Global Telehealth 2012
A.C. Smith et al. (Eds.)

doi:10.3233/978-1-61499-152-6-43

Randomised Controlled Trial of an In-Home Monitoring Intervention to Improve Health Outcomes for Type 2 Diabetes: Study Protocol

Karen CARLISLE[a,1], Robin WARREN[a], Paul SCUFFHAM[b] and Tracy CHEFFINS[a]
[a] *Townsville-Mackay Medicare Local*
[b] *School of Medicine, Logan Campus, Griffith University*

Abstract. Type 2 diabetes is a leading cause of death and morbidity and is a health priority in Australia. This randomised controlled trial will explore whether remote access to clinical care, supported by telehealth technologies over high speed broadband, leads to improved diabetes control in a way that benefits patients, carers and clinicians and improves the overall health system. People in the intervention arm of the trial will receive additional diabetes care from a care coordinator nurse via an in-home broadband communication device that can capture clinical measures, provide regular health assessments and videoconference with other health professionals when required. Patients in the control arm of the trial will receive usual care from their GP and participate in the clinical measurement and quality of life components of the evaluation. The trial evaluation will include biomedical, psychological, self-management and quality of life measures. Data on utilisation rates and satisfaction with the technology will be collected and cost -effectiveness analyses undertaken. The role of this technology in health care reform will be explored.

Keywords. Type 2 diabetes, in-home monitoring , telehealth, self-management

Introduction

The increasing prevalence of type 2 diabetes is a phenomenon which has created significant challenges for many countries including Australia. The estimated worldwide prevalence of diabetes among adults was 285 million in 2010 and this value is predicted to rise to around 439 million by 2030 [1]. In Australia over 818,200 people (4% of the population) have been diagnosed with diabetes; 10% have type 1 and 88% have type 2 diabetes (2% reported they did not know the type) [2] with an estimated 275 new cases of diabetes being diagnosed every day [3]. Type 1 diabetes, which accounts for the minority of cases, is primarily due to a combination of genetic, biological and environmental factors. The substantial increase in diabetes rates overall are in type 2 diabetes and although there is a strong genetic predisposition, the risk of

[1] Corresponding Author: Karen Carlisle, Townsville/Mackay Medicare Local, Queensland, Australia; E-mail: kcarlisle@tmml.com.au

type 2 diabetes is greatly increased when associated with lifestyle factors such as high blood pressure, overweight or obesity, insufficient physical activity and poor diet [4].

Diabetes is a chronic condition which accounts for 5% of the total burden of disease [5] and is the sixth leading cause of deaths in Australia [6]. Studies have shown that poor glycaemic control, as measured by glycated haemoglobin (HbA1c), significantly increases the risk of diabetes-related complications such as microvascular complications, neuropathy, retinopathy, nephropathy, myocardial infarction and stroke [7,8]. Indeed, chronic and preventable illness has reached the point where the Australian health system can no longer sustain the level of burden of disease [9-11]. Research consistently supports the notion that targeting populations at greater risk of chronic disease results in longer term savings to the health system. Findings from national and international research suggest that countries with stronger primary care systems and effective management of chronic disease systemic factors have better health outcomes and lower costs [9,12] .

Diabetes self-management which involves educating individuals to manage their diabetes is a key component of effective diabetes care. The goals of diabetes education are to optimize metabolic control, improve compliance with medical regimens, prevent acute and chronic complications and enhance quality of life. A systematic review of interventions targeting diabetes reported that active patient monitoring and encouragement of self-management behaviours positively impacted on disease management in the short term [13]. However the delivery of ongoing support to the growing number of people living with chronic conditions such as diabetes cannot be solved solely by conventional methods; other more cost effective alternatives that will reach a large number of individuals, particularly those who have poor access to health services due to geographical, financial and other barriers, should be considered.

The adoption of telehealth/telemedicine [2] offers a potential solution to chronic disease management as it can provide support to help a person manage their condition at a time and place which is convenient for them. The World Health Organisation's [14] broad definition states that telemedicine is 'The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers'. Research from large scale programs have shown that the use of telehealth technologies combined with a care coordination model of care can be effective in helping people manage their chronic health condition. A US study of over 17,000 patients enrolled in a home telehealth program reported a 20% reduction in hospital admissions and 25% reduction in bed days of care [15]. In the UK an evaluation of the Whole System Demonstrator telehealth/telecare trial reported that participation in the trial had a positive impact on patients' quality of life, independence and empowerment in relation to managing their chronic condition [16]. The study also highlighted the importance of patient and clinician engagement in this approach to care management.

