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Evaluation of a pragmatic community-tailored physical activity program with Aboriginal and Torres Strait Islander people

A dissertation submitted to James Cook University in fulfilment of the requirements for the degree of Doctor of Philosophy (Sport and Exercise Science)

By

Ashleigh Sushames

B.A., SpExSc (Hons)

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Statement on sources

The material presented in this thesis titled "Evaluation of a pragmatic communitytailored physical activity program with Aboriginal and Torres Strait Islander people" is my own work and has not been submitted for the award of any other degree or diploma in any other university or institution or tertiary education provider. To the best of my knowledge, this thesis contains no material previously published or written by another person, except where due reference is made in the text.

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I, the undersigned, the author of this thesis, which is in the fulfilment of the requirement for the degree of Doctorate of Sport & Exercise Science, understand that James Cook University will make it available for use within the university library and, via the Australian Digital Theses network, for use elsewhere.

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Declaration on ethics

The research presented and reported in this thesis was conducted within the guidelines for research ethics outlined in the National Statement on Ethics Conduct in Research Involving Humans (1999), the Joint NHMRC/AVCC Statement and Guidelines on Research practice (1997), the James Cook University Statement and Guidelines on Research Practice (2001). The proposed research methodology received clearance from the James Cook University Experimentation Ethics Review Committee (approval numbers H5763 and H5942).

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Preface Statement: Positioning of the Researcher

I am a non-Indigenous Australian woman who was born and raised in Darwin, Northern Territory. I spent my adolescent years living on the remote island of Groote Eylandt, which is the homeland of, and is owned by, the Warnindhilyagwa people. I left Groote Eylandt and moved to Cairns (Far North Queensland) for my high school education, as there were no high schools on the island. After high school, I went straight to university to study Sport and Exercise Science as I had a passion for sport and health. I have played representative rugby union and soccer for many years and it was through my sporting commitments that I made the connections with some of my Indigenous mentors. During my undergraduate degree, I realised that my true passion was to improve the quality of life of Indigenous people and I was lucky enough to have a well-respected honours supervisor who worked in Indigenous communities and helped me to expand my network by introducing me to her collaborating partners.

While living on Groote Eylandt, I witnessed the health inequalities between Indigenous and non-Indigenous people, and had a firsthand experience of how living remotely can affect a person's ability to access resources and can limit educational opportunities. I learnt about the inter-generational trauma that still exists in Indigenous societies and feel strongly that more work needs to be done to close the life expectancy gap between Indigenous and non-Indigenous Australians.

Prior to conducting my studies, it was important to me to understand my positional standpoint in relation to my research process. As a researcher, I believe in pragmatist epistemology as I see the importance of practical consequences.¹ I also recognise and respect viii

the ontological relationship that Aboriginal and Torres Strait Islander people have with the land and the sea, and I acknowledge that the social position that an Indigenous Australian may have politically and culturally will be different from my own.

 Morgan DL. Pragmatism as a paradigm for social research. Qualitative Inquiry. 2014;20(80):1045–53. doi: 10.1177/1077800413513733

Abstract

The health inequalities between Indigenous and non-Indigenous Australians, and the benefits of physical activity in the prevention and treatment of chronic diseases are well known. Yet, little research has been conducted on physical activity and health outcomes for Aboriginal and Torres Strait Islander people. The Australian physical activity guidelines, recommend that adults should accumulate 150-300 minutes per week of moderate activity or 75-150 minutes of vigorous activity or equivalent combinations of both. Currently, 47% of Aboriginal and Torres Strait Islanders in non-remote locations are sufficiently physically active, 0.9 times that of non-Indigenous Australians.

The purpose of this thesis was to investigate ways to improve the health of Indigenous Australians through a physical activity program. The first major aim (Study 1) was to synthesise previous evaluations of physical activity interventions implemented with Indigenous people in Australia and New Zealand and, based on this, to identify gaps in the literature and to recommend an agenda for future research in this field. The second aim (Study 2) was to assess the reliability and validity of the Fitbit Flex for measuring physical activity levels, as this device would be used in the succeeding study. The Fitbit Flex was selected as the comparative device as it is a waterproof accelerometer that can be worn 24 hours a day as a wristband, which may be more convenient for users and was hypothesised to lead to higher compliance in wearing time than the waist worn Actigraph GTX3+. The third aim was to implement and evaluate an 8-week community-tailored physical activity program in a rural and regional setting. The quantitative part of the evaluation of the program (Study 3) involved assessing changes in functional capacity for exercise, physical activity and various health outcomes. In a qualitative study (Study 4) barriers and enablers to participating in the program were examined.

Abstract

Study 1:

The systematic review was registered with the PROSPERO network and followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. A comprehensive search of the literature identified 13 studies which met the inclusion criteria. Due to the heterogeneity of the data and the contexts in which they were collected a meta-analysis was not feasible, so a narrative synthesis of the results was conducted. Only six studies measured physical activity objectively (n=2) or via self-report (n=4) and only five studies measured a component of fitness such as strength or sub-maximal aerobic capacity. There was no clear evidence that the interventions had increased activity levels in the short-term. However, 11 out of 13 studies reported improvements in fitness and other physical activity-related health outcomes such as reductions in weight and blood pressure.

Study 2:

A gap identified in the systematic review (Study 1) was the lack of objective measurements of physical activity, where only two out of the 13 studies had used pedometers. Therefore, in Study 2 the Fitbit Flex, a novel accelerometer, was validated against direct observation and a research-grade accelerometer (Actigraph GTX3+) under laboratory and free-living conditions. The validity of the Fitbit Flex was found to be dependent on the type of activity, where the number of steps taken during jogging and stair stepping were more accurate, compared to slow walking activities which were undercounted. The Fitbit Flex had overall moderate validity, was deemed more cost-effective and, due to the lower participant burden was expected to lead to higher compliance in wearing time. Consequently, the Fitbit Flex was selected as the method for objectively measuring activity levels of the participants in the planned physical activity program (Study 3).

Study 3:

In line with the recommendations from the systematic review, objective measures of activity with the Fitbit Flex were attempted in the evaluation of the physical activity intervention (Study 3). The primary outcome measure for the community-tailored 8-week physical activity program was the change in functional capacity, which was assessed by the six-minute walk test (6MWT).

The physical activity program was implemented in both a rural (n=12) and regional community (n=22) in Far North Queensland. An attempt was made to use a wait-listed control group, however, the intended site withdrew shortly before the intervention was to begin due to a lack of staff availability. Due to an insufficient number of participants and therefore lack of statistical power, the original plan to run the evaluation with a waitlisted control group had to be replaced with a pre-post study design. An intention to treat analysis was undertaken due to low program attendance. In the rural community, there was a 50% attrition rate, where six of the 12 participants completed follow-up assessment. There was a significant improvement in the 6MWT distance from 467.3 metres±56 to 557.8 metres±108 (p=0.01) and significant decreases in body fat (34.98±6.6% to 30.61%±6.92, p=0.009) and hip circumference (106.6cm±4.0 to 104cm±5.3, p=0.005). Attendance to the program was low. Eight participants did not attend a single training session, and four attended an average of seven out of 26 sessions. Six sessions were cancelled due to rain which affected the implementation of the program.

In the regional city, 18 of the 22 participants attended post-program assessments. There was an increase in the 6MWT distance, but this was not clinically significant (p=0.287). There were no significant reductions in weight (p=0.25), BMI (p=0.19) or body fat percentage (p=0.85). Significant reductions were measured in waist circumference (from 99.11cm±11.95 to 96.07cm±11.46 (p=0.006) and hip circumference (from 105.41cm±11.32 to 101.97cm±8.83 (p=0.019)). Reductions in both systolic (p=0.0002) and diastolic blood pressure (p=0.0002) were also evident. No significant improvements in pathology markers, such as HbA_{1c} or cholesterol, were evident. Unfortunately, the objectively measured physical activity data could not be used for the evaluation of the intervention due to poor compliance in wearing the Fitbit Flex accelerometres. Self-reported daily minutes of moderate to vigorous physical activity increased from 28.2 minutes ± 13.3 to 40 minutes ± 20.2 (p=0.09), but this was not significant.

Study 4:

After observing low attendance to the physical activity program, a qualitative evaluation was undertaken to better understand the factors that were influencing the attendance rate. Semi-structured interviews were conducted with twelve participants at the follow-up health assessments for Study 3. The interview guide was loosely based on the Health Belief Model. It was theorised that individuals would be more likely to voluntarily engage in the physical activity program if their current behaviour is perceived as a threat to their health. The findings from the interviews confirmed that despite low program attendance, there were positive attitudes and high levels of motivation towards the physical activity program. The enablers to participation were the inclusion of family members, no financial cost and a good relationship with the principal investigator, which was strengthened by the community-based participatory approach to the program design. Barriers to program attendance were mostly beyond the control of the individuals, such as sorry business, needing to travel away from the community and lack of community infrastructure.

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Abstract

Conclusion:

The purpose of this thesis was to investigate ways to improve the health of Indigenous Australians through a physical activity program. Based on the findings from the systematic review of the literature and the validation study, an 8-week physical activity program was implemented. The results of the program suggest that those who participated in physical activity during the study period had improvements in clinical health outcomes. However, more consideration of community-specific barriers and enablers is needed prior to implementation of programs to understand how they will affect attendance to the program. More work is needed to better understand how to improve participation rates in physical activity programs for Aboriginal and Torres Strait Islander people in rural and regional settings.

Thesis overview

This thesis includes a combination of peer-reviewed publications and traditional thesis chapters, some of which are intended for publication at a later date. The figure below will be inserted at the beginning of each chapter to help guide the reader, and a reference list is provided at the end of each chapter.

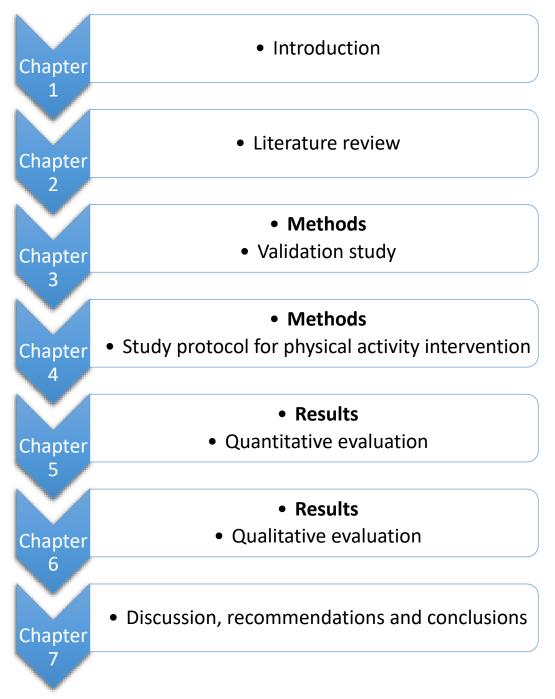


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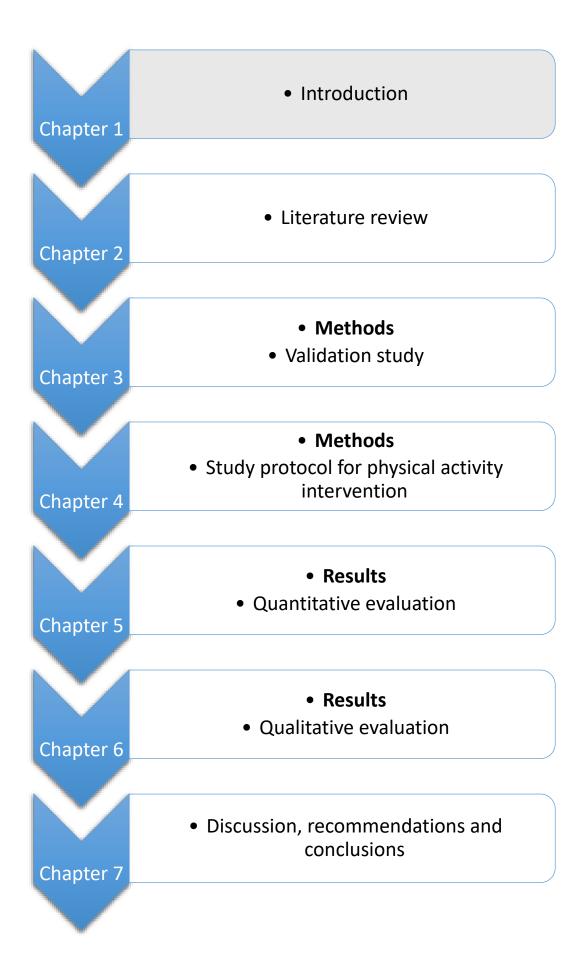
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List of acronyms

6MWT	Six-minute walk test	
ABS	Australian Bureau of Statistics	
AEE	Activity energy expenditure	
AIHW	Australian Institute of Health and Welfare	
APA	Australian Postgraduate Award	
BMI	Body Mass Index	
BMR	Basal metabolic rate	
CI	Confidence interval	
CPM	Counts per minute	
Cv	Coefficient of variation	
CVD	Cardiovascular disease	
DO	Direct observation	
FNQ	Far North Queensland	
HbA _{1c}	Glycated haemoglobin	
HDL	High-density lipoprotein	
HC	Hip circumference	
ICC	Intraclass correlation	
JCU	James Cook University	
LDL	Low-density lipoprotein	
MVPA	Moderate-to-vigorous physical activity	
NHMRC	National Health and Medical Research Council	
PA	Physical activity	
PI	Principal investigator	
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses	
RCT	Randomised controlled trial	
RPE	Rate of perceived exertion	
SD	Standard deviation	
SE	Standard error	
SES	Socio-economic status	
SF-12	12-Item Short Form Health Survey	
SPSS	Statistical Package for Social Sciences	

WC	Waist circumference
WHO	World Health Organization



Chapter 1: Introduction

This introduction provides the context and background for the chapters in this thesis. Firstly, a brief description of the history of Aboriginal and Torres Strait Islander people will be given to understand how history and culture impact the ability to undertake research with Indigenous Australians. This chapter will also describe the health benefits and the importance of physical activity and how a lack of physical activity can contribute to poor health and a reduced life expectancy in Indigenous Australians. Secondly, the introduction will illustrate the link between Indigenous chronic disease prevalence and life expectancy and how these outcomes are interrelated with physical inactivity. An additional section will describe the context of working with Indigenous Australians and includes considerations and barriers to undertaking research with this minority group. The final chapter of this thesis discusses recommendations for future studies, based on learnings from the four research studies.

