's lot	2(1.3%)	1(1.3%)	1(1.3%)
In home of family member	2(1.3%)	2(2.7%)	0
Low care wing RACF	1(0.6%)	1(1.3%)	0
Assisted-living facility	1(0.6%)	0	1(1.3%)

In order to consider the independence level of the living arrangement as an indirect outcome measurement, the number of participants who had an alteration in their living arrangements during the course of the study was examined and is described below. Although the trend slightly favours the Healing Touch group, the difference between the two treatment groups did not reach statistical significance, and the sample as a whole showed a very stable pattern of living arrangements over the course of the study.

**Table 46. Comparison between treatment groups: Change in living arrangements during time span of study**

N(%)	Placebo (n=75)	Healing Touch (n=78)	Test statistic	p value
Declined to a less independent living arrangement	5(6.6%)	3(3.8%)		

N(%)	Placebo (n=75)	Healing Touch (n=78)	Test statistic	p value
Stable or improved level of independence of living arrangement	70(93%)	75(96%)		
			Fisher's Exact Test	0.489

### Comparison of treatment groups on uptake of other Complementary and Alternative Therapies (CATs) during period of research study

Participants were not requested or required to forego any other types of complementary or alternative therapies during the 8 months of their time in the study, for ethical concerns in an ageing population. However, data were collected to observe for any variation in the uptake between treatment groups, as a possible confounding variable. The data is presented in Tables 47 and 48 below, and does indicate a higher uptake amongst the participants who were allocated to the Placebo treatment group, but not at a statistically significant level.

**Table 47. Comparison between treatment groups for tactile CAT usage**

	Placebo	Healing Touch	Test performed	p value
	(n=75)	(n=78)		
Week 0	9 (12%)	15 (19.2%)	Fisher's Exact Test	p=0.269
	(n=75)	(n=78)		
Week 8	8 (10.7%)	10 (12.8%)	Fisher's Exact Test	p=0.803
	(n=74)*	(n=78)		
Week 33	15 (20.3%)	12 (15.4%)	Fisher's Exact Test	p=0.525
Week 33 minus WEEK 0	+7 (7 new pts** took up a tactile CAT)	-3 (3 pts stopped using a CAT)		

\*not all participants answered all questions

\*\*pts = participants

**Table 48. Comparison between treatment groups for energy-based CAT usage**

N(%)	Placebo	Healing Touch	Test performed	p value
	(n=74)*	(n=78)		
Week 0	2 (2.7%)	1 (1.3%)	Fisher's Exact Test	p=0.613
	(n=75)	(n=78)		
Week 8	2 (2.7%)	3 (3.8%)	Fisher's Exact Test	p=1.000
	(n=75)	(n=78)		
Week 33	2(2.7%)	0 (0%)	Fisher's Exact Test	p=0.239

N(%)	Placebo	Healing Touch	Test performed	p value
Week 33 minus Week 0	0	-1 (1 pt** stopped using an energy CAT)		

\*not all participants answered all questions

\*\*pt = participant

## Comparison of treatment groups on data collected at each treatment session

### *Vital Signs*

The two treatment groups were essentially similar in their amount of changes from immediately before a treatment to immediately after a treatment in their five vital signs of temperature, pulse rate, respiratory rate, systolic blood pressure and diastolic blood pressure, which were obtained by the Principal Investigator during the home visit treatment sessions. Change variables were firstly computed for each of the five vital signs at each session. Statistical significance testing was then performed to compare the Placebo group to the Healing Touch group. These test results are presented in Appendix CC. Only five of the 35 tests produced statistically significant results for the differences between the two treatment groups, but these were not clustered around any particular treatment session number or any particular vital sign reading. The five statistically significant results occurred for the Session Three pulse rate, respiratory rate, and systolic blood pressure; and for Sessions Four and Seven, for the diastolic blood pressure.

Once any effects specific to a particular treatment session had been examined as described above, then vital sign readings from all seven sessions for each participant were averaged to create an average Pre-treatment and Post-treatment session reading for each participant on each vital sign. Change variables were then calculated for each participant by taking the average post-treatment session reading minus the average pre-session treatment reading. The average change in vital signs readings from pre- to post-treatment sessions were then compared between the two treatment groups, and these results are presented in Tables 49 through 53 below. Although the results for pulse and respiratory rate did not quite reach statistical significance, they approached it with p values of 0.084 and 0.055 respectively, and in each case the greater decrease in pulse and respiratory rates occurred in the Healing Touch group.

**Table 49. Comparison of the two treatment groups on changes in average temperature from Pre-treatment session to Post-treatment session**

Average temperature	Placebo	Healing Touch	Test Statistic	p value
	Mean(SD)*	Mean(SD)		
	(n=73)**	(n=77)		
Average Pre-Session Temperature (°C)	36.24 (0.34)	36.20 (0.44)		

Average temperature	Placebo	Healing Touch	Test Statistic	p value
	(n=72)	(n=77)		
Average Post-session Temperature (°C)	36.14 (0.29)	36.11 (0.42)		
	(n=72)	(n=77)		
	Median (IQR)***	Median (IQR)		
Change = Post-Session Temperature – Pre-Session Temperature (°C)	-0.16 (-0.25, +0.05)	-0.11 (-0.24, +0.05)	Mann Whitney 2576.5	0.457

\*SD = standard deviation

\*\*Not all participants had all measurements taken

\*\*\*IQR = inter-quartile range

**Table 50. Comparison of the two treatment groups on changes in pulse rate from Pre-treatment session to Post-treatment session**

Average Pulse	Placebo	Healing Touch	Test Statistic	p value
	Mean (SD)*	Mean (SD)		
	n=72**	n=76		
Average Pre-Session Pulse (beats per minute)	70.6 (8.8)	71.3 (10.9)		
	n=71	n=75		
Average Post-session Pulse (beats per minute)	67.7 (8.1)	66.9 (10.0)		
	n=70	n=74		
	Median (IQR)***	Median (IQR)		
Change = Post-Session Pulse – Pre-Session Pulse	-2.9 (-5.8, -1.1)	-3.9 (-6.6, -1.7)	Mann Whitney U 2158.0	0.084

\*SD = standard deviation

\*\*Not all participants had all measurements taken

\*\*\*IQR = inter-quartile range

**Table 51. Comparison of the two treatment groups on changes in respirations per minute from Pre-treatment session to Post-treatment session**

Respirations	Placebo	Healing Touch	Test Statistic	p value
	Mean (SD)*	Mean(SD)		
	n=72**	n=75		
Average Pre-Session Respirations per minute	16.8 (4.0)	16.9 (3.6)		
	n=71	n=75		
Average Post-session Respirations per minute	15.8 (3.8)	15.7 (3.5)		
	n=70	n=73		
	Median (IQR)***	Median (IQR)		
Change = Post-Session Respirations – Pre-Session Respirations	-0.85 (-1.7, -0.3)	-1.4 (-2.3, -0.6)	Mann-Whitney U 2082.0	0.055

\*SD = standard deviation

\*\*Not all participants had all measurements taken

\*\*\*IQR = inter-quartile range

**Table 52. Comparison of the two treatment groups on changes in systolic blood pressure from Pre-treatment session to Post-treatment session**

Systolic Blood Pressure	Placebo	Healing Touch	Test Statistic	p value
	Median (IQR)*	Median (IQR)		
	n=73*	n=77		
Average Pre-Session Systolic Blood Pressure (mm Hg)	135.1 (120,146)	129.7 (119, 137)		
	n=72	n=77		
Average Post-session Systolic Blood Pressure (mm Hg)	133.7 (120,149)	128.6 (119,138)		
	n=72	n=77		

Systolic Blood Pressure	Placebo	Healing Touch	Test Statistic	p value
Change = Post-Session Systolic Blood Pressure – Pre-Session Systolic Blood Pressure (mm Hg)	-0.86 (-4.8, +3.3)	+0.57 (-4.3, +5.1)	Mann Whitney U 2552.0	0.403

\*Not all participants had all measurements taken

\*\*IQR = inter-quartile range

**Table 53. Comparison of the two treatment groups on changes in diastolic blood pressure from Pre-treatment session to Post-treatment session**

Diastolic Blood Pressure	Placebo	Healing Touch	Test Statistic	p value
	Median (IQR)**	Median (IQR)		
	n=73*	n=77		
Average Pre-Session Diastolic Blood Pressure (mm Hg)	70.6 (64,74)	67.1 (63, 67)		
	n=72	n=77		
Average Post-session Diastolic Blood Pressure (mm Hg)	68.9 (64,75)	69.1 (63,74)		
	n=72	n=77		
Change = Post-Session Diastolic Blood Pressure – Pre-Session Diastolic Blood Pressure (mm Hg)	-0.29 (-2.6, +2.5)	+0.29 (-2.0, +2.7)	Mann Whitney U 2521.0	0.340

\*Not all participants had all measurements taken

\*\*IQR = inter-quartile range

### ***Participants' rating of perceived health status***

These were again compared on a session by session basis, and for each of the dimensions of health that participants were asked to rate immediately before and after their treatment session, on a 1-10 scale: physical, emotional, intellectual and spiritual health status. Statistical significance testing was then performed to compare the Placebo group to the Healing Touch group. These test results are presented in Appendix DD. Only three of the 28 tests produced a statistically significant result: Session One for spiritual health; Session Five for cognitive health; and Session Seven for emotional health. These findings were not clustered around any particular session number or any particular health dimension. Given the lack of a clear

pattern, the two treatment groups were considered to be essentially similar in this outcome measurement as well.

## Comparison of treatment groups on the participants' evaluation of the treatment

### *Belief regarding group allocation status*

At the time of the Week 8 data collection only, the RA asked additional questions that were not included at the Week 0 or Week 33 visits. The first seven questions were asked and noted by the RA in writing, and are presented in the next section. The last five questions were conducted as an audio-taped semi-structured interview, with the RA asking clarifying or following up questions based on the participants' responses regarding their noted effects and perceived experiences during and after their treatment sessions (questions one through three) and their opinion regarding their group allocation (question four) and their interest in any future research where they would be guaranteed to receive the actual Healing Touch treatment (question five).

The rich qualitative data from the first three semi-structured audio-taped questions will be examined at a later point using thematic content analysis, but the responses from the final two questions fell clearly into distinct categories and are presented in Table 54 below. In the Healing Touch group, 75.6% of them believed (*correctly*) that they had been randomised into the Healing Touch group. By comparison, a slightly smaller proportion (70.7%) of the participants in the Placebo group believed (*incorrectly*) that they had been randomised to receive the Healing Touch intervention. Agreement between actual treatment group and the believed treatment group (collapsed to "believed being in healing touch" versus all other) was assessed as close to non-existent by the kappa statistic as 0.041 ( $p=0.620$ ). Likewise, the responses of both groups were similar regarding their interest in participation in a future study where participants would be guaranteed to receive the Healing Touch treatment, if such a study were conducted.

**Table 54. Comparison of two treatment groups: Belief regarding group allocation status and interest in future treatment**

Brief version of question:	Total sample	Placebo	Healing Touch	Test statistic	p value
<b>Do you think you were in the actual Healing Touch treatment group or the placebo (mimic Healing Touch) group?</b>	(n=153)	(n=75)	(n=78)		
	n(%)	n(%)	n(%)		
Unsure	20(13.1%)	10(13.3%)	10(12.8%)		
Mixed: Thought some of 7 sessions were Healing Touch and some were Placebo	6(3.9%)	2(2.7%)	4(5.1%)		
Believed got Healing Touch	112(73.2%)	53(70.7%)	59(75.6%)		
Believed got placebo	14(9.2%)	9(12.0%)	5(6.4%)		

Brief version of question:	Total sample	Placebo	Healing Touch	Test statistic	p value
Answer not recorded	1(0.7%)	1(1.3%)	0		
Comparison of agreement of two treatment groups				Kappa = 0.041	p=0.620
<b>If it turns out you did get the placebo, would you want to be in a future study where you were guaranteed to get actual HT?</b>	(n=153)	(n=75)	(n=78)		
	n(%)	n(%)	n(%)		
No, would NOT want future participation	16(10.5%)	8(10.7%)	8(10.3%)		
Yes, would want future participation	125(81.7%)	61(81.3%)	64(82.1%)		
Unsure	11(7.2%)	5(6.7%)	6(7.7%)		
Answer not recorded	1(0.7%)	1(1.3%)	0(0%)		
Comparison of two treatment groups				Fisher's Exact Test	p=0.975

### ***Satisfaction with treatment***

Here again the responses of those in the Healing Touch treatment group were essentially similar to those in the Mimic Healing Touch (Placebo) treatment group. In both groups, around 70% of the participants felt the length of each session in minutes was appropriate, and around 50% were satisfied with the number of treatment sessions. For both groups, approximately 97% would recommend the treatment to friends/family. For both groups, about 85% would want a treatment again if it was available at no cost to them, and only about 56% would want another treatment if they had to pay for it out of pocket.

**Table 55. Comparison of two treatment groups: Satisfaction with treatment**

n(%)	Total sample	Placebo	Healing Touch	Test Statistic	p value
<b>Question and possible responses:</b>	n(%)	n(%)	n(%)		
<b>Duration of Treatment Session in minutes:</b>	(n=153)	(n=75)	(n=78)		
Wish they were longer	40(26.1%)	20(26.7%)	20(25.6%)	Fisher's Exact test	
Wish they were shorter	5(3.3%)	3(4.0%)	2(2.6%)	0.368	0.862
Same duration	108(70.6%)	52(69.3%)	56(71.8%)		
Comparison of two treatment groups					
<b>Number of Treatment sessions (7):</b>	(n=153)	(n=75)	(n=78)		

n(%)	Total sample	Placebo	Healing Touch	Test Statistic	p value
Wish there were more	67(43.8%)	36(48.0%)	31(39.7%)	Fisher's Exact test	
Wish there were less	4(2.6%)	2(2.7%)	2(2.6%)	1.217	0.555
The same number	82(53.6%)	37(49.3%)	45(57.7%)		
<b>Recommend HT to friend/family?</b>	(n=153)	(n=75)	(n=78)		
No thanks	5(3.3%)	2(2.7%)	3(3.8%)	Fisher's exact test	
Probably yes	58(37.9%)	31(41.3%)	27(34.6%)	0.886	0.653
Definitely yes	90(58.8%)	42(56.0%)	48(61.5%)		
<b>Supportive of a change in Medicare reimbursement so can receive Healing Touch at free or reduced cost?</b>	(n=152)	(n=75)	(n=77)		
Unsure	1(7.0%)		1(1.3%)		
No thanks	15(9.9%)	5(6.7%)	10(13.0%)	Fisher's exact test	
Probably yes	67(44.1%)	37(49.3%)	30(39.0%)	3.391	0.287
Definitely yes	69(45.4%)	33(44.0%)	36(46.8%)		
<b>Have again at no cost?</b>	(n=152)	(n=75)	(n=77)	Pearson Chi-square*	
No thanks	19(12.5%)	8 (10.7%)	11(14.3%)	1.231	0.540
Probably yes	41(27.9%)	23(30.7%)	18(23.4%)	Fisher's Exact test 1.235	0.577
Definitely yes	92(60.5%)	44 (58.7%)	48 (62.3%)		
<b>Have again if you had to pay for them yourself?</b>	(n=153)	(n=75)	(n=78)	Pearson Chi-square*	
No thanks	67(43.8%)	33(44.0%)	34(43.6%)	4.472	0.107
Probably yes	70(45.8%)	38(50.7%)	32(41.0%)	Fisher's Exact test	
Definitely yes	16(10.5%)	4(5.3%)	12(15.4%)	4.419	0.111
<i>*Chi square assumptions are met</i>					

**Table 56. Comparison of two treatment groups: Amount willing to pay per session out- of-pocket for a future session**

n(%)	Placebo	Healing Touch
<b>If so, how much would you be willing to pay?</b>	(n=75)	(n=78)
Not applicable, as they were unwilling to pay at all (so amount would pay = 0)	33(44.0%)	33(42.3%)
Not willing to specify an amount	10 (13.3%)	9(11.5%)
Number given of \$5	0	1(1.3%)
Number given of \$10	4(5.3%)	5(6.4%)
Number given of \$15	0	1(1.3%)
Number given of \$20	14(18.7%)	7(9.0%)
Number given of \$25	0	2(2.6%)
Number given of \$30	4(5.3%)	5(6.4%)
Number given of \$35	2(2.7%)	0
Number given of \$40	4(5.3%)	3(3.8%)
Number given of \$45	1(1.3%)	0
Number given of \$50	3(4.0%)	7(9.0%)
Number given of \$65	0	1(1.3%)
Number given of \$75	0	2(2.6%)
Number given of \$100	0	2(2.6%)

Of note, only participants from the Healing Touch group indicated a willingness to pay the three highest dollar values. The results displayed above for the amount that a participant would be willing to pay out-of-pocket themselves for a future Healing Touch treatment was collapsed into a categorical variable for ease of statistical significance testing between the two treatment groups. These results are presented in Table 57 below. While the trend showed that 28.2% of those who received Healing Touch were willing to pay above \$20 per session, while only 18.7% of those in the placebo group were willing to pay that higher amount, the differences between the two treatment groups again did not reach or approach statistical significance.

**Table 57. Comparison of two treatment groups: Amount willing to pay  $\leq$  \$20 versus  $>$  \$20 per session out- of-pocket for a future session**

n(%)	Placebo	Healing Touch	Test statistic	p value
<b>Amount willing to pay:</b>	(n=75)	(n=78)	Pearson Chi-square	
$\leq$ \$20 per session	61(81.3%)	56(71.8%)	1.933	0.164
$>$ \$21 per session	14(18.7%)	22(28.2%)		

## Comparison of treatment groups on protocol adherence: treatment protocol and data collection protocol

### *Adherence to Treatment Protocol*

Both treatment groups had a median treatment duration of 42 days, with minor differences in IQR and the minimum to maximum range, which did not reach statistical significance. A series of seven treatments, usually placed 7 days apart (i.e. on the same day of the week each week) results in a 42 day treatment duration, showing excellent adherence to the treatment protocol for both treatment groups. Thus both treatment groups adhered closely to the treatment protocol as originally designed, with comparable performance on treatment protocol adherence between treatment groups, as per Table 58 below. As noted on the Participant Flow Diagram (Figure 3), three participants in the placebo group and one participant in the Healing Touch group took longer than expected to complete the treatment protocol, but their data was still included in analysis, in keeping with the modified intention-to-treat analysis method chosen.

**Table 58. Duration of Treatment (Number of Days between Treatment Session One and Treatment Session Seven)**

Duration of Treatment	Total Sample	Group A	Group B	Test statistic	p value
	n=150	n=73	n=77		
	Median IQR Min-Max Range	Median IQR Min-Max Range	Median IQR Min-Max Range	Mann Whitney	
Days between S1 and S7	42.0 (40.0, 42.25) 28 to 155	42.0 (39.0, 45.0) 28 to 155	42.0 (41.0, 42.0) 28 to 77	2611.0	0.431

The total number of minutes of treatment time was recorded for most treatment sessions, and was comparable between treatment arms, when comparing those cases for whom treatment time in minutes was recorded for all seven sessions. The treatment time excluded the energy assessment (genuine or simulated) before and after the treatment, and also excluded the time during which the energy assessment was recorded on the session documentation sheet (see Appendix W). Treatment time for the placebo sessions was set to be a 30 minutes, with 3 exceptions for clients for whom either the position on the massage table and/or the use of the sleeping mask generated sufficient discomfort or anxiety as to require a shorter treatment time to avoid attrition. Thus the total protocol treatment time for a full series of seven sessions should approximate 210 minutes. In addition, participants from both treatment arms at times requested shorter treatment times to accommodate other subsequent appointments or engagements. As discussed above, in order to maintain the authenticity of Healing Touch treatments as practiced outside of a research context, Healing Touch techniques were selected to address client goals and the results of the energy assessment. When the technique was completed, if sufficient time did not remain to complete another Healing Touch technique, the session was concluded. This intention to authentically represent the variety of Healing Touch techniques that might be used in a given session

resulted in slightly greater variability in the IQR for the Healing Touch group than for the Placebo group, but not a statistically significant difference. In terms of minutes of treatment time, the two treatment arms were comparable, as per Table 59 below.

**Table 59. Total treatment time in minutes for full series of treatments (“Dose” of treatment)**

	Total Sample	Group A	Group B	Test Statistic	p value
	n=105	n=49	n=56		
	Median IQR Min-Max Range	Median IQR Min-Max Range	Median IQR Min-Max Range	Mann Whitney	
Total minutes of treatment time (S1 + S2.....+S7)	199.0 (188.5, 211.0) 112 to 258	200.0 (195.0, 211.5) 112 to 232	197.5 (182.0, 211.0) 161 to 258	1189.5	0.241

Finally, data was collected and analysed regarding the number of treatment sessions experienced by participants in each treatment arm, and compared for those cases for whom data on outcomes were analysed (153 cases). Again the two treatment arms were comparable on this measure of ‘dose’ and of adherence to treatment protocol, as per Table 60. As discussed earlier, if data was collected for all three time points within the data collection protocol, the cases were analysed, regardless of whether the full treatment protocol of seven sessions was completed or not, in keeping with the modified intention-to-treat analysis selected.

**Table 60. Number of treatments completed: Comparison between treatment groups**

	Total Sample	Placebo	Healing Touch	Test performed	p value
Number of Treatments:	(n=153)	(n=75)	(n=78)		
Seven	150	73	77		
Six	1	1	0		
Five	1	0	1		
Three	1	1	0	Fisher’s exact test, 2 sided	p=0.485

### ***Adherence to Data Collection Protocol***

Adherence to the data collection protocol was also comparable between both treatment arms, and adhered closely to the protocol design, with no statistically significant differences between treatment arms. In both treatment groups, baseline (Week 0) data was collected within the set two week timeframe prior to commencement of the treatment series, with a median time of 4 days prior to treatment in both treatment arms. Similarly, post-intervention (Week 8) data collection occurred within the two week timeframe after conclusion of the treatment series, with a median time for both treatment arms of two days. Finally, the six

month follow-up data was designed to be collected within 180 days, plus or minus a 10% buffer of 18 days. The median for data collection was 176 days for the placebo group and 182.5 days for the Healing Touch group. Please see Table 61 for the detailed analysis.

**Table 61. Protocol Adherence: Data collection within protocol time frames**

Data Collection Protocol Adherence	Total Sample (n=153)	Placebo (n=75)	Healing Touch (n=78)	Test statistic	p value
	Median (IQR) Range	Median (IQR) Range	Median (IQR) Range		
Number of Days between Week 0 data collection by RA and Treatment Session # 1 by PI.	4.00 (2.0,7.0) 0 to 15.0	4.00 (2.0,7.0) 0 to 14.0	5.00 (2.0,8.0) 0 to 15.0	Mann Whitney 2551.5	p=0.170
	Total Sample (n=153)	Placebo (n=75)	Healing Touch (n=78)		
Number of days between final treatment session and Week 8 data collection by RA.	2.00 (1.0, 4.0) 0 to 14.0	2.00 (1.0, 5.0) 0 to 11.0	2.00 (1.0, 4.0) 0 to 14.0	Mann Whitney 2917.0	p=0.976
	Sample (n=153)	Placebo (n=75)	Healing Touch (n=78)		
Number of days between final treatment session and Week 33 (6 month follow-up) data collection by RA	180.0 (169.0,191.5) 154 to 241	176.0 (168.0,189.0) 154 to 228	182.5 (171.0, 192.3) 161 to 241	Mann Whitney 2457.0	p=0.087

### **Harms**

There were no incidences of participants suffering harm or injury due to the intervention or the placebo, although other circumstances of the treatment situation were occasionally noted to be of concern. Some participants found lying on the massage table to be uncomfortable due to chronic conditions of impaired mobility and/or joint pain. Alternate positioning and pillow placement was sufficient to resolve these concerns in nearly all cases. However, 3 participants chose to have the remainder of their treatment sessions sitting in a recliner rather than lying on the massage table, and 3 participants withdrew from the study due to their expressed discomfort from lying on the massage table.

During energy treatment sessions, transient awareness and/or increase in pain or other sensations in an affected area that is being treated can occur, as was mentioned in the

Participant Information/Consent. This possible pattern was noted for a few participants in this study. In each case the sensations subsided and returned to comfort levels at or above those reported prior to the treatment session commencing.

The other incidences of discomfort noted were related to the experimental conditions of the treatment protocol, which required the use of a top sheet and of a sleeping mask. One participant found the lightweight disposable top sheet to be uncomfortably warm, so it was substituted with her own cotton sheet instead. Similarly, one participant had a mild contact dermatitis reaction to the commercially manufactured sleeping mask, and so it was substituted with a folded hand towel snugly draped across her eyes to ensure her comfort, while still working within the parameters of the treatment protocol.

## **Chapter Summary of Main Findings**

### **Functional Health:**

A holistic approach was used to measure a number of health dimensions, with the primary outcome measure being the functional health of the participants. Despite randomization into the two treatment groups, the groups were not comparable at Week 0 on two demographic characteristics: income, and living arrangement. Given the potential for one or both of these demographic characteristics to be confounding variables that either obscured or exaggerated a true difference between the treatment groups, a stratified analysis had to be undertaken. This was accomplished by separating the participants into two strata (i.e. the 'poorer' and the 'richer' participants and the living independently or not living independently, respectively), and then comparing the two treatment groups within each stratum. This removed the potential confounding influence of income, as 'poorer' participants were only compared with other 'poorer' participants, while 'richer' participants were only compared with other 'richer' participants; and the same comparisons occurred in relation to varying living arrangements.

The first stratified analysis separated the participants into those living in homes or units in ordinary neighbourhoods, versus those living in more dependent, structured accommodation settings, mostly retirement villages. For the stratum of participants already living in retirement villages at Week 0, the amount of change in functional health from Week 0 to the Week 33 data collection point showed a statistically significant difference between the two treatment groups. The Healing Touch treatment group experienced a clinically relevant improvement in their ability to perform Basic Activities of Daily Living, while the Placebo group experienced a clinically relevant decline in their ability to perform Basic Activities of Daily Living (Basic ADLs).

This finding regarding Basic ADLs was not seen for the other stratum, that of the participants living in their own homes or units in an ordinary neighbourhood. Similarly, there were no statistically significant differences between the two treatment groups in either strata regarding a change over time in the participants' ability to perform Instrumental Activities of Daily Living (Instrumental ADLs), or a change in their Total ADL score (Basic ADLs plus Instrumental ADLs).

The second stratified analysis was based on their income. In both the poorer and the richer strata, the two treatment groups showed no statistically significant difference in their amount and direction of change during the course of the study, for all the primary outcome measures

measured. Specifically, in the stratified analysis for either of the strata defined by annual income, there were no statistically significant differences between the two treatment groups in regards to the change in their ability to perform Basic Activities of Daily Living (Basic ADLs), Instrumental Activities of Daily Living (Instrumental ADLs), or their overall ADL score (the sum of the Basic ADLs and Instrumental ADLs.)

### **Social Support:**

The only other health dimension that demonstrated a statistically significant difference between the two treatment groups was that of Social Support.

In the first stratified analysis, where participants were separated in to strata based on their living arrangements at Week 0, statistically significant differences between the two treatment groups were demonstrated, but only for one of the two strata. In the stratum of the ordinary residential neighbourhood, the Healing Touch treatment group experienced an improvement in Social Support, while the Placebo group experienced a decline in Social Support. In contrast, for the stratum of participants already living in structured accommodation (mostly retirement villages), there was no statistically significant difference between the two treatment groups, with both treatment groups showing a decline in Social Support over the time span of the study.

In the second stratified analysis, there were no statistically significant differences between the two treatment groups on change in Social Support, for either the stratum of the poorer (those with an annual income less than \$20,000/year), or the stratum of the richer (those participants with an annual income over \$20,000).

### **Other Health Dimensions:**

For all of the other main outcome measures measured in this study, there were no statistically significant differences between the two treatment groups, in either the analysis where participants were stratified by income, or in the analysis where participants were stratified by living arrangement. Thus for overall Quality of Life, for Psychological Well Being and for Spiritual Well Being, the two treatment groups were essentially similar in both of the two stratified analyses: income and living arrangement.

All of the other secondary outcome measures for which between group comparisons were performed were compared only on aggregated data (i.e. no stratification). There were no statistically significant differences found between the two treatment groups for the rest of these comparisons either: cognitive health, the number and severity of chronic conditions, the amount of time since their last hospitalisation, the acuity of their last hospitalisation setting, the absence or presence of a hospital visit during the time span of the study, the change to a more dependent living arrangement, their satisfaction with the treatment series, their belief that they had received the actual treatment rather than the placebo, or the amount of change in their vital signs and their perceptions of health from immediately before to immediately after each treatment session.

In conclusion, for the participants in this study, the only clearly demonstrable effects of the Healing Touch treatments were found to be regarding an improvement in their ability to perform Basic Activities of Daily Living, but only for the stratum of participants already living in a structured accommodation; and an improvement in levels of Social Support, but only for

those participants still living in their own homes or units in ordinary residential neighbourhoods.

## **CHAPTER FIVE: Discussion and Conclusion**

## **Introduction**

The main findings of this present study will be discussed and interpreted in the context of findings from similar relevant studies. One systematic review and an additional 14 primary source publications were located, representing studies that were conducted and/or published while this present study was being conducted. Therefore, firstly an overview table of these recent studies will be presented for the reader's convenience, again organised according to the evidence base hierarchy as described in Chapter Two, with further detail available in Appendix E. The discussion chapter will then progress to a comparison of the findings of this present study to the recently updated complete body of evidence regarding Healing Touch. Next the discussion will highlight the unique contribution this present study has made to increase the methodological rigour of Healing Touch research. The limitations of the present study will then be outlined, followed by some recommendations for policy, practice and future research regarding Healing Touch and other complementary therapies.

## **An update of the literature published regarding Healing Touch during the conduct of this present study**

Fourteen primary source publications and one systematic review were located during the update of the literature review undertaken in 2012. These studies are presented in the table below, Table 62 and are further detailed in Appendix E. They will be only briefly summarised here.

Two of the additional studies that were located qualify as Level V evidence. Curtis, Tegeler, Burdette and Yosipovitch (2011) is a single case study report, Level V-4; while Sutherland, Ritenbaugh, Kiley, Vuckovic and Elder (2009) is a formal qualitative study, Level V-3.

An additional four studies were found in the 2012 update of the literature review that used a case series pre/post-test design, thus qualifying as Level IV-1 evidence. Three of these studies gathered data before and after a single intervention condition of Healing Touch (Danhauer, 2008; Zimmer et al, 2009; Tang et al, 2010) while the fourth study used a slightly more complex design by collecting data after two sequential conditions, the second of which was Healing Touch (Kemper, et al 2009).

Only two studies were located during the 2012 literature update that reflected Level III Evidence, given that they only used a pseudo-randomisation process (Goldberg, 2011; Decker & Wardell, 2012). The second one is particularly pertinent to the context of the findings of the present study, given the inclusion of a measure of Activities of Daily Living and the focus on an older adult population.

Nearly half of the 14 newer studies (six) found during the literature update are situated at the Level II tier of evidence, which is an encouraging trend to see as the body of evidence builds in a more systematic way than was noted in the earlier years of researching Healing Touch. One study used a three parallel arm design (Lutgendorf, et al, 2010), by comparing Healing Touch to both standard care and to a relaxation therapy intervention. One of the other five studies used a three arm design (Jain, 2009), while the other four studies used a two arm parallel arm design (Hardiwick et al., 2012; Judson, et al., 2011; Schnepfer, 2009; Taylor, 2008). Of those four studies that used a two arm parallel design, two of them compared Healing Touch to

standard care (Judson et al., 2011; Hardwick et al., 2012). Of particular interest, the remaining three RCTs were doctoral dissertations where Healing Touch was compared to a placebo version of Healing Touch (Jain, 2009; Schnepfer, 2009; Taylor, 2008). For Jain's study (2009) a third arm of standard care was also included.

These final three additions to the evidence base of placebo-controlled trials join Cook et al (2004) and this present study in reaching the pinnacle of the positivist paradigm in using an RCT to test the efficacy of an intervention against a placebo version of that intervention. However, of necessity, the provider themselves in each study was aware that they were providing the verum treatment, which will always be a necessary limitation in a provider-delivered intervention, preventing the attainment of the further ideal of double-blinding.

A summary of the above 14 newer studies as they fit in to the evidence hierarchy is provided in Table 62 below, and additional detail regarding each study can be found in Appendix E. However, pertinent details of these newer studies will also be highlighted within the subsequent discussion of the findings of this present study against the context of the recently updated (2012) body of evidence for Healing Touch.