The cited benefits of telehealth such as greater access to healthcare services, improved health outcomes and more cost effective service delivery suggest that telehealth has the potential to change the delivery of healthcare [14]. Nevertheless there are a number of factors which can impact on its widespread adoption. Whilst the dearth of robust evidence for the value of telehealth remains a barrier [17-19], other factors including additional work loads and preference for the traditional approach of care have implications for the uptake of telehealth [20]. In addition, researchers have

identified lack of appropriate equipment, poor technology infrastructure and unreliable internet access particularly outside metropolitan areas as impacting on extensive usage of telehealth technology [21]. However the publication of standards for General Practitioners (GPs) offering video consultations [22] and the introduction of financial incentives in the form of new Medicare Benefits Schedule (MBS) items [23] reflect moves from the Australian Government to encourage nationwide implementation of telehealth. Furthermore the National E-health Strategy [24] and the National Digital Economy Strategy [25] both make specific reference to the implementation of telehealth solutions to enable a safer, higher quality, more equitable and sustainable health system.

This study attempts to address the need to support people with poorly controlled type 2 diabetes by examining the feasibility of using telehealth within a fully integrated case management model. The model of service delivery includes telehealth monitoring of key diabetes health indicators, home management, education and support. These services will be primarily delivered by care coordinator nurses dedicated to the trial, but will also allow for video consultations with GPs and remote group education with Allied Health Professionals. The trial participants are located in a regional area of Queensland (Australia) which is serviced by high speed broadband (National Broadband Network (NBN)); therefore a key objective of the trial will be to determine the ways in which the additional capacity of the broadband infrastructure can be utilised to deliver patient care.

1. Aims

This paper presents the study protocol for a randomised controlled trial (RCT) of a diabetes in-home telehealth monitoring system. The trial will explore whether remote access to clinical care, supported by telehealth technologies over high speed broadband, leads to improved diabetes control in a way that benefits patients, carers and clinicians, and improves the overall health system.

The primary aim is to investigate the effects of the diabetes in-home monitoring on health outcomes. Secondary aims include: to assess improvements in the experience of care for patients, their carers and clinicians; to determine if there is an improvement in primary care capacity and the integration of care; to assess any improvement in the efficiency of health service utilization (i.e. to determine the cost-effectiveness of the intervention compared with the control group); and to determine the utilization of the high speed broadband.

2. Methods/study design

The study is a two-arm prospective RCT in which a total of up to 210 adults with type 2 diabetes will be randomised to either the intervention (diabetes program) or to the 'usual care' control arm.

2.1. Study sample

Eligibility criteria include: patient diagnosed with type 2 diabetes with a recorded HbA1c of ≥ 7.5% in the previous 12 months; aged 18 years or over; living within the NBN footprint in their own home (i.e. not in residential care) and receiving primary care from a general practice. Patients are excluded if they are: diagnosed with severe unstable comorbidities with likely poor prognosis within 12 months; pregnant or diagnosed with gestational diabetes; diagnosed with dementia or intellectual and mental impairment (that would preclude use of technology); diagnosed with cancer (except non-melanotic skin cancer); have severe vision impairment (if deemed unable to use technology); suffer from chronic kidney disease and on dialysis or likely to be on dialysis within the timeframe of the trial; have a primary language other than English or currently enrolled in another intervention trial.

It is anticipated that complete data will be collected for 210 participants. With 210 completing participants, we will be able to detect intervention effects over usual care effects of at least a 0.4% reduction in HbA1c with 80% power and type I error of 5% (two-tailed). The calculations for HbA1c were based on standard deviations of change in HbA1c of 1% in both groups. An effect size of 0.4% in HbA1c was chosen for the sample size calculations based on Toobert et al., [26], who calculated that a change of 0.4% translates into a clinically substantial 14% reduction in risk of diabetes complications based on the analysis of the UK Prospective Diabetes Study in patients with type 2 diabetes [27].