The health of Indigenous people

The Aboriginal and Torres Strait Islander people are the Indigenous people of Australia and one of the oldest known living cultures in the world. For thousands of years prior to the arrival of the Europeans, Indigenous Australians lived with a high dependence on the land and survived through the development of hunter and gatherer skills. The arrival of the British settlers in 1788 resulted in the forceful dispossession of land and a loss of a deep rooted spiritual connection for the people.¹ The attempts to "breed out" Indigeneity by forcefully assimilating Indigenous children into Westernised societies resulted in children being systematically removed from communities to be raised in white Missions.² The legal and illegal trials and tribulations as a consequence of the 'discovery' of Australia by Europeans and British have emphasised the resilience of the Aboriginal and Torres Strait Islander people, but created many inequalities which persist today. Factors contributing to the

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disparities include the systematic loss of language and culture, dispossession of traditional lands, and marginalisation both socially and economically.³⁻⁵ There is an indisputable relationship between the enduring impact of colonisation and the current health status of Aboriginal and Torres Strait Islander people.⁶⁻¹⁰ Trends in premature mortality and high rates of chronic disease are not exclusive to the Indigenous people of Australia. High-profile documents published by *The Lancet* and the United Nations demonstrate that there are shared experiences of forceful colonisation, underpinning the continued social and health inequalities experienced by Indigenous groups across the world, including Native Americans, Pima Indians and the Maori people of New Zealand.³⁻⁵

Internationally, Indigenous people have disproportionately higher rates of preventable chronic disease which contribute to a lower life expectancy when compared with non-Indigenous people.¹¹⁻¹³ Australia, Canada and New Zealand are developed and wealthy nations. However, Indigenous people were almost as disadvantaged in 2006 as they were in 1981 relative to the non-Indigenous populations in employment, income and education.¹⁴ The disadvantage is also translated to a life expectancy gap of more than five years between Indigenous and non-Indigenous populations in Australia, Canada and New Zealand.¹⁴

In Australia, the life expectancy for Aboriginal and Torres Strait Islanders is ten years lower than that of non-Indigenous Australians.¹⁵ More specifically, in 2016 half of all deaths of Indigenous people in Queensland were at a median age of 58 years and 81 years for non-Indigenous.¹⁶ It is estimated that 70% of the inequalities in health for Indigenous Australians are caused by chronic disease.¹⁷ Obesity-related lifestyle diseases, such as type 2 diabetes and cardiovascular disease, are some of the leading causes of morbidity and mortality in Indigenous Australians.^{15, 18} The age-standardised mortality rate for type 2 diabetes in Indigenous Australians is four times higher than in other Australians,¹⁹ and the age-adjusted death rate for Indigenous adults from cardiovascular disease is almost twice that of other people in Australia.²⁰

Physical activity and health

Most risk factors for chronic disease are modifiable through a healthy lifestyle, which includes undertaking regular physical activity. Physical activity is described by the World Health Organization as any bodily movement produced by skeletal muscles that requires energy expenditure.²¹ It is important to note that physical activity encompasses a broad range of elements and can be defined in several ways. Physical activity can be described according to intensity, duration and frequency and its domains such as active transportation, at work, domestic household chores and leisure time.^{22, 23} Exercise is a subset of physical activity and described as planned, structured and repetitive bodily movement done to improve or maintain one or more components of fitness.²⁴

Regular engagement in physical activity has a variety of physical and mental health benefits. Undertaking the recommended amount of moderate or vigorous physical activity can reduce the risk of all-cause mortality²⁵⁻²⁸ and the greatest benefits in all-cause mortality are gained by those who move from being inactive to becoming moderately active.^{29, 30} There is substantial evidence for the benefits of physical activity in preventing, managing and improving conditions such as obesity, type 2 diabetes and cardiovascular disease.^{22, 31} Physical activity can increase insulin sensitivity both acutely and long-term, lower blood glucose levels, reduce body fat and improve cardiovascular function.³²

Chapter 1: Introduction

Insulin sensitivity, blood glucose and weight management are essential to the prevention of type 2 diabetes and cardiovascular disease. Complications from unmanaged diabetes can be severe and life threatening. Type 2 diabetes can cause kidney disease, blindness and also lead to the amputations of limbs.^{33, 34} One report estimates that in Australian adults there is one limb amputation every two hours, or approximately 84 limb amputations per week (12 per day), due to diabetes complications.³⁵ More alarmingly, Aboriginal and Torres Strait Islanders in Western Australia have diabetic amputation rates 38 times higher compared to non-Indigenous Australians with diabetes.³⁶ Another leading cause of death in Australia is cardiovascular disease, with one death every 12 minutes attributed to the illness.³⁷ Cardiovascular disease is one of the biggest burdens on the economy, with lower socioeconomic groups, Aboriginal and Torres Strait Islanders and people residing in remote areas having the highest rates of deaths and hospitalisations resulting from cardiovascular disease.¹⁹

Current Australian guidelines recommend that adults aged 18 to 64 should accumulate 150-300 minutes per week of moderate physical activity or 75-150 minutes of vigorous activity.³⁸ Based on self-reported data, more than half of Australian adults (56%) are not meeting the physical activity guidelines, while adults living in regional and remote areas are even less active (62% and 61% respectively).³⁹ Indigenous Australians have slightly lower rates of physical activity compared to the general population, with 38% of Indigenous people in non-remote locations meeting the physical activity recommendations. They are less likely to be sufficiently active for health (rate ratio 0.8) and to participate in any physical activity (rate ratio 0.9) compared to non-Indigenous Australians.⁴⁰ Moreover, 66% of Aboriginal and Torres Strait Islander people over 15 years of age are overweight or obese, more than among

non-Indigenous Australians (rate ratio of 1.1).⁴¹

It is estimated that physical inactivity causes over 5.3 million deaths globally per year.⁴² Low levels of physical activity, poor diet and social determinants of health are thought to contribute to the high prevalence of chronic disease and poor health outcomes in Indigenous Australians.¹⁵ The consequences of physical inactivity and poor health can lead to irreversible damage and unnecessary premature mortality.

Burden of disease/cost/preventable hospitalisations

Physical inactivity is placing a substantial economic burden on global health care systems. For 2013, it was estimated that the global cost of physical inactivity was \$53.8 billion INT\$.⁴³ The health care system of Australia is facing a number of challenges, including a growing burden of chronic conditions which are driving an increase in health service utilisation and rising health care expenditure. A recent study published in *The Lancet* estimates the financial burden of physical inactivity per year (INT\$) in Australia to be \$805 million, which includes \$640 million in direct costs and \$165 million in productivity losses.⁴³ The further economic burden to the healthcare system is through hospitalisation rates. Indigenous Australians are relatively high users of the public hospital system. Although Indigenous Australians represent only 3% of the total Australian population, they account for 4.2% of all hospital admissions.⁴⁴ With age-adjusted rates, Indigenous Australians in 2013-2014, with the rates being 896 and 384 per 1000 respectively. However, 86% of this difference is due to higher rates of hospitalisation for end-stage renal disease related dialysis.⁴⁴ End-stage renal disease is often a result of diabetes related complications.⁴⁵ Aside from the economic

burden of chronic diseases and physical inactivity, there are enduring impacts on the population through reduced quality of life and physical function and functional capacity for exercise.^{46, 47}A decreased quality of life has also been reported in family members who care for individuals with chronic disease, as there is a profound emotional impact and increased financial burden.⁴⁸

Limiting the incidence of preventable illness and disability can increase the quality of life for both individuals and society.⁴⁹ Self-assessed health status is commonly used to measure overall health as a reflection of a person's perception of their health at a given point in time.⁵⁰ Indigenous Australians are twice as likely to rate their health as fair or poor and almost half as likely to rate their health as excellent or very good, compared to non-Indigenous Australians.¹⁹ Overall, 39% of Indigenous Australians rate their health as excellent or very good, while 36% rated their health as good and 25% gave ratings of fair or poor.¹⁹ The self-rated health of Indigenous Australians may be misrepresented as high, due to the assumption of common experiences of health and illness between Indigenous and non-Indigenous people. English as a second language and socio-economic factors including income and education are known to create a scale perception bias, as a poorer health status can create a lower standard of the definition of good health.^{51, 52} The Australian Youth Development Index (YDI) found that health and wellbeing of Indigenous Australians has deteriorated significantly over the last 10 years due to mental health issues and increased substance abuse.⁵³ Indigenous people are also twice as likely to be hospitalised due to mental and behavioural issues¹⁹ and are three times more likely to experience high or very high levels of distress.⁴¹ Reported stressors for Indigenous people included the death of a family member or friend, serious illness, unemployment, alcohol or drug related problems and mental illness. High levels of distress are also evident in those who did not complete year 12

and to people who are unemployed.⁵⁴ Aboriginal and Torres Strait Islander people are less likely than non-Indigenous people to complete Year 12 or higher qualifications (35.9% vs 67.3%).⁵⁵ The national unemployment rate for Indigenous Australians aged 15 years and over is estimated to be 20.6%, however, these rates are not directly comparable with non-Indigenous Australians due to differences in the age structures of the populations.⁵⁶ This cycle of disadvantage is often linked back to the concept of inter-generational trauma and the social determinants of health.⁵⁷ Inter-generational trauma refers to Indigenous people's experiences of traumatic events, such as colonisation and the forceful removal of children, which have lasting negative effects that are passed on from generation to generation.⁵⁸ The cumulative effects of this trauma can cause widespread social disadvantage and reduce the capacity of Aboriginal and Torres Strait Islander people to fully and positively participate in their lives and communities.⁵⁸

The social determinants of health

It is critical to understand potential factors, besides physical inactivity, that may be contributing to the health disparities between Indigenous and non-Indigenous Australians. The World Health Organization describes the social determinants of health as "the conditions in which people are born, grow, work, live and age, and the wider set of forces and systems shaping the conditions of daily life".⁵⁹ Social, economic and education outcomes are contributing factors to the health inequalities of Indigenous Australians. Social and economic factors are classified as social determinants of health due to the impact on both the environment and conditions people live in.¹⁹ Socioeconomic factors attribute to around one third of the life expectancy gap between Indigenous and non-Indigenous Australians.¹⁹ In 2016, Indigenous Australians were half as likely as non-Indigenous Australians to report an

equivalised weekly household income of \$1000 or more, (20% compared to 41%). Employment rates were lower for Indigenous (47%) versus non-Indigenous Australians (72%).⁶⁰

Another important social determinant of health is education and health literacy. Lower levels of general literacy are more common among socially and educationally disadvantaged groups and those whose first language is not English such as refugees, migrants and Indigenous people.⁶¹ In Australia, Indigenous students are estimated to be behind non-Indigenous students by the equivalent of two-and-half-years of schooling.⁶² Without adequate literacy and numeracy skills at a young age it is harder to take advantage of opportunities later in life as the barriers may restrict many aspects of a person's life, including work, education and health. Health literacy is the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions.⁶³ Health literacy plays a significant role in the maintenance of a healthy lifestyle over the lifespan. Poor health literacy is linked back to lower levels of general literacy/numeracy in the adult population,⁶¹ as it places a significant constraint on a person's ability to access, read, comprehend and apply information, to make informed decisions and achieve self-efficacy.⁶⁴

Social determinants and risk factors

The social determinants of health can influence health behaviours.⁶⁵ Factors that affect health in a negative manner are referred to as risk factors, as they increase the likelihood of chronic disease development.⁶⁶ Commonly identified risk factors for chronic disease are smoking, nutrition, alcohol and physical inactivity,⁶⁷ often referred to as SNAP

risk factors, which are largely preventable and modifiable through behaviour change.⁶⁶ Smoking is a major risk factor for health as it can cause heart disease, stroke and cancer.⁶⁸ Indigenous people are twice as likely to smoke compared with non-Indigenous Australians, with a smoking prevalence of 45% versus 16%.⁶⁹ In regards to nutrition, the Australian dietary recommendations are that adults should consume two serves of fruit (small fruit such as apricots require two pieces to be considered as a serve) and five serves of vegetables per day. Poor nutrition influences overweight and obesity, cardiovascular disease and type 2 diabetes.^{66, 70} According to the most recent National Aboriginal and Torres Strait Islander nutrition survey,⁷¹ 54% of Aboriginal and Torres Strait Islanders consumed the recommended amount of fruit per day, while only 8% had an adequate vegetable intake. Rates of fruit and vegetable consumption are lower compared to non-Indigenous Australians, with the rate ratios being 0.9 and 0.8 respectively.⁷² Alcohol use is another important risk factor that contributes to poor health. Excessive drinking is not only a health issue, but also socially detrimental to the community. Although Indigenous Australians are less likely to drink compared to non-Indigenous Australians, those who drink are likely to do so at harmful levels.⁷³ The final risk factor in the SNAP model is physical activity which will be discussed in detail below.

Physical activity programs for Indigenous Australians

Physical inactivity is one of the identified SNAP risk factors to health. There is wellestablished evidence on the effectiveness of physical activity in the prevention and management of chronic disease.^{74, 75} However, little research has been undertaken to assess or evaluate interventions to encourage physical activity with Indigenous Australians. A systematic review of physical activity interventions for Indigenous people in Australia and

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New Zealand was undertaken by the author of this thesis. The systematic review focuses on Australian and New Zealand Indigenous populations due to geographical proximity, and similarities in life expectancy gaps. The decision not to include other Indigenous population groups residing in Canada and the United States was to avoid repetition of an existing systematic review on physical activity interventions.⁷⁶

Despite the acknowledgement of the need for more physical activity research, only 13 evaluations of physical activity interventions were identified that met the inclusion criteria.⁷⁷ It was noted in the review that a statistical synthesis of the results was not possible and that comparisons between the interventions were limited due to the lack of homogeneity in study design and measurement of activity and health outcomes. Furthermore, information on best practice in implementing and identifying barriers to physical activity interventions was difficult to assess. Methodological details, such as procedural implementation fidelity, end of project feedback, participants' experiences and evaluations, were rarely included.

The literature on physical activity interventions involving Indigenous Australians is limited, and there are few studies which have specifically implemented physical activity programs. There have only been two randomised controlled trials (RCTs). One study was a 12-week program designed for Indigenous females in Adelaide.⁷⁸ The study found significant reductions in weight and BMI at the follow-up assessment. The second RCT was also 12 weeks in duration and designed for inactive Indigenous men in regional New South Wales, and also reported significant reductions in weight and BMI.⁷⁹ There have been an additional seven Australian cohort studies in this population group. Three studies were conducted in the remote areas of Western Australia and reported improvements in metabolic markers such as triglycerides and glucose.⁸⁰⁻⁸² The remaining studies were conducted in an urban Queensland

population,⁸³ the Torres Strait Islands,⁸⁴ Tasmania⁸⁵ and in a Metropolitan area of Western Australia.⁸⁶

One of the studies included in the systematic review was conducted in New Zealand⁸⁸ and examined a physical activity intervention using culturally-based activities such as canoeing and family orientated activities. The study had an excellent attendance rate (90%) and was widely viewed as acceptable in the communities as it had local Indigenous mentors adding input and assisting with the delivery of the program. McAuley and colleagues⁸⁸ also incorporated a focus on strong cultural ties, family connections, community orientated and traditional activities, which may have contributed to the high attendance rate. The authors noted that a high level of support was required during the project period, and that support for maintenance of the lifestyle change was high. The physical activity component of the program was group exercise sessions four times a week with a variety of activities, including walking groups, waka ama (canoe paddling) and kappa haka (traditional song and dance). Individual progress checks were also conducted each fortnight over the period of the intervention and feedback was regularly sought as the program currently continued to run. A detailed description of these studies is provided in Chapter two, which is the systematic review of physical activity interventions with Indigenous Australian and New Zealander adults.77

Two of the studies which did not meet the inclusion criteria of our systematic review analysed levels of physical activity in Indigenous school children.^{89, 90} One of the studies explored the practices of physical activity for an Indigenous population living in the remote communities of the Torres Strait and Northern Peninsula Area of Far North Queensland.⁸⁹ The cross-sectional survey found that only 50% of the children reported being active for more

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than 30 minutes a day. Another cross-sectional study⁹⁰ utilised accelerometers to measure physical activity levels in rural school children. The authors reported that Indigenous children engaged in more moderate to vigorous physical activity (125 minutes per day) compared to non-Indigenous children (107 minutes per day). Similarly to research with Indigenous adults, there are still many gaps in the literature in regards to the implementation and evaluation of physical activity programs.⁷⁷

There have been several recommendations in regards to study design, project implementation and community engagement for future research into improving the health of Aboriginal and Torres Strait Islander people.⁹¹⁻⁹³ There are also a known variety of barriers to research, participation and engagement in Aboriginal and Torres Strait Islander populations. Reasons for low response rates can include mistrust in research and fear of exploitation,⁹⁴ lack of education⁹⁵ and low population numbers compared to non-Indigenous people.¹⁹ Research into socially disadvantaged groups has been lacking^{94, 96} and these groups are sometimes referred to as "hard-to-reach" or "hidden" populations as researchers continue to struggle to access, engage and retain participants. Indigenous Australians are unique in this regard, as there are concerns that this population group has been over-researched without corresponding health improvements.⁹³ The feeling of being over-researched without improvements, coupled with the complex interplay of social, behavioural and environmental factors for developing a chronic disease in Aboriginal and Torres Strait Islander populations³ can prove to be challenging.