**Table 62. Fourteen newer studies found in the 2012 Update of the Literature Review**

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication,
Level I	Systematic Review	1	n/a	Anderson & Taylor, 2011
Level II	Randomised controlled trial (RCT)	6		
Healing Touch vs. Placebo		2 Two arm	Healing Touch vs Placebo	Taylor, M., 2008
			Healing Touch vs Placebo	Schnepfer, 2009
Healing Touch vs. Placebo vs Standard Care		1 Three arm	Healing Touch vs Placebo vs Standard Care	Jain, 2009; Jain et al, 2011
Healing Touch vs. Standard Care vs. Active comparator		1 Three arm	HT vs Standard care or relaxation therapy	Lutgendorf, et al., 2010
Healing Touch vs. Standard care		1 Two arm	Healing touch vs Standard Care	Hardwick, Pulido & Adelson, 2012
Healing Touch & other CAMs vs. Standard care		1 Two arm	Healing Touch , massage AND hypnosis vs standard care	Judson, et al., 2011
III-1	Pseudo-randomised	2 Two arm	HT vs standard care	Goldberg, 2011

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication,
	controlled trial		HT vs Presence	Decker & Wardell, 2012; Wardell, Decker & Engebretson, 2012
<b>III-2</b>	Comparative study <u>with</u> concurrent controls	0		
<b>III-3</b>	Comparative study <u>without</u> concurrent controls	0		
<b>IV</b> Case series with either post-test or pre-test/post-test outcomes	IV-1 Case Series: pre-test/post-test 3	1	1 group, 2 sequential conditions: 1. Rest 2. HT	Kemper et al., 2009
		3	1 group, 1 condition (Healing Touch)	Danhauer et al, 2008 Zimmer, Meier & Rolf, 2009 Tang et al, 2010
	IV-2 Case series: post-test only			
	IV-3 Qualitative studies (case series: post-test only, but collected data consists of textual data, not numeric data)	Refer below to Level V-3	n/a	
<b>V-1</b>	Narrative Literature Review			
<b>V-2</b>	Program evaluation reports			

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication,
V-3	Qualitative studies about <u>patients</u> receiving Healing Touch	1	n/a	Sutherland, et al., 2009
V-3	Qualitative studies about <u>practitioners</u> of Healing Touch	0	n/a	
V-4	Descriptive case reports of individual patient(s)	1	n/a	Curtis et al., 2011
VI	Expert opinion	0	n/a	

## The Contribution of the present study to the evidence base for Healing Touch

### Primary Outcome Measure of Functional Health Status:

A holistic approach was used to measure a number of health dimensions, with the primary outcome measure being the functional health status of the participants. Due to baseline differences in living arrangements between the randomised treatment groups, a stratified analysis was undertaken. Therefore, the participants living in homes or units in ordinary residential neighbourhoods were analysed separately from the participants living in some form of structured accommodation, predominantly retirement villages.

For the stratum of participants already living in retirement villages at baseline, the amount of change in functional health status from the baseline Week 0 to the Week 33 follow-up data collection point six month after completion of the treatment series, showed a statistically significant difference between the two treatment groups. The Healing Touch treatment group experienced an improvement in their ability to perform Basic Activities of Daily Living (BADLs), while the Placebo group experienced a decline in their ability to perform these BADLs. However, for the BADL in the other stratum (participants living in homes or units in ordinary residential neighbourhoods), and for the Instrumental ADLs and Total ADLs in both strata, the amount of change in functional health was comparable in both treatment groups.

A substantial amount of functional decline was anticipated in this ageing sample by the six month follow-up data collection point, but only a very small amount of functional decline actually occurred. Due to the data being skewed towards the top end of the scale, with most participants enjoying a nearly perfect level of functional health as measured by this

instrument, the median was the most appropriate measure of central tendency. The median (50% cut-off point) value for many of the calculated change variables was between zero and one full point, and so the direction of change was more easily discernible by examination of the interquartile range (IQR: the 25% and 75% cut-off points).

For both of the sub-scales and for the Total ADL scale, a decline of one full point represents the difference between being able to perform one particular ADL with assistance versus without assistance; or alternatively, a decline of one full point represents the difference between being able to perform one particular ADL with assistance versus not being able to perform it at all. In practical terms, a decline of one point on, for instance, the Basic ADL sub-scale, can mean the participant has moved from being fully independent to bathe themselves to now requiring assistance in bathing, and thus the need to mobilise in-home support services for a family or a paid caregiver to assist with bathing on a daily basis. On the Instrumental ADL sub-scale, a decline of one full point may mean the participant can no longer independently transport themselves, either by driving their own private car or by independently accessing public transport. Again the everyday negative impact on quality of life of a decline of one point on this scale can be substantial, indicating clear clinical relevance and significance. Thus the finding for the retirement village strata of an interquartile range of (0.0, -1.0) for the placebo group on the Basic ADL measure versus the interquartile range of (0.0, +1.0) for the Healing Touch group on the Basic ADL measure does have clinical significance, as well as statistical significance, given the practical impact of movement up or down the scale by even one point; and the clear distinction between direction of change noted in the Placebo group (decline) versus the Healing Touch group (improvement) and illustrated in Figure 4.

Eight research studies investigating the effects of HT also addressed functional health as an outcome measure. The findings of the first three studies were discussed in the literature review and contributed to the design of the present study, since Healing Touch appeared to have some possible beneficial effect on functional health in these studies (Peck, 2007; Ziembroski et al., 2003; Cook et al, 2004). However, only one of these studies was an RCT (Cook et al, 2004). The current finding for the measure of Basic ADLs for the strata of participants living in retirement villages is congruent with their earlier research: Peck's qualitative study on frail aged and disabled participants receiving in-home assistive services (2007); a quantitative descriptive study by Ziembroski et al (2003) with 55 hospice patients; and a placebo controlled RCT by Cook et al (2004) for 62 women with cancer receiving radiation, where the Healing Touch group showed a statistically significantly more favourable outcome on change in physical functioning than the placebo group.

In marked contrast, in the five later studies, no statistical significance between comparison groups was observed. All of these were RCTs, although Decker and Wardell's study qualifies only as a pseudo-randomised trial (2012). All were published after the design of the present study had been stabilised (MacIntyre et al, 2008; Taylor, 2008; Schnepfer, 2009) or published after this present study had been completed (Judson et al., 2011; Decker & Wardell, 2012). Healing Touch did not appear to exert a beneficial effect on functional health when compared to standard care or a visitor intervention for 237 coronary artery bypass patients (MacIntyre et al, 2008); or when compared to a placebo for 17 Hepatitis C patients (Taylor, 2008); or when compared to placebo for 37 women with breast cancer receiving radiation therapy (Schnepfer, 2009); or when compared to standard care for 43 women with ovarian cancer receiving chemotherapy (Judson et al, 2011); or when compared to a presence intervention

for 20 non community-dwelling older adults with persistent pain in a pilot study (Decker & Wardell, 2012).

None of the other studies used the same instrument to measure functional health as the one selected for this present study. Cook, Guerrero and Slater (2004) used the Medical Outcomes Study SF-36, which includes a sub-scale for physical functioning; MacIntyre et al, (2008) used the Health Status Questionnaire (SF-12); Taylor (2008) used the 40 item Fatigue Impact Scale (FIS) with sub-scales for cognitive function, social function and physical function; Judson et al (2011) used the Functional Assessment of Cancer Therapy—Ovarian (FACT-O) quality of life assessment, which included functional well being as a sub-scale; Schnepfer also used the FACT instrument, but the FACT-B (Breast cancer variant); and Decker and Wardell (2012) used the Katz Index of Independence in Activities of Daily Living.

Thus for the outcome measure of functional health, the evidence for a beneficial effect from a Healing Touch intervention is very limited, both when considering the above studies and the present study together as a body of evidence; and also the evidence is mixed even within some of the individual studies themselves (Cook et al, 2004 and the present study). Earlier qualitative work (Peck, 2007) and descriptive quantitative work (Ziembroski et al, 2003) implied a possible benefit, but later studies that used inferential statistical testing for within group comparisons and/or between group comparisons resulted in mixed findings (Cook, et al., 2004 and this present study) or negative findings (MacIntyre, 2008; Taylor, 2008; Schnepfer, 2009; Judson et al, 2011; Decker & Wardell, 2012). Further robust research will be needed to clarify these conflicting findings, in order to ascertain if there are select populations who will experience a beneficial impact on their functional status by receiving Healing Touch treatments, and when that benefit will be demonstrable: either during or immediately after the treatment series and/or for some increment of a longer duration, such as the 6 month follow-up time frame used in this present study and in the MacIntyre et al (2008) and Judson et al (2011) studies.

## **Secondary Outcome measures: Other health dimensions**

### ***Social Support:***

In the stratified analysis of this present study sample, where participants were separated into strata based on their living arrangements at baseline, statistically significant differences between the two treatment groups were demonstrated for Social Support, but only for one of the two strata. In the stratum of the ordinary residential neighbourhood, the Healing Touch treatment group experienced an improvement in Social Support, while the Placebo group experienced a decline in Social Support. These findings reinforce those of one other quantitative descriptive study (Ziembroski et al, 2003), but contradict the findings from four RCTs, two of which compared Healing Touch to standard care (Goldberg, 2011; Judson et al 2011) and two of which compared Healing Touch to a placebo (Cook et al, 2004; Taylor, 2008).

The only study that had findings consistent with the current study was one undertaken with a very different sample of 55 hospice patients, where only descriptive analysis was undertaken. The findings of Ziembroski, Gilbert, Bossarte and Guldberg's (2003) study of hospice patients identified that the HT group improved for the interpersonal dimension, while the control groups' scores on that sub-scale worsened over time, using the Missoula Quality of Life instrument. In contrast to this present study, the RCT undertaken by Cook, et al. (2004) did not

find a statistically significant difference between the post-treatment score for social functioning in the HT group as compared to the post treatment score for social functioning in the Mock Healing Touch group, similar to Taylor's findings (2008) when comparing the Healing Touch group to her Mock Healing Touch group. Judson et al (2011) also reported no statistically significant differences on social well-being between the Healing Touch group and the standard care group in her study of 43 women with cancer. Goldberg (2011) also reported no statistically significant differences between the Healing Touch group and the standard care group on the social category of the Coping Resources Inventory in her doctoral research of 73 women undergoing breast biopsy.

The findings in this present study regarding the benefit of Healing Touch on improving social support for the strata of those older women living alone in their home or unit in an ordinary residential neighbourhood contrast with the findings of nearly all of the prior research on Healing Touch that included some measure of social health and well-being. Social isolation has been linked to numerous negative health consequences in older adults (Bharucha et al., 2004; Miller, 2012). Conversely, social support is a key element in preserving functional independence and maintaining a residence in the community (Bharucha et al., 2004; Miller, 2012). Social support has also been shown to positively correlate with numerous other variables that could be useful contributing factors to healthy ageing, including reduced stress and distress; reduced loneliness, depression and cognitive decline; improved life satisfaction, psychological health, functional ability, survival, and adjustment to institutionalization; and improved functioning of the cardiovascular, neuro-endocrine and immune systems (Chappell & Funk, 2010). Given the positive finding from this present study, there is some support for the potential for Healing Touch to beneficially impact the social support levels of older adults living in homes or units in residential neighbourhoods, which should be further explored, as such a benefit could be used to support the expressed preference of older adults to remain in the community, and is in keeping with the similar philosophical stance and funding strategies articulated in government policies of ageing in place.

### ***Other Secondary Outcome Measures:***

For all of the other secondary outcome measures measured in this study, there were no statistically significant differences between the two treatment groups, in either the analysis where participants were stratified by income, or in the analysis where participants were stratified by living arrangement, for the change from Week 0 to Week 8, or the change from Week 0 to Week 33. Thus for Spiritual Well Being, for overall Quality of Life, and for Psychological Well Being, the two treatment groups were essentially similar in both of the two stratified analyses: income and living arrangement. The lack of difference found in these measures in this present study conflicts with some of the earlier research on Healing Touch, yet reinforces the findings of other studies, as will be mentioned in the following discussion of each secondary outcome measure in turn.

### **Spiritual well being:**

The results for spiritual well-being demonstrated a variable pattern of change for both time frames and both strata that may reflect statistical artefact rather than true distinctions between the two treatment groups. Firstly, for the participants living in their own neighbourhood, the results showed a statistically significant difference in the amount and direction of change from Week 0 to Week 8 between treatment groups, with the Healing

Touch group improving and the Placebo group declining in their reported levels of spiritual well-being. By Week 33, although the trend of a better response in the Healing Touch group persisted, the differences in the amount of change from Week 0 to Week 33 between the two treatment groups no longer reached or approached statistical significance. The trend was in the opposite direction however, for the stratum of retirement village residents, where the non-significant trend ( $p = 0.089$ ) showed the Healing Touch group declining in spiritual well-being while the Placebo group was holding even by the Week 33 measurement. The authors also report a known ceiling effect for this instrument, with scores highly skewed (Bufford, Paloutzian & Ellison, 1991). Interestingly, this was not the finding in this present study, with the sample's scores on the SWBS being the only instrument that was normally distributed. This anomaly may contribute to the seemingly contradictory findings in the stratified analysis, where relative positions of the two treatment groups changed over the two time points, lending support to the interpretation of a statistical artefact for this measure in this sample.

Wardell, Rintala, Duan and Tan (2006) found no difference between Healing Touch and progressive muscle relaxation in their RCT pilot study of 12 spinal cord injured patients experiencing neuropathic pain, using the Diener Satisfaction with Life scale, which is comparable in content to the Existential sub-scale of the Spiritual Well-Being Scale used in this present study.

Goldberg (2011) however, found a clear benefit for spiritual health in her study, which compared Healing Touch against a standard care control group for 73 women, 42 of whom received a 15 minute Healing Touch treatment prior to undergoing a breast biopsy. A spiritual/philosophical category was part of the Coping Resources Inventory (CRI) instrument, collected three times: twice on the day of the biopsy, (pre- and post- biopsy), and then collected a third time on the following day. These findings indicated an immediate beneficial effect of Healing Touch on spiritual health, congruent with the finding in this present study for the participants living in an ordinary neighbourhood, where a statistically significant difference in the amount and direction of change for the Week 8 measurements after conclusion of the 7 week treatment series was noted, but only a non-significant trend was seen for the change experienced by the later measurements at Week 33.

Therefore, any beneficial effect of Healing Touch on spiritual health may need to be measured fairly promptly after treatment concludes, in order to be able to detect substantial effects. Similarly, this finding may imply that the beneficial effects subside over time, and repeated measures at closer intervals may be a fruitful future exploration to determine the 'half-life' of Healing Touch effects on spiritual measures.

The body of evidence to date for a beneficial impact of Healing Touch on measures of spiritual health is scant. Goldberg's findings indicate a clear difference for the Healing Touch group as compared to the standard care control group regarding improvement in spiritual health (2011). Conversely, within this present study, and within the Wardell et al (2006) study, the findings were negative.

### **Quality of Life**

In the present study, for overall Quality of Life as measured per the Duke Health Profile, there were no statistically significant differences between the two treatment groups, in either the analysis where participants were stratified by income, or in the analysis where participants were stratified by living arrangement, or in the original un-stratified analysis. The sample as a

whole showed a small but statistically significant increase in their scores of between 0-1 points on this 0 to 34 point scale for Quality of Life, where higher scores represent better health, but the amount of increase was essentially similar between the two treatment groups, and of questionable clinical significance.

Quality of Life has been studied often in Healing Touch research, using a variety of designs along a continuum of research rigour, applying varying degrees of sophistication in the statistical analyses conducted and in the reporting of methods and results, and obtaining mixed results. The less rigorous designs will be summarised first, followed by examination of the more rigorously designed RCTs, three of which compared HT to a placebo (Cook et al, 2004; Taylor, 2008; Schnepfer, 2009).

The first six studies demonstrated negative findings, firstly when Healing Touch was compared before and after treatment with descriptive statistics only (Wilkinson, 2004), and again when Healing Touch was compared between treatment groups, also with descriptive statistics only (Ziembroski et al, 2003). The remaining studies used inferential statistics, but did not demonstrate statistically significant differences when Healing Touch was compared to standard care (Wheeler-Robins, 1999; Judson et al, 2011), or when it was compared to relaxation therapy (Lutgendorf et al, 2010) or to chiropractic treatment (Weymouth, 1999).

The last three studies to be discussed compared Healing Touch to a placebo, which is a more robust analysis and so could reasonably be expected to make statistically significant between-group differences more difficult to detect. However, their findings are generally more favourable to the Healing Touch group than the methodologically weaker designs discussed above and are also more favourable than the findings in this present study.

Cook, et al (2004) used the Medical Outcomes Study SF-36, a measure of overall Quality of Life, to investigate the effect of Healing Touch versus mock Healing Touch. For within group comparisons, the HT group in Cook et al (2004) demonstrated a statistically significant improvement in their total SF-36 score over time, while the Mock HT group did not. However, the between group comparisons for the overall SF-36 score were not statistically significant.

Schnepfer (2009) also studied the effect of Healing Touch on Health Related QOL using the FACT-B instrument for breast cancer patients receiving radiation therapy, and she also used a Healing Touch versus Mock Healing Touch design, with 20 patients in each treatment group. Both the placebo group and the Healing Touch group reported an increase in QOL, but it appears that the amount of improvement was statistically significantly greater in the Healing Touch group than the amount of improvement noted in the placebo group.

Jain et al (2011) used the outcome measure of QOL, also measured by the Functional Assessment of Cancer Therapy-Breast (FACT-B) instrument, in her three arm design to test the effect of the technique of energy chelation as taught in the four year Barbara Brennan energy healing school (Jain, 2010). A modified form of this same technique is taught in the Level Three Healing Touch curriculum. Jain et al (2011) reported no statistically significant differences between the energy chelation group and the mock healing group, or between the mock healing group and the control group.

Once again for this outcome measure of quality of life, we see that the findings across numerous studies using a variety of instruments are predominantly negative, with the amount of improvement in the Healing Touch group not being significantly different from the amount of improvement in the mock healing touch (or standard care) group.

### **Psychological well being:**

In this present study, there were no statistically significant differences between the two treatment groups in regards to the change in Psychological Well Being scores from Week 0 to Week 8 or the change from Week 0 to Week 33. This outcome measure is the one most often studied in Healing Touch research, and also the one where the body of evidence is least equivocal, with the use of similar instruments across studies beginning to build the possibility for eventual meta-analyses.

The findings of this present study are in contrast with the majority of the prior research on Healing Touch, where previous findings tended to favour the Healing Touch group as experiencing a greater beneficial effect on some measure of psychological or emotional well being. However, eight studies are congruent with the findings of this present study, as no statistically significant differences for within group or between group comparisons were demonstrated in them, seven of which were RCTs. In contrast, thirteen studies support the efficacy of Healing Touch to positively influence emotional health, but only eight of these were RCTs.

### ***Negative findings:***

Jain et al (2011) compared standard care, mock healing and biofield healing (similar to Healing Touch) using the CES-D in their RCT for breast cancer patients. They found that neither mock healing nor biofield healing affected depression scores. Taylor (2008) also used the CES-D as an outcome measure on her RCT study of patients with hepatitis C, but found no statistically significant differences between Healing Touch and mock healing. Wardell, Rintala, Duan and Tan's (2006) RCT pilot study with 12 spinal cord injured patients experiencing neuropathic pain, also used the CES-D instrument, and the Profile of Mood States (POMS) and again found that there were no statistically significant differences between the Healing Touch group or the guided progressive relaxation group for their change over time on either the POMS or the CES-D. Wheeler Robins (1999) also used the Profile of Mood States (POMS) as one of her outcome measures, in her crossover RCT wait list control group design of 27 males with HIV, and found no statistically significant differences between the Healing Touch group and the standard care group. Judson et al (2011) used the Mental Health Inventory to evaluate psychological well being in their RCT of 43 women with ovarian cancer, and found no statistically significant differences between the standard care group and the integrative medicine group, who all received the three modalities of Healing Touch, massage and hypnosis. Two additional RCTs, the MANTRA I pilot study (Krucoff et al, 2001) and the MANTRA II main study with 748 cardiac inpatients (Krucoff et al, 2005), both used the Spielberger State Trait Anxiety Inventory and did not find any statistically significant differences between treatment groups. Wilkinson's second study (2004) was the only non-RCT in this group of negative results for psychological well-being, where the comparison of pre and post treatment scores of 15 men found no clear pattern of benefit on the various subscales, including one for emotional well-being, in the quality of life measure called the Functional Assessment of HIV Infection (FAHI). The findings of this present study are congruent with the above eight studies, seven of which were RCTs, and all of which failed to demonstrate any beneficial effect of Healing Touch over the comparator on the participants' psychological well being.

### ***Positive findings:***

While seven of the eight studies demonstrating negative findings above were RCTs, the thirteen studies demonstrating positive findings represent a greater diversity of design. However, there is still some duplication of instruments from those used in the studies demonstrating negative findings above, to those below, which demonstrated positive findings.

Post-White et al (2003) used the POMS in their crossover RCT of 164 cancer patients receiving chemotherapy and reported that the Healing Touch intervention reduced mood disturbance better than standard care did. Lutgendorf et al (2010) used both the CES-D and the depression sub-scale of the POMS in her RCT of cervical cancer patients and found that the Healing Touch group showed statistically significantly larger decreases in depression on both instruments, as compared to the usual care and relaxation therapy groups. Four studies used the Spielberger State Trait Anxiety instrument, and found beneficial effects at a statistically significant level for the Healing Touch group in an RCT design (MacIntyre et al, 2008; Hardwick et al, 2012; Goldberg et al, 2011) or for the Healing Touch treatment in a case series pre/post test design (Maville et al, 2008).

The Cook et al (2004) RCT did not find any statistically significant difference between the post-treatment score for emotional role functioning sub-scale of the SF-36 in the HT group as compared to the post treatment score for emotional role functioning in the Mock HT group, but they did report a statistically significant improvement over time for the within group comparison for emotional role functioning for the Healing Touch group.

Similarly, Kemper et al (2006) found that the personal accomplishment subscale of the Maslach Burnout Inventory showed statistically significant improvement in their single group pre/post design to study the impact of a semester long elective course in a medical school that covered Healing Touch and other touch therapies, and included experiential learning by receiving treatments from fellow classmates.

Five studies used visual analogue scales (VAS) and found beneficial results for the Healing Touch group in an RCT design (DuBrey, 2006; Krucoff et al, 2001; Rexilius et al, 2002), or for the post treatment scores in a case series pre/post test design (Kemper et al, 2009; Tang et al, 2010) on one or more of the VAS descriptors used: worry, stress, depression, anxiety, relaxation, well-being, sleep, calmness, pain reduction, feeling upset, feeling tense.

In summary, consistent findings from eight RCTs and five case series pre/post test designs, provide support for the beneficial effect of Healing Touch on psychological measures. However, another eight studies, seven of which are RCTs, lend no support to an effect of Healing Touch on psychological measures, and as such they are congruent with the findings of this present study.

### ***Ancillary Analyses:***

For all of the other secondary outcome measures in this present study, between group comparisons were performed only on aggregated data (i.e. no stratification was undertaken). These analyses showed that there were no statistically significant differences found between the two treatment groups for any of these ancillary measures: cognitive health, the number and severity of chronic conditions, the amount of time since their last hospitalisation, the acuity of their last hospitalisation setting, the absence or presence of a hospital visit during the time span of the study, the change to a more dependent living arrangement, their satisfaction

with the treatment series, their belief that they had received the actual treatment rather than the placebo, and the amount of change in their vital signs and their perceptions of the four dimensions of health from immediately before to immediately after each treatment session.

### ***Mini Mental Status Examination (MMSE)***

In the present study, within group comparisons were made using the Friedman test, and found that the differences were not statistically significant, indicating that the scores at Week 0, Week 8 and Week 33 were equivalent. This finding implied a stable cognitive status during the course of the study, for the sample as a whole and also for each treatment group. Given that the bulk of the data collected in this study was based on self-reporting, this cognitive stability provided reassurance of data reliability.

While the MMSE served primarily as a screening tool, it was collected at each time point, so between group comparisons were also done, and no statistically significant differences between treatment groups were found. These findings reinforce those of three other studies: Taylor (2008) found no difference between the amount of change in cognitive functioning in the Healing Touch group versus the mock healing touch group in her study of 17 patients with hepatitis, where the impact on cognitive function was a sub-scale of the Fatigue Impact scale. Similarly, Goldberg (2011) found no statistically significant differences between the Healing Touch group and the standard care group on the cognitive segment of the Coping Resources Inventory, and Wilkinson (2004) found none for the cognitive sub-scale of the Functional Assessment of HIV infection.

### ***Vital signs***

In this present study, the amount of change in vital signs from pre-treatment to post-treatment was firstly examined separately for all 5 vital signs across all of the seven treatment sessions (35 between group comparisons), and only five comparisons reached statistical significance. These were the Session Three pulse rate, respiratory rate and systolic blood pressure; and for Sessions Four and Seven, the diastolic blood pressure. The analysis then turned to a calculation of the average change from the average pre-treatment reading across all seven sessions to the average post-treatment reading across all of their seven sessions. In this analysis, the reduction in pulse rates and respiratory rates approached statistical significance ( $p = 0.084$  and  $p = 0.055$  respectively) with greater reductions post treatment in the Healing Touch group as compared to the placebo group, a trend that suggests the Healing Touch participants may have experienced greater physiological relaxation. These trends are congruent with the trends and statistical significances noted in some of the earlier research on Healing Touch that used vital signs as an outcome measurement.

Five studies included data on vital signs as an outcome measure, with beneficial effects for Healing Touch found on one or more of the vital signs in each study, but never for all vital signs. Maville, Bowen and Benham (2008) conducted a case series pre/post test study of 30 university students and found a statistically significant difference between the Pre and Post treatment systolic blood pressure readings. Similarly, Dubrey used the RCT design (2006) to study 148 recovering alcoholics who were randomised in to a Healing Touch treatment group as compared to control group who was read to from the Big Book of Alcoholics Anonymous. The Healing Touch treatment group had a statistically significantly greater reduction in heart rate from pre to post treatment than did the Big Book group, but the pulse rate changes were

comparable in both groups. Similar results were found by Post-White, Kinney, Savik, Gau, Wilcox and Lerner (2003) in their RCT study of 164 cancer patients receiving chemotherapy. The Healing Touch group demonstrated a statistically significant difference when compared to the standard care group for the amount of reduction in heart and respiratory rates, and in systolic blood pressure (SBP) and diastolic blood pressure (DBP). Lastly, Goldberg (2011) also found a greater reduction in respiratory rates and in systolic and diastolic blood pressures in the Healing Touch group as compared to the standard care group, but no difference between treatment groups on the amount of reduction in pulse rate post treatment, in her RCT of 73 women undergoing breast biopsy. In contrast, in this present study, there were no consistent findings across all seven sessions of a statistically significant difference between treatment groups for any of the vital signs recorded.

### ***Participant ratings of perceived health dimensions: Physical Emotional, Intellectual and Spiritual***

In the present study, although no Visual Analogue Scales were used, a conceptually similar method was used, by verbally asking participants to indicate a numeric rating of their health dimensions on a scale from 0 to 10, while the PI demonstrated the lower range by placing her hand at the bottom of the participant's field of view, then moving it upward to the top of the field of view as describing the top of the range as 10, "the best health you can imagine." This was conceptually similar to a paper version of a VAS, and was used to gauge the participant's perception of their physical health, emotional health, intellectual health and spiritual health immediately before and after each treatment session. However, despite the effectiveness of this simple method of measuring the perception of an emotional state in other Healing Touch research as described earlier under psychological well-being, there were no clear patterns of statistical significance that emerged for any of these four health dimensions in this present study, for any of the seven sessions where it was measured, as per Appendix DD. Of a total of 28 tests for statistical significance, only three reached the required p value: Session One for spiritual health, Session Five for cognitive health, and Session Seven for emotional health; which are likely to represent spurious findings due to multiplicity of testing.

### ***Hospitalisation***

MacIntyre et al (2008) noted shorter lengths of stay for the Healing Touch group in her study of elective coronary artery bypass graft surgical patients. Similarly, Krucoff et al (2001) used an RCT design to study 118 cardiac angioplasty patients who were randomised in to standard care versus four other noetic treatment groups, one of which was Healing Touch, in their MANTRA I pilot study. Their results demonstrated a 25-30% reduction in adverse peri-procedural outcomes in patients treated with any noetic therapy as compared with standard therapy. However, the MANTRA II main study of 748 cardiac patients found no differences on any of the outcome measures, including re-admission or mortality (Krucoff et al, 2005). The findings of this only multi-centre, large volume RCT are similar to those of this present study, where neither the incidence, recency or type of hospitalisation differed at a statistically significant level between the two treatment groups at Week 33.

### ***Belief regarding treatment group allocation***

In this present study, both treatment groups had a similarly high proportion of participants who believed that they had received the actual Healing Touch treatment, rather than the placebo, with 75.6% of the Healing Touch participants holding that belief, as compared to 70.7% of the placebo participants. Only four other studies used a mock healing or placebo treatment group. Of those, only three assessed the belief of the participants regarding their group allocation. Taylor (2008) did not assess the participants' belief regarding group allocation. In Schnepfer 's doctoral study of 40 breast cancer patients (2009), she found only 44.5% of the placebo participants believed they had received Healing Touch, while a much higher proportion (78.9%) of the Healing Touch participants believed they were in the Healing Touch group. Conversely, Cook et al (2004) found there was no statistically significant difference in the belief in group assignment between their actual HT group and their Mock HT group, indicating a successfully convincing placebo, and congruent with the findings in this present study. Cook et al (2004) also looked for a correlation between belief in group assignment and the primary outcome measure of Health-related Quality of Life as per the SF-36, but found no statistically significant association. Jain et al (2011) measured belief in group assignment and found that 75% of the women believed they were receiving actual healing, regardless of group assignment, a very similar value to the one obtained in this present study. Jain et al (2011) also looked at the predictive value of belief in allocation to the actual Healing Touch group, and found that belief predicted beneficial changes on the FACT-B scores, but belief did not predict changes on the Multidimensional Fatigue Symptom Inventory short form or on the Center for Epidemiological Studies Depression scale. In summary, the findings of this present study and those of Cook et al (2004), Schnepfer (2009), and Jain et al (2011) all clearly demonstrate that it is possible to design and execute a believable mimic or mock version of Healing Touch to use as a placebo comparator, thus achieving the most robust comparison for maximising internal validity.

### ***Satisfaction with treatment***

In this present study, both the Healing Touch group and the Placebo group were equally and highly satisfied with the length of treatment sessions and the number of treatment sessions. Jain et al (2011) also found that the mock and healing groups did not differ significantly on other aspects of treatment, such as their ratings of the friendliness of the practitioner, their feeling of connection with the practitioner, or their feeling that the treatment was helping them. Conversely, Post-White, Kinney, Savik, Gau, Wilcox and Lerner (2003) in their study of 164 cancer patients reported that both the massage group and the HT group rated the overall helpfulness of the provider and their satisfaction with the treatments more highly than those who received the control condition or the presence only treatment ( $p < 0.0001$ ). However, overall satisfaction with care was similar between the two intervention and between the two control conditions ( $p = 0.43$ ). The findings of this present study and those of Jain et al (2011) concur, and suggest that study participants can still be satisfied, even with a placebo intervention, meaning it is a feasible choice for an active comparator and it does not unduly disadvantage those participants who are randomly allocated in to the placebo comparator group.

## **Summary of this present study's findings as compared to the prior body of evidence**

When the findings in this present study on primary outcome measures, secondary outcome measures and ancillary analyses are compared to the body of evidence in the literature for Healing Touch, there are some areas of congruence, but also many areas of contradiction. The one clear consensus in the body of evidence seems to be the lack of any statistically significant findings to indicate that Healing Touch groups fare more poorly than their comparator groups on those outcome measures tested to date. In nearly all of the studies reviewed, benefits of Healing Touch are not clearly and consistently demonstrated across the multiple outcome measures used for each study. Rather, as in this present study, some outcome measures demonstrate a statistically significant difference for within group comparisons and/or for between group comparisons, while the same intervention protocol used on the same participants in the same study produces statistically non-significant results on other outcome measures.

The evidence-based paradigm searches for consistent findings within each methodologically robust study, as well as consistent findings across multiple robust studies (DiCenso, Guyatt & Ciliska, 2005). The body of evidence for Healing Touch as an intervention consists primarily of conflicting evidence, much of which is obtained from studies from the lower tiers of the evidence hierarchy, as detailed in Table 1 in the original literature review in Chapter Two, and Table 62 at the beginning of Chapter Five categorising the updated literature. In addition, in Appendix E, a final Table 63 is presented which combines both the older and newer studies together to form a comprehensive table of all the literature to date as of 2012, again in the evidence-based hierarchy.

While there are also a number of RCTs at the Level II tier of the hierarchy, most of them compare Healing Touch to standard care or to another active comparator that is equally unsupported by a strong evidence base, rather than comparing Healing Touch to a placebo (see Table 1 and Table 62, as referred to above). Placebo-controlled RCTs represent the pinnacle of methodological rigour for testing the efficacy of an intervention by removing the substantial threats to internal validity posed by the placebo effect, thereby maximising the confidence of a research consumer that the intervention itself is the factor responsible for any distinctive differences observed between the two comparison groups (DiCenso, Guyatt & Ciliska, 2005; NHMRC, 2009).

Four studies represent a notable exception to this trend of conducting research about Healing Touch with substantial limitations in design, even for those studies that enjoy a place at the Level II tier of RCTs. In addition to the one published placebo-controlled RCT discovered during the original literature review (Cook, et al, 2004), a further three randomised placebo-controlled trials were located during the update of the literature undertaken in 2012, all of which were other doctoral dissertations (Taylor, 2008; Schnepfer, 2009; Jain, 2009; Jain et al, 2011) conducted contemporaneously with this present study, only two of which have been published in the peer reviewed literature (Jain et al, 2011; Schnepfer, 2010). Although Taylor (2008) found no differences between Healing Touch and mock healing touch in her small pilot study of 17 patients, the other three randomised placebo-controlled trials enjoyed reasonable sample sizes and found beneficial effects on one or more of the outcomes that were measured in their chosen populations (Cook et al ,2004; Jain, 2009; Jain et al 2011; Schnepfer, 2009;

Schnepper, 2010;), while at the same time failing to find statistically significant between-group differences on many of the other outcomes that were measured.

This same mixed pattern was also found in this present study, of statistically significant findings for functional health, but only for the strata of participants in retirement villages; and statistically significant findings for social support, but only for the strata of participants living in ordinary residential neighbourhoods.