2.2. Recruitment procedures

Our primary recruitment method is via general practices. A range of other strategies are also being adopted to support this method including, active recruitment which comprises of liaison with diabetes clinics at hospital and community health, official trial launch and participation at technology-related community events within targeted areas. Passive recruitment methods include: leaflets and posters in general practices and other allied health professional practices, display equipment at Lifetec and pharmacies, advertisement in local newspapers, GP targeted e-publications and newsletters. Individuals who are interested in participating and meet the inclusion criteria are sent information about the trial and consent forms. After signing the consent forms patients are randomised to control or intervention arms of the trial.

2.3. Study arms

Patients in the control arm of the trial will receive usual care from their GP and participate in the clinical measurement and health assessment components of the evaluation.

People in the intervention arm of the trial will receive online diabetes care from a care coordinator nurse via an in-home broadband monitoring and communication device that can capture clinical measures, provide regular health assessments and videoconference with other health professionals when required. The GPs will continue to manage their patients' care in partnership with the care coordinator nurse, and they

will together formulate a care plan consistent with the RACGP/ Diabetes Australia type 2 diabetes guidelines [28] for each patient. The intervention period is 12 months.

The intervention will enable the patient to remain in their own home while receiving clinical care from health professionals. The usual clinical relationships between the patient, GP and other health professionals continues, with agreed protocols for when the GP is to be contacted by the trial care coordinator nurse for both routine and non-routine encounters.

Each care plan developed will include frequency for remote monitoring of clinical measures and patient health assessments and protocols for managing changes in the clinical status of the patient. For participants in the intervention arm, this program will include the following components, the results of which are delivered to the care coordinator nurse via the high speed internet connection:

- regular blood pressure monitoring
- regular blood glucose monitoring
- participation in monitored online health questionnaires to reinforce diabetes self-management and assist early detection of complications
- participation in clinical videoconferencing sessions, as required, with care coordinator nurse and GP.

The monitoring system the patient will use is based around a tablet computer operated with touchscreen prompts. The blood pressure and blood glucose readings will be sent from the measuring devices to the monitoring software using Bluetooth technology. The care coordinator nurse will provide in-home training in the use of devices for each participant, according to their needs, to ensure their comfort and optimal use of technology.

The care coordinator nurse will view patient results daily and respond appropriately to results that are outside set parameters i.e. they will contact the patient to ascertain if results are due to an urgent medical problem, equipment failure, incorrect measuring technique or other factor. The care coordinator nurse will contact the GP or appropriate health professional, if required. Parameters will be set individually to account for participants' clinical situations. Trial nursing protocols will be prepared to allow all clinical staff to respond consistently.

The care coordinator nurse will make regular contact with the patient, either by videoconference, telephone or home visit. The capability for case conferencing via videoconference between the nurse and the patient's GP will be available to ensure appropriate team-based clinical care. Communication between GP and care coordinator nurse will consist of:

- initial care-planning session
- regular emailed reports, the frequency of which are determined by the care coordinator's assessment of patient risk (monthly – quarterly)
- videoconferenced sessions to resolve emerging clinical complications
- telephone contact as required.

2.4. Randomisation

The study design is according to the recommendations of the CONSORT statement for randomised trials of non-pharmacologic treatment [29]. Randomisation occurs after eligibility is determined and the patient has given consent. Arm allocation is conducted using simple randomisation procedures (computerised random numbers) with the participant as the unit of randomisation. The trial manager will be contacted by the care coordinator nurse to allocate them into either the intervention or control group. The trial manager will not be given the location, identity or clinical status of the person. The care coordinator nurse will then advise the patient of which group they are in and arrange a visit for baseline assessment for both groups and installation of the health monitor for intervention patients.

3. Findings/outcome measures

The trial evaluation will include biomedical, psychological, self-management and quality of life measures. Data on utilisation rates and satisfaction with the technology will be collected and cost effectiveness analyses undertaken. Patient data will be collected by clinicians (GP and care coordinator nurse) at baseline and repeated as follows:

Table 1. Frequency of clinical outcome measures collected by clinicians (care coordinator nurse and GP) during trial

Data	Frequency
HbA1c	3 monthly
Cholesterol	12 months
Renal Function	12 months
Blood pressure – systolic and diastolic	3 monthly
Weight	monthly
Waist circumference	monthly

Clinical record audit data to identify diabetes complications will be collected by practice nurses and care coordinator nurse at the conclusion of the trial period. A complication will be recorded if the patient experiences a new episode of any of the following during the trial period:

- death due to diabetes
- hospital admission due to diabetes
- renal disease
- eye disease
- vascular disease
- neurological disease.