A challenge to non-Indigenous researchers is instilling a balance between Western and Indigenous research methodologies, and understanding how the application of Western quality indicators may impact the study results. Indigenous research methods involve decolonising research frameworks by putting Indigenous voices and epistemologies in the centre of the research process.⁹⁷ It is critical to understand the underlying assumptions that Western methods and beliefs are the only objective, true science.⁹⁸ For example, a Westernised description of physical activity is any bodily movement produced by skeletal muscles that requires energy expenditure.²¹ In contrast, an Indigenous description of physical activity is associated as necessary physical engagement with the environment.⁹⁹ Furthermore, physical activities in this context were described as natural and cultural resource management, physically active forms of social organisation and education that helped to build and maintain relationships, wealth and the environment. In regards to views on research methodologies, some would argue that Western researchers have exploited Indigenous people to benefit their own careers while disempowering people and bringing no tangible benefits to the communities.⁹⁸

Study design and barriers to research

The study design is a critical factor when undertaking an intervention with Indigenous population groups. Randomised controlled trials are not always feasible in minority groups due to the small population size and it may be considered unethical to recruit a control group when dealing with an at-risk population.^{82, 88} Some debate on the issue of traditional randomised controlled study designs came about due to sustainability concerns¹⁰⁰ and when 'well-designed' interventions failed to produce an impact.¹⁰¹

Other researchers have attempted to conduct RCTs with lifestyle interventions with Indigenous populations, but were limited to using a self-selected control group⁸² or the study became a cohort study as information was shared between the two groups.⁸⁸ This information is important as it highlights that traditional Western research methods are not always applicable and there needs to be flexibility in study design.⁹⁸ In the systematic review of physical activity interventions for Indigenous people in Australia and New Zealand,⁷⁷ one study utilised an interrupted time series design to examine the effect of health promotion and education on high-risk individuals to reduce insulin resistance¹⁰² and the remaining seven^{80, ^{81, 83-86, 103} were cohort studies.}

One of the common themes in the studies reviewed here was the rejection and nonfeasibility of implementing a RCT design. Concerns about the allocation of some participants to a control group that would not receive the intervention were often a result of the consultation with the community.⁸⁸ This is further supported by Rowley and colleagues,⁸² who noted that a real randomised design would not be a useful model in community-based interventions for Indigenous people and reasons for rejection of control groups included ethical considerations based on at-risk individuals not receiving appropriate advice. An alternate study design could include a wait-listed control group, however, this may not be feasible if a high sample size is required in a relatively small community setting.

The sample size required for sufficient statistical power is also an issue with small minority population groups. Aboriginal and Torres Strait Islanders represent approximately 3% of the total Australian population, and 28% of Indigenous people are residing in Queensland.¹⁹ To put this into context, one of the intervention sites in this thesis that requested to participate in the research has a population of approximately 100 persons residing in the community, of which not all would have been eligible to participate in the study.

There are also historical and cultural reasons that can affect the recruitment of a sufficient sample size. A systematic review on strategies for improving health and medical research with socially disadvantaged groups⁹⁴ attributed low response rates with hard to reach populations to mistrust in researchers. The same problem has also been described in studies involving Indigenous people in Australia.^{93, 104, 105} Opposed to random probability, alternative sampling methods, such as snowball or respondent driven sampling have been used in several studies to assist with recruitment.^{79, 83, 85, 86, 88, 106} Although this is considered as convenience sampling and not representative of the general population, it is considered to be pragmatic and effective for participant recruitment with Indigenous population groups.⁹⁴

Education

Inadequate formal education can limit knowledge of an individual's health needs and their ability to access resources from the health care system. Language and education are also important factors to consider when doing research with Indigenous populations. Researchers need to be aware that barriers, such as language and education, may prohibit the use of selfadministered surveys, as participants may not understand the forms.

Customisation of interventions may include the use of culturally appropriate models or multimodal approaches, such as verbal explanations accompanied by print-based information, for later reference. In addition to customisation, in some situations involvement of an appropriate Indigenous person acting as an advisor or "literacy broker" has been useful in facilitating communication flows between outsiders and local Indigenous people.^{78, 84, 88, 102} Reasons for the verbal explanations were also noted in a previous study, in which participants expressed the need for information to be relayed in their language for accurate

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understanding.⁹⁵ Poor communication leads to misinterpretation, and the researchers' inability to speak the local language may also add to the participants' fear of the research. The fear of research is amplified by a lack of trust in government agencies due to historical events (The Stolen Generation), fears regarding an invasion of privacy and confidentiality, and the suspicion that the study will cause judgement and biases.¹⁰⁷ This highlights the importance of having local mentors and leaders to assist with the project to act as support and cultural brokers. Germino et al.¹⁰⁸ engaged several community groups for promoting their research which included 'cultural brokers' to liaise between participants and researchers. The study reported high recruitment and retention rates.

Community engagement

Despite extensive training and experience, non-Indigenous researchers may still have limited knowledge of Indigenous values, attitudes and beliefs. Engagement with community elders and leaders in Australian Aboriginal communities, which have social hierarchical structures, is an example of community engagement. The involvement of community members in the development of programs is considered to increase their effectiveness, relevance and sustainability.¹⁰⁹ It would be promising if interventions in communities were implemented with advice and mentoring from local Indigenous leaders and could be proven to work with limited resources. If the local community is engaged with the design and implementation of programs in a community participatory approach,^{91, 110} there is the potential for sustainable long-term projects that could be continued by the community.

In health promotion interventions with Indigenous people, cultural adaptations should be incorporated to ensure programs are adhering to the community values and beliefs. Practical and spiritual experiences and family relations can all constitute unique ideologies in an Indigenous person's knowledge. This is due to Indigenous populations being a minority and diverse group that, due to cultural differences, need particular consideration when designing programs. An example of adhering to Indigenous ideologies is flexibility in appointment scheduling. For instance, Indigenous Australians have a 'here and now' approach, which may have a conflict with tightly regimented, appointment-based systems.¹¹¹ Therefore, an intervention conducted by Dimer et al.⁸⁶ used flexible timing of allocations of participant attendance to the program by not creating specific times for sessions.

On a side note, for people considering doing research with Indigenous Australians, there are some notable recommendations by organisations, such as the National Health and Medical Research Council, who have provided strategic frameworks (Road Map) and guidelines for ethical conduct for working with Indigenous populations.^{112, 113} I have ensured the research in this thesis, to the best of my ability, has included the six values of ethical conduct: reciprocity, respect, equality, responsibility, survival and protection, and spirit and integrity. The implementation of the program was assisted by local Indigenous mentors from collaborating organisations who have extensive knowledge of the local culture and provided advice and information on the appropriate engagement procedures for individuals.

Statement of the research problem

In summary, it is evident that physical activity is associated with health benefits for the prevention and management of obesity and chronic disease. However, a review of physical activity programs with Indigenous Australians is needed to examine what has been implemented previously, where the gaps in the literature are, and, most importantly, if activity levels and health outcomes improve after such interventions. Of particular interest is

the use of objective measures of physical activity and functional capacity for exercise, and the implementation of a community-tailored physical activity program in regards to feasibility, affordability and practicality. Additionally, understanding the barriers and enablers to implementation of physical activity programs in rural and regional communities is crucial. Identification of successful elements will contribute to best practice knowledge and potentially improved health for Aboriginal and Torres Strait Islanders. This research examined physical activity as a method to improve the health of Indigenous Australians.

Specifically, this PhD thesis contains the following studies:

- 1. A systematic review of evaluations of physical activity interventions with Indigenous people in Australia and New Zealand.
- An examination of the reliability and validity for measuring physical activity of the Fitbit Flex against the Actigraph GTX3+ in both laboratory and free-living conditions.
- 3. The changes in functional capacity to exercise and health outcomes after participation in an 8-week physical activity program.
- A qualitative evaluation of an 8-week physical activity program in a rural and regional setting to identify barriers and enablers to participating in a physical activity program.

Research questions

For the purpose of this PhD thesis, the research questions were:

1. Do physical activity programs for Indigenous people in Australia and New Zealand show significant effects on physical activity levels and health outcomes?

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- 2. Is the Fitbit Flex a valid and reliable measurement of physical activity when compared to direct observation and the Actigraph GTX3+?
- 3. Will there be a clinically significant improvement in functional capacity to exercise and other health outcomes after the implementation of the physical activity intervention that is part of this PhD thesis?
- 4. What are the barriers and enablers to participating in the physical activity intervention for Indigenous Australians in Far North Queensland?

Significance of the study

The difference in life expectancy between Indigenous and non-Indigenous Australians is the largest such gap in the world and is mostly attributed to preventable chronic disease. In the Cairns and Hinterland region, this gap is even more than 20 years.¹⁶ Despite evidence for the health benefits of regular physical activity in the prevention and management of chronic disease, few studies in this field of research have been conducted with Aboriginal and Torres Strait Islander people. There are many barriers to undertaking research programs with Indigenous people as there are also many complex factors contributing to health inequalities.

Delimitations of the study

The findings of this research are delimited to:

- The nature and location of the sample, namely Aboriginal and Torres Strait Islander people living in Far North Queensland
- (2) The exposure and attendance to the exercise program.

Limitations of the study

The conclusions drawn from this research are limited by the following factors:

- 1. Sample size.
- 2. Missing data from the Fitbit Flex and limited compliance by the participants to attending pathology collection centres.
- 3. Implementation issues in the rural and regional setting.

Summary

This research set out to investigate ways to improve the health of Indigenous Australians through a physical activity program. The program design was inspired by a previous study in New Zealand with Indigenous Maori people which was successful in improving activity levels and health outcomes.⁸⁸ Based on the unique components of these studies, such as the flexibility in delivery and the recruitment of local leaders, the research built upon these methods to create something unique to Indigenous Australians. The program involved implementing a pragmatic community-tailored 8-week physical activity program to improve functional capacity for exercise in Australian Aboriginals and Torres Strait Islanders. This research synthesised previous studies that evaluated such physical activity programs;⁷⁷ validated an accelerometer for objective physical activity measurement;¹¹⁴ created and implemented a program; and assessed the impact on participants' functional capacity and health outcomes.

Structure of the thesis

This thesis is divided into seven chapters. Chapter two is a systematic review of previous evaluations of physical activity interventions with Indigenous people in Australia

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and New Zealand. The systematic review protocol was registered with the PROSPERO network and followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.¹¹⁵ A comprehensive search of the literature identified a lack of homogeneity in outcome measures, which included a limited number of studies which had objective measures of physical activity and/or fitness. With such little evidence on changes in physical activity levels, it was undetermined if the changes in fitness and health were a direct effect from increased physical activity levels.

The identified lack of objective physical activity measurements in the systematic review was the predecessor for designing and conducting a validation study of accelerometers (chapter three). The purpose of the validation study was to examine the reliability and validity for measuring physical activity of a novel, practical and user-friendly accelerometer. The study was conducted using two accelerometers: the Actigraph and the Fitbit Flex. The results of this study were used to determine the utility of the Fitbit Flex. Previous studies have compared outputs from Fitbit activity monitors and the Actigraph, but with variability in protocols and device placement. Paul et al.¹¹⁶ found excellent agreement in the average step count per day between the two devices recorded in free-living conditions and worn on the waist. Similarly, Gusmer et al.¹¹⁷ found no significant differences in step counts between the Fitbit Ultra and the Actigraph G1TM, reporting that both devices can be used interchangeably to measure step count when they are both worn on the waist. Ferguson and colleagues¹¹⁸ compared several consumer-level devices, including the waist worn Fitbit One, against the Actigraph GT3X+ and found strong validity for the Fitbit's measurement of steps and moderate-vigorous physical activity (MVPA). However, none of these studies compared freeliving conditions and laboratory based activities across multiple outcome measures such as

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step count, MVPA and activity energy expenditure.

Chapter four of this thesis includes the study protocol of the 8-week physical activity program which was implemented in a rural and regional setting in Far North Queensland. The protocol includes the study aims, design, a description of the program and the outcome measures assessed and the proposed statistical analysis. The study protocol outlined in this chapter demonstrates the intended methodological approach for the research. All variations of the study protocol are discussed at the end of this chapter in regards to issues of feasibility and real world application.

Chapter five is an evaluation of a community-based physical activity program with Indigenous Australians in a rural and regional setting in Far North Queensland. After the validation study had been completed, the Fitbit Flex was utilised for interventions with two Indigenous communities. The program included participants aged 18- 45 with risk factors for, or an already established chronic disease. The primary aim of the study was to improve functional capacity to exercise, which was assessed with the six-minute walk test.¹¹⁹ The intervention activities were based on the recommendations by Indigenous mentors in the community, and a co-design approach with the community was determined to be more appropriate and ethical. The two mentors collaboratively decided upon the program inclusion criteria, the number of days to run activities and the types of activities that were best suited for their local community.

Following on from the quantitative evaluation, chapter six is a qualitative evaluation of the program. At the completion of the 8-week program, participants were individually interviewed using a semi-structured interview to identify perceived barriers and motivations to engage in physical activity. Additional questions were included to explore the participants' experiences of the program, where improvements could be made and what the perceived long-term consequences are if their current behaviour continues.

The final chapter examines and reviews the studies in this thesis and around physical activity interventions with Aboriginal and Torres Strait Islanders. This thesis includes a review of the evidence, a validation study and a mixed-methods evaluation of an intervention study. To summarise these findings, this chapter explains how to translate the research into practice and has several recommendations for future research as a contribution to the body of evidence in this field.

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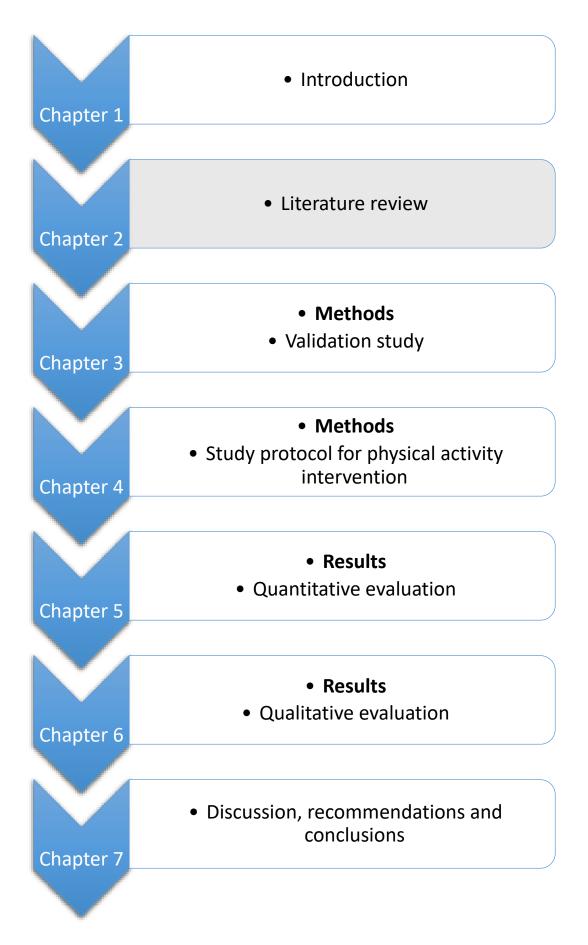
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Chapter 2: Literature review

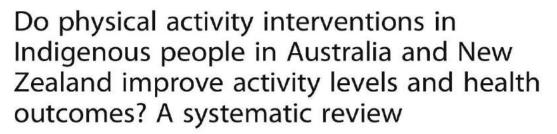
Sushames, A., van Uffelen, J. G. Z., & Gebel, K. (2016). Do physical activity interventions in Indigenous people in Australia and New Zealand improve activity levels and health outcomes? A systematic review. *International Journal of Behavioral Nutrition and Physical Activity*, 13(1), 129. doi:10.1186/s12966-016-0455 Sushames et al. International Journal of Behavioral Nutrition and Physical Activity (2016) 13:129 DOI 10.1186/s12966-016-0455-x

REVIEW

International Journal of Behavioral Nutrition and Physical Activity



CrossMark



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Abstract

Background: Indigenous Australians and New Zealanders have a significantly shorter life expectancy than non-Indigenous people, mainly due to differences in prevalence of chronic diseases. Physical activity helps in the prevention and management of chronic diseases, however, activity levels are lower in Indigenous than in non-Indigenous people.

Objective: To synthesise the literature on the effects of physical activity interventions for Indigenous people in Australia and New Zealand on activity levels and health outcomes.