Healing Touch may have a beneficial effect for selected older adult populations on selected health dimensions, depending on their area of deficit. Retirement village residents often relocate into that supported setting in response to anticipated or actual declines in functional health, so they may thus experience their beneficial response to Healing Touch in the functional health dimension. On the other hand, social isolation is less of a concern in retirement village settings, where numerous structured and supported social opportunities exist, but social isolation can be an area of concern for older adults in residential neighbourhoods, and hence this latter stratum experienced their beneficial effect from Healing Touch for the social health dimension. Energy therapies posit that humans are multidimensional energy systems, and that energy therapies will selectively and preferentially impact the client in their area of need, with different clients experiencing different benefits, as occurred with this sample (Bradford, 1993; Brennan, 1987; Gerber, 2001; Hover-Kramer, 2002; Hutchison, 1999; Mentgen, 2001; Oschman, 2000; Wardell & Mentgen, 1999).

The lack of statistically significant findings for a beneficial effect of Healing Touch on the rest of the outcome measures for both strata in this present study provides an interesting contrast to earlier research, particularly for vital signs and psychological well being, both of which enjoyed some modest support from multiple RCTs. Further research using a robust placebo-controlled RCT design will be needed to reconcile the discrepancies observed above between the findings of this present study and the findings from other studies designed to test the efficacy of Healing Touch as a nursing intervention.

## **The Contribution of the present study to increased methodological rigor in Healing Touch research**

### **Use of the Randomised Controlled Trial as a study design**

The body of research regarding Healing Touch shows a mixture of anecdotal, case study, expert opinion, qualitative research, and quantitative research, including the subset of quantitative research represented by the RCT approach. In keeping with the holistic perspective of our clients, the need to also use a holistic perspective to view the intervention of Healing Touch as well must be acknowledged. No one method of inquiry will reveal all the answers. The research community and the Healing Touch community both need to recognize the validity and necessity of viewing the intervention of Healing Touch from multiple perspectives in order to build an increasingly accurate model of its many facets and how they combine to create the whole experience of receiving Healing Touch treatments. While each method of study has a distinct purpose and a valid contribution to make, the RCT both enjoys and is burdened by its central role within the evidence-based paradigm (DiCenso, Guyatt & Ciliska, 2005; NHMRC, 2009). Health care professionals and consumers alike, not to mention government policy makers, all turn to the RCT as the gold standard for the hard decisions about which interventions are safe, effective, and worth funding. Health care insurers, be they privately funded or government sponsored, look to the evidence an RCT can provide to

justify the addition of reimbursement benefits for complementary therapies like Healing Touch.

The totality of the experience of both giving and receiving Healing Touch and the variety and complexity of the beneficial effects noted by participants often inspire researchers to respect and embrace the richness of the data that can be obtained through qualitative traditions such as phenomenology and grounded theory. However, the RCT, while only capable of illuminating a portion of that complexity, can still be pressed in to service to expand the knowledge base and further deepen our understanding about if, when and how Healing Touch can be of benefit to our clients. The requirement of an RCT is to accurately represent and quantify some aspect of the benefits that clients may receive and then compare those benefits between two groups: those receiving Healing Touch and those who do not receive it. The logic of this comparison is intuitively appealing, and indeed the finding in this study was that participants were immediately accepting of the necessity of two comparison groups, even as they were in the next breath expressing their hope to be one of the ones who was fortunate enough to receive the Healing Touch allocation rather than the placebo allocation. An open-ended question at the end of each session and a semi-structured interview after the series of treatments were complete, were both used to incorporate an embedded qualitative component that would provide the study participants with an opportunity to expand on their personal experience of receiving a Healing Touch treatment, and their responses will be analysed and reported at a later time. However, client testimonials alone will not address the many threats to internal validity that are present for those study designs from the lower rungs of the evidence hierarchy (DiCenso, Guyatt & Ciliska, 2005; NHMRC, 2009; Walach, Jonas, & Lewith, 2002). Therefore, verbal reports of beneficial changes by participants are not sufficient to empower policy and reimbursement changes, changes that may be progressed more effectively by evidence garnered from the RCT design. Providing a piece of robust evidence at a level that commands respect in the EBP paradigm to which policy-makers and health care insurers refer, was a key goal in choosing such a design for this present study. The qualitative research about Healing Touch provides a wealth of knowledge about possible benefits to draw from in choosing an outcome to quantify and measure within the framework of an RCT. The complexity of the lived experience of receiving a Healing Touch treatment can never be fully represented within the confines of an RCT, but a well chosen aspect of the treatment's beneficial effect for clients can and should still be demonstrable in a group to group comparison. Despite the philosophical and pragmatic concerns often voiced by practitioners of complementary therapies, the conduct of the present study is a testament to the fact that it is indeed possible to design and execute a methodologically rigorous RCT, even when the intervention being tested is a richly holistic complementary therapy. The embedded qualitative approach available in a mixed methods design (Creswell & Plano Clark, 2007) may represent the closest symbolic representation of a holistic perspective available to the complementary therapy researcher, and should continue to be used to complement the discoveries afforded by an RCT.

### **Choice of comparison group**

The literature review undertaken prior to the design of the present study revealed that a number of methodological concerns existed in the body of research to date. The first concern is the choice of a comparison group. Some researchers compared Healing Touch against standard care only, which did not address the threat to internal validity of the placebo effect. Other researchers, in a concerted attempt to address the criticism that any beneficial effects noted were due only to the placebo effect, designed a comparison group that experienced some other intervention, rather than comparing Healing Touch to standard care only. These comparison interventions were usually presented by the researchers as a proxy for a placebo

group. While these designs were a commendable attempt to address the placebo effect for researchers who had concerns about using a placebo version of Healing Touch, they in fact only addressed the Hawthorne effect (Polit & Beck, 2006) which overlaps with the placebo effect in that both rely on the component of increased attention and the formation of a therapeutic alliance with the provider of the active comparator. However, the participants in all of these 'placebo proxy' active comparators groups were still aware that they did not in fact receive the preferred intervention of interest, i.e. Healing Touch, and so they would have no expectation of benefit accruing to them from receiving Healing Touch, and such an expectation is a key component of the placebo effect (Murcott, 2005).

In addition, these placebo proxy interventions introduced a different design concern. In all these cases, comparison of the Healing Touch treatment group against these other interventions would only allow the researchers to comment on whether or not HT was equally or more effective than the other interventions, many of which did not enjoy a pre-existing solid evidence base for efficacy themselves. Methodologically speaking, the ideal comparison group is a credible but inert placebo (DeCenso, Guyatt & Ciliska, 2005), which only one of the randomised controlled trials found during the literature review undertaken in the planning phase of this present study, succeeded in executing (Cook, et al, 2004). Therefore, the use of a placebo proxy group helped to address the threat to internal validity of the Hawthorne effect, while still not addressing the threat to internal validity posed by the placebo effect. In all of the above designs, even though the participants were getting 'something' more than standard care done to them, they also knew that the 'something' they were getting was NOT Healing Touch, meaning they could no longer have an expectation of receiving the benefits they might have believed that Healing Touch could provide, and expectation of treatment-specific benefit is a critical feature in activating the placebo effect (Murcott, 2005).

## **The use of a placebo comparator**

The successful implementation of a credible but inert placebo to mimic the active intervention of Healing Touch, distinguishes this present study from most of the previously executed research regarding the efficacy of Healing Touch. A placebo comparison is the most stringent comparison (DeCenso, Guyatt & Ciliska, 2005; NHMRC, 2009). Without a placebo comparator, study participants who are randomised in to the true intervention group are able to know that they have achieved that preferential allocation, and any beneficial effects observed for the Healing Touch group will be influenced to some extent by that knowledge. Distinctions in outcome measures between the Healing Touch group and standard care or an active comparator will be due at least in part to that powerful placebo effect, which is comprised of three components: an expectation of benefit due to being allocated the intervention of interest instead of the standard care group or active comparator group; the effect of conditioning, including contextual cues in the setting or procedure; and the formation of a therapeutic alliance (Murcott, 2005). These three components are present for all participants who are actually receiving the intervention of interest (Healing Touch group), or who believe they are receiving the intervention of interest (credible placebo).

However, the strength of a placebo-controlled design is that any observed distinction between the Healing Touch group and the placebo group can now more confidently be attributed to the effect of the Healing Touch intervention itself, over and above any beneficial influence from the placebo components of expectation of benefit, therapeutic alliance and conditioning, all of

which are present in both groups when participants are convinced they are receiving the intervention of interest rather than the placebo. These considerations make the placebo-controlled trial design one of much stronger internal validity, i.e. consumers of research can be more confident that the beneficial effects observed in the Healing Touch group are likely to be due to Healing Touch itself and not just due to a placebo effect.

By the same token, the placebo-controlled design also sets a higher standard to be met in order to reach statistical significance, as the large component of the placebo effect that contributed to the observed improvements has now been incorporated into both groups, and thus is exerting its influence in both groups. Therefore, the intervention itself must contribute a strong enough influence on its own, over and above the placebo influence, in order to result in detectable differences between treatment groups at a statistically significant level. The use of a credible placebo in this present study may have resulted in a considerable placebo effect, making statistically significant differences between the Healing Touch group and the placebo comparison group more difficult to detect than has been the case in prior RCTS that used standard care or alternative interventions as the comparators. While a placebo comparator is a clear methodological strength, it is also a distinctive feature in this present study that has not been present in most of the prior research, and thus may contribute to the incongruity between the numerous outcome measures that at least some of the prior RCTS seemed to indicate would be beneficially influenced by Healing Touch (i.e. psychological well-being and vital signs), and the absence of a statistically significant finding for those outcome measures in this present study.

### **Credibility of the Placebo treatment**

A methodological concern often reported in the Healing Touch literature concerns the ability to devise a method to create a believable placebo or mimic version of a Healing Touch treatment. To fully address the threat to internal validity of the placebo effect, the placebo must be executed in such a way that the study participants believe they are receiving the experimental intervention rather than only receiving a placebo (Murcott, 2005). The components of the placebo effect have been identified (Murcott, 2005) as the expectation of a beneficial effect, the conditioned response, and the therapeutic alliance, as introduced above. If the participants become aware and/ or convinced that they are not in fact receiving the experimental intervention, they will cease to expect to receive a beneficial effect, which can negate the conditioned response and may also lead to some resentment against the provider of the placebo treatment, thus damaging the therapeutic alliance. Thus the credibility of the placebo being used is a key design feature to preserve the methodological benefits of its use, which was clearly achieved in this present study. The proportion of participants who in fact did receive the placebo, but believed they were receiving the actual Healing Touch treatment, was reassuringly high (70.7% in the Placebo group), indicating a high credibility factor for the placebo as it was delivered in this present study. Statistical significance testing was performed to test for a difference between the proportion of convinced participants in both treatment groups, and it revealed that the proportion of participants holding that belief was essentially similar in both groups (75.6% in the Healing Touch group,  $p = 0.566$ ).

### ***Consistency of Treatment Provider between Placebo and Healing Touch groups***

Another successful design decision to preserve credibility of the placebo intervention in this present study concerned the treatment provider. By having the PI provide the placebo treatments as well as the Healing Touch treatments, one very substantial threat to blinding of the participants was removed, that of identification by the participant of their group allocation. If the placebo provider is a different person, it is more likely that the participant will guess which provider is administering which intervention. If the same provider treats both treatment groups, the provider identity is a constant, removing a potential confounding variable, while also refraining from contributing potential information to aid the participant in guessing their group allocation. In addition, the consistency of the same treatment provider across the full series of treatments and for all participants in the study removed another threat to internal validity. If a variety of providers had been used, as has been the case in many prior Healing Touch studies, there is less confidence in adherence to the treatment protocol, for the Healing Touch group, but almost more importantly, for the placebo group.

Slater (1996) reported a number of enlightening considerations in her detailed description of the protocols used by the placebo providers in her single group, multiple condition study. The placebo providers, who were strategically chosen and screened to ensure they were untrained in Healing Touch techniques, all gave a number of treatments to the same clients. The concern was expressed that for some of them, they began unconsciously and intuitively to attune to the clients over the series of numerous sham treatments they were providing. Given that all humans are purported to have the capacity to learn and perform energetic modalities (Bradford, 1993; Brennan, 1987; Gerber, 2001; Hover-Kramer, 2002; Hutchison, 1999; Mentgen, 2001; Oschman, 2000; Wardell & Mentgen, 1999) and appear to do so fairly rapidly within the first few hours of Healing Touch classes (Hover-Kramer, 2002), it is possible that at least some of the placebo providers were experientially increasing their skills as they progressed through the study protocol. Slater (1996) reported that some of the placebo providers began to attune, sense energy, and move their hands intuitively to hold them over or directly on energetically active locations on the participants' body. Slater (1996) reported the later discovery of this phenomenon occurring, as well as a later disclosure by some of the placebo providers that although untrained in Healing Touch itself, they had been exposed to other similar energy healing modalities. Taking all these concerns together, Slater (1996) did not feel confident that the placebo treatment provided was consistently an inert intervention. In the present study, the design decision was made to use a trained Healing Touch provider, the PI, who knew the nature and importance of attuning to the client and facilitating energy flow, and so could immediately recognise any tendency towards attunement with the participant or towards the facilitation of energy flow, and thus could actively and deliberately ensure that neither process occurred during the placebo treatments.

### ***Method of blinding: The use of a sleeping mask***

Another closely related methodological concern is the issue of blinding the participants to their group allocation. In the present study, the use of a sleeping mask prevented the participants from observing the PI performing the treatment. If they had been allowed to observe, they would have seen actual direct touch or indirect touch occurring in genuine HT treatments, versus seeing the actions performed in the placebo version of Healing Touch: the use of the filled gloves being placed on body locations that are not major or minor chakras in

order to simulate direct touch, or the movements of the laminated hard stock booklets like a fan above the body as a method to simulate indirect touch. The use of a lightweight paper sheet over the top of the body also prevented the participants from sensing the leather texture of the filled gloves, which may have allowed them to identify the texture as not being the skin of the practitioner's hand.

A further aspect of the blinding of participants that was successful in this present study relates to the participants prior experiences with energy modalities. Participants who had previously been exposed to a Healing Touch session would be aware of the types of hand movements to expect and the physical and emotional sensations they were likely to experience. The geographical location of the investigator was a regional city of approximately 190,000 residents, where there had not previously been any training classes conducted in Healing Touch, and where there were no Healing Touch practitioners running a private practice delivering Healing Touch sessions. Thus the population in this area were highly unlikely to have had personal experience receiving a Healing Touch treatment. In addition, during phone screening, potential participants were asked about their prior experiences with Healing Touch and other related energy modalities, and they were excluded from the study if they had recent and frequent energy treatments, or had specifically experienced one or more Healing Touch treatments. This level of naivety to the process and effects of Healing Touch treatments also contributed to successful blinding of the participants.

### ***Placebo procedure did not restrict the use of the full range of Healing Touch techniques***

The only other RCT that used a placebo that was found during the initial literature review to inform the design of this present study, (Cook et al, 2004) accomplished blinding through the use of a vertical opaque screen at the level of the client's neck, which meant that no hand positions above the neck were used, which represents a substantial limitation in the breadth of treatment techniques available in the Healing Touch curriculum. Either those HT techniques that include hand positions on the neck or head were not used at all in their treatment protocols, and/or the techniques were used in a modified version, with the steps requiring those hand positions around the head and neck being eliminated. By contrast, in this present study, the use of the sleeping mask, ear plugs, and top sheet as methods of preserving blinding did not require elimination of any of the head/neck hand positions for those clients receiving the experimental intervention of actual Healing Touch.

Three other more recent studies found during the update of the literature in 2012 after the conclusion of the intervention and data collection/analysis phases, demonstrated alternative methods of providing a placebo. Two of these (Schnepper, 2009 & Taylor, 2008) restricted the Healing Touch practitioners to only using off-the-body techniques as a method to preserve blinding; while the third (Jain et al., 2011) used direct tactile contact by both the energy practitioners and by the placebo practitioners. In the first two studies, the full range of techniques available in Healing Touch were severely curtailed, potentially reducing the effectiveness of the Healing Touch intervention, similar to the concerns described above for the Cook et al study (2004). Conversely, in the Jain et al study (2011), the use of direct contact occurring at the same hand positions on the participant's body as would be used in a true treatment, even by untrained practitioners, introduced a strong possibility of actually influencing the participant's energy field, particularly as the placebo providers gained experience in sensing or directing energy flow over their repeated mock treatments during the

course of the study. Therefore the Jain et al (2011) study may have inadvertently increased the effectiveness of the placebo intervention, making it difficult to be confident that theirs was in fact an inert placebo, while the placebo procedure in the other three studies (Cook et al, 2004; Shnepper, 2009; Taylor, 2008) required the usual range of Healing Touch techniques to be substantially curtailed, thereby potentially reducing the effectiveness of the Healing Touch intervention.

Both of these potential pitfalls of enacting a placebo were avoided in this present study, with nearly the full range of Healing Touch techniques still being available for use at the practitioner's discretion according to her assessment of the participant's needs, and with the inert status of the placebo being assured by the use of a trained Healing Touch provider who was aware of the possibility and committed to ensuring that an energetic exchange did not occur, and who refrained from any actual tactile contact with the participants in the placebo group during the treatment sessions through use of the filled gloves placed on top of the sheet on body locations that were not minor or major energy centers.

### **Ability to provide authentic Healing Touch treatments while remaining within the parameters required for an RCT treatment protocol**

The treatment protocol was deliberately and carefully designed to minimise any modifications that would detract from the authenticity of a typical Healing Touch treatment session.

#### ***Timing***

Timing of the treatment session itself was recorded so that later data analysis could explore if treatments remained within the protocol parameters, and were equivalent between treatment groups. Recording this potential variable was seen as a more appropriate approach than being overly restrictive about timing of sessions. However, as has been previously discussed in Chapter Four, the results revealed that the protocol was adhered to in both treatment groups.

The treatment protocol included a range for the treatment time, from 20-40 minutes, with an expected average of 30 minutes. This flexibility allowed the PI to complete all the required steps in the techniques chosen for that week's session without having to end abruptly or prematurely due to time constraints. An intuitive sense that the energy flow has balanced and stabilised in a given location on the client's body is the signal that guides the practitioner to move her hands onward to the next location in the sequence for that technique (Hover-Kramer, 2002). After completion of the steps in a technique, the PI would then note the time and usually find that it had been near to 30 minutes anyway, and conclude the treatment. If however, sufficient additional time was remaining, a short technique with a smaller number of hand positions would then be chosen. Practical timing concerns are authentic to a Healing Touch treatment by a private practitioner in the community, due to the necessity of concluding a treatment in order to be available for the next scheduled client.

#### ***Range of techniques used***

The literature review revealed that some of the Healing Touch practitioners felt frustrated by the parameters of the research protocol, not just due to time constraints, but also particularly due to the available range of techniques (Slater, 1996; Taylor, B. 2001; Wardell et al., 2006). In authentic Healing Touch treatments, practitioners have at their disposal all of the HT

techniques for which they have received training, and can choose amongst them to match the one that best addresses the client's current concerns and the practitioner's assessment of the client's energy field. In the research protocol, an energetic assessment was performed both before and after the treatment, in keeping with a typical HT session, and the assessment was used to guide the choice of techniques, again in keeping with a typical HT session.

The 35 usual Healing Touch techniques were able to be used in the study. However, for three of the techniques, they were used with minor modifications to positioning or to 1-2 of the steps in the techniques, as described earlier in the Methods chapter. All of the other steps (sometimes as many as two dozen hand positions) within all of the other techniques were still able to be performed as per an authentic Healing Touch session outside of a research protocol. Thus the Healing Touch treatments within the research study would be very nearly identical to the treatments a client might receive in private practice.

In conclusion, other than the minor adaptations described above, the Healing Touch treatments delivered to participants in the study were congruent with treatments they might have experienced in a private Healing Touch practice, and represent an authentic reproduction of the intervention of Healing Touch as taught and practiced in the community.

### **Use of CONSORT guidelines in study design and reporting**

The CONSORT guidelines (Hopewell et al., 2008a; Hopewell et al., 2008b; Moher et al., 2001) were consulted prior to the design of the study, and informed by these best practice parameters of research, as many controls as possible were introduced, to maximise internal validity. In addition, the CONSORT guidelines were also consulted in the preparation of the dissertation, to maximise transparency of reporting, which allows the consumer of research to critically appraise the methods and findings before applying them in their own practice. Similarly, registration of the trial also allowed for public dissemination of protocol details, again promoting judicious application of evidence to practice, but also enabling future replication in systematic programs of research, and the potential for meta-analyses in future systematic reviews.

#### **TRIAL REGISTRATION:**

Australian New Zealand Clinical Trial Registry Number ACTRN12612000788875.

World Health Organisation Universal Trial Number is 1111-1132-2783.

### **Control of potential confounding variables:**

A cumulative measure of the burden of co-morbidity such as the CCI was not reported as either an outcome measure or a confounding variable in the studies that were found and discussed in the initial literature review preparatory to the design and implementation of this present study. The addition of this measure adds another useful control to the design of the present study, as does the collection of numerous demographic characteristics, two of which in fact were revealed to be substantially different at baseline between the two treatment groups, despite random allocation to treatment arms.

## **Adequate sample size and power for the primary outcome measure**

As discussed in more detail in the literature review, many of the earlier quantitative studies about Healing Touch either did not perform a power analysis and sample size calculation, or perhaps performed it but did not report it. Alternatively, as described well in MacIntyre et al (2008), a power analysis was done, but the required sample size was not achieved.

In the present study, early collaboration with a statistical consultant addressed this deficiency, and an appropriate power analysis was performed, as described in detail in Chapter Three. In addition, the conduct of a pilot study enabled the early identification of recruitment challenges that might delay the completion of the full study beyond the time constraints of a student PhD process. Therefore, additional recruitment processes were deployed to ensure that the required sample size was achieved, including adapting new methods and networks and revising the inclusion/exclusion criteria to be more lenient.

## **Statistical analysis**

The use of a statistical consultant to advise, direct and then double-check all processes and calculations performed by the Principal Investigator, while still blinded to treatment group condition, is a major strength in the present study, enabling the data analysis to address and rectify some of the statistically inappropriate processes that were noted in the literature review. For instance, some of the Healing Touch quantitative research previously performed, neglected to perform and/or to report a statistical analysis that compared the Healing Touch treatment group to the comparison group, even when two treatment groups were present. Instead the investigators reported a comparison within the groups, noting if the Healing Touch group's scores changed over time, and sometimes also noting if the comparison group's scores change over time. This statistical approach essentially reduced the group-to- group comparison study to the lesser methodological rigor of a single group before and after comparison study (NHMRC, 2009; Polit & Beck, 2006).

Similarly, some of the studies reviewed simply compared the post-intervention scores of the Healing Touch group against the post-intervention scores of the comparison group, without calculating a difference between the pre-intervention and post-intervention scores. A more appropriate and precise analysis would be to compare the amount and direction of change in the Healing Touch group with the amount and direction of change in the comparison group, as has been done in the present study. This method of analysis thus takes in to account the influence of the baseline scores on the later scores within each group, and therefore removes a potential confounding variable.

## **Other Successful Methodological Design Decisions**

### ***Choice of population: Older adults***

Investigators may balk at the choice of older adults as the focus of research, with concerns that they will have high attrition rates, cognitive decline, or co-morbidities that prevent them from completing the intervention and/or the data collection. However, the decision to focus on older adults for this present study was a fortunate and successful one. Many of them cited altruistic reasons for their participation, and took their role as a participant very seriously, giving thoughtful consideration to the data collection questions and to the instructions given

to them during the enrolment process and at each treatment session briefing. They were reliable historians, experiencing very little cognitive decline over the full 8 months of the study. Western societies often project a paternalistic or patronising attitude towards older adults, but studies such as the present study empowered them to have their own voice, rather than family or health care providers defining their health status for them. The stated aim of the study was to determine if Healing Touch could be a supportive intervention for them, and they expressed sincere appreciation for research that might shed light on ways they could promote their own health and independence.

Although availability was sometimes an issue for scheduling appointments for retirement village residents, who enjoyed a very active social calendar, in general the participants were very respectful of the RA's and PI's time, and kept appointments reliably or else conscientiously notified the research team of necessary changes. When the study design was described to them during the initial phone screening/enrolment conversation, the potential participants immediately grasped the logical need for a placebo comparison group, and were still eager to be involved, due to an altruistic attitude of seeing the benefit for the greater good from the findings of the study, even if they personally did not get to enjoy the possible benefits of being in the true intervention group. Lastly, data collection visits lasted at least 30 minutes, with over 100 questions being asked, but the participants were gracious about the length of the visit and the number of questions, and understood the importance of providing valid responses. The training of the RAs, and the criteria that they also be Registered Nurses, also worked well to support and encourage completion of data sets at each visit.

The use of a longitudinal study design with older adults was also successful, with the descriptive aspect of the data showing a picture of a relatively healthy sample who remained so over their 8 months in the study. These data contest the stereotype of the rapidly failing, cognitively declining, frail aged population. These are not study participants to be avoided as a methodological hurdle, but rather embraced as a valuable resource of reliable and conscientious participants with an altruistic desire to contribute to the creation of knowledge for the good of their peers and of future generations of older adults.

### ***Choice of recruitment methods and retention***

A related successful choice was that of recruitment methods. Given the early concern about potentially high attrition rates in a longitudinal design with an older adult sample, it was crucial to ensure that enrolment numbers were adequate. While all research projects have time constraints, they were particularly restrictive in the student context of completing a PhD, so recruitment needed to proceed expeditiously. Although indirect recruitment through other health care providers and health care facilities was envisioned as the most effective way to reach the desired population, in fact it was direct recruitment through older adults themselves that proved to be the most successful. Initial newspaper advertisements about the study generated direct queries from potential participants to the PI. Then word-of-mouth referrals from existing participants generated further enrolments. Again the picture is of independent, well connected older adults helping each other out by recommending a service they have been enjoying, rather than health care providers directing an older woman to get help here. Despite the lengthy treatment and data collection protocol, attrition was very low in this study, due in part to the enjoyable and convenient nature of the intervention, but also due to the tenacity and reliability of the participants in this sample. The intrinsic interest in complementary therapies by older adults was also a compelling force that assisted in

successful recruitment and retention, and is an understandable curiosity, given that conventional medicine cannot offer a cure for ageing.

### ***Choice of data collection methods and instruments***

The deployment of Registered Nurse/Research Assistants as data collectors was also a successful decision. Their pre-existing ability as nurses to establish rapport, enter a home respectfully, direct a conversation to a focused task, and achieve the required task without exhausting or distressing the participants were all vital skills to the success of the interviews. Questions were asked verbally by the RN/RA, who recorded the answers, thus avoiding the burden of writing, and circumventing any concerns with vision or dexterity, or low literacy levels. Family members were excluded from the conversation, with the interviews conducted in a separate room if a family member was in the home at the time of data collection. This approach established the autonomy of the participant and showed the respect of the research team for the participant's own voice. Data interference can occur with family members who may have a different and/or inaccurate perception of the participant's health status, and many of the questions on the social support and spiritual and psychological well being instruments were very personal. Although there can be recall errors and information bias in the self-report method of data collection, it fit the philosophical stance of supporting the empowerment of older adults, and achieved the aim of reliable and complete data.

### ***Choice of the home setting***

The final positive decision to be discussed was that of using the home setting for both data collection and intervention visits. Some older adults may have difficulty with transport, due to a reduced ability to drive themselves and/or financial concerns; and other Healing Touch studies have reported high attrition rates due to transport barriers (Wilkinson, 2004). The home setting was convenient, but also familiar and thus physically and emotionally comfortable for participants, and easily allowed for breaks in data collection if fatigue became apparent. For those with urge incontinence, easy availability to their own toileting facilities was also a comfort measure. Given the length of the treatment and data collection protocols, attrition was a concern, and making continued participation as convenient for the participants as possible was an important goal that was accomplished effectively by use of the home setting. Participants enjoyed having the company of a home visit, and expressed looking forward to their weekly treatment visit and to the return of the RN/RA for data collection, partly as a novel activity in their usual schedule. However, the stereotype of a lonely older adult desperate for company was clearly not reinforced, with many participants enjoying a more active social life than the research team members, thus making appointment scheduling sometimes quite challenging. But the participants did enjoy hosting the research team members, displaying a lovely mix of welcoming acceptance in to their homes, and simultaneous gratitude for someone taking the time and effort to visit them and provide a treatment. Knowing they would be having company also seemed to prompt a concerted effort to achieve a level of personal hygiene and household appearance, which could be a pleasure or a burden, depending on their health status. The home setting also provided the PI with the ability to make a more holistic assessment that included the home environment, particularly during the first visit with the full intake health history (see Appendix BB). Lastly, the warmth of a home setting was conducive to establishing rapport for data collection and to fostering the important provider/client relationship that is central to a holistic therapy such as Healing

Touch. Entering the home means entering the private space of the client, and can be symbolic of the energetic exchange that can occur in a Healing Touch treatment (Anderson & Taylor, 2011).

There were however some disadvantages to the home setting that had to be carefully managed. For instance, for professional boundaries and timing issues, the research team declined offers of refreshment to avoid burden or over-familiarity, and to avoid creating an increased effect of social desirability when answering questions. Information about the participant's usual doctor or General Practitioner (GP) and family member were obtained at enrolment, with permission to contact them if the research team arrived for a home visit and found the participant to be unwell and in need of assistance. Safety concerns were managed for issues of theft, vandalism, or car breakdown, with frequent communication and safety check-in phone calls between research team members, to ensure a safe return home from field work. Although the burden of transport was lifted from the participants, it was now an issue for the research team, with the home setting increasing costs for mileage reimbursement for the RA/RN, and donated mileage costs for the PI. Time for transport also reduced the number of treatment sessions that the PI could complete in a given day, making scheduling more restrictive and increasing the time frames for achieving the required sample size.

Lastly, careful management of the environment was necessary to achieve standardisation of the protocol trial. This included turning off potentially interfering noises such as a radio, phone or television; providing privacy for the participant's comfort but also to avoid unexpected disclosure of group allocation status to unexpected visiting family or neighbours; working around space constraints in smaller retirement villas or units; access for parking and carrying equipment (massage table, step stool, basket of pillows, locked briefcase of charts), in to the home, sometimes up stairs in the preferred design in Northern Australia of a Queenslander home on stilts; balancing temperature needs of the participant with environmental conditions such as fans, air conditioning, and closed curtains for privacy; and negotiating in the first briefing that the treatment will not be stopped to accommodate visitors at the door, but rather they will be politely sent away to return after the treatment concludes and/or a message will be taken for the participant. These environmental management precautions could be interpreted as intrusive by the participants, and may have contributed to a self-selection bias, with women who were uncomfortable having a visitor in their home, (particularly while they were resting and often asleep, and with a sleeping mask in place), may have prevented some potential participants from joining or continuing the study. However, only a few participants lost interest in participation when these conditions were explained during the initial phone screening conversation.

## **Limitations of the present study**

### **The use of a convenience sample and a self-selection bias**

The ideal sampling method to ensure accurate representation of the population and thus the highest degree of generalisability is best achieved by random sampling (Polit & Beck, 2006). However, for this present study, a variety of methods of recruitment were used in order to achieve the required sample size in a reasonable time frame for a PhD research project, resulting in a convenience sample. Once potential participants became aware of the study

through any one of these means, the next step required them to contact the PI for further information, screening and enrolment. This requirement for a certain level of participant initiative may have skewed the sample towards older women with higher levels of social skills, extroversion, comfort with communication technologies such as voicemail, and/or a philosophical openness to complementary therapies. Another consideration was the frequent success of snowball recruitment techniques, which may have also introduced a bias, with a higher likelihood for participants who were part of an active social network to hear of the study through those word of mouth referrals. Thus one limitation of this present study was the use of convenience sampling with its potential for a self-selection bias.

However, the variety of recruitment techniques, including interviews on the local ABC radio station and advertisements in the local paid newspaper and the local free community newspaper served to further widen the possible participant pool to include the community at large. In addition, communication through a variety of health care services, community groups and churches were used for opportunistic recruitment, and the use of this variety of methods in itself served to diversify the participant pool.

Lastly, any sample bias would have been reasonably expected to similarly occur in both treatment groups, given the randomisation process used for treatment allocation. The strength of the RCT design is its reliance on testing for the relative difference between the two treatment groups, both of whom were drawn from the same (potentially biased) sample. So while convenience sampling may limit generalisability to a wider population (i.e. external validity), it does not undermine the ability of the RCT to detect between-group differences (internal validity).

## **Sample Size Concerns**

Although appropriate sample size calculations were performed for the primary outcome measure and subsequent recruitment reached the targeted enrolment number, not all of the secondary outcome measures included in this present study were used to calculate sample size, so the power of this present study may not be adequate to detect distinctions between the two treatment groups on these secondary outcome measures and ancillary analyses. These concerns were further aggravated by the need to perform stratified analysis, which effectively reduced the sample size in each strata, particularly for the smaller retirement village strata ( $n = 52$ ). Sample size calculations based on the primary outcome measure recommended 70 participants per treatment group to detect clinically and statistically significant changes over the six month follow-up period for functional health. However, even in the larger strata of participants living in houses or units in ordinary residential neighbourhoods ( $n = 101$ ), comparisons were required to be restricted to smaller treatment groups ( $n = 54$  for placebo group and  $n = 47$  for the Healing Touch group), with yet again even smaller numbers in the retirement village strata ( $n = 21$  for Placebo and  $n = 31$  for Healing Touch). These unforeseen requirements for stratification may have rendered the study underpowered to detect distinctions between treatment groups, even for the primary outcome measure. Careful targeting during recruitment to achieve as homogenous of a sample as possible is one preventative measure to avoid this inadvertent reduction in sample size due to necessary stratification related to the unexpected finding of disproportionate demographic features at baseline between treatment groups, despite the use of randomisation in to treatment groups. Performing sample size calculations for all intended

secondary outcome measures would also provide some protection against this sample size concern.