Patient surveys will be undertaken at baseline (time 1), six months (time 2) and 12 months (time 3) and scores recorded for:

- quality of life (SF12)
- patient assessment of chronic illness care (PACIC)
- clinical depression and mental health (Kessler Psychological Distress Scale).

4. Data analyses

Control and intervention patient clinical measures and survey responses will be compared using mean values and independent t-tests for each indicator at baseline, intervals and conclusion of trial. Similar analyses will be conducted with clinical record audit data to compare the number of complications in the intervention and control groups. The utilisation of the technology will be assessed by monitoring the number of videoconferenced and face-to-face interactions between the patients and their GP, care coordinator nurse, other allied health and specialists.

Detailed economic data will be collected throughout the trial to enable a comprehensive evaluation of the intervention's efficiency when compared to routine care. Data on health care utilization will be obtained from participants at times 1, 2 and 3, GP records (for primary care services) and from Queensland Health (for admissions to public hospitals). Standard costs will be applied to all health care utilization (e.g. Medicare Item numbers will be mapped to MBS costs, and Australian-Revised Diagnostic Related Groups for hospital admission costs). The intervention arm will also incur the costs of the intervention including set-up costs that will be annuitized (e.g. home monitors) and operating costs.

Cost-utility analyses will be undertaken from the perspective of direct health care costs to the government. The analyses will be a 'within trial' analysis and a modelled analysis over the rest of life. Quality of life (SF-12) scores will be converted to utility weights using the SF-6D algorithm [30] for the calculation of quality-adjusted life years (QALYs) – the primary health outcome measure for the economic evaluation. The incremental costs and QALYs will be calculated as the differences between participants in the intervention and routine care groups. The resulting incremental cost-utility ratio will provide a measure of the relative value for money of the intervention using the additional cost per QALY gained. One-way and probabilistic sensitivity analyses will be undertaken for all parameters with uncertainty and/or variability [31].

5. Conclusions

The potential benefits of the trial for the wider community relate to the increasing prevalence of type 2 diabetes in Australia, which is putting additional strain on the health care system to provide primary and secondary care. New methods of delivering care such as this remote model will give patients access to services regardless of their locality. The research will test whether on-line monitoring of patients is not only effective in improving their diabetes, but whether it is feasible and acceptable to the patients and their health professionals. It provides an opportunity for new technology to be tested in a real setting, and for recommendations about its use to be made for

subsequent technological applications. The benefits for the participants relate mainly to improved access to diabetes education and help with self-management of their condition, and earlier detection of changes in their health status. Teamwork between patient, care coordinator nurse and GP is facilitated by the technology and will improve the continuity of care.

References

[1] Shaw JE, Sicree RA, Zimmet PZ. Global estimates of the prevalence of diabetes for 2010 and 2030. Diabetes Research and Clinical Practice 2010; 87(1):4-14

[2] Australian Institute of Health and Welfare. Australia's health 2010. Australia's health series no. 12. Cat. no. AUS 122. Canberra: AIHW, 2010

[3] Barr ELM, Magliano DJ, Zimmet PZ et al. The Australian Diabetes, Obesity and Lifestyle Study. Melbourne: The International Diabetes Institute, 2006

[4] Nolan CJ, Damm P & Prentki M. Type 2 diabetes across generations: from pathophysiology to prevention and management. Lancet 2011; 378: 169–181

[5] Begg S, Vos T, Barker B, Stevenson C, Stanley L & Lopez A. The burden of disease and injury in Australia 2003. Cat. no. PHE 82. Canberra: AIHW, 2007

[6] Australian Bureau of Statistics (ABS), Causes of Death, Australia, 2009, Cat. no. 3303.0. Canberra: ABS, 2009

[7] Stratton IM, Adler AI, Neil HAW et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes UKPDS 35: prospective observational study. BMJ 2000; 321: 405–412

[8] Sjølie AK, Klein R, Porta M et al. Effect of candesartan on progression and regression of retinopathy in type 2 diabetes (DIRECT-Protect 2): a randomised placebo-controlled trial. The Lancet 2008; 372: 1385-1393