Methods: The Cochrane Library, MEDLINE, SPORTSDiscus and PsycINFO were searched for peer-reviewed articles and grey literature was searched. Interventions targeted Indigenous people in Australia or New Zealand aged 18+ years and their primary or secondary aim was to increase activity levels. Data were extracted by one author and verified by another. Risk of bias was assessed independently by two authors. Data were synthesised narratively.

Results: 407 records were screened and 13 studies included. Interventions included individual and group based exercise programs and community lifestyle interventions of four weeks to two years. Six studies assessed physical activity via subjective (n = 4) or objective (n = 2) measures, with significant improvements in one study. Weight and BMI were assessed in all but one study, with significant reductions reported in seven of 12 studies. All five studies that used fitness tests reported improvements, as did four out of eight measuring blood pressure and seven out of nine in clinical markers.

Conclusions: There was no clear evidence for an effect of physical activity interventions on activity levels, however, there were positive effects on activity related fitness and health outcomes.

Trial Registration: The review protocol was registered with PROSPERO (registration number: CRD42015016915).

Keywords: Indigenous health, Australia, New Zealand, Physical activity, Intervention

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Background

Internationally, Indigenous people have disproportionately higher rates of preventable chronic disease that contribute to a lower life expectancy than non-Indigenous people [1–3]. Australia and New Zealand are both First World countries with substantial inequalities in health status between Indigenous and non-Indigenous people. In Australia, Aboriginal and Torres Strait Islanders are the Indigenous people, accounting for 3% of the population [4], and their life expectancy is 10 years lower than that of non-Indigenous Australians [5]. In New Zealand, the Mãori people are the Indigenous custodians, accounting for 15.6% of the population [6], and their life expectancy is 7.1 years lower than among the non-Indigenous population [7].

There is a variety of complex and interrelated social, economic and historical factors that contribute to premature death in Indigenous populations [8]. In Australia, it is estimated that 70% of the inequalities in health are caused by chronic disease [9]. Obesity related lifestyle diseases, such as type 2 diabetes and cardiovascular disease, are some of the leading causes of morbidity and mortality in Indigenous populations in Australia and New Zealand [5, 10]. For instance, the age-standardised mortality rate for type 2 diabetes in Indigenous Australians is nearly five times higher than in other Australians [11], and four times higher in Māori people compared to other New Zealanders [12]. The age-adjusted death rate for Indigenous adults from cardiovascular disease is almost twice that of other people in Australia [13] and New Zealand [6].

Excess body fat is a modifiable precursor of type 2 diabetes and cardiovascular disease [14]. In Australia, 66% of Aboriginal and Torres Strait Islander people over 15 years of age are overweight or obese, more than among non-Indigenous Australians (rate ratio of 1.1) [15]. In New Zealand obesity rates for adults are estimated to be 46% for Māoris (rate ratio of 1.8 compared to non-Māori) [16]. There is substantial evidence for the benefits of physical activity in preventing, managing and improving conditions such as obesity, type 2 diabetes and cardiovascular disease [17, 18]. For example, regular physical activity can increase insulin sensitivity both acutely and long term, lower blood sugar levels, reduce body fat and improve cardiovascular function [19]. Current physical activity guidelines recommend that adults aged 18 to 64 should accumulate 150-300 minutes per week of moderate physical activity or 75-150 minutes of vigorous activity [20]. However, in Australia, only 38% of Indigenous people in non-remote locations meet the physical activity recommendations. Furthermore, compared to non-Indigenous Australians, Indigenous people in Australia are less likely to be sufficiently active for health (rate ratio 0.8) and to participate in any physical activity (rate ratio 0.9) [21]. In New Zealand 50.1% of Māoris are sufficiently active compared to 51% in the overall population [16].

Physical activity interventions have proved effective to increase activity levels in the general population [22, 23], however, these studies usually only include a very small percentage of Indigenous people and results are not reported separately [24, 25]. Moreover, general population interventions may not always be appropriate for Indigenous population groups. Cultural adaptations should be incorporated to ensure that the interventions adhere to the community values and beliefs. This is due to Indigenous populations being a minority and diverse group that, due to cultural differences, need specific consideration when designing programs. Recommendations have previously been made by organisations, such as the National Health and Medical Research Council in Australia, providing a "Road Map" in regards to working with Indigenous populations and the cultural factors that researchers need to consider before designing programs [26].

A recent literature review aimed to synthesise the evidence on the effects of group-based sport and exercise programs for Indigenous adults on anthropometric and physiological outcomes and quality of life [27]. However, although this review was described as 'systematic,' the authors of this review, which synthesised six studies, omitted several studies that would have been eligible for inclusion in our view. Moreover, this review did not meet all the criteria of a systematic review, such as searching for grey literature, and the authors did not follow the PRISMA statement [28], nor did they report sufficient information on the methodology, such as search terms, to make the review replicable. A systematic review, including 64 studies, by Teufel-Shone and colleagues on Indigenous people in the United States and Canada found physical activity interventions to be effective on health outcomes related to physical activity such as fitness and blood pressure [29]. Some reviews have synthesised the findings of different kinds of interventions targeting chronic disease or risk factors for disease in Indigenous Australians and New Zealanders, however, these reviews were not specifically focused on physical activity interventions [30]. A literature review by Clifford and colleagues identified 20 interventions which addressed smoking, nutrition, alcohol misuse, or physical inactivity in Australian Indigenous populations [31]. However, only five of the interventions had a specific focus on physical activity, and this review did not summarise results of the interventions as its main objective was to describe and critique the methodology of the interventions. Overall, there is a lack of knowledge on the effect of physical activity interventions on activity levels and health outcomes in Indigenous people residing in Australia and New Zealand.

Given the gaps in the literature and the high prevalence of chronic disease and physical inactivity in Indigenous people in Australia and New Zealand and the important role that physical activity has in the prevention and management of these chronic diseases, a systematic review of effectiveness of interventions to promote activity in Indigenous populations is warranted. This systematic review fills significant gaps in the literature by identifying, critically appraising and synthesising the evidence on the effects of physical activity interventions designed for Indigenous people in Australia and New Zealand on activity levels and health outcomes. As well, we provide recommendations for future research in physical activity interventions for Indigenous people.

Methods

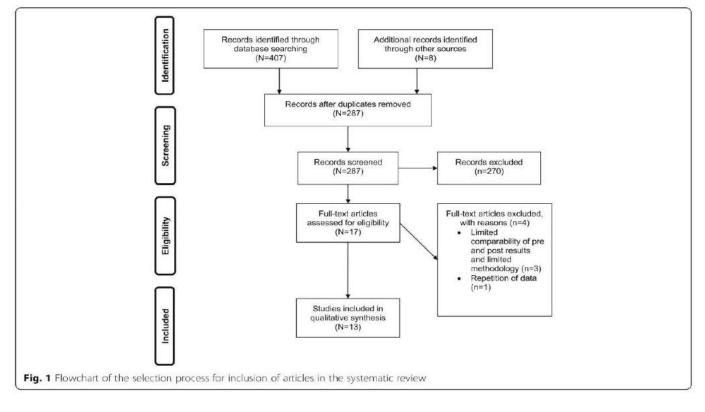
Literature Search

The PROSPERO database and the Cochrane Library were searched for systematic reviews on physical activity interventions designed for Indigenous people in Australia or New Zealand. Once it was determined that there were no such reviews published or in progress, the review protocol was registered with PROSPERO, the international prospective register for systematic reviews (registration number: CRD42015016915) [32]. This review follows the PRISMA statement for systematic reviews [28].

The Cochrane Library, MEDLINE, SPORTSDiscus and PsycINFO were searched from their start dates until the 14th of March 2016 for physical activity interventions for Indigenous people in Australia and New Zealand. Search terms for population were 'Oceanic ancestry group' OR 'population groups' OR 'Aborig*' OR 'Indigenous*' and were combined with 'intervention'' and physical activity related terms ('exercise' OR 'sports' OR 'motor activity' OR 'physical*') and the free terms 'physical*' OR 'fitness". No restrictions on language or publication years were applied. We undertook forward and backward citation tracking from the identified papers. Government websites and databases were searched for grey literature. Health departments were e-mailed in search of interventions that may not have been identified. Experts in the field were contacted to search for additional references. Search results and screening outcomes are presented in a flow-diagram (Fig. 1).

Study Inclusion and Exclusion Criteria

To be included in the review studies had to evaluate an intervention with a physical activity component for Indigenous people residing in Australia or New Zealand aged 18 years or over. Indigenous groups included Aboriginal people and Torres Strait Islanders in Australia and the Māori people in New Zealand. While it is acknowledged that Pacific Islander people are not Indigenous to New Zealand, there are historical and cultural connections with Māori people [33]. Therefore, studies conducted in New Zealand with Pacific Islander communities were also considered eligible for inclusion into the review. Physical activity is a broad term which encompasses different forms of body movement produced by skeletal muscle, resulting in energy expenditure above resting level [34]. This includes exercise, sport and incidental physical



activity. Studies with multi-component interventions were included if increasing physical activity levels was a core component of the intervention either through exercise programs or health education aiming to promote activity. Ideally the interventions would include a non-exposed control group. However, it has been found to be difficult to recruit participants for control groups in Indigenous communities [35, 36]. Therefore, uncontrolled studies with rigorous protocols were included. Protocols were deemed as rigorous if sufficient methodological details of the program were provided to allow for replication, and if the pre and post outcome measures were directly comparable. The studies had to measure physical activity and/or activity related health outcomes before and after the intervention. Studies were excluded if they did not specifically target Indigenous people, but only included them as sub groups.

Data Extraction and Analysis

Two authors (AS and KG) independently screened the articles found in the literature search and excluded those that did not meet the inclusion criteria based on title. abstract and full text. Differences in reviewers' decisions were resolved through discussion and consensus. Data were extracted by AS and cross-checked by KG. A standardised abstraction procedure based on Zaza et al. [37] was used to extract data from the included studies. Information extracted included study population, study setting (such as remote/rural), as well as demographic and baseline characteristics of the participants. Details of the intervention and control conditions along with the study methodology, recruitment strategy, retention rates, physical activity and activity related health outcomes, the timing of measurements, and the acceptability of the program to the Indigenous community were also extracted.

Appraisal of Study Quality

Two authors (AS and KG) independently appraised the quality of the included studies with the Quality Assessment Tool for Quantitative Studies [38] (Table 1). The tool is used to rate several aspects of studies, such as study design, selection bias, retention rates and data collection methods, as well as the study overall as strong, moderate or weak. Differences in ratings of study quality were resolved through discussion and consensus.

Data Synthesis

Because of the heterogeneity of the study designs, predictor and outcome variables and the contexts in which the data were collected, a meta-analysis was not possible. Therefore, a narrative synthesis of the evidence was conducted. The data synthesis contains findings from the included studies such as type of intervention, target population characteristics (Table 2), types of outcomes that were assessed and the duration of the intervention (Table 3). The effect of the intervention in each study is summarised and it is noted whether changes were significant, and what direction the changes were in (positive or negative).

Results

Through database searching 407 records were retrieved, all of which were published in English. Five additional records were identified through backward [39] and forward citation tracking [40-43] and three through searching the grey literature. After removing duplicates, 287 records were screened and 17 articles were initially considered eligible. Reasons for the exclusion of articles included studies that were based on animal research, were not conducted in Australia or New Zealand or did not have any physical activity components, e.g. a nutrition only intervention. After further consideration, the three studies from the grey literature were excluded due to insufficient information on, and lack of, comparability of pre and post measures of physical activity or health outcomes [44-46]. The grey literature included the Green Prescriptions Patient Survey 2014, which is a report on a study in New Zealand that monitors key performance indicators of health, including changes to physical activity [45]. An Australian study on a lifestyle program called Ngawa Kurumutamuwi (We Are Strong) was excluded due to lack of details on population demographics and statistical analysis [46]. A pilot study on a team-based weight loss competition in Aboriginal communities from the New South Wales Ministry of Health was excluded due to lack of details on the baseline and post measurements [44]. One study from the peer-reviewed literature was excluded because of the overlap of data with another included study [47], leaving 13 studies [35, 36, 39-43, 48-53] in the synthesis. Three studies were published before 2000 [35, 39, 42], four between 2000-2010 [36, 43, 50, 52] and six between 2011 and 2015 [40, 41, 48, 49, 51, 53]. There were three randomised controlled trials eligible for inclusion in the review [41, 48, 49], whilst the remaining studies used cohort designs [35, 36, 39, 40, 42, 43, 51-53] and an interrupted time series [50].

Figure 1 shows the flow diagram of the study selection process.

Appraisal of Study Quality

Using the Quality Assessment Tool for Quantitative Studies [38], the overall study quality was rated as poor in three studies [35, 48, 50], moderate in nine [36, 39–43, 49, 51, 52] and strong in only one study [53]. Overall scores for each quality rating item are presented in Table 3. Study selection bias had the weakest score overall, as nine studies were classified as weak due to not being representative of the target population and only one study [52] was

Author	Selection bias	Study design	Confounders	Blinding	Data collection method	Withdrawals and dropouts	Overall rating
Biddle et al. [48]	Weak	Strong	Weak	NA	Strong	Strong	Weak
Canuto et al. [49]	Moderate	Strong	Strong	NA	Strong	Weak	Moderate
Chan et al. [43]	Weak	Moderate	NA	NA	Strong	Moderate	Moderate
Coppell et al. [50]	Weak	Moderate	NA	Weak	Strong	Weak	Weak
Davey et al. [40]	Weak	Moderate	NA	NA	Strong	Moderate	Moderate
Dimer et al. [51]	Moderate	Moderate	NA	NA	Strong	Weak	Moderate
igger et al. [42]	Weak	Strong	NA	NA	Strong	Strong	Moderate
Gracey et al. [52]	Strong	Moderate	NA	NA	Strong	Weak	Moderate
McAuley et al. [36]	Weak	Moderate	NA	NA	Strong	Strong	Moderate
Mendham et al. [41]	Moderate	Strong	Strong	Moderate	Strong	Weak	Moderate
D'Dea [39]	Weak	Moderate	NA	NA	Strong	Strong	Moderate
Rowley et al. [35]	Weak	Moderate	Strong	Weak	Strong	Weak	Weak
Sukala et al. [53]	Moderate	Moderate	Strong	Moderate	Strong	Moderate	Strong
Overall score	1 strong, 3 moderate, 9 weak	4 strong, 9 moderate, 0 weak	4 strong, 0 moderate, 1 weak, 8 NA	0 strong, 2 moderate, 2 weak, 9 NA	13 strong, 0 moderate, 0 weak	4 strong, 3 moderate, 6 weak	1 strong, 9 moderate 3 weak