## **Multiplicity of testing**

A high number of tests for statistical significance were performed in this study, which can increase the likelihood of finding statistically significant differences between treatment groups due to chance alone, rather than due to a true distinction between the two treatment groups (Polit & Beck, 2006). The design of this research study capitalised on the methodological strengths inherent in a randomised controlled trial, while still preserving the holistic integrity of the complementary therapy being used for the intervention, that of Healing Touch. Many of the health dimensions that were measured as secondary outcome measures have a direct or indirect influence on the client's ability to perform their ADLs and thus maintain their current level of functional health and residence in the community. This multidimensional approach is also consistent with the theoretical premise of how energy therapies can impact on the client's health status, with the potential to improve their physical health, emotional health, intellectual health, spiritual health, or some combination of these health dimensions, depending on the client's current health status and goals for treatment (Brennan, 1987; Hover-Kramer, 2002). A multi-dimensional approach to health assessment, particularly for the older adult, is also encouraged by the World Health Organisation (as cited in Kaplan, 1985) and is consistent with their holistic definition of health. However, these design decisions to include a number of health dimensions as secondary outcome measures did result in a multiplicity of statistical significance testing, which can extend the risk of obtaining spurious results of  $p$  values less than 0.05, simply as a function of the quantity of comparisons being made (Polit & Beck, 2006). This limitation is acknowledged in this present study. However, multiplicity of testing was considered an acceptable concession in order to accurately and adequately capture the proximate contributing factors to functional health for older adults. If sample size calculations had been adjusted for all outcome measures to be treated as primary hypotheses, the prohibitively substantial increase in the required sample size would have precluded the conduct of the study within the constraints of time and funding present in the context of PhD student research. A Bonferroni adjustment for multiple testing retrospectively was not conducted, and the interpretation and applicability of the evidence overall is left to the discretion of each practitioner in regards to their own practice situation.

## **Information bias**

The use of self-reporting of data introduced a potential for information bias, if participants did not accurately answer the questions or did not accurately represent their true health status on any given outcome measurement. The serial collection of MMSE data provided assurance that cognitive impairment did not contaminate the data, but an inability to objectively identify and report their own health status could have been a factor in data corruption. However, this information bias, if present, would again be expected to occur in similar proportions in both treatment groups, due to the random allocation process. The precautions described to ensure standardisation of data collection across all home visits by an RA blinded to group allocation should have been sufficient to prevent any systematic information bias in one treatment group versus another. Therefore, any resulting bias would be towards the null hypothesis, leading to an under-estimation of the effect of the Healing Touch intervention.

## **Protocol adherence for timing of data collection**

The use of Research Assistants who were blinded to group allocation to collect the primary outcome data, rather than having the data be collected by the same person providing the treatments, was a clear strength of the study, but this feature also increased the expense of the study and required the use of some latitude in protocol parameters for the timing of data collection. Given the low volume and wide dispersion of the timing of the data collection visits, it was not possible to hire a dedicated full time RA for this project. Hence some flexibility in the data collection protocol had to be available, in order for the same RA to fit in all the data collection around her other work commitments. Despite this constraint, most data collection happened within 2-4 days of the final treatment, and the timing was essentially similar for both treatment groups, with both showing a median number of 2 days from the last treatment session to the RA's Week 8 data collection visit ( $p = 0.976$ ). However, some participant's qualitative reports in other studies indicated the positive benefits of their Healing Touch treatment began to subside within hours (Wardell, et al., 2006) or within 1-5 days after receiving the treatment (Dowd et al., 2006), so this necessary latitude in the timing of the post-intervention data collection may have prevented the benefits of the intervention from being demonstrated, at least for the change from Week 0 to Week 8 for the between group comparisons. Nevertheless, the primary hypothesis related to the long term health maintenance effects of Healing Touch, which were equitably measured in both groups, at or near the protocol time frame of 180 days +/- 18 days from the last treatment session. The median number of days between the final treatment session and the six month follow-up measurement was 176 days (IQR 168, 189) in the Placebo group, and 183 days (IQR 171, 192) in the Healing Touch group ( $p = 0.087$ ).

## **Short time frame for observation of functional decline in a stable sample**

A substantial amount of functional decline was anticipated in this ageing sample by the six month follow-up data collection point (Week 33), but only a very modest amount of functional decline actually occurred. The decline was often so subtle as to not cause a change in the median, and examination of the IQRs and the minimum to maximum range was necessary to detect the direction of the change over time. While this is an encouraging trend to note for the participants involved, the subtlety of the functional decline in this stable sample over a relatively short follow-up period made distinctions between treatment groups on the anticipated measure of functional decline more difficult to detect. A longer follow-up period and/or a later, fourth data collection point might have more clearly captured the downward slope of a naturally occurring functional decline trajectory. However, the timing constraints of a student research project within a University context, with its attendant restrictions of completion time frames, argued against this design. Similarly, the potentially high attrition rates for an elderly population in a more lengthy longitudinal study were also a consideration in the decision to forego additional data collection over a longer time span.

## **Alignment between outcome measures and characteristics of the chosen sample**

A more traditional focus for most RCTs is to recruit participants who have already been diagnosed with a disease, medical condition or symptom, thus resulting in a more homogenous sample than that achieved in this present study (Polit & Beck, 2006). The outcome measure is usually then aligned specifically to the disease, condition or symptom that was used for the inclusion criteria, making a change in that dependent measure for that sample both more likely to occur and also more likely to be detected by the outcome measure being used.

In contrast, for this present RCT, the only 'condition' was actually an absence of a condition, i.e. an absence of functional decline at baseline, given that the study focused only on women who were still functionally independent enough to live in their own in houses, units or retirement villas. An expectation that the absent condition would then present itself during the short time frame of the study, for even some of the participants, may have constituted an imprecise alignment between the sample being studied and the outcome measure being used.

This consideration is of concern in all preventative health contexts, but a more stringent sampling criteria that resulted in a more homogenous sample of women already experiencing greater levels of functional decline might have demonstrated more substantial changes over time that could be detected more easily by the outcome measures being used, and consequently might have resulted in more distinctive patterns of change showing up as statistically significant differences between the two treatment groups. A related concern mentioned above is that a longer follow-up period of data collection might have elucidated the trajectory of functional decline more clearly and also allowed treatment group differences to become more evident. However, a longer observation period would have also increased costs and the risks of attrition, requiring an even larger sample size to be recruited, as a higher attrition rate would be expected for a more lengthy study period, particularly with an older sample.

## **Uptake of other related Complementary and Alternative Therapies**

A final potential limitation relates to the uptake of other complementary and alternative therapies (CATs) by participants during the course of this present study. Participants were not requested or required to forego any other types of complementary or alternative therapies during the course of the study, given the length of the study protocol in an ageing population who might develop other chronic conditions for which they would desire to promptly initiate CATs. However, data were collected to observe for any variation in the uptake of CATs between treatment groups, as a possible confounding variable, and the data did indicate a slightly higher but not statistically significantly higher uptake amongst the participants who were allocated to the Placebo treatment group. A more stringent control of potential confounding variables could have included a restriction on participating in other complementary therapies during the course of the study, but this restriction would need to be weighed against the ethical considerations of the lost opportunity for a potential benefit, and the high likelihood of non-compliance to such a restrictive condition.

## **Protocol constraints on the Healing Touch intervention**

### ***Dose of intervention***

The possibility of an inadequate dose as an explanatory factor for the largely non-significant findings in the present study must be acknowledged. Prior research using Healing Touch as an intervention has found selected outcome measures to differ at a statistically significant level either between treatment groups and/or within treatment groups. These statistically significant findings seem to occur in some of the prior research even for lower doses of Healing Touch than those used in the present study or for similar doses. However, protocol restrictions on the length of individual sessions, the number of sessions, or the frequency of sessions have been criticised by the Healing Touch practitioners providing treatments in prior research (Slater, 1996; Wardell, et al., 2006). Dowd et al (2006) found a statistically significant difference ( $p = 0.037$ ) between participants who had 1-5 sessions versus those who had 5 or more sessions, with the latter group scoring an average of 13.7 points higher on the Healing Touch Comfort Questionnaire (HTCQ), which has a range of 35-210. They used a convenience sample of participants already receiving Healing Touch in the community. They also found a statistically significant ( $p < 0.05$ ) correlation between the number of sessions and their HTCQ scores (Dowd et al, 2006), with a higher score correlating with a higher number of sessions up to 20 sessions, at which time the correlation levelled off. Besides the issue of the number of treatment sessions, the timing of sessions is also relevant. Of note, participants receiving weekly treatments in Wardell, Tan and Rintala's report of qualitative data (2008) described their pain relief from HT wearing off after 3-4 days, so a twice weekly treatment regimen such as that used in Jain et al (2011), which yielded statistically significant distinctions between biofield healing versus placebo on cortisol variability and on the sub-scale of general fatigue, might be the optimum timing interval for non-institutionalised clients.

A varying treatment regimen, based on the client's current situation, goals for treatment, and the energetic assessment findings of the practitioner, is more closely aligned with the actual practice of a Healing Touch practitioner, but is not compatible with the treatment protocol requirements of a controlled trial. A very high level of adherence to the treatment protocol was achieved in this present study, whereas it might not have been sustainable to attract and/or retain participants for a more intense and/or a more lengthy treatment regimen. Taken together, these considerations indicate that the possibility of an inadequate dose as an explanatory factor for the largely non-significant findings in the present study must be acknowledged but considered unlikely.

### ***Setting of intervention***

Although numerous design concerns were addressed in advance to ensure a high level of congruency between HT as practiced in the community and HT as delivered in this study protocol, those few concessions made to the research protocol may have restricted the effectiveness of the Healing Touch as delivered in the study and thus made it more difficult to detect a difference in treatment outcomes between the two comparator groups. For instance, in private practice, the Healing Touch practitioner can set up a treatment room with a specific pleasant ambience, including soft music, candles or aromatherapy, aesthetic furnishings or decorations, etc. However, in a research protocol, the use of music or aromatherapy introduces additional interventions besides the one being tested. Similarly, the use of the participant's home as the setting for treatment delivery ensured a convenient and

comfortable location for the participant, but restricted some of the opportunities to control and enhance the ambience. The use of a well-padded and comfortably wide massage table, as well as clean and soft linens, with feminine and colourful pillows for positioning, constituted the closest approximation within the research protocol to the aesthetically pleasing ambience of private practice rooms. However, great care was still taken in the home setting to remove sources of interruption or distraction, by turning off televisions, radios and phones; by closing windows to street noise; and by providing ear plugs to dampen (but not obliterate) sound. In addition, finding the best time in the participant's schedule and keeping to that time each week allowed the participant to ward off interruptions by advising neighbours and family that "Thursday afternoon is my Healing Touch session, so don't bother me" and many of them reported taking this precaution at their own initiative.

### ***Use of sleeping mask***

The use of the sleeping mask may also have altered the dynamics between the client and the practitioner, introducing an element of fear of the unknown ("what is she really doing?") and also restricting the possibility of unlimited and spontaneous eye contact during the treatment itself. Conversely, the sleeping mask may have strengthened the effect of both treatments, as it was presented as a means to encourage their sense of having permission to tune out the rest of the world and enjoy their session (see Appendix D) Pre-Treatment Session Briefing), with no obligation to monitor or respond to the environment during this segment of time, knowing that the PI was present and, in a sense, keeping watch over them.

So while the presence of the sleeping mask is not a typical feature in a Healing Touch session in the community, it was well accepted and tolerated by all but a handful of the clients. Many enjoyed it, and found that it blocked out overhead lighting or window glare, and that it prompted them to settle in and just receive whatever benefit they might experience from the session. The mask the participant had been using through their treatment series was donated to all participants at the final session, as it was not hygienic to attempt to disinfect and reuse it. Most participants eagerly accepted it for use at night or during airplane travel, and their acceptance was seen as an indication of their positive attitude towards it.

In most Healing Touch treatment sessions conducted in a private practice setting or health care facility, participants voluntarily close their eyes anyway, often straightaway upon lying down on the massage table. However, many clients will observe the practitioner doing the energetic assessment and some practitioners will then discuss their energetic findings with the client prior to beginning the treatment. Once the assessment and any related discussion is completed, participants tend to close their eyes for the rest of the treatment session, so the sleeping mask was seen as only a minor deviation from authentic practice.

### ***Sequence of intervention steps: Energetic assessment, discussion of assessment, and formulation of mutual goals***

One final minor difference between Healing Touch as delivered in the research protocol and Healing Touch as experienced in a private practice session involves two missed steps and a change in the usual sequence of steps. Common practice by most HT practitioners is to conduct a pre-treatment energetic assessment and then briefly discuss those findings with the client, before agreeing on mutual goals for the treatment session. The choice of treatment techniques is informed in part by the findings of the pre-treatment energetic assessment, in

concert with the client's stated goals for treatment. Once the Healing Touch treatment has been given, a post-treatment energetic assessment is also conducted and then discussed with the client.

In this research protocol, energetic assessments were still conducted for participants in the HT group (or simulated for participants in the placebo group), but only after the participant had been settled in and their sleeping mask applied. The energetic assessment still helped to inform the choice of technique for those participants in the Healing Touch group, as per usual practice. Prior to removal of the sleeping mask, the post-treatment energetic assessment (real or simulated) was performed.

The two steps of the discussion of energetic findings (before and after treatment) had to be deleted, as there were no energetic assessments done on the participants in the placebo group, to avoid any potential attunement to, or energy exchange with, the participant. Therefore, to preserve blinding, the two steps of the discussions of findings from the pre- and post-treatment energetic assessments were deleted for both treatment groups.

The lack of a discussion of the findings from the energetic assessment also affected the usual method of establishing mutual goals. Instead, goals were set in the same way with all participants in both groups (to preserve blinding), but this step was done prior to the energetic assessment (real or simulated), while the participant was still sitting up on the massage table, before lying down and being settled in with the positioning of pillows, and application of the sleeping mask and ear plugs. Goals were based upon the discussion of the update of the client's status over the past week, and on their 1-10 ratings of perceived physical, emotional, intellectual and spiritual health.

It is possible that the omission of the two discussions of energetic assessment findings and/or the altered sequence and process for the step of setting mutual goals might have slightly detracted from the full benefit of the Healing Touch treatments within this research protocol. Conversely, retaining the step of the setting of mutual goals even for the participants in the placebo group, may have increased the expectation of benefit for those participants, and that expectation is a key component of the placebo effect (Murcott, 2005). In addition, research regarding the placebo effect (Bartz, 2011) has demonstrated that the more elaborate the contextual aspects of the delivery of the placebo, the stronger the placebo's perceived beneficial effect. The net result of these deleted steps and altered sequences may have been to decrease the impact of the Healing Touch treatment and/or to increase the impact of the placebo treatment, thus serving to narrow the distinction between the two treatment groups, and perhaps making a distinction between the responses of the two treatment groups more difficult to detect, particularly in this relatively healthy sample of participants who were only observed for eight months.

## **Generalisability**

The inclusion criteria limited the study to women over 65 in the local regional city where the PI resided, meaning that great caution would be necessary before generalising the findings to any of the following populations: younger women; all males; people of Aboriginal and Torres Strait Island descent; Australians residing in rural, remote or metropolitan areas; residents of other countries besides Australia; people already experiencing cognitive decline; people with lower levels of health status; and people already living in residential aged care facilities.

Replication of the present study in the above mentioned locations or care settings, and/or with the above mentioned populations, preferably in a multi-site study, could be a useful approach to validate or contest these findings.

## **Recommendations**

### **Recommendations for policy**

As discussed in the Literature Review chapter and in this Discussion chapter, the evidence base for Healing Touch is intriguing but certainly not definitive. The evidence base will need to continue building before policy changes can be considered at a national level. However, the repeated findings of improvement in some selected outcome measures for selected populations in those RCTs that have been conducted, warrants governmental policy support for funding more rigorous studies. Robust research will clearly elucidate what role, if any, that complementary therapies may play in maintaining and promoting wellness among Australians of all ages, but particularly among the burgeoning population of older adults who are preferentially at risk for the onset of functional decline and the negative impact that it can impose on the patient, their family, their community, the health care industry, and government funding from local, state and national bodies. Healthy ageing is a national priority area, and as such warrants strong government support to further explore innovative, low risk, non-intrusive methods of possibly preventing functional decline, such as the modality of Healing Touch.

### **Recommendations for practice**

Registered Nurses have a professional obligation to become competent and discerning consumers of research, in order to more capably guide their clients through the maze of conflicting claims that abound for complementary therapies. The absence of any harms in the body of evidence to date may suggest that Healing Touch is an appropriate consideration, particularly for clients with conditions for which conventional medicine cannot offer a cure, such as chronic diseases, terminal conditions, and the ageing process. However, the research base does not warrant inappropriate promises of improvement to consumers, but at best a cautious consideration of Healing Touch as a non-invasive and potentially beneficial option, after careful consideration of the prior Healing Touch research that is specific for the client's particular condition.

Within the community of Healing Touch providers, sharing of practice decisions about dosing decisions regarding treatment regimens may assist in practice decisions as well as in the design of further research studies where robust comparisons are made between different dosing regimens. Older adults in particular often do not have large discretionary incomes, and dosing beyond that required to achieve an effective result would not represent a prudent use of their limited financial resources.

A final practice recommendation that may also be inferred from the findings in this present study relates to the potential benefits of home visits for older adults. This benefit may accrue from either a volunteer social visitation program by laypersons or a more structured intervention program by registered nurses conducting a health status check including a set of vital signs. The stability of functional status in this at-risk sample, even for the placebo group,

may be due in part to the increased attention and monitoring in their home setting through the friendly visitation provided by the PI/RN at the time of the placebo intervention.

## **Recommendations for future research**

The findings of this present study, as well as the methodological trials and triumphs encountered during the conduct of the study, give rise to the following recommendations for future research with the intervention of Healing Touch, many of which are also applicable to other non-pharmacological complementary therapies.

### ***Study Design***

The RCT is the most methodologically robust design to establish effectiveness of an intervention by maximising internal validity (DiCenso, Guyatt & Ciliska, 2005) and will provide the most compelling evidence to knowledgeable consumers of research, including health care facility administrators, government funding bodies and health care clients themselves. If the comparator group in an RCT is a placebo, methodological rigour is further improved. As this study has shown, it is possible to design and implement a credible yet inert placebo for Healing Touch, and future research should continue to use a randomised placebo-controlled trial design for other populations and outcome measures. The use of a sleeping mask provided a comfortable and acceptable method of blinding the participants to their group allocation. The use of the soft stuffed gloves to simulate direct tactile contact through a lightweight sheet was also a successful strategy for creating a credible placebo, and both of these strategies can be replicated in future placebo-controlled studies. A credible placebo requires blinding of the participants, but blinding of data collectors who are not involved in delivery of the intervention is also a key methodological strength to be included whenever staffing/funding permits. Similarly, the control aspect of a Randomised Controlled Trial can be better achieved if participants are instructed to refrain from other similar complementary therapies during the observation period of the study, and/or if their uptake of such therapies is queried and recorded as part of the data collection process.

### ***Sample chosen***

For future RCTs, the investigators should carefully control recruitment to ensure that the eventual participants demonstrate the outcome measure of interest at a marked level, and can be reasonably expected to experience a large amount of change on that measure as part of the natural progression of the condition being studied. Such an approach is far preferable in an RCT design than having to examine the data minutely in order to discover only subtle nuances of change. Thus an RCT requires a tight alignment between the instrument being used to measure the outcome measure of interest, and the characteristics of the sample chosen to display that outcome measure very clearly during the course of the study. In the present study, if baseline differences had not alerted the Principal Investigator to explore the sub-groups within the sample, two potential benefits of the intervention (social support and functional health) might have been obscured from view.

## ***Instruments***

The use of well-validated instruments also increases the methodological rigour of Healing Touch research, and the use of instruments across repeated studies will allow for meta-analyses in systematic reviews. A number of instruments measuring aspects of psychological or emotional well-being have already been used across one or more HT studies, and those should be preferentially considered for inclusion when designing future Healing Touch research. They include: Spielberger's State Trait Anxiety Inventory (STAI), the Center for Epidemiological Studies—Depression (CES-D), Profile of Mood States (POMS) and Functional Assessment of Cancer Therapy (FACT).

Instruments also need to be appropriate for the population being studied and the outcome of interest, to ensure that subtle changes over the time-limited protocol will be detectable. To that end, once appropriate instruments have been chosen, they should be used to calculate the sample size, not just for the primary outcome, but for other secondary outcomes being measured. Without sufficient power to detect a statistically significant change, the value of collecting data for numerous secondary outcomes measures is diminished considerably.

This matching or alignment between the sample's expected area of need and the use of an instrument which will reveal a change in their scores in that area of need, is a key design feature for a successful RCT. A related concern is that the instrument chosen needs to be one that has adequate sensitivity to detect the size of incremental changes that are likely to occur in the chosen sample within the time constraints of the research project. If an instrument can only detect large dramatic changes, then the usefulness of it in an RCT is highly compromised, since the requirement of an RCT is to demonstrate effectiveness by revealing statistically significant differences between treatment groups (Polit & Beck, 2006).

Lastly, the choice of instruments and the outcome measures that they are measuring also needs to be closely aligned to the expected benefits or effects of the intervention being tested. In the present study, prior research by Peck et al. (2007) on clients with arthritis, Cook et al., (2004) on clients receiving radiation and Ziembroski et al, 2003) on hospice clients, all led the PI to theorise that Healing Touch might also have a beneficial effect on physical functioning in an older adult population. The requirement to produce original research for the doctoral degree precludes a replication study, so a lateral move to consider either a new population and/or a new beneficial effect besides those previously studied required some element of supposition. However, in non-student research, replication of outcome measures, of instruments and/or of populations is highly advised, particularly to increase the opportunities for the RCT design to do its job of being able to detect statistically significant differences between treatment groups.

The specificity of the instrument to the sample is also important when considering the theoretical premise of energy therapies, which is that that they will work on various health dimensions, such as the physical, emotional, mental and spiritual aspects of health, depending on the current area of need for the client (Bradford, 1993; Brennan, 1987; Gerber, 2001; Hover-Kramer, 2002; Joy, 1979). The findings in the present study show that for the sub-group of participants living in homes in residential neighbourhoods, their benefits were experienced in the area of social support. This is consistent with a greater need for social connection in this sub-group, versus those living in a retirement village, a living arrangement which excels in providing numerous opportunities for social connectedness as part of its design and purpose. Previous literature has commented on the social isolation that can be experienced by older

adults living in the community (Chappell & Funk, 2010). Similarly, retirement village residents would be more likely to be experiencing a deficit in functional health, as that is often the precipitating factor in the decision to buy into a retirement village setting; and so that subgroup experienced a benefit for their specific area of need in this present study, that of functional health, while not demonstrating a concurrent improvement in social support.

### ***Self-report Data***

The use of self-report data allows the participant's voice to be valued, a hallmark of holistic philosophy, yet at the same time having that self-report data be collected via a validated instrument, honours both the holistic tradition and the research tradition. Self-report data via an established instrument can provide the subjective perspective of qualitative data while still providing the quantification needed for statistical testing. If further in-depth data is desired or required, the use of an embedded qualitative component within the RCT can address this need, without sacrificing the benefits of an RCT in meeting the criteria of the evidence-based paradigm. A mixture of quantitative and qualitative data may result in the most truly holistic representation of the intervention under investigation, allowing each form of data to provide its own unique perspective, the blending of which will better capture the gestalt of the phenomenon under study.

As demonstrated in this study, even with a vulnerable population of older adults who are at a somewhat higher risk for the onset of cognitive decline, reliable self-report data were obtained, and resulted in a complete data set for nearly all participants. Use of a screening instrument like the MMSE, as used in this present study, can further ensure data reliability, and identify cognitive decline if it does occur. Older adults may be excluded from research due to concerns of investigators regarding cognitive decline affecting data reliability, but the present study has shown that these concerns can be successfully addressed.

### ***Statistical Analysis and Reporting***

The RCT design has been used in a number of Healing Touch studies, but the statistical analysis that has been reported does not always take full advantage of the statistical rigour available in the design, instead choosing to report statistical analysis of within group comparisons rather than the preferable and more robust statistical analysis of between group comparisons. The appropriate choice of statistical testing to be performed varies considerably with the type of data collected and the type of comparisons intended by the study design. The purpose of an RCT is to enable parallel comparisons, and these should be conducted and reported, or the rigour of the design has not been utilised and valuable data have been wasted. A closer adherence to the CONSORT reporting guidelines, as recommended by Anderson and Taylor (2011) in their systematic review of Healing Touch research, would strengthen the credibility of Healing Touch studies within the research community, and would allow for closer scrutiny and greater confidence when clinicians are exploring the status of the evidence base for Healing Touch prior to applying it to their own practice.

### ***Replication studies***

While there has been some limited attempt in the body of evidence for Healing Touch to build on prior projects, through the use of similar populations, conditions or outcome measures, there have not been pure replication studies. This trend is due in part to the large preponderance of student research in the body of evidence for Healing Touch, with its

requirement for an original contribution to the field. A logical progression is to take the best of the RCT designs and replicate them in well-funded, larger scale trials, preferably multi-site trials. Studies that demonstrated promising evidence for the benefits of Healing Touch for a particular health dimension can be replicated with larger sample sizes, sophisticated statistical analysis, and full and transparent reporting.

Randomisation of sites could minimise the concern noted in this present study, where relatives and next-door neighbours were being randomised in to different treatment allocations, thus greatly increasing their likelihood of discussing the study together, comparing notes and discerning that they were in different treatment groups, and perhaps even discerning who was receiving which treatment. To avoid this detection of group status, each week the participants received a different technique, whether it was a different Healing Touch technique or a different placebo technique, and they were advised upon enrolment that this would be the case. However, in actual HT practice, a technique that was well suited to a client's situation or condition might be repeated in subsequent sessions, but this repetition was not available in the treatment protocol. Although this design feature was successful in avoiding detection of the placebo allocation, it may have also slightly limited the available benefit of the Healing Touch treatments for participants in the intervention group.

### ***Funding***

Access to substantial funding allows many of the ideal design features noted above to be implemented. Statistical consultants, Healing Touch treatment providers and blinded data collectors may not be available as volunteers, and the ability to hire appropriately qualified personnel into full time research positions enables tighter control of data collection time frames, and also ensures provider availability to complete the treatment protocol as it was designed, while also being able to offer a day and time that is convenient for the participants, which will greatly affect retention rates. In addition, dedicated Healing Touch providers might be able to provide treatments without the tight time limits that were required in order for the PI to deliver all interventions for the required sample size in this present study, since there were no other trained Healing Touch providers available in the regional city in which the study was conducted. In other locations, a number of providers may be available, and funding will enable them to focus on the research project rather than fitting in study patients around the requirements of their primary employment or their existing private Healing Touch practice.

The under-funding of Healing Touch research projects also results in numerous studies of small sample sizes that are under-powered to detect statistically significant differences, even if they do exist. However, many of the studies designated as pilot studies or for other reasons limited to working with small sample sizes, have still been able to demonstrate statistically significant benefits for the participants receiving Healing Touch, most commonly for within group comparisons (pre-test/post-test designs) of the HT group for 22 male patients with HIV (Wilkinson et al., 2002); 16 participants with low back pain (Weymouth, 1999); 14 male inpatients of a locked dementia unit (Wang & Hermann, 2006); 12 male spinal cord injury patients (Wardell, Rintala, Duan & Tan, 2006); 12 adult leukaemia inpatients (Danhauer et al., 2008); nine paediatric oncology outpatients (Kemper et al., 2009); and 20 nursing leaders (Tang et al., 2010).

However, these small sample sized studies even demonstrated statistically significant differences for some outcome measures on between group comparisons that contrasted the

HT group to the comparator group(s). These included a sample of 51 university nursing students (Taylor, B, 2001,) a sub-group of whom demonstrated better stress management; a sample of 62 female oncology patients receiving radiation (Cook, Guerrerio & Slater, 2004) for whom the Healing Touch group outperformed the placebo group on three sub-scales of the SF-36: pain, vitality and physical functioning; a sample of 37 women receiving radiation for early stage breast cancer, for whom the Healing Touch group demonstrated a statistically significant difference in their amount of improvement on the Functional Assessment of Cancer Therapy (FACT) General and FACT-Breast scale and the physical well-being sub-scale (Schnepper, 2009); a sample of 60 women receiving chemo-radiation for cervical cancer, for whom the Healing Touch group showed a greater decline in depression when compared to the standard care and relaxation therapy groups combined (Lutgendorf, et al, 2010); and a sample of 76 fatigued breast cancer survivors, for whom the Healing Touch group outperformed the mock healing group on decrease in cortisol slope, a measure of physiological stress and on the sub-scale of general fatigue from the Multidimensional Fatigue Symptom Inventory—short form (Jain et al, 2011).

These findings are enticing, and warrant further exploration with research that redresses the methodological concerns, including ensuring adequate power by the use of larger sample sizes. Unfortunately, it appears that the pilot studies rarely lead to a later, larger study by the same investigators or by other investigators, with the notable exception of the MANTRA I (Kricoff, et al., 2001; Seskevich et al, 2004) and MANTRA II studies (Krucoff et al., 2005). With such further research, hopefully a clearer picture will emerge of a distinctive pattern of consistently beneficial effects on most/all outcome measures within a given sample, which is replicated across most/all research studies of an exemplary methodological standard. Such a consistent pattern would be preferable to the current inconclusive body of evidence comprised of scattered findings of benefit demonstrated in some studies that are then contradicted by the statistically non-significant findings of other studies. However, the opposite consistency may begin to emerge---that Healing Touch cannot, in fact, be shown to clearly and consistently demonstrate statistically significant benefits for participants when scrutinized more closely by rigorous methodological designs such as the one employed in this present study. An ethical approach to integrity in research requires the consideration of either eventual conclusion. Researchers need to subject complementary therapies to the highest possible standards of scientific scrutiny within the constraints imposed by the reality of their contextual circumstances, with an ongoing intellectual curiosity to observe all discoveries as they emerge.

## **Chapter Summary**

This chapter began by contextualising the findings from this present study within the existing body of evidence located during both the original and the updated literature review. Both congruent and disparate findings were discussed, for each of the primary and secondary outcome measures, as well as for the ancillary analyses. Methodological strengths of this present study were then highlighted, given that they represent a number of incremental and distinctive improvements in contrast to the numerous design limitations noted in the studies reviewed in Chapter Two for the purpose of informing the design of this present study. The present study contributes a rigorously designed placebo-controlled RCT, only one other of which was located during the original literature review. The limitations of the present study

were then described, followed by brief recommendations for practice and policy and more substantial recommendations for future research. The findings of this present study indicate a potential for Healing Touch to improve both the functional ability and the social support of selected community-dwelling older women, thereby promoting healthy ageing, and potentially delaying or removing the need for the eventual placement in residential aged care facilities that can be necessitated by the onset of functional decline.

## Overview of Thesis

This dissertation began in Chapter One with a description of the significant issue of the rapid growth of the older adult segment of society, for whom the higher incidence of functional decline represents a risk to their continued quality of life. Healing Touch was discussed next, as a possible intervention that may assist older adults to prevent, delay or minimise functional decline. The history and philosophy of Healing Touch, as well as the established curriculum of techniques included in this nursing intervention were covered next. Chapter Two included a comprehensive literature review regarding prior research about Healing Touch, with a particular focus on quantitative studies that used the RCT design employed in this present study. Chapter Three detailed the specifics of the method used in this present study, a randomised placebo-controlled trial. Inclusion and exclusion criteria were used to define the desired sample, and recruitment methods were detailed. The instruments used for primary and secondary outcome measures were discussed next, and power and sample size calculations were performed based on the primary outcome instrument. Data collection methods and statistical analysis procedures were then described.

Chapter Four detailed the results of the statistical analysis, first providing descriptive statistics regarding the sample, and then detailing the statistical significance testing conducted between the Healing Touch group and the placebo. The two key findings from the research focused on the primary outcome measure of functional health and a secondary outcome measure of social support. A statistically significant difference was observed between the treatment groups for the stratum of participants living in retirement villages, with the Healing Touch group showing a clinically relevant improvement in their ability to perform Basic Activities of Daily Living, while the placebo group experienced a clinically relevant decline in those abilities. A statistically significant difference was also observed between the treatment groups for social support, but only for the stratum of participants living in houses or units in ordinary residential neighbourhoods. For those participants, the Healing Touch group showed an improvement in their levels of social support, while the placebo group experienced a decline in social support. Declines in functional health and in social support are both predictors of relocation to residential aged care facilities (Bharucha, et al., 2004). Therefore further exploration of the potential of Healing Touch to provide a buffering effect against the need for residential care placement is warranted.

Chapter Five discussed the findings of this present study in the context of findings from previous Healing Touch research, outlining congruencies and disparities between earlier research and the results obtained in the present study. The primary outcome measure identified in the research question as functional health was found to differ at a statistically significant level for the Healing Touch group as compared to the placebo group, but only for the stratum of those participants living in retirement villages. Participants in the Healing Touch group showed a clinically relevant improvement in their functional ability to perform

Basic Activities of Daily Living, while the participants in the placebo group showed a clinically relevant decline in their functional ability to perform Basic Activities of Daily Living. For Instrumental Activities of Daily Living, and for Total Activities of Daily Living, the two treatment groups were essentially similar, in both strata: clients living in retirement villages and clients living in houses or units in ordinary residential neighbourhoods. For all secondary outcome measures and ancillary analyses, the two treatment groups were similar, with one exception. The strata of clients living in ordinary neighbourhoods demonstrated a statistically significant difference between treatment groups, with the clients in the Healing Touch group showing an improvement in their levels of social support, while the clients in the placebo group showed a decline in their levels of social support. Differing benefits for differing participants is in keeping with the stated intention that is central to energy work, that treatment sessions are intended for the client's highest good (Hover-Kramer, 2002) which may entail changes to other aspects of health and well-being besides those chosen as outcome measures for this study.