[9] Swerissen, H & Taylor M. System reform and development for chronic disease management. A report prepared by the Australian Institute for Primary Care. La Trobe University, Melbourne: Policy, Planning and Resourcing Division, Queensland Health, 2008

[10] National Health and Hospital Reform Commission. A healthier future for all Australians – Final report of the National Health and Hospital Reform Commission. Canberra: Commonwealth of Australia, 2009

[11] Productivity Commission. Australia's Health Workforce, Research Report. Canberra: Productivity Commission, 2005

[12] Macinko J, Starfield B & Shi L. Quantifying the health benefits of primary care physician supply in the United States. International Journal of Health Services 2007; 37: 111-126

[13] Norris S. Effectiveness of Self-Management Training in Type 2 Diabetes. Diabetes Care 2001; 24(3): 561-587

[14] World Health Organisation. Telemedicine: opportunities and developments in Member States: report on the second global survey on eHealth (Global Observatory for eHealth Series, 2). Geneva: WHO Press, 2009

[15] Darkins A, Ryan P, Kobb R et al. Care coordination/home telehealth: The systematic implementation of health informatics, home telehealth and disease management to support the care of veteran patients with chronic conditions. Telemedicine and eHealth 2008; 14(10): 1118-1126

[16] Tyas D. A view from the inside: Whole System Demonstrator and Beyond. Information and Technology in Aged Care conference 2012. Melbourne, 19-20th April, 2012

[17] Wotton R. Twenty years of telemedicine in chronic disease management – an evidence synthesis. Journal of Telemedicine and Telecare 2012; 18: 211-220

[18] Mistry H. Systematic review of studies of the cost effectiveness of telemedicine and telecare. Changes in the economic evidence over twenty years. Journal of Telemedicine and Telecare 2012; 18: 1-6

[19] Barlow J, Singh D, Bayer S, & Curry R. A systematic review of the benefits of home telecare for frail and elderly people and those with long-term conditions. Journal of Telemedicine and Telecare 2007; 13: 172-179

[20] Moffat JJ, Eley DS. Barriers to the up-take of telemedicine in Australia – a view from the providers. Rural and Remote Health 2010; 11:1581.http://www.rrh.org.au/publishedarticles/article_print_1581.pdf (last accessed 30-07-2012)

[21] Tracy J, Rheuban K, Waters RJ, DeVany M, Whitten P. Critical Steps to Scaling Telehealth for National Reform. Telemedicine and e-Health 2008; 14(9): 990-994
[22] Royal Australian College of General Practictioners. The RACGP implementation guidelines for video consultations in general practice: A telehealth initiative. http://www.racgp.org.au/telehealth, 2011 (last accessed 30-07-2012)
[23] Department of Health and Ageing. Specialist video consultations under Medicare. http://www.mbsonline.gov.au/telehealth, 2012 (last accessed 30-07-2012)
[24] Department of Health and Ageing. National eHealth Strategy. http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Ehealth+Strategy, 2008 (last accessed 30-07-2012)
[25] Department of Broadband, Communications and the Digital Economy. National Digital Economy Strategy. Canberra: DBCDE, 2011
[26] Toobert D, Glasgow R, Strycker L et al. Biologic and quality-of-life outcomes from the Mediterranean Lifestyle Program: a randomised clinical trial, Diabetes Care, 2003; 26(8): 2288-2293
[27] UK Prospective Diabetes Study (UKPDS) Group: Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). The Lancet 1998; 352(9131):837-853.
[28] Harris, P., Mann, L., Phillips, P., Bolger-Harris, H., Webster, C (Eds). Diabetes Management in General Practice – Guideline for Type 2 Diabetes. Diabetes Australia in conjunction with the Royal Australian College of General Practitioners, 2011
[29] Boutron, I., Moher, D., Altman, D., Schulz, K. & Ravaud, P. Extending the CONSORT statement to randomised trials of nonpharmacologic treatment: explanation and elaboration, Annals of Internal Medicine, 2008; 148(4): 295-309
[30] Brazier, J., Roberts, J., & Deveril, M. The estimation of a preference-based measure of health from the SF-36. Journal of Health Economics, 2002; 21(2): 271-292
[31] Doubilet, P., Begg, C., Weinstein, M., Braun, P., & McNeil, B. Probabilistic sensitivity analysis using Monte Carlo simulations: a practical approach. Medical Decision Making, 1985; 5(2): 157-177