Table 2 Description of study, participants, in	ntervention and	retention rates
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Study	Ethnicity, location; Study design and size; Participant characteristics and age.	Study title and aim	Intervention	Study retention rates
Biddle et al. [48]	Pacific Islanders, Auckland, New Zealand; RCT, $N = 20$ (control $n = 9$, intervention $n = 11$); Mixed genders, age: 34.8 ± 12.6 years.	Randomised controlled trial of informal team sports for cardiorespiratory fitness and health benefits in Pacific adults. Assess the effectiveness of small-sided games-based exercise on fitness and health parameters among Pacific adults over four weeks.	3 × 45 minute training sessions per week, consisting of small-sided games such as volleyball, touch rugby and cricket.	Intervention: 82% Control: 78%
Canuto et al. [49]	Indigenous Australians, Adelaide, Australia; RCT, $N = 101$ (control $n = 49$, intervention $n = 51$); All female, age: Control: 40.7 years (CI: 37.7–43.6), Intervention: 39.8 (CI: 36.7–43.1).	Pragmatic randomised trial of a 12-week exercise and nutrition program for Aboriginal and Torres Strait Islander women: clinical results immediate post and 3 months follow-up. Evaluate the effectiveness of a 12 week structured exercise and nutrition program.	Structured 12 week group fitness program including exercise classes, incidental activity and walking and nutrition workshops.	Intervention: 57% Control: 61%
Chan et al. [43]	Indigenous Australians, urban Queensland, Australia; Cohort, $N = 101$ (females $n = 69$, males $n = 63$); Mixed gender, age: Diabetics: 56.5 years (52.8–60.1), Non-diabetics: 43 years (39–47).	Short-term efficacy of a lifestyle intervention programme on cardiovascular health outcome in overweight Indigenous Australians with and without type 2 diabetes mellitus: The healthy lifestyle programme (HELP). Determine the effectiveness of lifestyle intervention on improving diabetes and cardiovascular risk factors.	The lifestyle intervention was a community based education program including self-monitoring of fasting glucose and monitoring of physical activity with a pedometer.	80%
Coppell et al. [50]	Māori, rural East Coast of New Zealand; Interrupted time-series, $n = 286$ (Survey 1), $n = 236$ (Survey 2); Mixed genders, age survey 1: 50.25 years (female), 51.4 years (male), survey 2: 49.35 years (female), 50.95 years (male)	Two-year results from a community-wide diabetes prevention intervention in a high risk indigenous community: the Ngati and Healthy project. To reduce the prevalence of insulin resistance in a high risk community.	Local community health promotion programs, a community education program for high risk individuals including cooking classes, exercise class and opportunistic weigh ins.	Survey 1: 48.5% Survey 2: 47.7%
Davey et al. [40]	Aboriginal Australians, Tasmania, Australia; Cohort, $n = 92$ (females $n = 56$, males $n = 36$); Mixed genders, age: ≤ 49 ($n = 35$), 50–59 years ($n = 35$), >60 years ($n = 22$).	Tasmanian Aborigines step up to health: evaluation of a cardiopulmonary rehabilitation and secondary prevention program. To create an ongoing sustainable program of direct benefit to participants and promote the benefits of physical activity to other Aboriginal health service programs and the wider Aboriginal community.	8-week program consisting of two supervised exercise sessions (Thour) and one educational session (Thour) per week.	78%
Dimer et al. [51]	Indigenous Australians, Metropolitan area, Western Australia, Australia; Cohort, $n = 98$ (females $n = 63$, males $n = 35$); Mixed gender, age: 55 ± 13 (19–82).	Build it and they will come: outcomes from a successful cardiac rehabilitation program at an Aboriginal medical service. Evaluate the uptake and effects on lifestyle, and cardiovascular risk factors, of cardiac rehabilitation at an Aboriginal Medical Service.	Exercise prescription and education sessions over 8 weeks Stationary cycling and dumbbell exercises were prescribed and supervised. An outdoor walking group was implemented and participants were asked to record their activity levels. Education sessions included diet, nutrition, risk factor modification and medication usage.	29%
Egger et al. [42]	Torres Strait Islanders, Australia; Cohort, $n = 47$; Male only, age: 41 years \pm 12.3 years.	Abdominal obesity reduction in indigenous men. To decrease bodyweight and body fat in Indigenous males in the Torres Strait Islands.	There were four lifestyle messages for the program, which included: reducing fat intake, increasing dietary fibre, increasing daily movement, and changing obesogenic habits. The program was delivered in groups via audio-taped conversations.	66%

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Table 2 Description of study, participants, intervention and retention rates (Continued)

Gracey et al. [52]	Aboriginal Australians, Remote Western Australia, Australia; Cohort, $n = 416$; Mixed gender, age: 38.7 ± 14.9 [18–82years] (male), 41.0 ± 17.4 [18–88years] (female).	An Aboriginal-driven program to prevent, control and manage nutrition-related "lifestyle" diseases including diabetes. To heighten awareness about lifestyle diseases and promote healthier living through better diet and regular physical activity.	Increase awareness of and promotion of healthier living through better nutrition and the encouragement of regular exercise, sports and active recreation.	Not specified
McAuley et al. [36]	Mãori, New Zealand; Cohort, $n = 36$ (female $n = 28$, male $n = 8$); Mixed gender, age: 41.3 years [24–60].	Implementation of a successful lifestyle intervention programme for New Zealand Maori to reduce the risk of type 2 diabetes and cardiovascular disease. To reduce the risk of type 2 diabetes and cardiovascular disease.	Participants were prescribed individual diet and exercise programs. In addition, participants were invited to exercise sessions four times per week and a healthy food sessions once a month in the form of a cooking group.	86%
Mendham et al. [41]	Indigenous Australians, Regional New South Wales, Australia; RCT, $N = 26$ (control $n = 10$, intervention $n = 16$); All male, age: 39.5 ± 10.6 years (intervention), 36.1 ± 16.1 years (control).	A 12-week sports-based exercise programme for inactive Indigenous Australian men improved clinical risk factors associated with type 2 diabetes mellitus. To assess changes in clinical risk-factors following a 12-week exercise program.	Supervised group-based cardiovascular and resist ance exercises were conducted at a local fitness centre over 12 weeks.	Intervention = 41% Control = 63%
O'Dea [39]	Indigenous Australians, Remote Western Australia, Australia; Cohort, $n = 14$ (diabetics $n = 10$, non-diabetics $n = 4$); Mixed, age: 59.3 \pm 1.8 years (diabetics), 52.3 \pm 4.3 years (non-diabetic).	Marked improvement in carbohydrate and lipid metabolism in diabetic Australian Aborigines after temporary reversion to traditional lifestyle. Improve all aspects of carbohydrate and lipid metabolism that are linked to insulin resistance after temporary revision to traditional lifestyle.	Participants were taken to a remote location and lived a hunter/gatherer lifestyle for 7 weeks.	100%
Rowley et al. [35]	Aboriginal Australians, Remote Western Australia, Australia; Cohort, $n = 96$; Mixed gender, age: 49 ± 3 years (intervention), 43 ± 4 years (control).	Effectiveness of a community-directed 'healthy lifestyle' program in a remote Australian aboriginal community. Assess the sustainability and effectiveness of a community-directed program for primary and secondary prevention of obesity, diabetes and cardiovascular disease in an Aboriginal Community.	Formal and informal education sessions about nutrition, regular physical activity sessions such as hunting groups, sports (2–3 sessions) and walking groups (3–4 times per week, for an hour) and walking groups.	51%
Sukala et al. [53]	Polynesian (New Zealand Māori, Cook Island Māori, Samoan, Fijian, Tokelauan & Tongan), Porirua, New Zealand; Cohort, $n = 18$ (females $n = 13$, males $n = 5$); Mixed genders, age: 49 ± 5 years.	Exercise improves Quality of Life in Indigenous Polynesian peoples With type 2 diabetes and visceral obesity. The aim of the study was to evaluate the differential effects of 2, group-based exercise modalities on quality of life (QoL) in indigenous Polynesian peoples with type 2 diabetes (12DM) and visceral obesity.	Intervention included 3 exercise sessions per week (40–60minutes), consisting of resistance training and aerobic training.	69%

	Objective outcome measures	Subjective outcome measures	Metabolic measures	Data collection points, duration of intervention	Cultural consultation and adaption
Biddle et al. [48]	Vo2 peak**↑, leg strength (maximal quadriceps at 60deg/second)*↑	PAR-Q	Fasting glucose and glycated haemoglobin (HbA₁c), lipid profile (HDL)*↑, blood pressure and C-reactive protein	Baseline, 4 weeks, IP	Community consultations
Canuto et al. [49]	Height, weight*1, BMI*1, waist and hip circumference, and blood pressure, Step count [data not shown]	Sallis seven-day physical activity recall survey (1985), Quality of life (SF36)	Fasting venous samples of glucose and serum insulin, total cholesterol, high-density lipoprotein (HDL) and triglyceride concentration. HbA_{1c} and c-reactive protein	Baseline, 12 weeks, IP, 12WP,	Community consultations
Chan et al. [43]	Weight, Waist*↓ and hip circumference, Blood pressure*↓, Step count		Plasma glucose (fasting), HbA _{1c} *↓, Lipid profile*↓ (LDL cholesterol, HDL cholesterol, triglycerides*↓, Homocysteine, C-peptide, Serum creatinine, Microalbuminuria, Insulin resistance, Triglyceride, Homocysteine levels	Baseline, 6 months	Community consultations
Coppell et al. [50]	Weight, waist circumference, blood pressure*↓, BMI	Medical history, self-reported physical activity*↑ and dietary behaviours**↑↓ (New Zealand Health Survey, 1999).	75g fasted oral glucose tolerance test (OGTT)*↑, Fasting insulin, fasting lipids ↓*and urate*↓ and a mid-stream urine sample*↑.	Baseline, ongoing, two years post intervention	Community consultations
Davey et al. [40]	Age, gender, health conditions, Weight*↓, BMI*↓, waist circumference *↓, 6 minute walk test (6MWT)*↑, Incremental shuttle walk test (ISWT)*↑, Timed Up and Go (TUG)*↓	Chronic Respiratory Questionnaire (CRQ), Quality of life (SF36)*†		Baseline, 8 weeks, IP	Community consultations
Dimer et al. [51]	Weight, BMI*↓, 6 minute walk test (6MWT)**†, Blood pressure*↓, Waist girth**↓			Baseline, 8 weeks, IP	Community consultation
Egger et al. [42]	Weight**↓, Waist & hip circumference (cm)**↓, BMI**↓, hip circumference **↓, Waist to hip ratio, Body fat through bio-impedance analysis**↓., fat mass (kg)**↓			1 year follow up	Community consultation
Gracey et al. [52] †	Weight, BMI, Blood pressure		HbA_{Lc} glucose, cholesterol (total, LDL, HDL), triglycerides	Not specified	Community consultation
McAuley et al. [36]	Weight**↓, height, waist and hip circumference**↓, blood pressure*↓, BMI**↓, Body composition (fat free mass)*↓, and submaximal exercise test (one mile walk test)**↑	4 day diet record pre and post intervention and a daily diet record. *↓ PAR-Q Physical activity levels: Based on the Life in New Zealand (LINZ)	fasting insulin, glucose**1, and lipids, insulin sensitivity**1	Baseline, 4 months, IP	Community consultation
Mendham et al. [41]	Body mass*↓, blood pressure, waist circumference*↓ (WC) and hip circumference, BMI*↓ A graded exercise test (GXT)*↑ to determine peak oxygen consumption	PAR-Q	Leptin (pg mL ⁻¹)**↓, Glucose regulation: Fasting glucose test and oral glucose tolerance test (OGTI), Inflammatory markers: C-reactive proteins and inflammatory cytokines. Matsuda ISI (μ IUmL ⁻¹ , mg mL ⁻¹)*↑, HOMA-IR (μ IUmL ⁻¹ , mg mL ⁻¹)*↑	Baseline, 12 weeks, IP	Community consultation

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Table 3 Outcome measures,	impact and intervention	n development and durat	ion (Continued)
Table & Outcome measures,	, impact and intervention	in developmente una darac	ion (continued)

	(VO2 peak) and maximal aerobic workload (Wmax)				
D'Dea [39]	Weight, BMI	Physical activity levels on a scale of 1–5.	Oral glucose tolerance test*↓, fasting plasma insulin *↓Plasma triglycerides*↓ , plasma cholesterol Fasting plasma glucose*↓	Baseline, 7 weeks, IP	Unsure
Rowley et al. [35]•	Body weight, BMI**↓	Diet and physical activity questionnaires [not specified]	75g oral glucose tolerance test (OGTT)**↓, Fasting plasma triglyceride*↓ and insulin concentrations*↑ Fasting plasma glucose *↓	Baseline, 6M, 12M, 18M, 24M, 48M	Community consultation
Sukala et al. 53]	Weight, BMI, Blood pressure	SF36 (Quality of Life)*↑		Baseline, 16 weeks, IP	Community consultation

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classified as strong. No study rated weak in study design or data collection methods, while confounding bias and blinding were not applicable to the majority of the studies. In data collection methods, all studies rated strong due to utilising validated and reliable measures for health outcomes and/or physical activity levels.

Population

All studies were focused on Indigenous adults aged 18 years and over. Nine of the 13 studies were based in Australia and four in New Zealand. The number of participants varied from 14 [39] to 418 in a cohort study that involved four different Aboriginal communities [52]. Seven of the studies had 50 or more participants [35, 40, 43, 49-52]. Locations of the interventions varied from metropolitan, urban and regional areas, [36, 40, 41, 43, 48, 49, 51, 53] to rural and remote locations [35, 39, 42, 50, 52]. Several studies were designed for a specific ethnic group such as Aboriginal Australians [35, 40, 52], Torres Strait Islanders [42], and New Zealand Māoris [36, 50]. In other interventions different ethnic groups were combined such as Indigenous Australians [39, 41, 43, 49, 51], Pacific Islanders [48] and Polynesians [53]. Ten studies had male and female participants, one study exclusively targeted women [49] and for two studies only male participants were recruited [41, 42]. The mean age of participants across all studies ranged from 34 to 55 years and with 18-88 [52] and 19-82 years [51], two studies had very wide participant age ranges.

Recruitment and Retention of Participants

The intervention programs varied by the recruitment strategies, and the nature and delivery methods of the physical activity component. Some studies had an open invite for all community members [52], recruited through a health centre or patient register [40, 50, 53] or utilised referrals through community leaders or other participants [36, 40, 41, 43, 48, 51]. In some studies it was unclear how participants were recruited [35, 39, 42], and for two studies [36, 49] protocol papers were published which described the methodology in greater detail [54, 55].

Almost half of the studies either did not report information on withdrawals from the study and drop-outs from the physical activity intervention [52] or had less than 60% of participants complete the study or failing to have complete data sets [35, 41, 49–51]. Three studies had a retention rate of participants to the program of 60–79% [40, 43, 53] and for four it was 80% or more [36, 39, 42, 48]. Six of the studies had high numbers of participants lost to follow up, and in one of these studies the drop-out rates from the program or failure to attend follow up data collection were so high that it resulted in the under powering of some of the statistical analysis [49]. Two studies were statistically underpowered in some outcome measures despite moderate to high retention rates [43, 48].

Study Designs and Interventions

Three studies were randomised controlled trials (RCTs); two were of 12 week exercise interventions [41, 49] and one was a shorter 4 week intervention which consisted of small sided (small number of players per team) team sports [48]. Another study attempted to run an RCT to examine the effect of community directed lifestyle programs on the primary and secondary prevention of obesity and chronic disease, but used a self-selected control group and therefore was not a true randomised controlled trial [35]. An additional study had participants share information on the nature of the diet and exercise lifestyle intervention and became a cohort study, as the control group was integrated into the intervention [36]. One study utilised an interrupted time series design to examine the effect of health promotion and education on high risk individuals to reduce insulin resistance [50] and the remaining seven [39, 40, 42, 43, 51-53] were cohort studies. Some cohort studies measured data pre and post intervention [39, 40, 51, 53], while two studies measured data periodically [42, 43] and one study did not specify when data collection occurred [52].

Ten studies focussed on prevention or management of chronic diseases, such as type 2 diabetes and heart disease [35, 36, 40–43, 50–53], one study focused on cardiorespiratory fitness and health [48] and Canuto et al. [49] evaluated the effectiveness of a 12 week exercise and nutrition program on waist circumference, weight and biomedical markers in Australian Indigenous women. The main objective in the study by O'Dea [39] was to improve clinical risk factors linked to insulin resistance.

Most of the studies included facilitated exercise sessions [35, 36, 40, 41, 48–51, 53]. The modality of exercise sessions varied between the studies. For example, while most studies incorporated mixed aerobic and resistance training programs two to six times per week [36, 40, 41, 49–51, 53], other studies used hunting groups [35] or small-sided (small number of players per team) team sports [48]. In one study physical activity was encouraged through self-monitoring with a pedometer and participants were asked to record their daily step counts [43]. Other studies encouraged physical activity through education and lifestyle messages [42, 52] and in one study participants were taken to a remote location to live a hunter-gatherer lifestyle for seven weeks [39].

Cultural adaptations were noted in all studies. Specific efforts to make programs culturally appropriate included consultation with community members such as elders or an advisory group [36, 49]. Examples of cultural adaptations for interventions were using appropriate local dialect in promotion material [36, 42, 49, 50], using traditional games or historically important cultural activities such as paddling [36] and hunting [35, 39].