Methodological strengths of the present study were discussed as a contribution to building the rigour of the evidence base for Healing Touch, but limitations were detailed as well. Chapter Five concluded with some brief recommendations for policy and practice, followed by some more substantial recommendations for future research about Healing Touch and other complementary therapies, based both upon the literature review undertaken in preparation for this present study, and based on the experiences of the Principal Investigator while conducting it. Some of the key methodological recommendations are summarised below. The importance of comparing a complementary therapy to a placebo, whenever possible, was stressed, and the feasibility of doing so was evidenced by the successful implementation of a placebo comparator in this present study. Additional recommendations for careful selection of outcome measures were made, specifically that they be well-validated instruments rather than investigator-created tools; that they reflect those treatment benefits noted in earlier qualitative studies regarding the intervention of interest; that they be specific to the population of interest; and that they be sufficiently sensitive as to detect a clinically relevant improvement over the time frame dictated by the circumstances of the research context. Earlier qualitative research should not only be consulted for outcome measures, but also be consulted for appropriate selection of populations from which to sample. Once outcome measures have been determined, statistical expertise should be sought to accurately determine and achieve the sample size required to ensure the study has sufficient power to observe the theorised improvements for the population and outcomes selected above. Funding should be aggressively sought to ensure studies achieve the required sample sizes, and to engage blinded third parties to function as unbiased data collectors and data entry personnel. Statistical consulting should again be utilised to ensure appropriate and accurate statistical analysis occurs, maximising the statistical power of the study's design. Comprehensive and transparent reporting of all methodological decisions, according to the CONSORT guidelines (Moher et al, 2010) should be undertaken. Such reporting, in concert with trial registry, enables both replication and meta-analyses to occur, which further enables the systematic construction of a robust evidence base for potentially valuable complementary therapies.

This present study was designed to further build and clarify the evidence base regarding the supportive, non-invasive complementary therapy of Healing Touch, by providing a methodologically rigorous placebo-controlled randomised trial that exemplifies the feasibility of the use of both the RCT design and the placebo comparison in complementary therapy

research. It is the hope of the Principal Investigator that ongoing robust research will allow Healing Touch and other potentially beneficial complementary therapies to make their appropriate contributions to the health and wellness of the communities that are served by all of the health care industry's practitioners and researchers.

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## **Appendices**

**APPENDIX A: 2012 UPDATE OF LITERATURE REVIEW**

## **Update of the Literature Review in 2012: An additional 14 studies**

The update of the literature review undertaken in 2012 resulted in locating an additional 14 research projects regarding Healing Touch. As discovered in the original literature review undertaken in 2008 to inform the design of this present study, the study designs used in these research projects spanned the full spectrum of the level of evidence hierarchy. Brief summaries of these studies will be presented below, again in the order of the levels of evidence hierarchy employed for this purpose in Chapter Two, in order to provide further reference to the reader in considering the contribution of these studies to the contextual background against which the findings of the present study were discussed in Chapter Five. In addition, the Evidence Table has been updated to include these additional studies at their appropriate level of evidence, as per Table 63 below. The process utilized in the updated literature review is also described in full below.

In early May of 2012, a comprehensive update of the literature was undertaken to contextualize the findings of this present study and in preparation for compiling the thesis for submission. The processes described for the original literature review were again used. In addition, a second professional organisation, Healing Touch Program, now also maintains a research bibliography on their website, which was also used for ancestry searching. In addition to an ongoing search alert on the Proquest database as described above, an overarching database entitled "One Search" available through the PI's university library was also accessed. The One Search database includes access to 92% of the James Cook University Library's electronic journal holdings, by querying multiple databases concurrently. The search parameters were the phrase "healing touch" as the search term, with no restrictions on date or subject terms, but restrictions were chosen for English language and for publication types: either journal articles or scholarly publications, including peer-reviewed publications.

This search resulted in 904 items, amongst which there were many sources using the term "healing touch" in a more general way than the specific nursing intervention being discussed in this dissertation. In addition, there were many duplicate entries, and many studies that had been previously identified in the literature searching done in 2008. Examination of the search results included screening the article titles, then reviewing the potentially relevant abstracts for applicability, and then obtaining and reviewing the full article, thesis or dissertation when possible.

A number of these search results were journal articles containing systematic, integrative or partial literature reviews of multiple energy therapies, including Healing Touch as one of many, in regards to their efficacy for specific symptoms, diagnoses or patient populations. Ancestry searching was performed on the reference lists of these review articles, to ensure no primary sources of relevant Healing Touch research had been neglected in the above processes. When the citation referred to the secondary source of an abstract in the biennially self-published Healing Touch International Research Survey, these studies were not included. Also not included were the few Healing Touch studies listed on the Clinical Trials.gov website, for which conduct of the study is ongoing or completed, but published information has not yet been made available.

**Table 63. Levels of Evidence mapped against all studies of Healing Touch, including those from the 2012 update**

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication,
<b>I</b>	<b>Systematic Review</b>	1	n/a	Anderson & Taylor, 2011
<b>II</b>	<b>Randomised controlled trial (RCT)</b>	22		
<b><u>Level II: RCT, Two parallel arm designs:</u></b>				
		11		
Healing Touch vs. Placebo		4	Healing Touch vs Placebo	Cook, Guerrero & Slater, 2004
			Healing Touch vs Placebo	Taylor, M., 2008
			Healing Touch vs Placebo	Schnepper, 2009
			Healing Touch vs Placebo vs Standard Care	Jain, 2009; Jain et al, 2011
Healing Touch vs. Standard Care		3	Healing touch vs Standard Care	Ziembroski, et al., 2003
			Healing touch vs Standard Care	Goldberg, 2011
			Healing touch vs Standard Care	Hardwick, Pulido & Adelson, 2012
Healing Touch & other CAMs vs. Standard care		1	Healing Touch , massage AND hypnosis vs standard care	Judson, et al., 2011
Healing Touch vs		3	HT with music playing vs. Rest with music playing	Taylor, B., 2001

Level and Descriptors	Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication,
An active comparator		HT vs Guided Progressive Relaxation	Wardell, Rintala, Duan & Tan, 2006
		HT vs. Being read to from Big Book of Alcoholics Anonymous	Dubrey, 2006
<b><u>Level II: RCT, three or more parallel arm designs</u></b>			
6			
Healing Touch vs. standard care (std) vs. active comparator(s)	5	Std or massage	Silva, 1996
		Std care or off-site prayer or imagery or stress relaxation	Krucoff, et al., 2001; Seskevich et al., 2004 (MANTRA I -- pilot)
		Std or acupuncture	Kaye, et al., 2003
		Std or prayer alone or MIT alone or both prayer & MIT (MIT = music, imagery and Healing Touch)	Krucoff et al., 2005 (MANTRA II)
		Std or visitor	MacIntyre et al., 2008
		Std or relaxation therapy	Lutgendorf, et al., 2010
Healing Touch vs. Two or more active comparators	1	Massage or Supportive visit	Rexilius, Mundt, Megel & Agrawal, 2002
<b><u>Level II: Crossover RCTs</u></b>			
3			
<b>Level II: Crossover RCTs</b>	1	Randomised in to either HT group or Wait list control group, who then went on to also have HT	Wheeler Robins, 1999

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication,
			next.	
		1	HT or Massage or Rest with presence (Also modified crossover: randomised in to 2 sequences: standard care then intervention vs intervention then standard care)	Post-White, et al., 2003
		1	HT or coaching or both or neither (i.e. standard care). Wait list control group, who then got either HT or coaching	Dowd, Kolcaba, Steiner & Fashinpaour, 2007
<b>III-1</b>	Pseudo-randomised controlled trial	1	HT vs Presence	Decker & Wardell, 2012; Wardell, Decker & Engebretson, 2012
<b>III-2</b> <b>Comparative study with concurrent controls</b>	Non-randomised experimental trial	2	HT vs Chiropractic	Weymouth, 1999
			HT vs Standard care	Wang & Hermann, 2006
	Cohort study	0		
	Case control study	0		
	Interrupted time series <b>with</b> a control group	0		
<b>III-3</b> <b>Comparative study without concurrent controls</b>	Historical control study	0		
	Two or more single arm study	0		
	Interrupted time series <b>without</b> a parallel control	0		

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication,
	group			
<b>IV</b> <b>Case series with either post-test or pre-test/post-test outcomes</b>	<b>IV-1 Case Series: pre-test/post-test</b>  10	1 group,	Randomised into different sequences of 3 sequential conditions: HT, sham HT & interview re their chronic pain.	Slater, 1996
		3 consecutive conditions	All had in same order: 1: Rest w/CHTP in room; 2: Healing Touch; 3, 4, 5, 6: Healing Touch with music & guided imagery	Wilkinson, 2002
		3	All had in same order: 1: Rest w/ RA at Univ. 2: Rest w/ CHTP @ her private practice room. 3, 4, 5, 6: Healing Touch @ CHTP's private practice room.	Wilkinson, 2004
		1 group,	Single group, All had Rest 1st, then HT condition 2nd.	Kemper et al., 2009
		2 sequential conditions	1	
		1 group, 1 condition	1 group, 1 condition (Healing Touch)	Darbonne & Fontenot, 1997
		6		Kemper et al., 2006
		Danhauer, et al., 2008		
		Maville, Bowen & Benham, 2008		
		Zimmer, Meier & Rolf,		

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication,
				2009
				Tang et al, 2010
	<b>IV-2 Case series: post-test only</b>	2	n/a	Collinge, Wentworth & Sabo, 2005
				Dowd et al., 2006
	<b>IV-3 Qualitative studies</b> (case series: post- test only, but collected data consists of textual data, not numeric data)	Refer below to Level V-3	n/a	
<b>V-1</b>	<b>Narrative Literature Review</b>	1	n/a	Wardell, et al. 2004
<b>V-2</b>	<b>Program evaluation reports</b>	13	Queens' Medical Center	Walker & Irvine, 1997
			The Toledo hospital, Toledo, Ohio	Villaire, 1999
			Naval Medical Center, San Diego, California	Hess, 1999
			Fairview Univ. Med Ctr & Queen's Hospital	Umbreit, 2000
			No. Hawaii Cmty Hosp	Becker, 2000
			Boca Raton Cmty Hosp, Boca Raton, FL	Chilton, 2001
			Scripps Center for Integrative Medicine, San Diego, California	Edelblute, 2003; Kiesling, 2004; King, 2005; Gazella, 2005; Mason, 2006
			Health East Care	Svensden & Bolles,

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication,
			System, Minnesota	2005
			Wake Forest Uni Baptist Med Ctr	Larrimore, 2006
			Grant Medical Center, Columbus, Ohio	Galewitz, 2007
			New York Univ Med Ctr	Rodrigues, 2007
			Suburban hospital, Bethesda, Maryland	Pierce, 2007
			Greenwich Hospital, Greenwich, Connecticut	Blanchet, 2008
V-3	Qualitative studies about <u>patients</u> receiving Healing Touch	11	n/a	Moreland, 1997
				Cristiano, 1997
				Holbrook, 1998
				Kelly, 1999
				Wardell, 2000
				Kopecki, 2001
				Tatsumura, 2003
				Van Aken, 2004; Van Aken & Taylor, 2010
				Peck, 2007
				Ka'oppua, Gotay & Boehm, 2007
Sutherland, et al., 2009				
V-3	Qualitative studies about <u>practitioners</u> of Healing Touch	7	n/a	Engebretson, 1996
				Geddes, 1999
				D'Eramo et al., 2001
				Wardell, 2001; Wardell & Engebretson, 2006

Level and Descriptors		Number of studies with Healing Touch as intervention	Comparator used, if applicable (group or condition)	Author(s) and year of publication,
				Weymouth, 2004
				Miller & Rudenick, 2006
				Sharoff, 2008
<b>V-4</b>	<b>Descriptive case reports of individual patient(s)</b>	12	n/a	Wetzel, 1993
				Ercums, 1998
				Chapman, 1998
				Umbreit, 2000
				Weber, 2003
				Slater, 2004
				Guarneri & King, 2005
				Burr, 2005
				Scandrett-Hibdon, 2005
				Kissinger & Kaczmarek, 2006
				Wardell, Rintala & Tan, 2008
Curtis et al., 2011				
<b>VI</b>	<b>Expert opinion</b>	5	n/a	Mentgen, 1996
				Wardell & Mentgen, 1999
				Mentgen, 2000
				McSweeney, 1999
				Kemper, 2004

## **Level V Evidence**

Two additional studies were located in the 2012 update of the literature review that qualify as Level V evidence. The first is a single case study report, Level V-4, while the second is a formal qualitative study, Level V-3.

Curtis, Tegeler, Burdette and Yosipovitch (2011) reported on a 25 year old male with severe traumatic brain injury and subsequent ischemic stroke 3 years ago, who presented with a six month history of central neuropathic itch. After 4 months of bi-weekly sessions of Healing Touch, the itch fully resolved.

Sutherland, Ritenbaugh, Kiley, Vuckovic and Elder (2009) used a qualitative approach to follow 13 patients with chronic headaches experiencing 3-6 Healing Touch treatments by a CHTP on a weekly basis at an outpatient Pain Clinic. Open ended interviews and a card sort of 37 phrases from question items of existing instruments in use at the Oregon Center for Complementary and Alternative medicine were used to elicit participant comments. Appropriate data analysis processes were used and reported. Findings included reports of a decrease in pain intensity by 12 of the 13 participants, and other improvements in pain-associated characteristics such as decreases in duration and/or frequency of pain, a decrease in use of pain meds and an improvement in relaxation and in sleep by some/most participants. An unexpected finding was the reporting of transformative changes including the quality of transformation and a different orientation towards oneself or towards one's life.

## **Level IV Evidence**

Four studies were found in the 2012 update of the literature review that used a case series pre/post-test design, thus qualifying as Level IV-1 evidence. Three of these studies gathered data before and after a single intervention condition of Healing Touch (Danhauer, 2008; Zimmer et al, 2009; Tang et al, 2010) while the fourth study used a slightly more complex design by collecting data after two sequential conditions, the second of which was Healing Touch (Kemper, et al 2009).

Danhauer et al (2008) used a case series pre/post- test design and administered three 30-minute treatments per week for 3 weeks to 12 inpatient adult leukemia patients in their hospital rooms, and used three established instruments, none of which showed statistically significant changes from pre-treatment series to post-treatment series: Profile of Mood States (POMS)-short form, the M.D. Anderson Symptom Inventory (MDASI), and the Women's Health Initiative Insomnia Rating Scale (WHIIRS). In contrast, single item symptom ratings for fatigue and nausea collected before and after selected individual treatment sessions did show statistically significant changes, while none were demonstrated for the other two measured symptoms of pain and overall distress. Positive responses were again noted in the limited qualitative data collected, including a request for longer and more frequent sessions from most participants.

Zimmer et al (2009) used a retrospective chart review of data collected clinically on 1,613 pediatric surgical clients (age 0-21 years). Participants received a treatment in the post-anesthesia unit by one of two CHTPs using a variety of techniques, using only the short term outcome measurements of a VAS for pain and one for comfort, ranked by the treatment provider based on observation. While this method introduces a high risk for bias, the large sample size is an unusual finding in the body of research for Healing Touch. Subgroups of

sleeping children, awake children (n = 455) and crying children (n = 115 for pain observations; n = 254 for comfort observations) were analysed separately. Statistically significant pre/post changes in a beneficial direction were found for pain and for comfort in the sub-group of awake children and in the sub-group of crying children, but not in the sub-group of sleeping children, who comprised the largest group (n = 889 for pain observations; n = 965 for comfort observations).

Tang et al (2010) evaluated 20 nursing leaders one to two weeks before and four weeks after attending a 17.5 hour intensive Level One weekend continuing education course. Unfortunately no established instruments were used, with outcome measures being 7 negative and 6 positive investigator-created Visual Analogue Scales (VAS) about mood states, and heart rate variability testing. Participants ranked the overall impact of the course as a three on a zero to four scale of no benefit to very beneficial impact. All 5 parameters measured in the heart rate variability testing showed statistically significant changes in a direction indicative of an increased sense of vitality and “an optimal physiological state associated with a sense of well-being” (McCraty, Atkinson, Tiller et al., as cited in Kemper et al, 2010, p. 840). Six of the 13 VAS scores showed statistically significant improvements: stress, depression, anxiety, relaxation, well-being and sleep.

Kemper et al (2009) used two sequential conditions for their study of nine paediatric oncology outpatients who had one condition of rest with presence for 20 minutes in the outpatient clinic, with outcome measurements pre-post condition; followed by a 20 minute session of a Chakra Connection on their next outpatient visit. Heart rate variability and VAS for stress, anxiety, depression, relaxation, vitality and overall well-being were measured, with statistically significant decreases found only in stress for the Healing Touch condition, while total power of heart rate variability was lower in the HT condition, indicating relaxation.

### **Level III Evidence**

Only two studies were located during the 2012 literature update that reflected Level III Evidence, given that they only used a pseudo-randomisation process. They will again be presented chronologically. The second one is particularly pertinent to the context of the findings of the present study, given the inclusion of a measure of Activities of Daily Living and the focus on an older adult population.

Goldberg (2011) used pseudo-randomisation (based on odd or even days of the week selected by the participants for their first appointment) to allocate women undergoing breast biopsy in to a Healing Touch group(n=42) and a standard care group (n=31) to study the effect of one 15 minute treatment session using the Magnetic Clearing technique administered by the PI with Level 4 training within the 30 minutes immediately prior to the breast biopsy procedure. Another Level 4 trained RN involved in data collection and recruitment remained in the room during the treatment and functioned as a scribe to record the PI's observations, and to hold the energy of the room.

Outcome measures included the Coping Resources Inventory and the STAI administered pre- and post- biopsy and the following day; and vital signs taken pre-and post-biopsy. The Coping Resources Inventory (CRI) has five sub-scales related to the “social, emotional, cognitive, physical and spiritual/philosophical aspects of how individuals experience stressors and how they cope with these life experiences” (p. 18).

Statistically significant between- group differences were noted for the emotional and spiritual/philosophical sub-scales and for the total CRI, as well as for both the State and Trait anxiety sub-scales. The Healing Touch group showed an improvement over time on emotional and spiritual/philosophical coping, as well as on the total CRI, while the standard care group declined on all three of these CRI measures. Trait anxiety declined in the HT group while increasing in the standard care group. State anxiety declined in both groups, but more so in the Healing Touch group. Vital signs also showed two statistically significant between-group differences, with blood pressure and respiratory rate declining in the HT group, while in the standard care group, blood pressure increased and respiratory rate was stable.

Decker and Wardell (2012) also used a pseudo-randomised design for their pilot study of 20 older adult residents of nursing homes or assisted-living facilities experiencing persistent pain. Healing Touch was compared to a Presence Care only intervention. Seven sessions of 30 minutes duration each were administered by a CHTP, three times per week, using any techniques at the discretion of the CHTP, with the most commonly utilized techniques being the Chakra Spread, Scudder and Pain Drain. As noted in other earlier studies, the CHTPs felt participants would have benefited from longer and/or more frequent sessions. Outcome measures included the Katz Index of Independence for Activities of Daily Living; the EuroQOL5 measure for quality of life; and two measures of pain: Verbal Descriptor Scale and an investigator-created observation-based instrument entitled the Pain Assessment tool in Cognitively Impaired Elders (PATCIE). No statistically significant differences in changes over time between treatment groups were observed on any of the outcome measures, including overall QOL score and the five sections of the EuroQoL 5 (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Descriptive statistics reported in tabular form without p values indicated a non-significant improvement in Katz ADL scores from 3.5 to 4.25 (scale from 0 to 6) for the Healing Touch group, as compared to a non-significant decline from 3.63 to 3.60 in the Presence Care group; a non-significant reduction in pain from pre to post-treatment series for both groups; a non-significant reduction in anxiety/depression for the Presence Care group; and a non-significant increase in anxiety/depression for the Healing Touch group. Qualitative results were later reported as well using a case study method (Wardell, Decker & Engebretson, 2012) with the main finding being the wide variation in participant response to Healing Touch treatments ranging from 'no perceived or noticeable benefit to a decrease in pain and improvement in other physiological and psychosocial symptoms.' (p. 194).

## **Level II Evidence**

Nearly half of the 14 newer studies (six) found during the literature update are situated at the Level II tier of evidence, which is an encouraging trend to see as the body of evidence builds in a more systematic way than was noted in the earlier years of researching Healing Touch. One study used a three parallel arm design (Lutgendorf, et al, 2010), by comparing Healing Touch to both standard care and to a relaxation therapy intervention. Four of the other five studies used a two arm parallel arm design. Judson et al (2011) and Hardwick et al (2012) compared Healing Touch to standard care. Of particular interest, three doctoral dissertations were located where Healing Touch was compared to a placebo version of Healing Touch (Taylor, 2008; Schnepfer, 2009; Jain, 2009). For Jain's study (2009) a third arm of standard care was also included. These final three additions to the evidence base of placebo-controlled trials join Cook et al (2004) and this present study in

reaching the pinnacle of the positivist paradigm in using an RCT to test the efficacy of an intervention against a placebo version of that intervention.

### **Level II Evidence: Healing Touch versus relaxation therapy and standard care (one study)**

Lutgendorf, Mullen-Houser, Russell, DeGeest, Jacobson, Hart, Bender, Anderson, Buekers, Goodheart, Antoni, Sood, Lubaroff (2010) used a 3 arm design in their study of 60 women receiving chemoradiation for cervical cancer. Participants were randomised to receive either standard care, Healing Touch, or a relaxation therapy in a series of on average 15 sessions (4 times per week) conducted immediately following their radiation treatment, during their 6 week course of chemoradiation. HT sessions were 20-30 minutes long, conducted predominantly by 2 CHTPs working as a team, and included the specific techniques of pain drain, chakra connection, magnetic unruffling and mind clearing, with other techniques added as time permitted and at the practitioners' discretion. Statistical analyses included "multilevel regression analyses to evaluate the effects of treatment condition, time and treatment by time interactions on dependent variables" (p.1234). One contrast compared relaxation therapy to standard care, while the other contrast compared Healing Touch to relaxation therapy and standard care combined. A further contrast between Healing Touch and relaxation therapy would have been a more rigorous comparison. Outcome measures included the CES-D, the POMS depression scale, the FACT quality of life instrument, the Fatigue Symptom Inventory (FSI) and natural killer cell cytotoxicity (NKCC). Neither fatigue or quality of life, nor red or white blood cell counts, demonstrated any statistically significant interactions. The between group comparisons done by the regression analyses described above showed that Healing Touch participants had a very minimal decrease in NKCC compared to marked decreases in the standard care and relaxation groups. HT participants also experienced a greater decrease in both measures of depressed mood (CES-D and POMS) than did the standard care and relaxation group. Within group comparisons showed that anxiety significantly decreased over time, but did so equally well in all treatment conditions.

### **Level II Evidence: Healing Touch versus Standard Care (Two studies)**

Judson et al (2011) studied women with ovarian cancer and compared the 22 women randomised into the standard care to the 18 women randomised into the integrative medicine group, (who received all of 3 modalities: Healing Touch, massage and hypnosis). The intervention group received multiple Healing Touch techniques including chakra connection, mind clearing and magnetic passes, tailored to their needs after an energy assessment was performed by the same CHTP, who was used for all treatments and all patients. The Healing Touch Sessions were 30 minutes long and occurred with each of 6 chemotherapy cycles, administered once every 3 weeks. Outcome measures included two quality of life questionnaires, the Functional Assessment of Cancer treatment—Ovarian (FACT-O) and the Mental Health Inventory (MHI), both administered prior to chemotherapy cycles 1, 3 and 6 and again 6 months after the chemotherapy treatment had been completed. There were no statistically significant differences between the control versus treatment arms at any time point. Anti-emetic use and immunologic profiles (CD4, CD8 and NK cell counts) also showed no statistically significant differences between treatment groups, although all 3 immunologic measures were higher for the integrative medicine group, but not statistically significantly higher. Sample size calculations were not performed in this feasibility study.

Hardwick, Pulido and Adelson (2012) used block randomisation to allocate 20 patients to the HT group and 21 to the standard care group in their study of patients undergoing bilateral total knee arthroplasty. The four Healing Touch treatments occurred immediately after surgery in the post anesthesia care unit, then daily in between their two physiotherapy treatments and approximately 2 hours after pain medication was given. Treatments were 30 minutes long, and administered by one of two CHTPs, although it is not stated if the patient-CHTP dyads were maintained over the course of the four sessions.

Outcome measures included range of motion and distance of ambulation as obtained from the physical therapist's notes; dose equivalent opioid analgesic consumption; a VAS for pain levels; the State-Trait Anxiety Inventory; and two investigator-created tools: the Global Assessment Questionnaire and a Patient Satisfaction Questionnaire. The T-anxiety measure was done once at baseline and found equivalence between the two treatment groups; the VAS and the S-Anxiety measures were done daily, before and after HT sessions; the GAQ on the day of discharge; and the PSQ at the routine 1 month postoperative clinic visit. There were a few non-significant trends that favoured the HT group (pain, anxiety, GAQ and PSQ) but no statistically significant differences between treatment groups were observed.

### **Level II Evidence: Healing Touch versus Placebo (Three studies)**

Taylor, M.A.(2008) used a randomised placebo-controlled design in her pilot study of 17 patients with hepatitis C receiving interferon and ribiviran to compare Healing Touch to a placebo version of Healing Touch. However, there were no statistically significant differences detected in her three outcome measures: the Centers for Epidemiological Studies Depression scale; the six item Schwartz Cancer Fatigue Scale measured weekly; and the 40 item Fatigue Impact Scale (FIS) measured before and after the full treatment series. The FIS included sub-scales for cognitive function, social function and physical function.

All participants were instructed to forfeit any other energy-based interventions during the period of the study, but their adherence to this request is not verified in the data collection procedures mentioned. All participants received the same scripted greeting and discharge communications at each visit and all treatments were performed in the same clinic room. Both the HT and the placebo sessions were 30 minutes long, with the treatment time lasting 15 minutes, once a week, for three weeks. Practitioner-patient dyads were maintained whenever possible throughout the series for both treatment groups.

The HT treatment consisted of the technique Magnetic Clearing. The two HT providers had completed a minimum of Level Three of Healing Touch training and had practiced HT consistently for a minimum of two years. The PI did not perform any treatments. The placebo treatment consisted of 15 minutes of hand movements distinctively different from the magnetic clearing technique above, which were performed on either side of the body, in a protocol designed by the PI who then trained the placebo providers. They were also instructed to mentally perform mathematical calculations, to avoid any inadvertent focus on the patient.

The three placebo providers were all RNs, but there were difficulties in both recruitment, with potential providers stating they felt a placebo intervention was unethical; and in retention, with placebo providers withdrawing and having to be replaced mid-study. The scripted information given to all participants included statements that they might find the intervention relaxing, and/or might experience a reduction in fatigue. This sets up the expectation of benefit, which is one of the key features of the placebo effect (Murcott, 2005),

thus strengthening the internal validity of this placebo controlled design. However, data collection was done by either the PI, the RA or one of two on site Nurse Practitioners, introducing a significant potential for poor inter-rater reliability. Questions on the tools were asked verbally, and the data collector recorded the participants' spoken response.

Schnepper (2009) also used a randomised placebo-controlled design for her doctoral research studying the Health Related Quality of Life (HRQOL) of 37 women receiving radiation therapy for early stage breast cancer at the renowned Mayo Clinic. This two parallel arm design also compared Healing Touch to a placebo version of Healing Touch. The instrument Functional Assessment of Cancer Therapy-Breast (FACT-B) consists of four sub-scales to assess the impact of the cancer on physical, emotional, social and functional well-being, which are summed to produce the FACT-general score; and an additional sub-scale with questions specific to breast cancer patients, which is added to the FACT-general score to create the FACT-B score. The FACT-general, the FACT-B and the physical well-being sub-scales demonstrated a statistically significant difference in the amount of improvement experienced by the Healing Touch group as compared to the placebo group.

All participants in the HT group received a non-touch version of two of the HT techniques available in the curriculum, the "Chakra Connection" and "Magnetic Clearing" which were performed in each of their 20-30 minute treatment sessions each week for 4-6 weeks. CHTPs were also allowed to direct energy to any other noted area of need, without direct contact, within the set time interval. The placebo treatment involved no contact on or over the body, but simply walking at the side of the massage table in a set pattern from head to foot with periodic stops, while mentally distracting themselves from a focus on the patient by either performing multiplication equations or reviewing the content from their nursing classes.

The placebo providers were given 1.5 hours of protocol training by the PI and performed a return demonstration of the placebo protocol on the PI to ensure consistent execution of the research protocol. The CHTPs also received one hour of protocol training from the PI. Placebo providers were two RN graduate assistants enrolled in a Master's of Nursing program and untrained in Healing Touch techniques, while the HT treatments were provided by three female RN Certified Healing Touch Practitioners, with a decade of experience beyond the certification process. Usually the same treatment provider was paired with the same participant each week.

Participant blinding was accomplished by the use of only non-contact versions of the chosen HT techniques; by participants' wearing a sleeping mask (eye shade) during treatment, as was done in the present study; by set scripts used by both placebo and HT providers for the minimal verbal interaction allowed with the participants; and by conducting the PI's protocol training sessions for both the placebo providers and the CHTPs in a private room at the clinic. Potential identification of the CHTPs who were known to the clinic staff may have prevented full co-provider blinding. Participant blinding was somewhat effective, with 44.5% of the placebo participants believing they had received an actual Healing Touch treatment, as compared to 78.9% of the HT group with the same belief. However, only 5.2% of the HT group felt they got the placebo, while 33.3% of the placebo group felt they had received the placebo, indicating a third of the placebo participants correctly guessed their group allocation. A slightly larger number of placebo participants (22.2%) than HT participants (15.8%) were uncertain which treatment they had received. This has implications for the ability of the placebo to function as intended, since the 33.3% of placebo

patients who correctly guessed they were in the placebo group would have none or lower expectations of benefit and/or might feel some resentment towards the provider. Expectation of benefit and therapeutic alliance could have both been negatively affected, and they are two of the key components of the power of the placebo effect (Murcott, 2005).

Jain, Pavlik, Distefan, Bruyere, Acer, Garcia, Coulter, Ives, Roesch, Jonas and Mills (2011) also used a randomised placebo-controlled design in their study on 76 fatigued breast cancer survivors for Jain's doctoral research, the final study to be discussed. However, they included a third arm of standard care as well. They assessed the effects on fatigue and cortisol variability for participants receiving either standard care, mock healing or "biofield healing." The mock and genuine treatments were 2/week for four weeks for a total of 8 sessions. Outcome measures included the Multidimensional Fatigue Symptom Inventory-- short form (MFSI-sf), the FACT-B, the CES-D and salivary cortisol levels.

These investigators do not label their intervention as Healing Touch, but do mention that the specific technique used in the research protocol (entitled "energy chelation") is one of the techniques included in the Healing Touch curriculum. The technique as taught and practiced in the Healing Touch curriculum is actually a combination of three other techniques (Hover-Kramer, 2002), sourced from Dr. Brugh Joy's technique entitled chakra connection, from Barbara Brennan's technique of energy chelation, and from the technique by the same name by Reverend Roslyn Bruyere (one of the co-authors for the Jain et al 2011 study). While the technique can then be reasonably assumed to be very similar to the technique of energy chelation as taught in the Healing Touch curriculum, the level of training of the providers is another notable distinction. Chelation is taught in Level 3 of the Healing Touch curriculum, the third of (3) two day intensive courses, with no set requirements for hours of practice in between the course levels, in contrast to the energy healing practitioners in Jain's doctoral research, who were all graduates of the Barbara Brennan four year energy healing training program (Jain, 2009). Despite those distinctions in the detail of the technique and level of the training of the treatment providers, the Jain et al (2011) study will still be included in this updated literature review, as it is one of only 4 placebo-controlled trials including one or more Healing Touch techniques as the experimental intervention.

The placebo protocol training by the PI included teaching the placebo providers the same correct hand placements and sequence as the true healing technique, in order to preserve participant's blinding to group allocation. However, as Slater (1996) noted, repeated physical contact may provide a learning curve that results in placebo providers beginning to energetically connect and attune to the clients and in fact be giving active treatments. This effect is even more likely given the permitted direct tactile contact over energetically active major and minor chakra centers. This is the only study reviewed where the placebo providers were allowed to actually have direct contact with the participants. While this contact would have served to better preserve blinding by more closely mimicking the actual healing intervention, it also introduced the possibility for an effect from tactile contact alone, due to incidental touch and/or comfort touch.

Findings of statistical significance in this study were also mixed, as they were in the other placebo-controlled studies by Cook et al (2004) and by Schnepfer (2009) and in this present study. HT performed as well as mock healing for some outcome measures and better than mock healing for other outcome measures. Cortisol slope significantly decreased for biofield healing versus mock healing and versus control. However, mock healing and biofield healing both performed equally well, but better than standard care, in decreasing

fatigue as measured by the overall MFSI-sf. When sub-scales were examined, further different patterns emerged. For the sub-scale of general fatigue, biofield healing decreased fatigue more than either mock healing or the control group did. For the other sub-scales, biofield healing did not perform statistically significantly better than mock healing in decreasing mental fatigue, emotional fatigue or physical fatigue, or in increasing vigour. However, biofield healing did perform better than the control group for the sub-scales of decreasing physical and emotional fatigue and increasing vigour.

These mixed findings across these three more recent placebo-controlled RCTs are similar to those found in this present study and in Cook et al (2004). The mixed findings underline the importance of the choice of a comparator group, and the substantial contributing effect that the components of the placebo effect exert in all active treatment groups: expectation of benefit, therapeutic alliance and contextual factors. All these components are also operating in the Healing Touch treatment group and therefore the differential effectiveness of the HT group over the placebo group is the most accurate measure of the influence contributed by the Healing Touch intervention itself, forming the basis of a compelling argument for the continued use of placebo-controlled trials.

### **Level 1 Evidence: Systematic Review of RCTs**

Only one systematic review was located in the updated literature review, conducted by Anderson and Taylor (2011). Using appropriately stringent quality criteria, they included only five of the RCTs, all of which have been discussed in either the original literature review (Krucoff et al., 2001; Post-White et al., 2003; cook et al., 2004 and Seskevich et al., 2004) or in the update literature review presented in this appendix (MacIntyre et al., 2008). Anderson and Taylor (2011) conclude their review with similar recommendations as those offered in this dissertation regarding using established instruments, conducting sample size calculations and achieving the targeted sample size. The variety of patient populations and outcome measures is also a drawback to the current body of evidence for Healing Touch, where later research has not always built upon populations, conditions and outcome measures used in prior research. A more systematic approach that is ideally seen in a strategic program of research would improve the evidence base for the use of Healing Touch by clarifying its efficacy in achieving specific outcomes for particular conditions and populations. Such systematic research involving similar outcomes and even similar instruments to measure them, would also improve the opportunities for replication and meta-analyses. Anderson and Taylor (2011) refer the reader to use of the Patient-Reported Outcomes Measurement Information System (PROMIS) website, which is based on the National Institutes of Health Roadmap Initiative, and can be accessed at <http://www.nihpromis.org/Web%20Pages/PSYCHO%20Metricians.aspx>

Stricter controls regarding the specific Healing Touch techniques used in the treatment protocol, and removal of concurrent modalities (i.e. music) were also suggested as ways to improve internal validity.

## **APPENDIX B: LIST OF HEALING TOUCH TECHNIQUES**



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## Healing Touch Techniques / Methods Worksheet

This worksheet allows HTP Apprentices to track techniques / methods they are using in their client practice. Level 5 Instructors look at 100 documented sessions to see if all Healing Touch curriculum methods have been incorporated during the apprenticeship period. Rate your confidence level ranking from 1 – 5, 1=low to 5=high. Each method should be checked off at least several times if not many.

Name \_\_\_\_\_

Level 1	Total	How Confident?
Centering, Grounding, Attuning, Setting Intention		
Magnetic Passes: Hands in Motion (HIM) & Hands Still (HS) done together as an intervention		
Magnetic Passes: (done separately)	////////////////////	////////////////////
Hands In Motion		
Hands Still		
Magnetic Clearing		
Chakra Connection		
Pain Management: //////////////////////	////////////////////	////////////////////
Ultra Sound		
Laser		
Pain Drain		
Pain Ridge		
Sealing a Wound		
Headache Techniques: //////////////////////	////////////////////	////////////////////
Tension Headache		
Sinus Headache		
Head Trauma		
Migraine Headache/Pain Spike		
Chakra Spread		
Mind Clearing (original)		
Scudder Technique		

Level 2	Total	How Confident?
Spiral Meditation – open/close		
Back Methods: //////////////////////	////////////////////	////////////////////
Lower Body Connect		
Opening Spinal Energy Flow		
Vertebral Spiral Technique		
Hopi Back Technique (4 steps)		

<b>Level 2 continued</b>	<b>Total</b>	<b>How Confident?</b>
CC with Body Centered Interview		
Modified Mind Clearing		

<b>Level 3</b>	<b>Total</b>	<b>How Confident ?</b>
Hara Alignment Meditation (Practitioner Prep) to include Hara Line, Open Chakras, and expansion of Core Star		
Chelation of 1 <sup>st</sup> Four Levels (preceded by Hara Alignment Meditation)		
Spinal Cleansing (2 steps x a minimum of 3 rounds)		
Additional Deep Cleansing Methods 		
Sandwich		
Double hand (cone)		
Scooping		
Fifth Level Interventions 		
Spiritual Surgery		
Etheric Template Clearing		
Lymphatic Clearing (Drain)		
6 <sup>th</sup> Level Intervention		
7 <sup>th</sup> Level Intervention		

<b>Level 4</b>	<b>Total</b>	<b>How Confident?</b>
Full Body Connection		
Etheric Vitality		

<b>Intake Interview (15 minimum required)</b>	<b>Total</b>	<b>How Confident?</b>
Intake Interview		

## **APPENDIX C: CENTERING MEDITATION SCRIPT**

A Protection Affirmation was done for all participants, placebo or experimental, setting an intention that the treatment session would be safe and comfortable for them, free of any interruption, injury or infection. The Centering Meditation, described below, was done *only* for the experimental group participants. However, for the placebo participants, the HTP continued to stand still in the same location for another 2-3 minutes after doing the Protection Affirmation, to mimic doing the full centering meditation, to preserve blinding of participants to their group allocation. She stood facing away from the placebo participant and silently made this statement of intent, based in part on the knowledge that all placebo participants would be offered a later sample session of a genuine Healing Touch treatment after the conclusion of the study: This session is intended for the highest good of the entire health care industry and all people they will serve. This is not her time, not now, not yet.

Healing Touch is not affiliated with any particular religious organisation, but rather embraces all spiritual traditions (Hover-Kramer, 2002; Hutchison, 1999). All HTPs are taught to use their own spiritual belief system as a supporting framework for the work they do in a Healing Touch session. While this particular protection affirmation and centering meditation reflects the Christian belief system of the Principal Investigator (Thomas, 1994), other HTPs might use different wording, concepts and/or imagery to accomplish the same task of becoming centred and aligned with their concept and name for a Life Source or Universal Energy Source or God. For participants who asked about this aspect of Healing Touch, a simplified explanation was given describing the HTP as drawing on that same life source that exists all around us in nature, which causes a wound to naturally knit itself back together or a seedling to sprout.

#### Protection Affirmation:

(While visualising their placement around the treatment area, facing away from the client):

“May the Archangels Michael, Gabriel & Raphael form a protective ring around us, to keep us safe from any harm, injury, infection, irritation, itching, or interruption; so that this time may be safe, comfortable and appealing for \_\_\_\_\_.”

#### Centering Meditation:

{During this meditation, the HTP continued to stand quietly with eyes closed and pictured the elements of nature described in the wording, and strove for a felt sense of connection with each of them in turn, as she progressed through the meditation. In addition, the HTP assumed certain body positions and/or used specific hand movements to energetically active areas (energy centres or chakras) on her own body, to accompany sections of the meditation. The visual images and elements of nature described in this meditation are combined and adapted from two different centering meditations found in the Healing Touch textbook: the Hara Alignment and the Core Star Expansion (Hover-Kramer, 2002).}

Standing, feet shoulder width apart, weight evenly distributed, arms straight at sides.

“From Mother Earth below.....through the soil, the water table around the globe, the solid bedrock of the earth’s crust, the living molten lava, the solid steel center.”

(Picture straight line from body through the many layers of the earth down in to the center, then wait for felt sensation of it spontaneously moving back upward through body as a line of light or pulse of energy.)

Hands moved to abdomen to cover the sacral chakra.

“From Father God above.....Lord of the lightning, the thunder, the wind and the rain, the sun, the moon and all the stars above.....bountiful, glorious, abundant, like Your lovingkindness, mercy, longsuffering, compassion, Your infinite healing light and love.”

(Picture a line of light from the vastness of the starry sky straight down through the center of the body right into the earth, all the way to the center of the earth. Body is aligned exactly on this line, hung from heaven, anchored in the earth)

“From Mother Earth below, and Father God above, through all of creation, please let Your healing flow.”

Move both hands on top of each other over the solar plexus chakra in center of body.

“Lord, we are not worthy to receive You, but only say the word, and we shall be healed.”

Hands spread apart, with fingers spaced open during next paragraph.

“Help me to step aside, out of the way, that nothing may interfere with the flow of Your love and healing through me, that I may be of service. Let me be a clear and wide open channel, that your love and light and healing may flow fully and freely through me to \_\_\_\_\_.”

Hands move to cover high heart chakra

“Please bless and sanctify this time for \_\_\_\_\_, that she may receive all that she needs to be fully restored to Your perfect health. We ask the healing angels to join us.” (Picture the 3 archangels turning inward while also being able to remain turned outward as guards, and any other healing angels as needed, coming closer to the massage table in assistance.)

“From my highest good, to \_\_\_\_\_’s highest good, please let Your healing flow.”

Hands remain over high heart chakra during ‘For my highest good’ then move to hands together in a cupped palm up position in front of HTP towards client as if offering a gift, during ‘to \_\_\_\_\_’s highest good’ and ending with hands spread out to side, with open palms facing client on massage table during ‘please let Your healing flow.’

Open eyes, approach client lying on massage table and begin assessment of energy system.

**APPENDIX D: PRE-TREATMENT SESSION BRIEFINGS**

## **(Full version for First Session only)**

This briefing was conducted after the Intake History had been completed, while both the HTP and the participant were still seated comfortably at a dining room table or in the lounge. If the participant interrupted with questions, those were addressed at that time, and then the HTP returned to the sequence of the briefing script below.

“Thank you for all your helpful answers. That Intake History will be a foundation we can refer back to over the next few weeks as we are working together. Now I want to give you an overview of what will happen in each session. First of all, I will bring in all the equipment as I did today (pointing to massage table, basket of pillows, step stool and rolling pilot-style briefcase), and I also have a clean set of linen that I will label with your participant code number, and bring back each week to use just for you. From here on out, nothing will have your name on it, just your participant code number, sort of like a spy number like James Bond being 007 😊.

From next week onward, I will set up the equipment as soon as I arrive. But we will chat together as I’m doing that, so you can tell me how your week has been, how you’ve been feeling, what’s on your mind that you might want me to address in today’s session, etc. But today we have already done that very thoroughly in our Intake History, so we’ll be able to move on to the next step.

Once I have set up the massage table and made it up with your specific linen, then we’ll have you slip off your shoes and then use the little step stool and I’ll help you up onto the massage table, just sitting to begin with. While you’re sitting up, I’ll ask you the same four short health rating questions each week, but we’ve already done those for today while we were sitting here comfortably in the lounge (or dining room). Next I will take your temperature, your pulse rate for a full minute, listening on your chest wall directly, and last I will take your blood pressure.

Once we’ve finished the health ratings and the vital signs, then I’ll help you to lie down, either on your back or stomach, and I’ll arrange the pillows to be sure that your back is well aligned and each part of your body is fully supported and comfortable. It’s very important that you’re comfortable, so we might play around a bit with the different pillows I have, to be sure we’re using the right ones for you. I want you to speak up if you would like a softer or harder pillow, or one that is flatter or taller. If you are lying on your back, I’ll also put a pillow under your knees, which supports your back and keeps it well aligned.

Then I’ll cover you with just a light weight sheet for privacy and comfort. Once you’re settled in, then I’ll do a short version of this briefing we’re doing now. For today I’m explaining everything very thoroughly for you, but once you’ve had your first treatment, you’ll know how it all works, and we’ll only do a short version of this briefing.

After the briefing, I will apply your ear plugs, which won’t block out all the noise, but will at least mute it, so that if there is traffic noise outside, or if your neighbour is playing their TV or radio loudly, that noise won’t disturb your session. Also in your linen pack, I have for you your own personal sleeping mask, so that if there is a bright light on the ceiling over head, or bright sunlight coming in the window, we can block all that out for you. So we are creating your own little cosy cocoon where nothing will interfere with your being able to fully relax and enjoy being pampered during your session.

Once you are comfortably settled on the massage table, then I will step aside for a few minutes and do a deep breathing exercise and a little meditation, just to get myself in the right frame of mind for doing this kind of work. I find this is an important step, and if I don't do it well, then the work we are doing together may not be as effective. But I always like to let my patients know that that is what I'm doing, so you don't think I've left and gone to McDonalds for a cappuchino! ☺ It will take me a few minutes to get myself centred and then I will come back to the table where you are lying and begin an assessment of your energy system, and make some notes to myself of that assessment, which helps me to do a good job of choosing which one of the 35 techniques in Healing Touch will be the best fit for you today. After the assessment, I'll get all my Healing Touch books out of the briefcase and look at the possibilities before I make a final choice of what technique to do this week. Then I'll do the technique itself, which takes about 30 minutes.

Healing Touch is actually a collection of 35 different techniques, so we will probably do a different technique each week, just to give you a sense of the variety available within the Healing Touch repertoire. Some of the techniques use direct touch, and some of them use INdirect touch, and some techniques use both direct and indirect touch on different locations on the body, so I'll describe each of those for you. With direct touch I am gently placing one or both of my hands in very specific locations, (demonstrating with my right hand on my own upper left arm) in a certain sequence. It is very gentle, not a rough or kneading motion like in massage, but just a soft gentle touch, sometimes not even felt by clients. I'll hold my hands in each position for anywhere from a minute to sometimes as long as 5 minutes or more. The length of time may vary from one location to another, but when it feels right, I'll move on to the next location on your body, and the next and then next, until I've gone through all the steps in that technique. Some techniques have just a few locations, while other techniques may have more steps and locations.

With INdirect touch, my hands are placed above the skin, either holding still or in a soft sweeping motion, during which some clients report feeling gentle air movement, like a soft breeze, but again, other clients may not feel any sensation (again demonstrating with my right hand on my own upper left arm). Depending on the technique or the location on your body, I'll use either direct or indirect touch. For instance, over your chest or groin area, I will always use INdirect touch, just so that it is not awkward or uncomfortable for you.

After I finish all the steps for whatever technique we are doing today, then I'll re-assess your energy system and again make some notes to myself. Then I will do something called grounding, as you may be very relaxed and a little floaty by then and we need to bring your feet back down here on the ground with the rest of us. ☺ Usually I'll ground you by using direct touch, but with a firmer pressure, on your legs and/or feet, 2-3 times. It will feel different than the other types of touch I'll be using in the treatment, so it is also a bit of a cue to let you know we're finishing up. But I don't want you to sit up right away, so I'll give you a few minutes to come to full alertness, while I begin cleaning up a bit, putting some of the books away, etc. But I'll be keeping an eye on you, and when I have determined that you are ready, I'll come to the head of the table and tell you that we are finished. Then I'll remove the ear plugs for you, and then I'll remove your sleeping mask. When you are ready, and there's no rush at all, take your time, I will help you to sit up. Then we'll do your temperature, pulse and blood pressure again, and we'll do the four short questions again. Then I'll help you down the step stool off the massage table, pack up my gear, and return your lounge to its former glory! ☺

Now the last thing we need to talk about is interruptions. Most people become very relaxed during a Healing Touch session, and so it is important that we try to avoid interruptions. There are usually 3 we need to worry about. The first is that while you're in that deeply relaxed state, the noise of a phone ringing would be quite startling and make you jump {and I would do a startle reflex to demonstrate}. So I usually suggest that we take the phone off the hook, or unplug it from the wall, or turn it on silent. If you're not sure how to do that on your phone, I can do it for you.

The second possible interruption is an unexpected visitor coming to the door. We won't be able to stop a treatment session part way through if someone comes to your door, because this is a research protocol, so I have to do all the same steps in the same sequence for each session for each participant. But the other reasons are that you will benefit more from an uninterrupted session, and because I need to complete each session in roughly the same amount of time, and then move on to my next appointment and keep to a schedule. So the way I usually handle that situation (if this is okay with you), is that you have me as your personal doorman for the next hour 😊. So I will answer the door, explain that you are having a relaxation session and cannot be disturbed, but will be available again in about an hour, and politely send them away. I am also happy to take a short message for you from whoever is at the door. Then I'll return to the massage table and complete the sequence of steps for the technique that we are doing today.

And the third and final interruption can be your bladder, so I usually recommend that you take a trip to the ladies' room before the treatment session begins, so that your bladder doesn't interrupt your relaxing session. However, if you do need to stop to go to the loo during a session, just let me know, and I'll stop wherever I'm working, assist you to get off the table so you can go to the toilet, and then when you come back, we'll pick up where we left off.

Would you like to use the ladies' room now, while I set up?

(Often participant will want to go to the toilet now, so I begin setting up the massage table while she is doing so. If not, we just continue with small talk. Upon her return, I'll assist her up the step stool and to a seated position on the massage table. While seated, we'll do the 4 health rating questions, and then the vital signs. Once the vital signs and health rating questions have been done in a seated position, I'll assist the client to lie down and then deliver the last segment of the briefing as below)

From next week and onward, this is the time when we will do our short version of the briefing. But we have discussed most of it already, so there are only a few last points I need to mention now.

Your arms can be in any position that is comfortable for you. Some people like to have their arms lying on the massage table at their sides. Other people prefer to fold their arms across the chest or their stomach. Whatever position you prefer is fine, and if you want to change your arm position part-way through the treatment, that is fine too. You don't need to lie still like a statue, and it's important that you're comfortable. If you become uncomfortable and want to change positions, just let me know. I'll stop working on whatever area that I'm working on at that time, and help you to move, adjust a pillow, etc, to ensure that you are comfortable again. Then I'll return to the areas where I was working and continue working on the area, and then continue to move through the sequence of hand positions for whatever technique we are doing today. Also, if I need to move your hands or arms to reach a particular part of your body, I'll gently re-position them while I work on, for

instance, your abdominal area, and then I'll put your arms back in to your preferred position when I'm done working in that area.

For some of the techniques, I will be sitting on the little step stool, if I am going to be working on one area of your body for a while. But for other techniques, I will be either standing or moving around the massage table.

It may be helpful for you to make a statement of intent or affirmation or even prayer, whatever fits your belief system, where you say something along these lines to yourself at the beginning of each session: "I will receive from this session whatever I most need to receive for today." Once you have done that, there is nothing further you need to do or think or say---just enjoy the session. Of course, if you become uncomfortable for any reason, do speak up and let me know, but otherwise Healing Touch is not so much a talking kind of therapy, but rather a very quiet and peaceful type of treatment session.

Are you comfortable with the pillows? Then I'll apply your ear plugs and sleeping mask now. And you just relax and enjoy!

## **Pre-Treatment Session Briefing (Short version for Second to Seventh Sessions)**

{After settling the client comfortably on the massage table, but before applying the ear plugs and sleeping mask, the following pre-treatment briefing was given. The same basic points were covered as in the initial session briefing above, but they were discussed in less detail at the subsequent sessions.}

We'll use either direct touch placing one or both hands in specific locations for a period of time, anywhere from 1 minute to 5 minutes or more, then moving on to the next location and the next and the next, until I've gone through all the steps for that particular technique. Or we may use INdirect touch, (again demonstrating on my own upper left arm), where my hands are placed above the skin, either holding still or in a soft sweeping motion. Over your chest or groin area, I will always use INdirect touch, just so that it is not awkward or uncomfortable for you.

For some of the techniques, I will be sitting on the little step stool, if I am going to be working on one area of your body for a while. But for other techniques, I will be either standing or moving around the massage table.

Your arms can be in any position that is comfortable for you: at your side, on your stomach or on your chest or some combination of those. You don't need to lie still like a statue, and it's important that you're comfortable. If you become uncomfortable and want to change positions, just let me know. I'll stop working on whatever area that I'm working on at that time, and help you to move, adjust a pillow, etc, to ensure that you are comfortable again. Then I'll return to the areas where I was working and continue working on the area, and then continue to move through the sequence of hand positions for whatever technique we are doing today.

Once you are comfortably settled on the massage table, then I will step aside for a few minutes and do a deep breathing exercise and a little meditation, just to get myself in the right frame of mind for doing this kind of work. Then I will come back to the table where you are lying and begin an assessment of your energy system, and make some notes to myself of that assessment, which helps me to do a good job of choosing which one of the 35 techniques in Healing Touch will be the best fit for you today. After the assessment, I'll get all my Healing Touch books out of the briefcase and look at the possibilities before I make a final choice of what technique to do this week. Then I'll do the technique itself, which takes about 30 minutes.

After I finish all the steps for whatever technique we are doing today, then I'll re-assess your energy system and again make some notes to myself. Then I will do something called grounding, using direct touch, but with a firmer pressure, on your legs and/or feet, 2-3 times. I'll give you a few minutes to come to full alertness, while I begin cleaning up a bit, putting some of the books away, etc. But I'll be keeping an eye on you, and when I have determined that you are ready, I'll come to the head of the table and tell you that we are finished. Then I'll remove your ear plugs and sleeping mask for you. When you are ready, I will help you to sit up and we'll do your vital signs and the four short questions again.

It may be helpful for you to make a statement of intent or affirmation or even prayer, whatever fits your belief system, where you say something along these lines to yourself at the beginning of each session: "I will receive from this session whatever I most need to receive for today." Once you have done that, there is nothing further you need to do or think or say---just enjoy the session. Of course, if you become uncomfortable for any reason, do speak up and let me know, but otherwise Healing Touch is not so much a talking kind of therapy, but rather a very quiet and peaceful type of treatment session.

Are you comfortable with the pillows? Then I'll apply your ear plugs and sleeping mask now. And you just relax and enjoy!

**APPENDIX E: SPRINGER PUBLISHING COMPANY COPYRIGHT PERMISSION**



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**APPENDIX F: LETTER OF INVITATION**



## “Healing Touch Supports Healthy Older Women at Home”

---

Letter of Invitation to participate in research study

### Are you.....

- A woman 65 or older???
- Living alone in your own home (house, unit, apartment, etc.)???
- Able to speak, read and write English???
- Receiving some support or help at home???

(This can be help with transport, meal preparation, hygiene and/or home/yard maintenance; or help from nurses, personal carers, occupational or physiotherapists, etc. or any other paid or volunteer caregivers who help you at home, including family or neighbours.)

If you answered **YES** to all of the above questions, then.....

You may qualify to receive a series of weekly sessions of Healing Touch in the comfort and convenience of your own home, at no cost to you, as part of a research study.

Healing Touch is.....

a complementary therapy, based on the same principles of energy medicine as acupuncture and acupressure. Healing Touch “...is an energy based therapeutic approach to healing that uses touch to influence the energy system thus affecting physical, emotional, mental and spiritual health and healing.” (Mentgen & Bulbrook, 1993).

You can either sit in a chair, or lie down, fully clothed, on a massage table for about 30-45 minutes, while the Healing Touch Practitioner places her hands in specific locations and sequences to balance, clear and improve the flow of energy around and through your body.

The Healing Touch Practitioner uses light touch and hand movements on or near your skin. Some early research suggests that Healing Touch is useful for relaxation, but more research is needed to determine if it works for other purposes as well. I hope to help answer that question through this study, which is part of the requirements for my PhD in nursing.

I have been involved in Healing Touch since 2001, first as a client and later as a student/practitioner of Healing Touch. The training program for practitioners is structured and rigorous, and over 71, 000 people have been through at least Level 1 of the program, all over the world. There is a professional organisation, Healing Touch International, that has written and endorses the Code of Ethics and Code of Conduct for all Healing Touch Practitioners. I have done Level 4 of the 5 Levels available, and will be doing all your sessions in this study myself, so you know you'll be getting a well qualified professional working with you.

If you would like to learn more about Healing Touch in general, you can visit the website for Healing Touch International at:

[www.healingtouchinternational.org](http://www.healingtouchinternational.org)

Or for information about the Australian branch, the Australian Foundation for Healing Touch, Inc go to:

[www.afht.org.au](http://www.afht.org.au)

**If you would like to learn more about this study in particular, or sign up to participate in this study, please ring me, the Principal Investigator, Mrs. Kristin Wicking, at James Cook University at 4781-5353.**

Or if you prefer, leave your name and phone number with the nurse here today, and s/he will pass them on to me, and I will call you shortly to tell you more about the study.

I look forward to hearing from you, and working together for your good health!!!

Kind regards,

Kristin Wicking,  
Lecturer and PhD student  
School of Nursing, Midwifery & Nutrition



Phone: 07 4781-5353



Mentgen, J. & Bulbrook, M.J.(1993). Healing Touch Level 1 Notebook. Carrboro, North Carolina: North Carolina Center for Healing Touch.



**Queensland  
Government**  
Queensland **Health**

## Townsville Health Service District

I \_\_\_\_\_ (print your name)  
authorize the Townsville Health Service District or other health service staff member  
to give my name and contact details to the Principal Investigator, Kristin Wicking, so  
that she can call me to further discuss my possible participation in her research  
project "Healing Touch Supports Healthy Older Women" (HT SHOW).

**NAME OF PARTICIPANT:** \_\_\_\_\_

**SIGNED:** \_\_\_\_\_

**DATED:** \_\_\_\_\_

**PHONE NUMBER(S) OF PARTICIPANT:**

**Home phone number:** \_\_\_\_\_

**Mobile phone number:** \_\_\_\_\_

**Any other relevant contact phone number:** \_\_\_\_\_

**APPENDIX G: SIGN FOR BROCHURE RACK**



**S**end your patients home with the gift of Healing Touch!

**G**ive them this invitation and information sheet about participation in a research study where they receive a free series of 7 Healing Touch sessions in their homes.

**R**esearch indicates that Healing Touch may empower patients to manage their own health more successfully. I am looking to recruit 180 frail older women living alone at home as participants in my PhD research.

**I** have been trained extensively in the energy-based complementary therapy of Healing Touch and would like to provide this gentle touch therapy to your patients, fully clothed, in the comfort and convenience of their own home, at no cost to them.

**T**his research project has been approved by the Ethics Committees of both James Cook University and the Townsville Health Service District. For a sample session for yourself, ring me at JCU: 4781-5353.



Kristin Wicking, RN, BSN, MSN, PhD(candidate)  
Lecturer, School of Nursing, James Cook Uni  
Room NS210, Douglas campus

**APPENDIX H: ADVERTISEMENT PLACED IN NEWSPAPERS, COMMUNITY  
NEWSLETTERS AND CHURCH BULLETINS**

**Are you a woman over 65, living on your own in a house, unit, granny flat or retirement villa???**

As part of a research study, you may be eligible to receive a free, in-home series of 7 weekly sessions of the relaxing complementary therapy Healing Touch, delivered by a specially qualified Registered Nurse.

Healing Touch:

- Is gentler than massage.
- You remain fully clothed.
- Balances your energy system.
- May promote well-being.

**To enquire/enrol in this PhD study, contact Kristin Wicking, Registered Nurse, Lecturer, Director of Undergraduate Studies (External) & PhD student; School of Nursing, JCU at (07) 4781-5353 immediately.**

(Approved by the Ethics Committees of both JCU and the Townsville Health Service District of Queensland Health)

## **APPENDIX I: MEDIA RELEASE**

2 June, 2010

## **The power of touch to help older women**

Older women living on their own are being invited to take part in a project involving a relaxing therapy called Healing Touch, as part of a new research study at James Cook University.

Kristin Wicking, a lecturer in Nursing, Midwifery and Nutrition at JCU, was recently awarded a Mentgen/Brandreth scholarship from the Australian Foundation of Healing Touch to conduct the study.

“Each week for seven weeks, a specially trained Registered Nurse will come to their home with a portable massage table to pamper them with a Healing Touch session for about an hour,” Ms Wicking said.

Ms Wicking said Healing Touch used gentle touch to strengthen and balance the energy system, similar to other complementary therapies such as acupressure, Therapeutic Touch and Reiki.

“It is based on similar energy principles as self-care practices like Tai Chi and yoga,” she said.

“It is gentler than massage and the service is provided at no cost to the women, in the convenience of their own homes, without any need for them to undress.”

Mrs Wicking said Healing Touch was proven to be pleasant and relaxing, but this new study would determine if it also helped keep older women independent in their own homes.

“The rapid rise in the population of older adults and the costs associated with long-term residential care mean we need to re-double our efforts to find safe and effective ways to support older adults to remain healthy enough to continue to manage on their own at home.”

“The most gratifying aspect of the study is being able to do something positive and supportive for a generation of women who have worked tirelessly for decades to care for their families and communities.

“Now it’s their turn for some pampering and nurturing for themselves.”

There are currently 55 places still available, so women over 65 who live on their own are welcome to contact Ms Wicking on 4781 5353.

**Media enquiries: Caroline Kaurila, JCU Media, on 4781 4586 or 0437 028 175.**

**APPENDIX J: ARTICLE IN THE TOWNSVILLE SUN**



## Fancy a little relaxing therapy free of charge in comfort of your own home?

**OLDER women living on their own are being invited to take part in a project involving a relaxing therapy called Healing Touch, as part of a new research study at James Cook University.**

**Kristin Wicking, a lecturer in Nursing, Midwifery and Nutrition at JCU, was recently awarded a Mentgen/Brandreth scholarship from the Australian Foundation of Healing Touch to conduct the study.**

**“Each week for seven weeks, a specially trained registered nurse will come to their home with a portable massage table to pamper them with a Healing Touch session for about an hour,” Ms Wicking said.**

**She said Healing Touch used gentle touch to strengthen and bal-**

**ance the energy system, similar to other complementary therapies such as acupressure, therapeutic touch and reiki.**

**“It is based on similar energy principles as self-care practices like tai chi and yoga,” she said.**

**“It is gentler than massage and the service is provided at no cost to the women, in the convenience of their own homes, without any need for them to undress.”**

**Ms Wicking said Healing Touch was proven to be pleasant and relaxing, but this new study would determine if it also helped keep older women independent in their own homes.**

**“The rapid rise in the population of older adults and the costs associated**

**with long-term residential care mean we need to re-double our efforts to find safe and effective ways to support older adults to remain healthy enough to continue to manage on their own at home,” she said.**

**“The most gratifying aspect of the study is being able to do something positive and supportive for a generation of women who have worked tirelessly for decades to care for their families and communities.**

**“Now it’s their turn for some pampering and nurturing for themselves,” she added.**

**There are currently 53 places still available for women over the age of 65, living on their own.**

**For more information contact contact Ms Wicking on 4781 5353.**

**APPENDIX K: ARTICLE IN THE TOWNSVILLE BULLETIN**



# Harnessing the power of touch

OLDER women living on their own are being invited to take part in a project involving a relaxing therapy called Healing Touch, as part of a new research study at James Cook University.

Kristin Wicking, a lecturer in Nursing, Midwifery and Nutrition at JCU, was recently awarded a Mentgen/Brandreth scholarship from the Australian Foundation of Healing Touch to conduct the study.

Each week for seven weeks, a specially trained registered nurse will come to their home with a portable massage table to pamper them with a Healing Touch session for about an hour, Ms Wicking said.

Ms Wicking said Healing Touch used gentle touch to strengthen and balance the energy system, similar to other complementary therapies such as acupressure, therapeutic touch and Reiki.

"It is based on similar energy principles as self-care practices like Tai Chi and yoga," she said.

"It is gentler than massage and the service is provided at no cost to the

women, in the convenience of their own homes, without any need for them to undress."

Ms Wicking said Healing Touch was proven to be pleasant and relaxing, but this new study would determine if it also helped keep older women independent in their own homes.

"The rapid rise in the population of older adults and the costs associated with long-term residential care mean we need to re-double our efforts to find safe and effective ways to support older adults to remain healthy enough to continue to manage on their own at home," Ms Wicking said.

"The most gratifying aspect of the study is being able to do something positive and supportive for a generation of women who have worked tirelessly for decades to care for their families and communities.

"Now its their turn for some pampering and nurturing for themselves."

**There are currently 53 places still available, so women over 65 who live on their own are welcome to contact Ms Wicking on 4781 5353.**



HEALING TOUCH . . . thanks to a scholarship, Kristin Wicking will bring her therapy to women living alone

## **APPENDIX L: PHONE SCREENING SCRIPT**

### Introduction:

Hello, this is Kristin Wicking from the School of Nursing at James Cook University. You had left a message about the research study we are doing about Healing Touch for older women at home. (Wait for acknowledgement, small talk chat as needed, thank them for their interest, etc.)

Can I ask first how you heard about the study?

(Find out if they've only seen the newspaper/newsletter/church bulletin advertisement, or have they received the 2 page pink Letter of Invitation and/or the green 4 page full Patient Information/Consent form? Or did they hear about the study from a word of mouth referral, with a limited or full description by a previous participant?)

What I have found works best when folks ring in about the study, is that I first describe the study fully for you, so that you know what is involved, and then give you a chance to ask any questions that you may have. Then if it sounds like something that you would like to pursue, then I'll ask you some questions, to make sure that you meet the eligibility requirements for the study, and if you do, then we'll schedule your appointments. I find that takes a good 20 minutes. Is this a good time for you?

(If yes, proceed. If no, make arrangements of a suitable time to ring the potential participant back.)

### Description of the study:

We have set the study up as an experiment, a before and after experiment. So before you and I begin working together, the first thing that happens is my Research Assistant, who is a Registered nurse like me, comes to your home to ask you a number of questions and fill out some forms with you. Then after you and I have worked together over 7 weeks, at the end of that time, Leah or Ylona comes back to see you again and asks you all the same questions and fills out the forms again. Then we just wait for 6 months, and after that, she comes back to see you and asks you the same questions the third and final time. This means it is a long term study, so we can track your progress over time and see what, if any, benefit you received from the treatments and if it was a lasting benefit. Are you comfortable with a long term involvement like that?

(If yes, proceed; If no, thank her for her interest, encourage her to tell other women she knows who are over 65 and live on their own about the study to feel free to ring in with any questions they may have, thanks, bye.)

### Description of the Home Visits:

What people are usually most curious about are the home visits, so I'll describe one of those for you next, if that's okay. We have set everything up so that we come to you, so you don't need to worry about getting all the way out to the University. So I have everything with me, and arrive to your place on the day/time we've agreed upon with all the equipment. I bring with me a portable massage table, a basket of pretty pink pillows in all different shapes and sizes so we can be sure you are completely comfortable, a little step stool to make it easy for you to get up onto the table, and a set of clean linens for the massage table that will be used for only you, for your whole series of treatments. I set up the table in whatever room you prefer, but usually the lounge room works out

best to have enough room for me to work around all 4 sides of the table. It's a well padded table, extra long and extra wide, a deluxe table, only the best for my ladies! 😊

While I am setting up the massage table, we will chat a bit, so I can see how you're doing that week, which helps me to know which technique might be most suitable for you. Now you don't need to undress for a Healing Touch treatment, but I'll just have you slip off your shoes is all. Then I'll help you to first sit on the table, while I take your temperature, pulse and blood pressure (your vital signs), and ask you the same 4 short questions each week. Then I'll help you to lie down, either on your back or stomach, and I'll arrange the pillows to be sure that your back is well aligned and each part of your body is fully supported and comfortable. Then I'll cover you with just a light weight sheet for privacy and comfort.