Effects on Physical Activity Levels

Although all studies evaluated an intervention with physical activity as a single or core component, only six studies assessed physical activity via subjective or objective measures before and after the intervention [35, 36, 39, 43, 49, 50], with significant increases in only one study [50]. Two studies employed an objective measure of physical activity (pedometers) [43, 49] and four studies utilised self-reported measures. Self-reported physical activity was measured with a variety of tools such as the Life in New Zealand questionnaire [36] and a validated seven-day recall questionnaire [49]. The variation in the measurement of physical activity levels across studies resulted in data being represented in two older studies as categorical (exercise intensity) [35, 39] and continuous (step counts, or minutes of self-reported physical activity per week) [43, 49], thus making them incomparable. Five studies [36, 40, 41, 48, 51] used tests of functional or exercise capacity and aerobic fitness as outcome measures, and all found significant improvements.

Effects on Health Outcomes

Nine studies collected metabolic markers, including fasting glucose, insulin, cholesterol and oral glucose tolerance tests [35, 36, 39, 41, 43, 48-50, 52]. Significant improvements were found in seven of these studies [35, 36, 39, 41, 43, 48, 50]. Five of the seven studies that assessed lipid profiles reported significant improvements [35, 39, 43, 48, 50]. In regards to diabetes related markers, HbA1c was measured in three studies [43, 48, 49], but a decrease was only found in one of them [43]. All three studies that used an oral glucose tolerance test reported significant decreases in glucose levels [35, 39, 50]. Three studies measured quality of life with the SF-36 survey [40, 49, 53], with improvements reported in two of the three studies [40, 53] and both studies that reported dietary behaviours had significant positive changes with increased intake of dietary fibre and wholegrain [36, 50] and reduced saturated fat consumption [36]. There were significant reductions in seven of the 12 studies that assessed weight and/or BMI [35, 36, 40-42, 49, 51]. No significant reductions or increases in weight/BMI were reported in four studies [39, 43, 48, 50, 53] and one study did not provide enough information to determine if there were statistically significant differences [52]. Of the eight studies that assessed blood pressure, half had significant reductions in systolic and/or diastolic pressure [36, 43, 50, 51] while the other four did not report significant changes [41, 49, 52, 53].

Long Term Effects on Physical Activity Levels and Health Outcomes

Seven of the 13 studies only collected follow-up data immediately post intervention [36, 39-41, 48, 51, 53]. In one study the follow-up period was not specified, but only referred to as "several months" after the intervention [52] and two other studies collected follow up data three [49], and six months [43] after the intervention. Only three studies collected long-term follow-up data (12 months or more) [35, 42, 50]. Long term follow-up data collection periods were one [42], two [50] and four years [35]. There were mixed results in regards to maintenance of changes in health outcomes. Canuto et al. [49] implemented a 12 week program and reported modest reductions in weight, BMI and blood pressure immediately post program and 12 weeks later. There were no significant changes in waist circumference and metabolic markers at follow up, but the authors noted that this could be due to a low participant retention rate, which underpowered some of the study results. The intervention group had reductions in median weight from baseline (81.8kgs) to immediately post intervention (80.2kgs), but had gained weight back at the 12 week follow up (81.7kgs). The waitlisted group had an increase in weight over all data collection points prior to receiving the intervention (90.6kgs, 93.2kgs and 95.2kgs respectively). Rowley and colleagues [35] followed participants up during a four year uncontrolled community intervention with mixed results. The program achieved significant reductions in fasting insulin concentrations at 6, 12 and 18 months. At further data collection points (two and four years) fasting insulin concentrations continued to drop significantly in the older age group (35 years and over), but in the younger participants (15 to 34 years), there was no statistically significant reduction over time. There were no changes in the prevalence of overweight or obesity among the older participants, and among younger participants weight increased over time as seen in the BMI data collected at baseline (22.6 kg/ m^2), two years (24.3 kg/m²) and four years (24.8 kg/m²) (p for trend = 0.028). Chan et al. reported that six months into a two year intervention there were significant reductions in waist circumference, blood pressure and clinical markers such as HbA_{1c} and cholesterol [43]. However, for this study data were only reported for the first six months of the intervention. A study in New Zealand [50] reported increased physical activity levels and reductions in the prevalence of insulin resistance after two years of the intervention. The most significant changes were in women aged 25-49 years and those who had the highest levels of participation and marked lifestyle changes. In the one year intervention by Egger et al. the Indigenous Australian men who participated were tested at baseline, 6 and 12 months, and showed

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continuous reductions in bodyweight, waist circumference and a decrease in fat mass at all time points [42].

Discussion

Despite the high rates of physical inactivity and preventable chronic disease among Indigenous people in Australia and New Zealand, there is a dearth of evaluations of physical activity interventions for these population groups. Moreover, similar to other reviews of interventions for Indigenous people [29, 30, 56], not only did we find just a small number of studies, but also that most of them were not methodologically strong. The lack of RCT designs across studies limits the overall internal validity of the findings, however, study methodology and evaluation issues are not unique to the South Pacific. Similar to our findings, a systematic review on physical activity interventions in American Indian and Alaskan native populations in North America reported that the majority of community-based programs was not rigorously evaluated [29].

The effects of the interventions on physical activity levels were hard to determine. Only two of 13 included studies in this systematic review used objective measures of physical activity (pedometers) [43, 49] and another four studies used self-report measures [35, 36, 39, 50] which limits the validity of the data due to recall and social desirability bias [57], especially as these self-report measures were not specifically designed for this population group. In terms of health outcomes, all but one of the included studies used weight or BMI as an outcome measure and seven of these reported significant reductions. However, it is unclear if these significant improvements in weight or BMI were due to an increase in physical activity alone or changes in energy intake which were not reported. Five studies [36, 40, 41, 48, 51] employed some form of fitness test. Improvements in fitness capacity are a valid indicator of increased physical activity, as regular exercise improves anaerobic and aerobic fitness [58]. If objective measures of physical activity were not available, the use of tests of exercise capacity is appropriate. A functional capacity test, such as the six-minute walk test, can be administered to a variety of population types of various fitness levels and health status and requires little equipment [59].

The results from this systematic review need to be interpreted with caution as in all but one study the methodological quality was rated as moderate or poor which limits their internal and external validity. Methodological issues, such as participant recruitment methods, may have caused selection bias. For example, an open community invitation recruitment [52] is subject to selection bias as volunteers are more health conscious [60] and may lead to a sample that is not representative of the target group. In terms of attrition bias, participants lost to follow up may differ from those who completed the study. Participants who could not be reached at follow up had significantly lower weight and/or waist circumference at baseline [35, 40, 42] compared to the participants that remained in the study. Attrition bias also reduces the sample size, which can result in studies being underpowered and therefore caution needs to be taken when interpreting data [42, 48, 49]. Identified factors that can affect attrition rates were highly mobile young populations [50], work commitments, and needing to care for children [61]. However, most of these issues also affect studies in non-Indigenous populations.

The strength of the intervention study designs varied. It is difficult to assess the effect of confounding variables on the study outcomes as most were uncontrolled and non-randomised which is a limitation of the evidence. Despite the benefits of internal validity of randomised controlled trials, as mentioned before, RCTs may not always be feasible in Indigenous populations because it could be considered to be unethical to recruit participants for control groups [35, 36]. Consultations with community members, leaders and health workers were undertaken prior or during almost all of the interventions in order to tailor the design to suit the community resources and culture. Availability of and access to resources for interventions, such as infrastructure, equipment, recreational facilities and health workers, are influenced by geographical location [62], which in five of the primary studies were in rural or remote communities [35, 39, 42, 50, 52].

Cultural consultations, adaptation and flexibility in the delivery of programs are important for interventions in Indigenous populations. Interventions that included facilitated exercise sessions, as opposed to written information, might be more appropriate for some Indigenous populations with lower levels of literacy. Gracey et al. [52] noted that the older people may be semi or non-literate and the local people were not comfortable with "high English" as it was a second or third language behind their native tongue. In regards to flexibility in interventions, McAuley et al. [36] noted that their lifestyle intervention had to evolve continuously over time to ensure it was still acceptable to the local Māori people. Similarly, Dimer et al. [51] allowed flexible timing of allocations of participant attendance to the program by not creating specific times for sessions in order to comply with Aboriginal ideologies that conflict with tightly regimented, appointment-based systems. Concepts of time may differ between Indigenous and non-Indigenous people due to cultural values. For instance, Indigenous Australians have a 'here and now' approach, meaning that important and immediate priorities will be seen regardless of prior commitments [63]. Specific in-depth details of cultural adaptations may not always be available as adaptations may be seen as part of the usual development process in Indigenous-based programs and are not necessarily described [29].

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Gaps and Limitations in the Current Literature and Directions for Future Research

This systematic review provides a much needed insight into the gaps in the current literature on the effect of physical activity interventions on activity levels and health outcomes in this particular population group. A primary limitation of the existing literature is the challenge of undertaking rigorous study designs, specifically in relation to recruiting control groups. Additionally, only three studies reported long term follow-up data. Without long-term follow up information the sustainability of the impact of the intervention in the community cannot be assessed. This has been noted previously in regards to other Indigenous groups around the world where physical activity interventions are not translated into 'real-world' practice despite having short term significant effects, communities lacked resources to sustain the programs [56]. Another limitation of most studies in this review was a lack of reporting of methodological details. Moreover, lack of information in the description of the intervention methodology, such as details about cultural adaptation, cost and process of developing the program, creates issues around best practice as it would then be difficult to replicate successful programs. Missing information from studies included sample size calculations and statistical details on adjustment for confounding variables. The inclusion of sustainability plans, cost-benefit analysis [40], and information on community feedback on factors such as barriers to attendance would be beneficial.

Recommendations for Practice and Research

Future evaluations of interventions aimed at increasing physical activity levels in Australian or New Zealand Indigenous populations would be improved by more rigorous study designs. Validated objective measures of physical activity would be desirable. Using pedometers or accelerometers would increase the validity and comparability of data between studies. Causal pathways for the health effects of regular physical activity levels include increased aerobic capacity and strength, outcomes that other health behaviours, such as changes in dietary behaviour, would not influence. Therefore, if objective measurement of physical activity is not available due to lack of funding, graded exercise testing or functional capacity assessments are low cost options for researchers and communities to examine direct effects of changes in activity levels.

Community consultations are important to include in study protocols. Although this process can be time consuming [64], it is necessary to make the intervention culturally acceptable to the participants. For example, whilst the challenges and appropriateness of having randomised controlled trials can be determined by the community, pragmatic study designs should be considered. A notable example of working around this problem was the study conducted by Canuto et al. [49], which was the only study to utilise a wait-listed control group.

Studies with low retention rates should also provide information on factors which led to people not attending as it may help researchers in the creation of risk management plans. Coppell and colleagues [50] limited the age range of participants for their intervention to 25 years and over as the community often had young adults leave to get further education or employment in larger towns. Increasing the minimum age of participants could possibly reduce the attrition rates in some communities, however, evidence on effects of physical activity in early prevention of chronic disease in young Indigenous people would be desirable. In most studies, the age range of the participants was limited with no studies focused specifically on young adults. While the incidence of type 2 diabetes in young people in Australia has not changed since 2002 [65], the prevalence of type 2 diabetes has significantly increased in Indigenous Australian adults 35 years and older [66]. In New Zealand, the number of people with diabetes has doubled in the past ten years, with 40 new confirmed diagnoses every day [67]. Therefore, earlier prevention and detection would be beneficial and young adults may be an ideal target group for physical activity interventions in primary health care prevention to avoid or delay acquiring chronic diseases and the later complications that typically manifest 15-20 years after diagnosis [68].

Canuto et al. [61] wrote that logistical aspects, such as transport to classes and competing commitments like family obligations, were factors that influenced attendance of their physical activity intervention and concluded that future studies could identify potential barriers with preprogram workshops. To minimise attrition in their intervention Davey et al. [40] organised free transport for their participants to get to the exercise sessions. They found that the majority of the participants used the provided transport and concluded that this might have contributed to retaining participants.

For future studies, cost-benefit analyses would provide useful information on economic feasibility, sustainability and scalability which can help inform best practice for studies that aim to address the needs of vulnerable populations. Therefore, interventions need to be tested and implemented with economically feasible methods [56].

Conclusions

Despite of the high rates of chronic disease and physical inactivity in Indigenous populations in Australia and New Zealand, only a very small number of evaluations of physical activity interventions for these population groups have been published. Only 13 studies were identified in this systematic review. Due to the lack of validated measures of physical activity in most studies it is

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unclear how successful interventions are at increasing activity levels in Indigenous adults in Australia and New Zealand. However, there is evidence to support that interventions with elements of physical activity are successful in improving health outcomes such as weight and various clinical markers. Comparisons between studies was difficult as there was a lack of homogeneity in study designs and outcome measures, which may be due to communities instigating intervention adaptations to be tailored towards their individual needs. Validated measures of physical activity and in-depth detail around the cultural consultation phases, end of project feedback, including strengths and weaknesses, and cost-benefit analysis would be useful in guiding best practice for physical activity interventions in Indigenous settings.

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Authors' contributions

AS and KG independently screened the articles found in the literature search and excluded those that did not meet the inclusion criteria. Data were extracted by AS and cross-checked by KG. AS and KG independently appraised the quality of the included studies and wrote the manuscript. JvU contributed to the writing of the manuscript. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

Ethical approval was not required for this secondary analysis.

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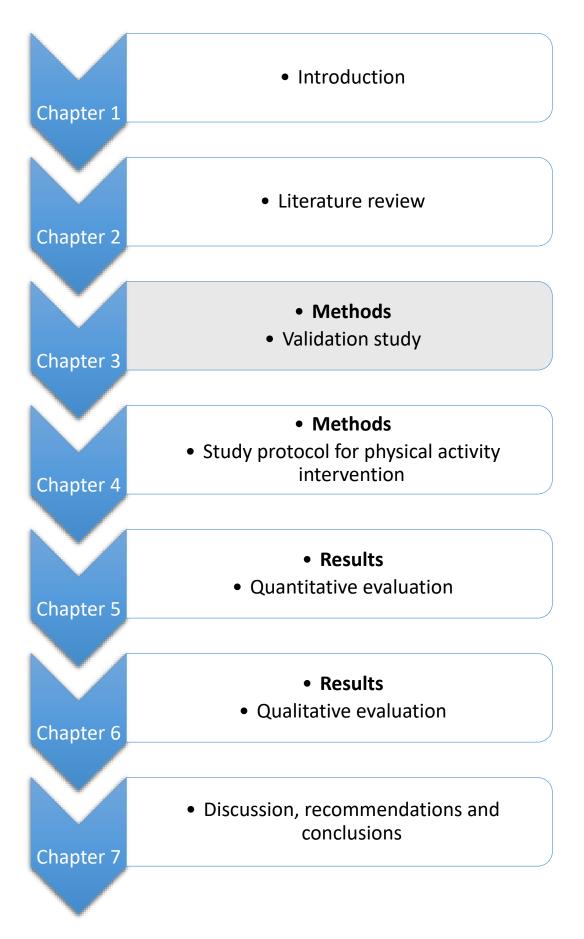
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Chapter 3: Validation Study

Sushames, A., Edwards, A., Thompson, F., McDermott, R., & Gebel, K. (2016). Validity and reliability of the Fitbit Flex for step count, moderate to vigorous physical activity and activity energy expenditure. *PLoS One*, 11(9), e0161224



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Validity and Reliability of Fitbit Flex for Step Count, Moderate to Vigorous Physical Activity and Activity Energy Expenditure

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Abstract

Objectives

To examine the validity and reliability of the Fitbit Flex against direct observation for measuring steps in the laboratory and against the Actigraph for step counts in free-living conditions and for moderate-to-vigorous physical activity (MVPA) and activity energy expenditure (AEE) overall.

Methods

Twenty-five adults (12 females, 13 males) wore a Fitbit Flex and an Actigraph GT3X+ during a laboratory based protocol (including walking, incline walking, running and stepping) and free-living conditions during a single day period to examine measurement of steps, AEE and MVPA. Twenty-four of the participants attended a second session using the same protocol.