I also bring for each client, their own personal sleeping mask, so that if there is a bright light on the ceiling over head, or bright sunlight coming in the window, we can block all that out for you. Then you also get a set of ear plugs, which won't block out all the noise, but will at least mute it, so that if there is traffic noise outside, or if your neighbour is playing their TV or radio loudly, that noise won't disturb your session. So we are creating your own little cosy cocoon where nothing will interfere with your being able to fully relax and enjoy being pampered during your session.

Once we have you comfortably settled on the massage table, then I will do an assessment of your energy system, which together with our chatting as I set up the table, helps me to know which one of the 35 techniques in Healing Touch will be the best fit for where you are at that week and how you are feeling. After the assessment, I'll do the technique itself, which takes about 30 minutes, and then I'll re-assess your energy system again. I'll make some notes to myself during this time, of what I found on each assessment and which technique I used that week.

After the technique is finished, I'll assist you to sit up, and I'll take your temperature, pulse and blood pressure again, and we'll do the four short questions again. Then I'll help you down the step stool off the massage table, pack up my gear, and return your lounge to its former glory! 😊

(Answer her questions as they arise during the above description. Or if none do, pause here and ask if she has any questions so far, and answer those for her. Usually they ask to know more about Healing Touch itself at this point, but if not, proceed with next section anyway.)

#### Description of Healing Touch:

Healing Touch is actually a collection of 35 different techniques. While most people find all of the techniques to be pleasant and relaxing, many of them have more specific purposes as well. For instance, one is useful when you're feeling like your mind is going too fast or in circles, to help clear and settle your thinking and help you to focus better. Another one is good for boosting your immune system, and a number of them can be helpful for pain relief. Some of the techniques use direct touch, and some of them use INdirect touch, and some techniques use both direct and indirect touch on different locations on the body, so I'll describe each of those for you. With direct touch I am gently placing one or both of my hands in very specific locations, in a certain sequence. It is very gentle, not a rough or rubbing motion like in massage, but just a soft pressure, sometimes not even felt by clients. With indirect touch, my hands are placed above the skin, either holding still or in a soft sweeping motion, during which some clients report feeling gentle air movement, like a soft

breeze, but again, other clients may not feel it. Depending on the technique or the location on your body, I'll use either direct or indirect touch. For instance, over your chest or groin area, I will always use Indirect touch, just so that it is not awkward or uncomfortable for you.

Healing Touch is thought to support and strengthen your energy system, which in turn can have flow-on effects for better physical, emotional, intellectual or spiritual health, or some combination of the above. Usually we will only have enough time to do one technique per session, and with 35 techniques to choose from and only 7 sessions to work together, we will probably use a different technique each week. That way you'll have a chance to experience the variety that is available within the Healing Touch collection. Everyone's experience is different, even from one week to the next, depending on which technique we use. You may notice a benefit in your physical health, or your emotional health, etc. or you may not notice any benefit at all.

(Pause again, ask if any questions about Healing Touch, the home visits or the study? Answer them.)

Placebo:

In order to make this a true experiment, as people enrol in the study, we will use computer generated random numbers to randomly assign them to one of two groups. One group will receive the Healing Touch treatment, and the other group will receive a mimic or simulated Healing Touch treatment. That way we can compare the two groups to each other, and see which group, if any, received the most benefit over time. This is a pretty standard type of experiment in health care research, similar to when they are testing a new medication. In those kinds of studies, one group gets the new medication, and the other group gets a sugar pill, or a placebo. Then it is possible to tell what benefit, if any, comes from the actual medication or treatment.

In this study, all of the patients will be told at the end of the study, whether they ended up being in the actual Healing Touch group or the mimic Healing Touch group. Any participant who ended up being in the group that gets the simulated or mimic Healing Touch, will be offered one sample session of the actual Healing Touch, if they would like to have it. We are doing this as a thank you for the time that you are giving us to be involved in the study, and because we realise you may be curious to experience the actual Healing Touch, but the sample session is completely optional.

Screening/Booking appointments:

If this sounds like something you would like to participate in, then I'll need to ask you some questions, to make sure that you meet the eligibility criteria for the study. If you do, then we can arrange the appointment times for you.

(Use the Screening Form to fill out all fields, as per the attached).

Well that's all the questions, and I'm pleased to tell you that you are just the kind of gal we are looking for! So now we will set up your appointment times. I find it is best to allow a good 1.5 hours for each appointment. The middle 45 minutes or so is the actual treatment time, but we also need time for me to unload the equipment, set it up, have a quick chat, take your vital signs, etc, and then do all of that in reverse after the treatment. When we set up a time, I let all my clients know that it is an approximate time, depending on what part of town I am coming from with my last client. So for instance, a 3pm appointment might happen 10-15 minutes before OR after 3pm.

I have found that what works best is if we pick a time that suits you and stick to that same day of the week and time each week for your entire series of 7 treatments. That makes it easier for both of us to remember the appointments. I will be booking patients one after the other, so we need to be certain that it is a day and time that you can commit to be at home and ready for your appointment each week, as I don't have a lot of options of times to reschedule your appointment in to, as I am continuing to work as a lecturer at the university while I am doing this study. Also, I don't want you to give up any other activities or groups that you belong to, so we will work around your other activities. Can you tell me first of all what days of the week & times of day will NOT work for you, because of other commitments?

(Write down all their other activities on booking sheet. Negotiate a weekly booking time as per my availability and theirs, starting them as soon as possible so they don't lose interest and leave the study. Repeat back to them the agreed upon dates and times. Work around any trips away to be sure that the RA has enough time to see them before and after I do.)

For our first appointment, before we have the treatment, we'll sit and talk for awhile, so I can get your full health history, medications, surgeries, etc. That will take us a good 30 minutes, maybe even 45 minutes if your history is complicated.....or if we're having a good chin wag! 😊 So we sometimes need to book that first appointment a little differently, to be sure we have enough time to do justice to that health history. But it is an important foundation that helps me to choose the best techniques for your health status and your health goals.

I will mail you out a package with a list of these appointment times, as well as some further information about the study and my business card with my mobile phone number on it. There will be the green Patient Information/Consent form, which covers all the information we have talked about today on the phone. Please read it over in advance, and please feel free to ring me if you have any questions at all about that information. Here is my mobile phone number, which is the best way to reach me, as I am often going from house to house for appointments and not at my desk at the University. Then when Leah or Ylona comes to see you for the first visit to ask you the questions and fill out the forms, you and she will sign two copies of the Consent Form together. She will bring one copy back to store in our locked files, and she will also leave one copy for you for your own records.

Leah or Ylona will ring you directly to set up her appointment with you, as she works both at the hospital and at the University, so her schedule is a bit complicated. But she will clearly identify herself as being part of the Healing Touch study, so you will know that she is with me.

Wrapping Up:

Do you have any further questions? Is there any place in particular that I should park at your place? I'm glad you rang up about the study and I look forward to working together over the next few weeks. If you have any questions or if something comes up that you can't keep our arranged appointment, please ring me on my mobile phone to let me know as soon as possible, but otherwise, I look forward to seeing you on \_\_\_\_\_ at \_\_\_\_\_ am/pm!

**APPENDIX M: PHONE SCREENING FORM**

Thank them for their interest, then obtain their permission to ask a series of questions to determine if they fit the requirements of the study.

1. Date/time of phone screening conversation: \_\_\_\_\_
2. Name:
3. Phone Number:
4. Address:
5. Female
6. Age (date of birth)
7. Ethnicity (ATSI?)
8. Able to read/write English?
9. Living arrangements
10. Current partner/marital status
11. Current home services:  
Meals on Wheels\_\_\_\_ Transport\_\_\_\_ Housecleaning\_\_\_\_ Yard work\_\_\_\_ Home  
Repairs\_\_\_\_ Hygiene \_\_\_\_ Shopping\_\_\_\_ Other\_\_\_\_\_
12. Healing Touch client/practitioner?
13. Therapeutic Touch client/practitioner?
14. Touch for Health client/practitioner?
15. Pranic healing client/practitioner?
16. Reiki client/practitioner?
17. What service or program referred you to me for this study? \_\_\_\_\_
18. What types of health care worker(s) are coming to your home at the moment?  
\_\_\_\_\_
19. Can you commit to being in Townsville and at your home at the negotiated and scheduled dates/times for the entire series of the 9 appointments (RA x 2, PI x 7) over approximately 2 months, beginning \_\_\_\_\_?

20. Family member name \_\_\_\_\_ relationship \_\_\_\_\_ Phone  
number: \_\_\_\_\_

21. GP Name \_\_\_\_\_ Phone number \_\_\_\_\_

While conversing, assess for English speaking skills, as reading/writing skills are generally even poorer than spoken literacy. Also be assessing for cognitive status problems.

If they fit all the screening criteria, then go over the key points of the information sheet/consent form with them, and answer any questions they may have, without revealing enough information to enable them to see through the placebo version (mimic Healing Touch).

If they state they want to proceed, then book them in for their 7 appointments with me. At the time of Ylona's/Leah's first visit, she will witness their signature of the Information Sheet/Consent form x 2 copies, leaving one signed copy with them and bringing the other signed copy back to me.

Enrolment Checklist:

\_\_\_\_\_ Diary

\_\_\_\_\_ Palm Pilot

\_\_\_\_\_ GPS

\_\_\_\_\_ Excel appt form (Print \_\_\_\_\_ Load in to briefcase \_\_\_\_\_ Move to patient chart in pilot bag \_\_\_\_\_)

\_\_\_\_\_ Add to MDR

\_\_\_\_\_ Print

\_\_\_\_\_ Load into briefcase

\_\_\_\_\_ Email to:

\_\_\_\_\_ Self

\_\_\_\_\_ Ylona

\_\_\_\_\_ Leah

**APPENDIX N: PATIENT INFORMATION/CONSENT (PIC) FORM**

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## **PARTICIPANT INFORMATION SHEET**

**PROTOCOL NAME:**

**“Healing Touch Supports Healthy Older Women” (HT SHOW)**

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Full Title: A Randomized Controlled Trial of the effects of the Energy-based Complementary Therapy of Healing Touch on the Functional Health Status of Community-dwelling Single Older Women.

**INVESTIGATOR:**

**Kristin Wicking, RN, BSN, MSN, PhD candidate, Lecturer, James Cook University**

---

I am conducting the above study in partial fulfillment of the requirements for a Doctor of Philosophy degree (PhD), and would like to invite you to participate. The study involves the use of a complementary therapy called Healing Touch. This therapy is based on the same principles of energy medicine as other complementary therapies, such as acupuncture, acupressure and Reiki. The Healing Touch Practitioner uses light touch and hand movements on or near your skin. Some early research indicates that Healing Touch is useful for relaxation, but more research is needed to determine if it works for other purposes as well. I hope to help answer that question through this study, which is part of the requirements for my PhD in nursing.

Please be aware that as a complementary therapy this intervention is to be used alongside all your other usual medical care, NOT as a substitute for it. Whether or not you participate in this study, any other support services that are being set up for you will continue as planned.

The Sequence of Events: what will happen when:

I am interested to see if receiving a series of weekly Healing Touch (HT) sessions in your home for 7 weeks will be helpful for you. First, one of my Research Assistants will visit you at home, to obtain some baseline information. She will ask you a number of questions about your health status in order to complete some forms. Then within the following week, at a time you and I have organized together over the phone, I will come to your home and deliver either the actual Healing Touch intervention sessions to half of the participants (the experimental group), or the

mimic version of Healing Touch to the other half of the participants (the placebo group).

It is necessary to have some people get a placebo version, in order to test for any differences between those of you who get the mimic HT, and those of you who get the actual HT. I will have you wear ear plugs and a sleep eye mask, (similar to what you get on a long international flight), during the treatment sessions, so that you are undisturbed by noise or light, and also to ensure that you are unaware of which type of session you are receiving. You will be told by letter at the very end of the research project, which treatment group you had been randomly assigned to join.

I will come every week, for 7 weeks in a row, to do your HT sessions. I need to be sure to schedule your series of sessions when you will be here in town, at home, and available for your sessions. After the 7 sessions have finished, then the Research Assistant (RA) will come back again and ask you the same questions as she did in the beginning. She will also ask you a few additional questions in a short interview, and tape record your answers. Lastly, 6 months after the HT sessions have finished, the RA will visit you one last time and repeat the questions again. I will need to be told if you move during those 6 months, but if you are still here in the Townsville area, we will come visit you in your new location to do the follow-up questions, which are a VERY important part of this study. For that reason, we may send you a letter or phone you at some point(s) between your final HT session and the 6 month follow-up questions, to verify your current address.

#### Description of a typical HT session:

I will assist you to lie, fully clothed, on a padded massage table, usually on your back, but sometimes on your stomach, with the ear plugs and sleep eye mask applied. Alternatively, some HT techniques can be performed with you sitting in a chair.

Then I will place my hands in specific sequences and locations, either directly on your body, or immediately above it in your energy field, in order to balance, clear and improve the flow of energy around and through your body. I will ask you how you feel before and after each session, as well as taking a set of observations or vital signs: Temperature, Pulse, Respirations, Blood Pressure. I will ask you to verbally rate different aspects of your health (physical, emotional, mental and spiritual) on a scale of 1 to 10 at that time, with 1 being the worst possible health status and 10 being the best possible health status.

It is generally more effective for you to lie quietly during the sessions, but if you do need to ask me a question or tell me something that you're feeling during the session, then you can briefly do so.

Once we have finished a session (usually about 30-45 minutes on the massage table), I will ask you the same questions as we did before the session and take your vital signs again. Because I will be doing a number of patients each day, unfortunately I will not be able to linger for a good chat or a cuppa, but instead I will need to move along to my next scheduled appointment. For that reason, it will be important for you to be available at the time we have organized, for each of the 7 weeks of the HT sessions, (although there will be some limited availability to reschedule an appointment, probably in to one of the evening time slots, if you are unable to keep your scheduled appointment time).

Risks and Benefits: It is rare for anyone to feel negative sensations during a HT session, but some people report feeling tingling sensations, pressure or temperature changes, and in a couple of isolated cases, an increase in pain part way through the session, with relief later in the session. Most people find it relaxing, but everyone's experience can be different, and you may receive no benefit at all from the Healing Touch sessions, no matter which group you are randomly assigned to join.

What if.....?

At any time during the study, if you decide you would rather not participate in the HT sessions, then you are completely free to withdraw from the intervention. I would ask that you still let us come back and do the questions if possible, but of course you can choose not to do that either.

Although it is unlikely, if at some point in the study, there is a need to make a substantial change to the study protocol, then you will be notified of the proposed changes. Again, you are free to withdraw at that time.

Although again unlikely, there is always the possibility that due to unforeseen circumstances such as serious illness, the research study may need to be delayed or stopped. Again you would be notified of that situation in a timely manner.

And lastly, while again unlikely, as with any intervention that is still being researched, it is possible that there are negative effects from the HT sessions that are as yet unknown to us. I will be interested to hear your feedback on your experiences of receiving these HT sessions, as such feedback is vital in helping us to know if/when this particular complementary therapy can be helpful to patients, now and in the future.

This study has been reviewed and approved by the Townsville Health Service District Human Research Ethics Committee and James Cook University. Should you wish to discuss the study with someone not directly involved, particularly in relation to matters concerning policies, information about the conduct of the study or your rights as a participant; or should you wish to make an independent complaint you can contact the Chairperson, Townsville Health Service District Human Research Ethics Committee via email at [TSV-Ethics-Committee@health.qld.gov.au](mailto:TSV-Ethics-Committee@health.qld.gov.au) or telephone (07) 4796 1003.

The training program for Healing Touch Practitioners is structured and rigorous, spanning 5 levels, and over 71, 000 people (mostly nurses) have been through at least Level 1 of the program, all over the world. The professional organisation, Healing Touch International, has written and endorses the Code of Ethics and Code of Conduct for all Healing Touch Practitioners. I have been involved in Healing Touch since 2001, first as a client and later as a student/practitioner of Healing Touch and will be doing all your sessions in this study myself, so you know you'll be getting a well qualified professional working with you.

If you would like to learn more about Healing Touch in general, you can visit the website for Healing Touch International at:  
[www.healingtouchinternational.org](http://www.healingtouchinternational.org)

Or for information about the Australian Foundation for Healing Touch, Inc go to:  
[www.afht.org.au](http://www.afht.org.au)

**If you would like to learn more about this study in particular, or sign up to participate in this study, please ring me, the Principal Investigator, Mrs. Kristin Wicking, at James Cook University at 4781-5353.**

Or if you prefer, leave your name and phone number with the nurse here today, and s/he will pass them on to me, and I will call you shortly to tell you more about the study.

I look forward to hearing from you, and working together for your good health!!!

**INVESTIGATOR CONTACT NAME: Kristin Wicking**

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**INVESTIGATOR CONTACT TELEPHONE NO. (07) 4781-5353**

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**DATED:**

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**SIGNATURE OF CONTACT INVESTIGATOR:**

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## **PATIENT/PARTICIPANT CONSENT FORM**

**PROTOCOL NAME:** "Healing Touch Supports Healthy Older Women" (HT SHOW)

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Full Title: A Randomized Controlled Trial of the effects of the Energy-based Complementary Therapy of Healing Touch on the Functional Health Status of Community-dwelling Single Older Women.

**INVESTIGATOR:** Kristin Wicking, RN, BSN, MSN, PhD candidate, Lecturer, James Cook University

- 
1. The nature and purpose of the research project has been explained to me. I understand it, and agree to take part in the full duration of the research project, including a follow-up data collection 6 months after the Healing Touch sessions have concluded, (unless I indicate otherwise to the Principal Investigator at a later date).
  2. I have been given an Information Sheet which explains the purpose of the study, the possible benefits, and the possible risks.
  3. I understand that I may not directly benefit from taking part in the trial.
  4. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
  5. I understand that I can withdraw from the study at any stage and that it will not affect my medical care, now or in the future.
  6. I have had the opportunity to discuss taking part in this investigation with a family member or friend.
  7. I understand that the Researcher(s) are obligated to report any instances of Child Abuse or Elder Abuse that they may unexpectedly come across during the home visits.
  8. I consent to the Researcher(s) contacting either a nominated family member or my General Practitioner, if they arrive for a home visit and find me unwell and in need of assistance.

**NAME OF SUBJECT:**

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**SIGNED:**

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**DATED:**

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I certify that I have explained the study to the patient/volunteer and consider that he/she understands what is involved, and that a copy of this document will be provided to the participant.

**SIGNATURE of Investigator/Research Assistant:**

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## **APPENDIX O: PLACEBO PROTOCOLS**

### Placebo Protocols for Mimic Healing Touch Control Group's Sequence of 7 Sessions

Exclusion criteria to include no previous experience either giving or receiving an energy modality (i.e. Healing Touch, Therapeutic Touch, Reiki, Touch for Health, etc.)

*The sequence of techniques will now vary between clients (in response to intake history) and the Healing Touch Practitioners' body placement and movement during the placebo mimic techniques had to be modified to more closely resemble body placement and movement that occurs during the actual Healing Touch treatments. These changes were necessary to preserve credibility of the placebo in the context of participants in close relationships in retirement village communities, who were comparing notes on such details of their treatment experiences at the retirement villages' social events. In addition, some clients could not tolerate the prone position, so additional supine mimic techniques were devised for them. For some techniques, additional 'hand' (glove) locations were added to improve credibility and more closely mimic the sensory input of an authentic Healing Touch session.*

1. Mimic Chakra Spread (no direct tactile contact, air movement only)
2. Mimic Chakra Connection (supine only, tactile contact, legs & arms x 6 positions)
3. Mimic Hopi Back Technique (prone only, tactile contact, back x 6 positions)
4. Mimic Pain Drain (supine only, tactile contact one to two locations only on abdomen, but alternating my "hands" halfway through)
5. Mimic Lower Body Connection (prone only, tactile contact legs only x 4 positions)
6. Mimic Opening Spinal Energy Flow (prone only, direct tactile contact on back x 4 different positions than back technique above)
7. Mimic Lymphatic Drain (supine, then prone, no direct tactile contact, air movement only).
8. Mimic Magnetic Clearing (patient supine, no direct tactile contact, no air movement, aware of practitioner at side of table walking slowly from head to foot, on alternating sides.)
9. Mimic Etheric Clearing (patient supine, no direct tactile contact, minimal air movement).
10. Full Body Connection (patient supine, direct tactile contact, no air movement).

#### Specific detailed sequencing of glove placement for each mimic technique:

- Mimic Chakra Spread (seated in chair or supine on massage table, no direct tactile contact, air movement only): Will use an A5 size hardback book to mimic the slight air movement that would occur during the technique, doing a gentle horizontal sweep every 1 minute x 2- 3 sweeps at each location, starting at head and working from left side, then right side, down the body at a new location for each sweep (top of head from left, right and top; front of head; upper chest; upper abdomen; lower abdomen; knees; ankles; soles of feet from right side, left side and bottom).

- Mimic Lower Body Connection: prone only, tactile contact legs only x 6 positions, each held 5 minutes: 1. Both hands mid shin right side; 2. mid-shin and mid-thigh on right side; 3. Both hands mid thigh on right side. Repeat 3 positions on left side.
- Mimic Chakra Connection patient supine only, HTP seated on one side, work up body, then move to opposite side and repeat. Tactile contact legs & arms x 6 positions: Move gloves to following locations every 5 minutes: 1. Mid shin and mid-thigh on right side; 2. Mid-shin and mid-thigh on left side; 3. Mid-shin both sides 4. Mid forearm and mid upper arm right side 5. Mid forearm and mid upper arm left side 6. Mid upper arm both sides.
- Mimic Lymphatic Drain: supine only, as too difficult to turn patient mid-way through treatment with sleeping mask and ear plugs in place. No direct tactile contact, air movement only: Three sweeps each location, a sweep per minute, horizontally across body or vertically down limbs, with A5 size laminated hardback book in sequence: 1. Upper chest from left side 2. Upper chest from right side 3. Abdomen from left side 4. Abdomen from right side 5. Left arm 6. Right arm 7. Left leg 8. Right leg 9. Left side of head 10. Right side of head 11. Top of head
- Mimic Magnetic Clearing: patient supine, no direct tactile contact, no air movement, client advised I will be slowly walking at side of massage table from head to foot, numerous passes (approximately 5 per side) on each side before alternating to opposite side, then back again, repeating for the 30 minute session.
- Mimic Etheric Clearing: patient supine, no direct tactile contact, minimal air movement. Healing Touch Practitioner begins at head, remains at various points along the body for 5 minutes per location, then moves to next location till reaches feet, Repeats on other side of patient. Sweeps are vertical in orientation rather than horizontal as in other mimic techniques.
- Full Body Connection: From one side x 3 positions, then repeated on the other side for 3 positions, each held for 5 minutes. 1. Mid shin and mid thigh 2. Mid thigh and lower abdomen, not over sacral chakra 3. Lower abdomen and mid forearm.
- Mimic Hopi Back Technique: prone only, tactile contact back x 3 positions from one side, then repeat from three positions on the other side, moving gloves every 5 minutes: 1. Right and left "hands" on opposite sides of lower spine (not over ovaries). 2. Right and left "hands" on opposite sides of upper spine (not over kidneys/adrenals). 3. Right and left "hands" near shoulder blades. Lower hand is the one reaching farthest over client's back, from each side in each position. Change sides and repeat.
- Mimic Opening Spinal Energy Flow: prone only, direct tactile contact on back, first from one side of patient x two locations held 7 minutes each, then repeated from other side of patient x 2 locations, held 7 minutes each. Glove placement: 1. to client's left of sacral spine and right of cervical spine 3. To client's left of sacral spine and right of cervical spine. Not on spine itself.
- Shorter Techniques
  - Mimic Pain Drain: supine only, tactile contact one to two locations on abdomen only, but alternating my "hands" halfway through. Avoid placement over spleen, liver, stomach, ovaries or sacral & solar plexus chakras. So place left hand glove to one side or the other of umbilicus

x 5-10 minutes. Then place right hand glove on same location x 5-10 minutes. Repeat in general area but move location slightly for second iteration. Also used on additional sessions in other locations, for patients who could not tolerate the two prone mimic techniques and/or who repeatedly requested work on a specific body part.

- Mimic Spiritual Surgery: Used for clients when prone position not available. Placed gloves on or near client's expressed area of concern, repeated on opposite side after explaining need for balance, held at each location for 7-10 minutes. Combined with pain drain to create a full 30 minute placebo session.
- Mimic Hands in Motion/Hands Still: Used for patients who could not tolerate the two prone mimic techniques. Combined with pain drain and/or spiritual surgery to create a full 30 minute placebo session.

Gloves placed to drape over extremity without being held in place for nearly all positions, except for clients who were unable to lie supine and had treatments on their side. Gloves then braced in a fingers upright position on pillow at patient's back being used to support side-lying position.

Once gloves placed, hands removed quietly, being careful to not jostle gloves, table or patient's body. Hands rested in practitioner's lap until 5 minutes were up, then gently removed gloves and re-located self and gloves to new position.

Generally began with a direct touch technique for the first placebo session, then alternated between direct and indirect touch techniques, as per the briefing directions that each session would feel different.

**APPENDIX P: RESEARCH ASSISTANT DATA COLLECTION QUESTIONNAIRE-  
DEMOGRAPHIC AND WEEK 8 SECTIONS ONLY, LAST FOUR PAGES ONLY.**

(Other instruments are copyright protected and can be found in the sources identified in the text of  
Chapter Three, Methodology)

## Investigator-Created Demographic Questionnaire

### **Ethnicity**

Australian born  Yes  No

If born overseas, what country? \_\_\_\_\_

Migrated to Australia in \_\_\_\_\_ (e.g., 1980)

English is my \_\_\_\_\_ language (e.g., first, second, third)

### **Faith**

Please indicate your religion/faith: \_\_\_\_\_

### **Education** (please tick highest level achieved)

- Year 6 or less
- Year 10 or less
- Year 12 or less
- Completed high school
- TAFE or other vocational institution
- Completed Bachelor's degree
- Completed Master's degree
- Completed PhD, doctorate or medical degree

### **Annual Income** (please tick)

- Less than \$10,000 per year
- \$10,000 to \$19,999 per year
- \$20,000 to \$29,999 per year
- \$30,000 to \$39,999 per year
- \$40,000 to \$49,999 per year
- \$50,000 to \$74,999 per year
- \$75,000 to \$100,000 per year
- Greater than \$100,000 per year

### **Marital Status** (please tick all that apply)

- Widowed How long ago? \_\_\_\_\_ days / weeks / months / years
- Divorced How long ago? \_\_\_\_\_ days / weeks / months / years
- Married – living separately
- Married – living together
- De facto partner – living separately
- De facto partner – living together
- Never married

### **Current Living Arrangements**

Please put a tick next to the type of living arrangement which applies to you **AS OF TODAY**:

- Living alone in your own home or unit in an ordinary residential neighbourhood
- Living alone in your own home or unit in a retirement village
- Living in a 'granny flat' or separate building that is on the same piece of land as your family's home
- Living with family members inside their home
- Living in an assisted-living facility
- Living in a hostel

- Living in a low-care wing of a residential aged care facility
- Living in a high-care wing of a residential aged care facility
- Other – please describe: \_\_\_\_\_

How long has it been since you were last in a hospital?

\_\_\_\_\_ days    OR    \_\_\_\_\_ weeks    OR    \_\_\_\_\_ months

Were you:

- just in the Emergency Department (Accident & Emergency)?    OR
- admitted overnight (or longer) in to the hospital?

**Health Care Providers/Support Services**

Please put a tick next to any of the following complementary therapies that you are using now (meaning at least once within the past two months) or have used in the past or have never used. Please select at least one choice for each therapy.

	<u>Now</u>	<u>In the Past</u>	<u>Never</u>
Massage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reiki	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Therapeutic Touch	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bowen Therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Kinesiology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Touch for Health	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pranic Healing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cranio-sacral Therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Acupuncture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Acupressure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chiropractic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

***These questions are for only one of the three data collection points, the Post-Intervention, Week 9 data collection point.***

Were you satisfied with the duration of the sessions, or did you wish they had been longer or shorter?

Longer  Shorter  The same duration

Were you satisfied with the number of sessions (7), or did you wish there had been more or less sessions given?

More  Less  The same (7)

Although this research project only had funding to offer each participant a series of seven (7) weekly sessions, if further Healing Touch sessions were to become available to you at no cost at some point in the future, would you want to receive Healing Touch sessions again?

No thanks  Probably Yes  Definitely Yes

At the moment, most complementary therapies are not reimbursed through Medicare or through private health cover. If you had to pay for Healing Touch sessions out-of-pocket in the future, did you find them valuable enough that you would be willing to pay for them yourself?

No thanks  Probably Yes  Definitely Yes

If you did so, what dollar amount per session would you be willing to pay (for a session similar to the ones you experienced)?

\$\_\_\_\_\_ per session

Would you be supportive of a change to Medicare reimbursement that allowed you to receive Healing Touch at a reduced or free cost?

No thanks  Probably Yes  Definitely Yes

Would you recommend Healing Touch as a beneficial complementary therapy to a friend or family member?

No thanks  Probably Yes  Definitely Yes

## *Semi-Structured Interview Questions for Post-Intervention (Week 9)*

### *Interview*

1. Please describe for me in your own words, your experience of receiving the Healing Touch sessions over the past 7 weeks.  

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2. There can be varying responses to Healing Touch, including having no response at all. During your Healing Touch sessions, while you were lying on the massage table, what (if anything) did it feel like to receive a Healing Touch session?  

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3. In the hours or days following your Healing Touch session, did you notice any changes in yourself that you feel are related to the Healing Touch session?  

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4. Even I do not know which group you were in, as only the Healing Touch Practitioner knows each participant's group assignment, and the participants will not be notified of their group assignment until after the final data collection point six months from now. But, in your own opinion, do you believe that you were in the actual Healing Touch treatment group or that you were in the placebo (mimic Healing Touch) group? Why do you believe that?  

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5. We are asking everyone this question, regardless of which group they are in: If it does turn out that you were in the mimic Healing Touch group, are you interested in being contacted if there is a similar follow-on study, in which you can be guaranteed to be in the actual Healing Touch treatment group the next time around?

**APPENDIX Q: FINAL SESSION BRIEFING SCRIPT**

Conduct session as usual, except during the pre-treatment briefing, add in this paragraph:

After grounding you, I'll help you to sit up on the massage table. Since this is our last session, rather than re-folding the top sheet in with the rest of the linen, instead I'll be leaving it with you, as it can't be laundered and re-used. So feel free to use it for anything you would like, or just throw it out if you do not want it for anything. Similarly, I'll leave your ear plugs and sleeping mask here with you as well, as some of my clients have asked to keep them for naps and sleeping at night. Again, I can't wash and re-use them for other clients, so you may as well have the use of them, or if you don't want them, just toss them in the bin.

After grounding the client and helping them to sit upright on massage table with step stool under their feet, I'll deliver the following 'speech' to them, standing at eye level to them while they are sitting.

Well since this is our last session, you get to hear a brand new speech, lucky you. ☺ If we had to give this one a title, it would be "What happens from here." First of all, my Research Assistant, (Leah or Ylona, state name of RA doing data collection for this client) will ring you, if she hasn't already, to arrange a time to come and see you again, usually within the next few days. It's important that we don't wait too long, as we want your experience to be fresh in your mind, but as long as it gets done in the next week or so, that will be alright.

She will ask you all the same questions over again, but will also ask you an additional five questions at the end. For these questions, she'll have a little tape recorder going to record your answers. These are open questions, where you can state in your own words what it was like for you to receive these treatment sessions. It is actually a really important part of the research, so I want to encourage you to be completely honest and say whatever was true for you. Only myself, the RA and the professional transcriptionist listens to these tapes, and your name is never attached to them, only your code number, just like with all the other paperwork we've done together.

Then about once a month, (Leah or Ylona) will ring you for just a brief 5 minute chat, just to check in and say hi, so we can keep track of you, in case you are moving, taking a long trip, etc. She'll ring you about once a month for the next 6 months. Then after the 6 months, (Leah or Ylona) will come back to see you for the third and final time, to ask you all the same questions again. In some ways, this final follow-up visit is the most important of all the visits, because this follow-up allows us to see if any benefits that you might have received from the treatments are actually lasting benefits. So we want to be sure that we are able to come and see you for that last visit, and don't lose track of you.

Then you won't hear anything from us for quite a while, as we are finishing the study, and doing the home visits for the rest of the participants in the study. We need to see 180 women in total, so it's a major study, and that will take some time. To date we've seen \_\_\_\_ women, and we hope to finish with all the treatment sessions by the end of next year (or this year for the 2010 patients). Then everyone needs to have their 6 month follow up visits to finish the data collection. After that, we will type into the computer all the data from all those patients, for instance all these blood pressure readings we've been taking etc. Then we'll crunch the numbers to see if the folks who got the Healing Touch treatments did any better than the ones who got the mimic or simulated Healing Touch treatments. So all those steps will take us awhile to complete.

But once we've done all that, we'll be sending a letter to everyone who was in the study, and that letter will have a number of things in it. First of all, it will have some preliminary results, usually just a one page summary is all the detail most people want. But if you would like more detail, we're happy to provide that as well, even so far as giving you copies of journal articles about the study as we publish them.

Next, the letter will tell you which group you ended up being in, the group that received the actual Healing Touch, or the group that received the mimic Healing Touch, the placebo. For those folks who received the mimic Healing Touch, or the placebo, then they will be given the opportunity, if they want it, to have one sample session of Healing Touch itself, just as a thank you from us and to satisfy their curiosity.