Results

Intraclass correlations (ICC) for test-retest reliability of the Fitbit Flex were strong for walking (ICC = 0.57), moderate for stair stepping (ICC = 0.34), and weak for incline walking (ICC = 0.22) and jogging (ICC = 0.26). The Fitbit significantly undercounted walking steps in the laboratory (absolute proportional difference: 21.2%, 95%CI 13.0–29.4%), but it was more accurate, despite slightly over counting, for both jogging (6.4%, 95%CI 3.7–9.0%) and stair stepping (15.5%, 95%CI 10.1–20.9%). The Fitbit had higher coefficients of variation (C_v) for step counts compared to direct observation and the Actigraph. In free-living conditions, the average MVPA minutes were lower in the Fitbit (35.4 minutes) compared to the Actigraph (54.6 minutes), but AEE was greater from the Fitbit (808.1 calories) versus the Actigraph (538.9 calories). The coefficients of variation were similar for AEE for the Actigraph (C_v =

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36.0) and Fitbit (C_v = 35.0), but lower in the Actigraph (C_v = 25.5) for MVPA against the Fitbit (C_v = 32.7).

Conclusion

The Fitbit Flex has moderate validity for measuring physical activity relative to direct observation and the Actigraph. Test-rest reliability of the Fitbit was dependent on activity type and had greater variation between sessions compared to the Actigraph. Physical activity surveillance studies using the Fitbit Flex should consider the potential effect of measurement reactivity and undercounting of steps.

Introduction

The health benefits of physical activity are well established [1]. The current Australian physical activity guidelines recommend for adults to accumulate at least 150 to 300 minutes of moderate intensity activity or 75 to 150 minutes of vigorous activity per week [2]. Based on self-report it has been estimated that up to 60% of Australian adults do not meet the recommended activity levels [3]. However, self-reported measures of physical activity can be inflated due to recall and social desirability bias [4]. For instance, based on accelerometry, a study in the USA found significantly lower compliance rates with activity guidelines than previously estimated through self-reported activity [5].

Physical activity can be assessed using a variety of validated techniques. Methods such as direct observation and doubly labelled water can provide useful information, however, they are associated with an increased participant burden and a high cost [6]. One of the most extensively validated accelerometers utilised to measure physical activity is the Actigraph GT3X+ [7, 8], a triaxial accelerometer used to measure moderate to vigorous physical activity (MVPA). The Actigraph calculates activity levels through predetermined cutpoints and has been validated against doubly labelled water techniques for estimating energy expenditure (R = 0.3) [7] and for step counts against the Yamax Digiwalker pedometer in free-living conditions with a 98.5% accuracy [9]. However, the Actigraph GT3X+ does not provide online user interaction or real-time outputs and is relatively cumbersome to wear at the hip, making it uncomfortable for participants to wear it at night [10]. The Actigraph also requires specific training for analysing data post-activity and an annual payment for a relatively expensive software license.

Globally, Fitbit has the largest market share for activity monitors, has sold more than 25 million devices and in 2015 had a revenue of US\$1.8 billion [11]. The Fitbit Flex is a waterproof device that can be worn 24 hours a day as a wristband, which may be more convenient for users than the waist worn Actigraph. In addition, the Fitbit Flex provides access to an online database where users can view their activity outputs, join groups and interact with other users. Interaction with other users through social media platforms has been found to facilitate positive health behaviour changes through peer-support [12]. Moreover, real time feedback on physical activity levels can assist with self-monitoring. This has been demonstrated with the use of pedometers to be associated with a significant increase in physical activity, and a reduction in body mass index [13, 14]. Other health related data, such as sleep duration and nutritional breakdowns of user food logs, and estimation of kilocalories burned in response to activity, can also be viewed in combination with the physical activity information. The Fitbit Flex is a very popular consumer based activity tracker, is not very expensive, is user-friendly and has lots of other features that are interesting and motivating for users. However, before the

Fitbit Flex can be used in a research setting as well, more information about the validity and reliability is needed. An earlier model of the Fitbit, the waist worn Fitbit One, was validated in laboratory conditions for treadmill walking against direct observation and showed substantial concordance (0.97-1.00) [15] and reasonable inter-device reliability (ICC = 0.90) [16]. However, few studies have assessed the validity and reliability of the wrist worn Fitbit Flex [17, 18].

Some studies have compared outputs from Fitbit activity monitors and the Actigraph, but with variability in protocols and device placement. Paul et al. [19] found excellent agreement in the average step count per day between the two devices recorded in free-living conditions and worn on the waist. Similarly, Gusmer et al. [20] found no significant differences in step counts between the Fitbit Ultra and the Actigraph G1TM, reporting that both devices can be used interchangeably to measure step count when they are both worn on the waist. Ferguson and colleagues [21] compared several consumer-level devices, including the waist worn Fitbit One, against the Actigraph GT3X+ and found strong validity for the Fitbit's measurement of steps and MVPA. However, none of these studies compared free-living conditions and laboratory based activities across multiple outcome measures such as step count, MVPA and activity energy expenditure (AEE). Comparisons between several measures will give greater depth to existing knowledge in regards to validity of the device in potential field-based studies. The aim of the present study was to examine the validity and test-retest reliability of the Fitbit Flex against direct observation for measuring steps in the laboratory and against the Actigraph for step counts in free-living conditions and for MVPA and AEE overall.

Methods

Twenty-five students (12 females, 13 males) were recruited through convenience sampling (word of mouth and noticeboard postings) from James Cook University in Cairns, Australia. All participants were free of illness and medical conditions that would contraindicate exercise. Participants provided written informed consent prior to participation in the study. The study was approved by the Human Research Ethics Committee of James Cook University (Approval number: H5763) and data were collected from June to August 2014.

Collection of demographic data and anthropometric measures was conducted onsite at the university in a private room. Baseline assessments included height, weight and body fat. Body fat was assessed using bioelectrical impedance analysis (Tanita body fat monitor/scale, BF-522, Tanita Corporation, Tokyo, Japan). Following baseline assessments, participants were fitted with an accelerometer (GT3X+, Actigraph, Florida, USA) on an elastic strap around the hips and a Fitbit Flex (Fitbit, Inc., San Francisco, USA) worn on the wrist. To maintain the same wear time, the participants were asked to remove both devices during water based activities.

The Actigraph GT3X+ accelerometer is a light weight device used to measure steps, moderate-to-vigorous physical activity and activity energy expenditure in free-living environments. The device was worn on participants' preferred hip (just above the iliac crest) on an adjustable elastic belt during waking hours of a single day. During the initialisation of the device participant details were entered such as sex, height, weight, and age. The recording frequency was set to 30Hz and to measure activity in 60 second epochs. Moderate to vigorous physical activity was analysed using the Freedson equation using the cutpoints of 1952–5724 counts per minute (CPM) for moderate activity, 5725–9498 CPM for vigorous and >9498 CMP for very vigorous activity [22]. The data was downloaded using the ActiLife Data Analysis Software version 6.2.

The Fitbit Flex is also an accelerometer and records data using 60 second epochs. The device is worn on the wrist using a fitted band and can be worn 24 hours a day. Therefore, although the two devices are worn differently, they were both evaluated for reliability and validity in their optimal respective device placement. The wrist display of the Fitbit Flex uses five LED lights to represent quintiles of the daily goal which can be set as step count, distance or calories burnt. In our study, the daily goal was set to 10,000 steps but participants did not have access to online results. Complete data, including exact step count, minutes of MVPA and AEE, is available for users to access on the Fitbit website (www.fitbit.com).

Two data collection sessions in the laboratory were conducted for all study participants. There was missing data as a result of one participant failing to attend the second session, and one participant having a Fitbit device malfunction during the second session. This resulted in a total of 48 data samples for analysis. The treadmill based element of the exercise protocol required participants to be filmed undertaking six minute bouts of walking, incline walking, jogging and stair stepping. There was a four minute rest between the six minute bouts. Walking and jogging paces were self-selected using Borg's Rate of Perceived Exhaustion scale (RPE) [23] for the first exercise session to estimate a walking pace with an RPE of 4 and an RPE of 7 for jogging. These speeds were exactly replicated for the second exercise session to assess testretest reliability. The speeds for walking and jogging ranged from 5km/hr to 6.5km/hr and 8km/hr to 10km/hr respectively. The incline was set at 5% and the simulated stepping phase used the same 15cm high plyometric box for all participants, regardless of their height. Once the protocol was complete, participants were instructed to wear both devices for the remainder of the waking day. Since all the laboratory sessions were done in the morning hours, all participants had similar wear times for the measurements in free-living environments. However, the devices were not reset, nor was any data immediately recorded at the end of the session, so step counts, MVPA and AEE results from the free living conditions would include data from the laboratory session. A second laboratory session was completed within the same week in which the same protocol was repeated, and the walking and jogging speeds were matched to the selfselected speeds of the first session. The video footage from the laboratory sessions was reviewed by two persons who counted the number of steps. If the differences in the direct observations were greater than 10 steps, the footage was viewed a second time by both reviewers and this revised estimate was used. Data for direct observation was only available during the laboratory conditions, which included walking, incline walking, jogging and stair stepping. The step counts from both reviewers were averaged to create a single count for each activity. There were technical difficulties with video recording resulting in missing data for some activities for four participants in the first session and six participants in the second session. The availability of data for these participants by activity type and session for direct observation and the Fitbit and Actigraph devices is displayed in Table 1.

Statistical Analysis

Step count data, AEE and MVPA are reported for the first and second laboratory data collections for the Actigraph and Fitbit devices (Table 1). The average of first and second step counts, AEE and MVPA were also derived for each participant. For the Actigraph and Fitbit devices, step count at first collection was used in place of the average for two participants who had missing second collection step counts. For direct observation, the first or second measure was used in place of the average depending on which of the two data collection points had missing data (n = 6).

Unlike the Actigraph, the Fitbit Flex does not just measure activity energy expenditure, but total energy expenditure. Hence, for comparability, activity energy expenditure results from the Fitbit were calculated by subtracting the basal metabolic rate (BMR) from the total daily energy expenditure. One participant's data was excluded in the AEE analysis due to the total daily energy expenditure being less than the estimated basic metabolic rate. The distribution of step counts, AEE and MVPA in minutes were assessed using kernel density plots and Shapiro-Wilk tests for normality.

	Dire	Direct observation					Actigraph				Fitbit				
Activity	n	mean	SE	(95% CI)	C,	n	mean	SE	(95% CI)	Cv	n	mean	SE	(95% CI)	Cv
Walking step count							3) 								9.0
First measures	21	674.8	8.9	(656.3, 693.2)	6.0	25	726.1	9.0	(707.5, 744.7)	6.2	25	588.1	21.8	(543.1, 633.1)	18.5
Second measures	19	697.4	10.7	(674.9, 719.9)	6.7	23	722.6	9.7	(702.4, 742.8)	6.5	23	583.1	17.3	(547.3, 618.9)	14.2
Average of measures	23	684.0	10.0	(663.2, 704.8)	7.0	25	709.8	13.0	(683.0, 736.6)	9.1	25	583.6	16.1	(550.4, 616.8)	13.8
Incline walking step	coun	t		Barki) (2011				10		<i></i>				NVIL SVE	
First measures	22	691.0	9.2	(672.0, 710.1)	6.2	25	738.3	10.7	(716.3, 760.3)	7.2	25	643.3	22.2	(597.4, 689.2)	17.3
Second measures	21	701.1	10.6	(679.1, 723.1)	6.9	23	728.3	11.3	(704.9, 751.8)	7.5	23	652.9	17.4	(616.7, 689.0)	12.8
Average of measures	24	698.9	9.0	(680.3, 717.4)	6.3	25	714.2	19.3	(674.3, 754.0)	13.5	25	641.5	18.5	(603.2, 679.8)	14.5
Jogging step count														10-a (). ().	
First measures	23	945.9	9.8	(925.5, 966.3)	5.0	25	1009.4	13.2	(982.1, 1,036.6)	6.5	25	960.3	19.7	(919.5, 1,001.0)	10.3
Second measures	20	944.1	10.3	(922.6, 965.6)	4.9	23	1013.2	14.5	(983.1, 1,043.4)	6.9	23	977.6	18.3	(939.7, 1,015.5)	9.0
Average of measures	24	947.2	8.9	(928.8, 965.6)	4.6	25	1011.2	11.0	(988.5, 1,033.9)	5.4	25	971.1	14.7	(940.8, 1,001.5)	7.6
Stair stepping															
First measures	23	559.1	17.0	(523.9, 594.4)	14.6	25	578.6	24.1	(528.9, 628.2)	20.8	25	572.0	26.1	(518.1, 625.8)	22.8
Second measures	19	582.7	19.9	(541.0, 624.5)	14.9	23	538.8	23.3	(490.5, 587.2)	20.8	23	584.0	20.6	(541.3, 626.8)	16.9
Average of measures	23	569.2	16.9	(534.1, 604.3)	14.2	25	558.8	16.9	(523.9, 593.7)	15.1	25	575.3	17.9	(538.2, 612.3)	15.6
Energy expenditure-	Calo	ries*		1										direct at	
First measures	-	-	-	-		24	532.4	43.9	(441.7, 623.2)	40.4	24	818.2	69.0	(675.5, 960.9)	41.3
Second measures	123	-	120	2	2	23	563.1	58.1	(442.7, 683.6)	49.4	23	840.1	74.4	(685.7, 994.5)	42.5
Average of measures		-		-	-	25	538.9	38.8	(458.8, 619.0)	36.0	25	808.1	56.6	(691.3, 924.9)	35.0
Active minutes*										-1-					
First measures		-		-	-	24	53.8	4.0	(45.4, 62.1)	36.7	24	33.7	3.0	(27.4, 40.0)	44.3
Second measures	220	<u>14</u> 0	1. <u>11</u> 1)	2	2	22	57.0	4.0	(48.8, 65.2)	32.6	22	38.1	3.2	(31.5, 44.7)	39.3
Average of measures				-	-	24	54.6	2.8	(48.7, 60.5)	25.5	24	35.4	2.4	(30.5, 40.3)	32.7

Table 1. Summary of direct observation, Actigraph and Fitbit at first and second measures and combined.

SE: standard error, CI: confidence interval, Cv: Coefficient of variation

-: No data available

*: Comparisons are between the Fitbit and Actigraph

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Coefficients of variation were calculated to describe the distribution of values for direct observation and both devices. Absolute differences and absolute proportional differences for step counts between each of the three measurement methods were calculated. Absolute proportional differences were calculated as the absolute differences between the Fitbit and direct observation, or the Fitbit and the Actigraph, divided by values for the Fitbit. Paired samples *t*-tests were also used to examine the differences in mean step count data between each of the three measurement methods at both data collection sessions and the derived average step counts of the two data collections. A *p* value <0.05 was considered significant for all analyses.

Intraclass correlation coefficients (ICC) were calculated to compare the reliability of the three measurement methods against each other during laboratory sessions and only for the Fitbit and the Actigraph during free living conditions. The type of ICC used was two-way mixed methods with absolute agreement. Bland-Altman plots comparing the three measurement methods were created for the average step counts and energy expenditure measures from the first and second data collections where applicable. The test-retest reliability between the first and second sessions for the three measurement methods was assessed using intraclass correlations, absolute differences and absolute proportional differences.

Results

The mean age (\pm SD) of participants was 23.7 \pm 5.8 years. Females (n = 12) had an average height and weight of 165.6 \pm 5.8cm and 62.3 \pm 7.6kgs respectively and a BMI of 22.7 \pm 2.2 kg/m². Males (n = 13) were taller (175.7 \pm 4.4cm) and heavier (85.3 \pm 16.2kgs) and had a higher BMI (27.7 \pm 6.1 kg/m²). Body fat percentages for females and males were 26.3 \pm 4.8%, and 21.5 \pm 6.2% respectively.