Lastly, some of the clients in the study and some of the nurses who helped us recruit clients for the study, are keen to learn how to do Healing Touch themselves. If we have enough interest, we'll run an evening introductory class here in Townsville for Healing Touch and then perhaps later the first level of the training. Although most of the people who learn Healing Touch are nurses, you don't actually have to be a nurse to learn it, so anyone can come along to a class. A model that we've seen used successfully with other groups is a support group model. So for instance, if you and I were both clients in my study, we could go along to a class and both learn Healing Touch, and then we give each other treatments, as an exchange. That is more economical than having to pay for a Healing Touch session. So if you're interested in either coming to a class and learning Healing Touch, or being a client for someone else to practice Healing Touch on, then there will be a place in the letter for you to indicate your interest in that.

(Now help client down from the massage table, and begin to pack up gear as per usual. While doing so, give the next section of the speech):

The other thing I need to tell you about is the confidentiality aspect of the study. Now in a town as small as Townsville, the chances are good that I may run in to you in K-Mart or Woolies at some point in the future. But because of the privacy aspect of the study, I can't go up to you and start a conversation, as I'm then letting everyone know that you are one of my study participants. It's fine for you to tell people you're in my study, but I can't violate your privacy by telling anyone that you were one of my clients. However, if YOU want to come up to me, that's just fine, and I really love to see my ladies and have a chat, so please do come up and say hi. But I like to let everyone know about that, so they don't think that I haven't recognised them or that I don't want to talk to them. I always love having a chat with my ladies, so do please come up and say hi.

I want to really thank you for all the time you have given us for this study \_\_\_\_\_ (client's name). We know it was a lot of your time, which is valuable, and we're very grateful for that.

Now begin taking supplies out to load in to the car. At the final trip to the car with the last of the gear, give the rest of speech as per below

Thank you again so much for all of your time \_\_\_\_\_. I am really glad you put your hand up for this study, as I've thoroughly enjoyed meeting you and working with you over the past few weeks. And if you do run in to me at Woolie's, I hope you will come up and say hi and we can have a quick catch up chat! Thank you again, all the best, good bye.

## **APPENDIX R: SUMMARY OF RESULTS FOR PARTICIPANTS**



## *Summary of results for participants in the study:*

### *Healing Touch Supports Older Women at home*

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#### **Changes over time for everyone in the study:**

When we looked at all the participants in this study together, on average everyone had a fairly stable health status over the course of the study. There were no substantial changes observed in intellectual health, in level of social support, or in the number of new chronic diseases developed. There was only a very small decline observed in functional, emotional, and spiritual health status. Lastly, overall Quality of Life showed a small improvement over the course of the study, again when looking at all the participants together.

#### **Healing Touch versus Mimic Healing Touch (placebo):**

Next we separated the data into the two treatment groups so that we could compare them to each other, to see if there were any differences between the Healing Touch treatment group and the Mimic Healing Touch (the placebo) group. We wanted to know if one group did substantially better than the other group, on any of the various dimensions of health that we measured.

The only substantial difference we found between the two treatment groups was for social health, or social support. The Healing Touch group, on average, improved the scores on these questions by the end of the study, indicating a higher degree of social support; whereas the scores declined, on average, in the Mimic Healing Touch group (the placebo).

The social support section of the survey consisted of 19 questions about different types of support. Each participant was asked to consider how often each of the following kinds of support “are available to you if you need it?” The possible answers for each of these questions ranged from none of the time, a little of the time, some of the time, most of the time or all of the time. Answers closer to ‘all of the time’ resulted in a higher score, indicating better social support. Some example questions were: Someone to help you if you were confined to bed, who hugs you, who you could get together with for relaxation, who understands your problems, who would prepare a meal if you couldn’t, who would give you good advice about a crisis, to take you to the doctor, to love and make you feel wanted, etc.

For all the other health dimensions that we measured, the two treatment groups were essentially similar in the pattern of change over the course of the study. This similarity held true for the

number of new diseases developed, for overall quality of life, for intellectual health, emotional health, spiritual health, and for functional health (with one exception, which is described below).

In addition, for both treatment groups, we also found a similar amount of change in the participant's vital signs (blood pressure, temperature, pulse rate and respiratory rate) from before the treatment session as compared to after the treatment session. Lastly, the amount of change in the participant's self-perceived ratings between 0 to 10 of physical, emotional, intellectual and spiritual health was also essentially similar between both treatment groups.

The only other exception to this lack of difference between the two treatment groups occurred for one of the two sub-scales of functional health, the one about Basic Activities of Daily Living (i.e. the ability to wash, dress, groom, feed yourself etc. with or without assistance). For this measure of functional health, we zoomed in to look at only those participants who were already living in some form of structured accommodation (mostly retirement villages) at the beginning of the study. In that specific situation, the participants in the Healing Touch group had on average a very small improvement in their ability to do Basic Activities of Daily Living, while the participants in the Mimic Healing Touch (placebo) group had on average a very small decline in their ability to do Basic Activities of Daily Living.

However, for all the other dimensions of health that we measured, the Healing Touch group and the Mimic Healing Touch (Placebo) group did equally well. These findings indicate that there were no other beneficial effects of Healing Touch on the health of the older women in this study.

### **Satisfaction with Treatment:**

At the Post intervention interview only, we asked everyone a number of questions to gauge satisfaction with the treatment program. The responses of those in the Healing Touch treatment group were essentially similar to those in the Mimic Healing Touch treatment group. In both groups, around 70% of the participants felt the length of each session in minutes was appropriate, and around 50% were satisfied with the number of treatment sessions. For both groups, about 85% would want a treatment again if it was available at no cost to them, and only about 56% would want another treatment if they had to pay for it out of pocket. For both groups, approximately 97% would recommend the treatment to friends/family. For both groups, approximately 73% felt that they had been randomised into the group who received the actual Healing Touch treatment, rather than the Mimic Healing Touch group (the placebo). In both groups, about 82% would want to be included in a future study where they would be guaranteed to receive the actual Healing Touch treatment, if such a study were conducted. To date, such a study has not been funded.

**If you would like to be sent further details about the study results, please tick the box for that option on the enclosed green sheet, and return it to me in the pre-addressed, pre-paid envelope. Similarly, if you need to discuss any aspect of the study with me further, please again indicate that option on the green sheet and return it to me in the envelope provided.**

**APPENDIX S: NOTIFICATION OF RANDOM TREATMENT GROUP  
ALLOCATION**

## Notification of Treatment Group Allocation

Dear \_\_\_\_\_

The treatment group that the computer randomly assigned you to be in, for all 7 weekly sessions in the series of treatments delivered for this research study was the:

\_\_\_\_\_ Healing Touch group  
(Placebo) group

\_\_\_\_\_ Mimic Healing Touch

If you were randomly allocated in to the Placebo group, you are eligible to receive one free sample session of Healing Touch. Just tick the “Yes please” option on the green sheet and mail it back to me. However, we can only offer this sample session in the Townsville area, so if you’ve moved much more than 100km from Townsville, unfortunately a treatment in your home will not be an option.

Thank you again for contributing your valuable time to this research study! Kind regards,  
Kristin

## **APPENDIX T: OPTIONS SHEET**

**If you are interested in receiving any of the following options, please mark “YES” and then return this green sheet to me in the enclosed, addressed, pre-paid envelope. Please also update your address/phone number below:**

Your Name: \_\_\_\_\_

Phone number(s): \_\_\_\_\_

Current Postal address: \_\_\_\_\_

Current Residential address: \_\_\_\_\_

1. Would you like to be sent a copy of a journal article when we publish the study's results?

Yes please \_\_\_\_\_ No thanks \_\_\_\_\_

2. Would you like to be sent information about learning Healing Touch yourself, by attending a class in Townsville in June of 2012 or later in the year?

Yes please \_\_\_\_\_ No thanks \_\_\_\_\_

3. Would you like your name and contact details to be included on a list to possibly develop a support group of people who want to learn Healing Touch and practice on each other?

Yes please \_\_\_\_\_ No thanks \_\_\_\_\_

4. Do you have further questions or concerns about the study that you feel you need to discuss with me by phone?

Yes please \_\_\_\_\_ No thanks \_\_\_\_\_

5. ONLY for participants who ended up in the Mimic Healing Touch (placebo) group: Would you like to receive one free sample session of Healing Touch later this year? This may occur on campus at JCU by either Kristin or another Healing Touch nurse, rather than in your home, all depending on availability and timing, which we will organise together closer to the time.

Yes please \_\_\_\_\_ No thanks \_\_\_\_\_

**APPENDIX U: COVER LETTER FOR PARTICIPANT MAIL OUT AT END OF  
STUDY**

«First» «Last»

«Addr1»

«Addr2»

«Addr3»

«Addr4»

«Addr5»

**Faculty of Medicine, Health and Molecular Science**

Acting Senior Lecturer      Kristin Wicking  
Tel;      07 4781 5353  
Fax:      07 4781 4026  
email:      kristin.wicking@jcu.edu.au

Dear «First»,

Thank you again for your participation in the research study: Healing Touch Supports Healthy Older Women at Home. We are very grateful for your valuable contribution to the study, both in giving your time, and also in your thorough and candid responses to the survey questions we asked you at three different points in the study.

We reached our full quota of patients for the study, and they have all had their full series of 7 weekly treatments and also their 6 month follow-up home visits to ask the survey questions. We very carefully entered all of this data into a computer program to help us analyse the data, and the analysis is now complete.

I have included the following items in this package:

- A summary of the results (pink sheet).
- A short one page journal article describing the placebo effect.
- A page of options that you can select if you so desire (green sheet), and then return your choices to me by mail.
- A smaller pre-paid, addressed envelope to use to send the green sheet back to me, if you choose to do so.
- A note inside the smaller envelope notifying you of the treatment group to which you were randomly assigned by the computer at the beginning of the study (i.e. the actual Healing Touch treatment group, or the Mimic Healing Touch treatment group, also known as the placebo.)

With the data analysis completed, my focus will now turn to an intense writing phase, in order to finish producing the doctoral dissertation document, hopefully in time for the JCU health faculty's graduation ceremony later this year.

Thank you again for your time and effort in assisting us with this research project. I will always consider the opportunity to have met and spent time with each of you as both a privilege and a pleasure, and indeed the highlight of this project for me. So let me take this final opportunity to wish all of you the very best in your future health and happiness!

Kind regards,

Mrs. Kristin Wicking, RN, BSN, MSN, PhD candidate, Healing Touch Nurse and Principal Investigator for "Healing Touch Supports Healthy Older Women at Home"

**APPENDIX V: TREATMENT PROTOCOL SEQUENCE**

- HTP arrives at front door, wearing JCU id badge (and on first visit at least, JCU shirt), and carrying basket of pillows/linens and rolling pilot bag.
- Greets client, briefly makes small talk (But on first visit, introduces self and has a longer, rapport-building chat and asks if have parked in a suitable location).
- Returns to car to collect and bring in massage table and step stool. Sets up table while chatting.
- Sits down facing client if room set up/furniture allows. Always seated for first visit intake interview. (On subsequent visits, HTP proceeds to assist client to be seated on massage table at this point.)
- Opens client chart to write answers: Asks how the week has been? Anything noted after last session? Any changes in health status or new developments? Anything in particular to focus on as a goal for this session?
- HTP asks client to rate P/E/M/S health 1-10
- HTP takes set of obs: T/P/R/BP. Oral digital thermometer. Apical pulse through clothing x 30 seconds. Holds stethoscope in position another 30 seconds to count respirations. Unless contraindicated, takes BP on left arm. Notes arm used on documentation form and uses same arm each visit.
- HTP assists client to lie down on table supine (or prone as suits history for that week). Arranges pillows to client's comfort. Covers client with light sheet.
- HTP reads or recites Briefing script to client.
- HTP assists client to apply ear plugs securely, then sleep mask.
- HTP grounds
- HTP centers
- HTP sets intention
- HTP attunes to client
- HTP does pendulum asmt
- HTP does hand scan asmt
- HTP performs 1-3 selected HT techniques (or mimic HT techniques)/documents which ones used and in what order.
- HTP re-assesses by hand scan/documents
- HTP re-assesses by pendulum/documents
- HTP dis-connects from client
- HTP grounds client, awakens.

- Asks client “What was this session like for you?” (If further prompting needed, ask more specific questions: Any sensations, images, ideas come to mind for you during the session? )
- HTP documents any client comments on HT doc’n form
- HTP assists client to sit up on massage table for obs.
- HTP takes obs again & documents
- HTP asks ratings P/E/M/S & documents
- Assists client off table slowly and carefully.
- While chatting, folds up massage table and packs up everything.
- Takes massage table and step stool out to car first.
- Comes back for pilot bag and basket.
- Confirms next appt date/time.
- Thanks client for their time and contribution to the research, says goodbye for now.
- (Last visit, confirm Leah’s post-intervention visit date/time if known, and remind re the monthly phone calls from Leah and the final follow-up visit from her in 6 months.
- Also mention that we may run into each other around town in the shops, etc., but that due to confidentiality restrictions , I won’t be able to come up to them and greet them. However, if they choose to break confidentiality and come up to me and greet me, then that allows me to have a friendly chat. But the choice is always up to them, as it is not my place to break their confidence unless they choose to acknowledge me.
- Deliver Final Session Script)

**APPENDIX W: SESSION DOCUMENTATION FORM**

# Healing Touch Session Documentation

Date \_\_\_\_/\_\_\_\_/\_\_\_\_ Session #: \_\_\_\_\_

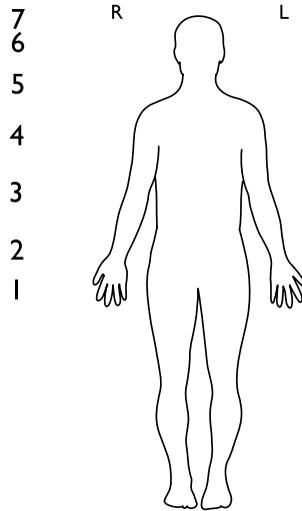
Client: \_\_\_\_\_ Practitioner: \_\_\_\_\_

Session Length: \_\_\_\_\_ Last Treatment: \_\_\_\_\_

## 1. Intake / Update:

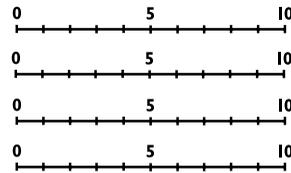
## 2. Practitioner Preparation:

## 3. Pre-Treatment Assessment:



## 4. P.E.M.S Health Issues / Problem Statement(s) to be addressed in this session.

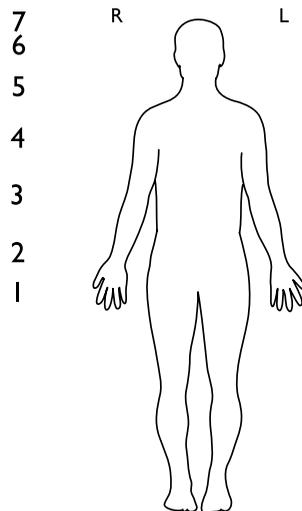
(Physical, Emotional, Mental, Spiritual)



## 5. Mutual Goals / Intentions for Healing (short/long term):

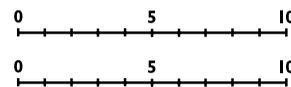
## 6. H.T. Interventions / Treatment:

## 7. Post Treatment Energetic Assessment:



## 8. Ground and Release:

## 9. Evaluation and Feedback:



## 10. Plan (growth work, self care, referrals, appt.):

**APPENDIX X: PRE-TREATMENT PROTECTION AFFIRMATION SCRIPT**

The first section, the Protection Affirmation, was done for all participants, placebo or experimental. The second section, the Centering Meditation, was done only for the experimental group participants. However, for the placebo participants, the HTP continued to stand still in the same location for another 2-3 minutes after doing the Protection Affirmation, to mimic doing the full centering meditation, to preserve blinding of participants to their group allocation.

Healing Touch is not affiliated with any particular religious organisation, but rather embraces all spiritual traditions (Hover-Kramer, 2002; Hutchison, 1999). All HTPs are taught to use their own spiritual belief system as a supporting framework for the work they do in a Healing Touch session. While this particular protection affirmation and centering meditation reflects the Christian belief system of the Principal Investigator (Thomas, 1994), other HTPs might use different wording, concepts and/or imagery to accomplish the same task of becoming centred and aligned with their concept and name for a Life Source or Universal Energy Source or God. For participants who asked about this aspect of Healing Touch, a simplified explanation was given describing the HTP as drawing on that same life source that exists all around us in nature, which causes a wound to naturally knit itself back together or a seedling to sprout.

Protection Affirmation Script:

{During this affirmation, the HTP closed her eyes and mentally pictured the room in which they were working, with each of 3 brilliant and imposing archangels in positions facing outward, guarding the area around the massage table with the client lying on it, and the HTP standing near it.}

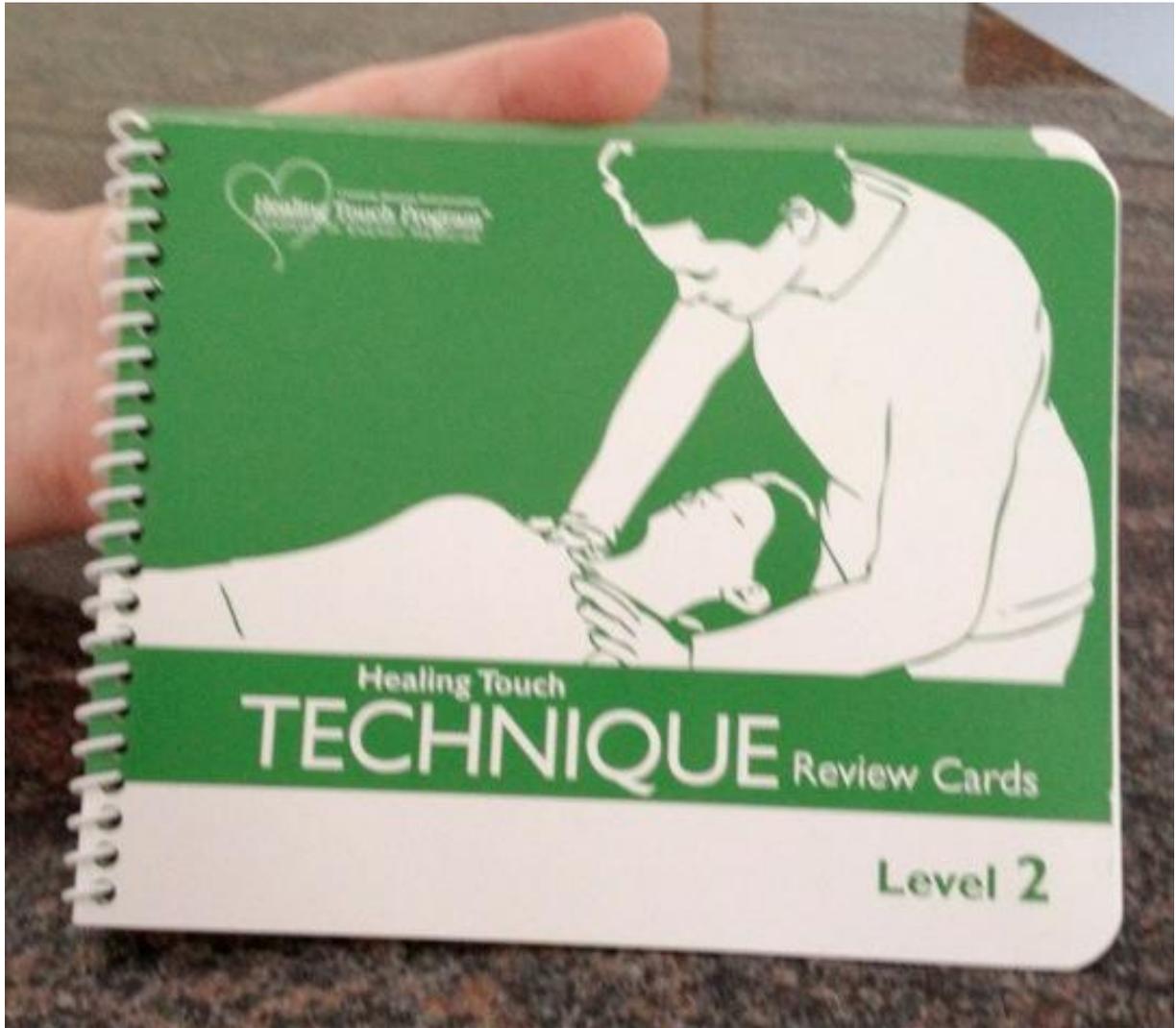
“We ask that the archangels Michael, Gabriel and Raphael form a tight protective ring around us, keeping us safe from any harm, injury, infection, interruption or irritation. May this time be completely safe, comfortable, appealing and convincing for \_\_\_\_\_.”

**APPENDIX Y: PICTURES OF FILLED GLOVES USED FOR DIRECT CONTACT  
PLACEBO PROTOCOLS**





**APPENDIX Z: PICTURES OF A5 BOOKLET USED FOR INDIRECT CONTACT  
PLACEBO PROTOCOLS**





**APPENDIX AA: LETTER TO GP FOR PARTICIPANTS WHO SCORED LOW ON  
THEIR MMSE**

Faculty of Medicine, Health and  
Molecular Science, School of Nursing,  
Midwifery & Nutrition

Lecturer Kristin Wicking  
Tel: 07 4781 5353  
Fax: 07 4781 4026  
International: 0011 61 2 4781 5353  
Email: Kristin.Wicking@jcu.edu.au

Date

Name/Address

Dear Dr. \_\_\_\_\_

I am writing to advise you of assessment information that may be useful in the ongoing clinical management of your patient \_\_\_\_\_, who has identified you as her General Practitioner.

I am conducting a research project for my PhD in Nursing at James Cook University and your patient was enrolled in this research project "Healing Touch Supports Healthy Older Women". As part of the screening process at the first home visit, the research nurse administered a Mini Mental Status Examination (MMSE). Any participant whose score was under 28 out of 30 at the time of this screening did not meet the eligibility requirements for this project and was unable to proceed into the intervention phase. Your patient's score was \_\_\_\_\_.

The terms of the consent form for this research project require me to relay information onward to you, although you may already be well aware of her current cognitive status from your own screening processes and ongoing management. However, since this recent MMSE result could possibly represent a decline in her cognitive status that had not yet been detected, then I am required to advise you of the results we obtained, in order to fulfill my own duty of care as a clinical researcher and in accordance with the protocol lodged with both the James Cook University (Project H 3077) and the Townsville Health Service District (Protocol 35/08) Human Research Ethics Committees.

It is not necessary for you to reply to me or to provide me with any other confidential information about this patient's management, as she is no longer enrolled in our study. I have also enclosed some further details of the research project for your information.

Regards,

Kristin Wicking, RN, BSN, MSN  
Lecturer and Principal Investigator for  
"Healing Touch Supports Healthy Older Women"  
School of Nursing, Midwifery & Nutrition, James Cook University

**APPENDIX BB: HEALTH HISTORY/INTAKE FORM FOR SESSION ONE**

# Healing Touch Intake Interview

Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Practitioner: \_\_\_\_\_ Referred By: \_\_\_\_\_

Client: \_\_\_\_\_ Phone: \_\_\_\_\_ Date of Birth: \_\_\_\_/\_\_\_\_/\_\_\_\_

Address: \_\_\_\_\_

E-mail: \_\_\_\_\_ Occupation/Education: \_\_\_\_\_

## Reason for Seeking HT Treatment(s):

## Experience with Energy Medicine, Healing Touch or related Modality:

## Social Support / Living Situation (family, alone, pets, etc.):

## Health Professionals Seen and When (circle what applies):

Physician      Nurse Practitioner      Physical Therapist      Nutritionist      Chiropractor  
Counselor/Therapist      other: \_\_\_\_\_

## Have you had any surgeries? Yes / No What kind? When?

## Medical Problems/Health History (circle what applies)

Heart    Lung    Digestive    Thyroid/hormonal    Bronchitis    Liver    Asthma    Heart Attack    Circulation  
Stomach    Gall Blader    Stroke    Reproductive Organs    Urinary Tract    High Blood Pressure    Clot    Colon  
Sexual Assault/Abuse    Eating Disorder    Seizures    Cancer    Diabetes    Vision    Kidneys    Hearing  
Depression    Weight Problems    Headaches    Serious Accident/Trauma    Alcohol/Drug Problems    Allergies

## Medications / Supplements (circle what applies):

Over the Counter Medicine    Perscription Medication    Homeopathics    Vitamins/Supplements/Herbs/Remedies

**Do You Use?** Type/Frequency?    Alcohol    Recreational Drugs    Tobacco    Caffeine

**Nutrition:**

**Water Intake:** Glasses per day \_\_\_\_\_

**Elimination:** Regular    Constipation

**Sleep Patterns:** Insomnia?    Aides?

**Personal Stresses : Use scale from 0 (no stress) to 10 (extreme)**

From: Illness \_\_\_\_ Work \_\_\_\_ Relationships \_\_\_\_ Finances \_\_\_\_ Loss \_\_\_\_

**Relaxation / Self Care:** (circle what applies)    Exercise/sports    Hobbies    Friends    Support Groups

Describe: \_\_\_\_\_

**Religious / Spiritual Practice and/or Belief:**

**What do you believe is the reason for your current health issues?**

**Is there anything else you want to tell me? Questions about me / Healing Touch?**

**Additional Information:**

**APPENDIX CC: CHANGE IN FIVE VITAL SIGNS BEFORE/AFTER TREATMENT  
AT EACH OF SEVEN SESSIONS IN TREATMENT SERIES.**

**Test Statistics<sup>a</sup>**

	S1 After temp minus Before temp	S1 After pulse minus Before pulse	S1 After resp minus Before resp	S1 After Systolic BP minus Before SBP	S1 After Diastolic BP minus Before DBP
Mann-Whitney U	2609.000	2529.500	2286.000	2721.500	2541.500
Wilcoxon W	5384.000	5610.500	5289.000	5496.500	5316.500
Z	-1.025	-1.058	-1.895	-.607	-1.276
Asymp. Sig. (2-tailed)	.305	.290	.058	.544	.202

a. Grouping Variable: Experimental vs Placebo Group

**Test Statistics<sup>a</sup>**

	S2 After temp minus Before temp	S2 After pulse minus Before pulse	S2 After resp minus Before resp	S2 After Systolic BP minus Before SBP	S2 After Diastolic BP minus Before DBP
Mann-Whitney U	2526.000	2716.000	2704.500	2703.000	2828.000
Wilcoxon W	5376.000	5719.000	5707.500	5553.000	5678.000
Z	-1.464	-.637	-.696	-.811	-.355
Asymp. Sig. (2-tailed)	.143	.524	.487	.417	.722

a. Grouping Variable: Experimental vs Placebo Group

**Test Statistics<sup>a</sup>**

	S3 After temp minus Before temp	S3 After pulse minus Before pulse	S3 After resp minus Before resp	S3 After Systolic BP minus Before SBP	S3 After Diastolic BP minus Before DBP
Mann-Whitney U	2561.500	2321.500	2389.000	2350.000	2748.000
Wilcoxon W	5642.500	5402.500	5470.000	5431.000	5829.000
Z	-1.332	-2.220	-2.018	-2.101	-.648
Asymp. Sig. (2-tailed)	.183	.026	.044	.036	.517

a. Grouping Variable: Experimental vs Placebo Group

**Test Statistics<sup>a</sup>**

	S4 After temp minus Before temp	S4 After pulse minus Before pulse	S4 After resp minus Before resp	S4 After Systolic BP minus Before SBP	S4 After Diastolic BP minus Before DBP
Mann-Whitney U	2678.500	2621.500	2567.000	2709.500	2346.500
Wilcoxon W	5759.500	5624.500	5570.000	5484.500	5427.500
Z	-.768	-.852	-1.076	-.651	-1.998
Asymp. Sig. (2-tailed)	.443	.394	.282	.515	.046

a. Grouping Variable: Experimental vs Placebo Group

**Test Statistics<sup>a</sup>**

	S5 After temp minus Before temp	S5 After pulse minus Before pulse	S5 After resp minus Before resp	S5 After Systolic BP minus Before SBP	S5 After Diastolic BP minus Before DBP
Mann-Whitney U	2777.500	2533.500	2829.500	2370.000	2789.000
Wilcoxon W	5552.500	5614.500	5604.500	5145.000	5564.000
Z	-.401	-1.309	-.214	-1.905	-.359
Asymp. Sig. (2-tailed)	.688	.190	.831	.057	.720

a. Grouping Variable: Experimental vs Placebo Group

**Test Statistics<sup>a</sup>**

	S6 After temp minus Before temp	S6 After pulse minus Before pulse	S6 After resp minus Before resp	S6 After Systolic BP minus Before SBP	S6 After Diastolic BP minus Before DBP
Mann-Whitney U	2820.500	2566.000	2357.000	2444.000	2561.000
Wilcoxon W	5595.500	5569.000	5360.000	5219.000	5336.000
Z	-.106	-1.063	-1.871	-1.509	-1.079
Asymp. Sig. (2-tailed)	.915	.288	.061	.131	.281

a. Grouping Variable: Experimental vs Placebo Group

**Test Statistics<sup>a</sup>**

	S7 After temp minus Before temp	S7 After pulse minus Before pulse	S7 After resp minus Before resp	S7 After Systolic BP minus Before SBP	S7 After Diastolic BP minus Before DBP
Mann-Whitney U	2745.500	2716.500	2626.500	2779.000	2164.000
Wilcoxon W	5748.500	5642.500	5327.500	5480.000	4865.000
Z	-.245	-.220	-.576	-.119	-2.441
Asymp. Sig. (2-tailed)	.806	.826	.565	.906	.015

a. Grouping Variable: Experimental vs Placebo Group

**APPENDIX DD: CHANGE IN PERCEIVED HEALTH STATUS ON FOUR  
DIMENSIONS OF HEALTH BEFORE/AFTER TREATMENT AT EACH OF SEVEN  
SESSIONS IN TREATMENT SERIES.**

**Test Statistics<sup>a</sup>**

	S1 After minus Before Physical health rating	S1 After minus Before Emotional health rating	S1 After minus Before Cognitive health rating	S1 After minus Before Spiritual health rating
Mann-Whitney U	2531.000	2683.500	2664.500	2375.000
Wilcoxon W	5306.000	5686.500	5439.500	5150.000
Z	-1.082	-.488	-.723	-1.976
Asymp. Sig. (2-tailed)	.279	.625	.470	.048

a. Grouping Variable: Experimental vs Placebo Group

**Test Statistics<sup>a</sup>**

	S2 After minus Before Physical health rating	S2 After minus Before Emotional health rating	S2 After minus Before Cognitive health rating	S2 After minus Before Spiritual health rating
Mann-Whitney U	2791.500	2597.000	2739.000	2566.000
Wilcoxon W	5641.500	5447.000	5589.000	5416.000
Z	-.226	-.975	-.436	-1.025
Asymp. Sig. (2-tailed)	.821	.329	.663	.306

a. Grouping Variable: Experimental vs Placebo Group

**Test Statistics<sup>a</sup>**

	S3 After minus Before Physical health rating	S3 After minus Before Emotional health rating	S3 After minus Before Cognitive health rating	S3 After minus Before Spiritual health rating
Mann-Whitney U	2865.500	2627.500	2666.500	2622.500
Wilcoxon W	5715.500	5477.500	5516.500	5625.500
Z	-.084	-1.012	-.883	-1.167
Asymp. Sig. (2-tailed)	.933	.312	.377	.243

a. Grouping Variable: Experimental vs Placebo Group

**Test Statistics<sup>a</sup>**

	S4 After minus Before Physical health rating	S4 After minus Before Emotional health rating	S4 After minus Before Cognitive health rating	S4 After minus Before Spiritual health rating
Mann-Whitney U	2693.000	2744.500	2498.500	2458.500
Wilcoxon W	5619.000	5519.500	5273.500	5159.500
Z	-.467	-.409	-1.432	-1.719
Asymp. Sig. (2-tailed)	.641	.683	.152	.086

a. Grouping Variable: Experimental vs Placebo Group

**Test Statistics<sup>a</sup>**

	S5 After minus Before Physical health rating	S5 After minus Before Emotional health rating	S5 After minus Before Cognitive health rating	S5 After minus Before Spiritual health rating
Mann-Whitney U	2447.500	2802.000	2339.000	2520.000
Wilcoxon W	5148.500	5503.000	4967.000	5148.000
Z	-1.559	-.181	-2.003	-1.499
Asymp. Sig. (2-tailed)	.119	.856	.045	.134

a. Grouping Variable: Experimental vs Placebo Group

**Test Statistics<sup>a</sup>**

	S6 After minus Before Physical health rating	S6 After minus Before Emotional health rating	S6 After minus Before Cognitive health rating	S6 After minus Before Spiritual health rating
Mann-Whitney U	2667.500	2543.000	2732.000	2534.000
Wilcoxon W	5442.500	5318.000	5507.000	5309.000
Z	-.574	-1.072	-.346	-1.305
Asymp. Sig. (2-tailed)	.566	.284	.729	.192

a. Grouping Variable: Experimental vs Placebo Group

**Test Statistics<sup>a</sup>**

	S7 After minus Before Physical health rating	S7 After minus Before Emotional health rating	S7 After minus Before Cognitive health rating	S7 After minus Before Spiritual health rating
Mann-Whitney U	2452.000	2280.500	2651.500	2324.500
Wilcoxon W	5008.000	5283.500	5654.500	4952.500
Z	-1.150	-2.004	-.541	-1.961
Asymp. Sig. (2-tailed)	.250	.045	.589	.050

a. Grouping Variable: Experimental vs Placebo Group