Table 1 presents the distribution of step counts for direct observation and the Actigraph and Fitbit devices at first and second data collections and the average of these two collections. Energy expenditure and active minutes for each activity are also provided for the Actigraph and Fitbit. The greatest difference in step count was for walking, in which the average Fitbit estimate from both data collections ($\bar{x} = 583.6, 95\%$ CI 550.4–616.8) was 15% lower compared to direct observation ($\bar{x} = 684.0, 95\%$ CI 663.2–704.8). In contrast, the Actigraph overestimated step counts relative to direct observation for all activities except stair climbing, in which, similar to the Fitbit, it was also comparable to direct observation. Compared to direct observation and the Actigraph, the Fitbit generally had higher coefficients of variation for step counts. However, for stair climbing, the coefficient of variation was high for both devices. Outside of the laboratory, the Fitbit had lower estimates of free living average step counts (7,582.9±3,368.6 steps) compared to the Actigraph (10896.0±4,364.9 steps) and greater variation in step counts, as indicated by a slightly higher coefficient of variation (44.4 and 40.1 respectively). The Fitbit estimates for energy expenditure in calories were consistently higher compared to the Actigraph and the MVPA minutes were lower.

Table 2 displays the differences between the Fitbit and direct observation during laboratory stepping activities and between the Fitbit and Actigraph for free living outcomes, including steps, MVPA and AEE. In the laboratory, the largest differences between direct observation and the Fitbit were during the walking phase. When the results from sessions one and two were averaged, the absolute difference between these two measurement methods was over 100 steps ($\bar{x} = 110.3, 95\%$ CI 74.3–146.3). As a proportion, this difference was 21% ($\bar{x} = 21.2, 95\%$ CI 13.0–29.4) and a paired samples *t*-test for mean differences was significant ($\bar{x} = -104.0, 95\%$ CI -143.5–64.5, *p*<0.001). There were similar differences for incline walking and stair climbing. For jogging however, the Fitbit was much more comparable to direct observation with a proportional difference of 6% ($\bar{x} = 6.4, 95\%$ CI 3.7–9.0) across the two data collections.

Outside of the laboratory there was high measurement discord between the Fitbit and the Actigraph (Table 2). For the average of both data collections, the absolute difference in free-living steps was over 3,000 or 47% as a proportion ($\bar{x} = 47.2, 95\%$ CI 34.7–59.6). Similar proportional differences were seen for AEE and MVPA and all *t*-tests for mean differences were significant.

Table 3 displays the results of ICC analyses between direct observations and each of the two devices. The Fitbit had poor (r = 0.1-0.3) to moderate correlations (r = 0.3-0.5) with direct observation on average measures of step count activities, ranging from 0.01 for stair stepping (95%CI -1.48–0.59, p = 0.491) to 0.34 for jogging (95%CI -1.41–0.71, p = 0.145). In contrast, the Actigraph was significantly correlated with direct observation for almost all activities, with the only exception being stair stepping (0.42 95%CI -0.36–0.75, p = 0.104). Outside of the laboratory, the Fitbit and the Actigraph were highly correlated (r = 0.5-1.0) for total free-living steps (0.78, 95%CI -0.19–0.94, p < 0.001) AEE (0.56, 95%CI -0.23–0.84, p < 0.001) and MVPA (0.52, 95%CI -0.18–0.84, p < 0.001) (data not tabled).

Bland-Altman plots demonstrated the Fitbit had a high level of measurement discord with direct observation relative to the Actigraph. For almost all of the laboratory activities, as the mean steps measured by the Fitbit and direct observation increased, the differences between these measurements also increased. During walking, the Fitbit underestimated steps for small

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	Absolute	differences	Absolut differen	e proportional ces	Paired samples t-test for differences					
Activity	Mean	(95% CI)	Mean	(95% CI)	Mean	SE	(95% CI)	p		
Walking step count										
First measures	118.7	(77.3, 160.1)	24.5	(13.2, 35.8)	-93.4	25.7	(-147.1, -39.8)	0.0017		
Second measures	129.5	(85.9, 173.1)	25.2	(15.2, 35.2)	-126.4	21.8	(-172.2, -80.7)	<0.001		
Average of measures	110.3	(74.3, 146.3)	21.2	(13.0, 29.4)	-104.0	19.0	(-143.5, -64.5)	<0.001		
Incline walking step co	ount									
First measures	84.4	(42.9, 125.9)	16.8	(5.1, 28.6)	-56.9	24.1	(-107.1, -6.6)	0.0283		
Second measures	75.6	(45.6, 105.6)	12.5	(7.1, 17.9)	-49.4	19.2	(-89.6, -9.3)	0.0183		
Average of measures	77.0	(40.5, 113.4)	15.1	(4.7, 25.5)	-60.2	20.3	(-102.2, -18.3)	0.0068		
Jogging step count										
First measures	66.4	(37.3, 95.5)	7.1	(3.6, 10.6)	21.1	19.4	(-19.1, 61.4)	0.2883		
Second measures	83.2	(58.7, 107.6)	8.9	(5.9, 11.9)	22.9	21.7	(-22.7, 68.4)	0.3066		
Average of measures	60.2	(38.2, 82.2)	6.4	(3.7, 9.0)	26.2	15.5	(-5.9, 58.3)	0.1052		
Stair stepping										
First measures	104.9	(62.7, 147.0)	19.1	(11.6, 26.6)	15.8	30.0	(-46.5, 78.1)	0.6035		
Second measures	78.7	(43.2, 114.3)	16.4	(5.9, 26.9)	-9.7	25.0	(-62.2, 42.9)	0.7031		
Average of measures	86.6	(55.0, 118.2)	15.5	(10.1, 20.9)	3.0	23.9	(-46.6, 52.6)	0.9014		
Free living steps*							2002 - 100 - 100			
First measures	3855.3	(3,012.2, 4,698.3)	57.9	(46.1, 69.6)	-3851.8	409.8	(-4,697.7, -3,006.0)	<0.001		
Second measures	3243.7	(2,074.4, 4,413.0)	44.6	(28.6, 60.5)	-3218.0	570.5	(-4,401.1, -2,034.9)	<0.001		
Average of measures	3313.2	(2,462.0, 4,164.3)	47.2	(34.7, 59.6)	-3313.2	412.4	(-4,164.3, -2,462.0)	<0.001		
Energy expenditure-C	alories*									
First measures	294.8	(198.9, 390.7)	34.4	(27.3, 41.6)	285.8	48.8	(184.9, 386.6)	<0.001		
Second measures	285.6	(198.9, 372.2)	32.0	(23.7, 40.3)	276.9	44.3	(185.0, 368.9)	<0.001		
Average of measures	277.1	(195.1, 359.2)	32.4	(25.2, 39.6)	269.2	42.0	(182.6, 355.8)	<0.001		
Active minutes*					1					
First measures	20.1	(14.6, 25.5)	82.2	(28.0, 136.4)	-20.08	2.6	(2,089.0, -25.5)	<0.001		
Second measures	18.9	(13.5, 24.3)	57.0	(35.7, 78.3)	-18.91	2.6	(1,495.0, -24.3)	<0.001		
Average of measures	19.1	(15.3, 23.0)	60.4	(43.2, 77.6)	-19.15	1.9	(5,029.0, -23.0)	< 0.001		

Table 2. Comparisons and differences of direct observation and the Fitbit in the laboratory and the Fitbit and Actigraph in free living.

SE: standard error, CI: confidence interval

*: Comparisons are between the Fitbit and Actigraph

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amounts of activity and became increasingly accurate as the mean number of steps increased (Fig 1). Within a six minute period, the Fitbit may estimate as much as 283 steps lower and up to 75 steps higher than direct observation. In contrast, the Actigraph had much less measurement discord, with the lower and upper limits for step estimates as -22 and 94 respectively. This contrasting accuracy between the Fitbit and Actigraph held for all laboratory activities, with the exception of stair climbing. For this activity, both devices had high and comparable levels of measurement discord with direct observation (Fig 2).

Outside of the laboratory, Bland-Altman analyses indicated there was high measurement discord between the Fitbit and Actigraph for free-living steps (Fig 3). The Fitbit tended to undercount steps compared to the Actigraph and this underestimate grew stronger as the total number of steps increased.

In terms of test-retest reliability, the mean absolute difference in steps for the Fitbit between session 1 and 2 ranged from 71.9 for walking to 83.1 for incline walking. As mean proportions, these differences were 13.6% (95%CI 4.6–22.6) and 12.3% (95%CI 7.8–16.9) respectively. In

Validity of the Fitbit Flex

	ICC Actigraph	vs direct obser	vation	ICC Fitbit vs d	irect observatio	n	ICC Fitbit vs A	ctigraph	
	Average ICC	(95% CI)	P	Average ICC	(95% CI)	p	Average ICC	(95% CI)	p
Walking step count		zů.							-246
First measures	0.67	(-0.23, 0.90)	<0.001	0.11	(-0.48, 0.55)	0.353	0.09	(-0.23, 0.43)	0.298
Second measures	0.75	(0.29, 0.91)	0.001	0.00	(-0.29, 0.37)	0.503	0.16	(-0.17, 0.50)	0.097
Average of measures	0.73	(-0.14, 0.91)	<0.001	0.05	(-0.30, 0.42)	0.390	0.10	(-0.15, 0.39)	0.195
Incline walking step c	ount					- Sector			
First measures	0.75	(-0.17, 0.93)	< 0.001	0.07	(-0.82, 0.57)	0.421	-0.06	(-0.66, 0.42)	0.583
Second measures	0.71	(0.31, 0.88)	0.002	0.19	(-0.58, 0.63)	0.281	0.21	(-0.33, 0.60)	0.202
Average of measures	0.74	(0.07, 0.91)	< 0.001	0.11	(-0.58, 0.56)	0.356	0.02	(-0.45, 0.43)	0.467
Jogging step count									
First measures	0.57	(-0.20, 0.84)	0.001	0.40	(-0.39, 0.74)	0.116	0.58	(0.08, 0.81)	0.008
Second measures	0.35	(-0.25, 0.71)	0.035	0.11	(-1.22, 0.65)	0.399	0.38	(-0.34, 0.73)	0.116
Average of measures	0.46	(-0.23, 0.78)	0.005	0.34	(-0.41, 0.71)	0.145	0.52	(-0.01, 0.78)	0.018
Stair stepping									
First measures	0.18	(-1.01, 0.66)	0.329	-0.06	(-1.63, 0.56)	0.553	0.69	(0.28, 0.86)	0.004
Second measures	0.53	(-0.10, 0.81)	0.041	0.51	(-0.32, 0.81)	0.077	0.43	(-0.26, 0.75)	0.085
Average of measures	0.42	(-0.36, 0.75)	0.104	0.01	(-1.48, 0.59)	0.491	0.72	(0.38, 0.88)	0.001

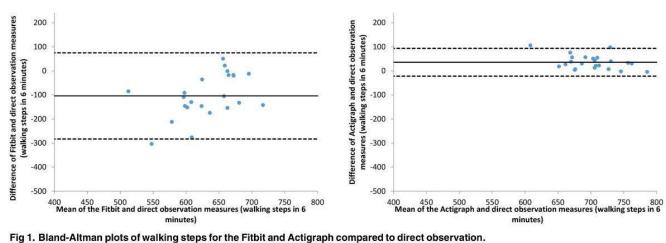
Table 3. Intraclass correlations between Fitbit and Actigraph and between devices and direct observations.

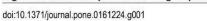
CI: confidence interval, ICC: Intraclass correlation

doi:10.1371/journal.pone.0161224.t003

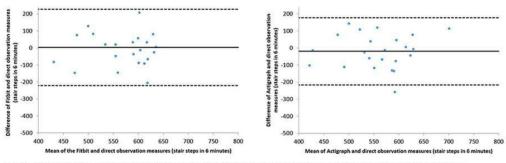
contrast, the mean absolute proportional differences for the Actigraph on the same measures were lower, at 4.8% (95%CI 2.8–6.8) and 4.7% (95%CI 2.7–6.7) respectively. Stair climbing was the exception to this trend, with both the Fitbit and Actigraph having mean proportional differences of around 20% between first and second data collections. For direct observation, the mean proportional difference for stair climbing was 10.6% (95%CI 4.4–16.7) with a mean absolute difference of 56.8 steps.

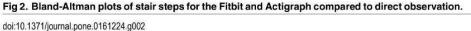
Test-retest reliability analyses using intra-class correlations indicated the Fitbit had greater variation between the first and second data collections relative to the Actigraph for most of the laboratory activities (data not tabled). Between the two laboratory sessions, the Fitbit had a moderate correlation for the walking activity (ICC = 0.57, 95%CI: -0.02,0.82, p = 0.028), as did



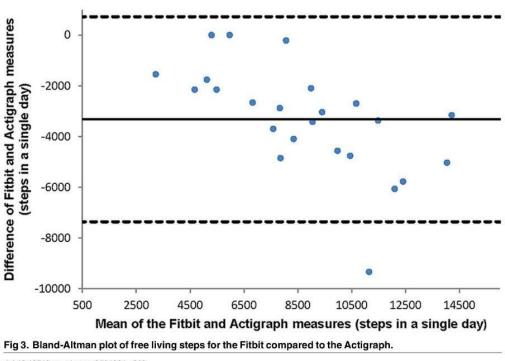


Validity of the Fitbit Flex





the Actigraph (ICC = 0.59, 95%CI: 0.03,0.83, p = 0.022). The Fitbit had modest and non-significant correlations for incline walking (ICC = 0.22, 95%CI: -0.92,0.68, p = 0.288 and jogging (ICC = 0.26 95%CI:-0.73,0.69, p = 0.239). On these measures, the Actigraph performed somewhat better between the two sessions, with a strong correlation for incline walking (ICC = 0.75, 95%CI: 0.41,0.89, p = 0.001) and a moderate agreement for jogging (ICC = 0.49, 95%CI: 95% CI: -0.23,0.78, p = 0.067). Both the Fitbit and Actigraph had low and non-significant agreement for stair stepping between first and second laboratory sessions with ICCs of 0.34 and 0.19 respectively.



Total free living steps

doi:10.1371/journal.pone.0161224.g003

Discussion

Summary of Principle Findings

We compared results from the Fitbit Flex against direct observations of step counts in a laboratory setting and free-living and overall steps, moderate to vigorous activity and activity energy expenditure against the Actigraph. The results from our study indicated that the Fitbit has moderate validity relative to direct observation and the Actigraph. It tended to vary between over-counting and under-counting steps, depending on the activity type. Our findings contrast a previous study which utilised the same device placement and compared the step count outputs of the Actigraph against the Fitbit Flex over a seven day period [24]. In that study there were no significant (p = 0.052) differences between the devices, however, the differences in the findings could be due to variation in study protocols. Dierker and Smith [24] compared step counts between five activity monitors, using a protocol that advised participants to remove the devices during exercise. This essentially would not capture all free-living activity and encompassing different exercise modalities that were assessed in our study. In the present study, the mean MVPA minutes were lower in the Fitbit (35.4) compared to the Actigraph (54.6), but AEE was greater from the Fitbit (808.1 calories) compared to the Actigraph (538.9 calories). In terms of test-retest reliability across the two sessions, the Fitbit had greater variation in step count estimates compared to the Actigraph for most of the laboratory activities.

Implications of Findings

The Bland-Altman plots showed that the magnitude and direction of step count difference between these devices varied depending on the type and volume of activity. This indicates that the divergence in terms of the Fitbit Flex step count between direct observations is not constant and is affected by the type of activity and the number of steps taken, which is also evident in the weak to moderate intraclass correlation coefficients and test-retest reliability. Previous work has indicated that the hip worn Fitbit Ultra is reliable and valid for activity monitoring in terms of flat surface step count, but is not recommended for incline activity [25]. In our study, there were significant differences in step counts between direct observation and the wrist worn Fitbit Flex during treadmill walking (p<0.001) and incline walking (p = 0.007) which suggests that the Fitbit Flex may have low validity for low to moderate intensity walking and walking on an incline. Due to variations in fitness levels, the participants self-selected the treadmill speeds, which was not optimal as the device validity was dependant on the treadmill speed. Two nonsignificant differences were obtained during jogging and the stair stepping activity. The higher accuracy in step counts of stair stepping, may have been due to participants stepping up and down a box, having a more pronounced arm movement.

Free living step counts in our study were significantly underestimated by the Fitbit Flex compared to the Actigraph. The more steps, the greater the underestimation which is seen in the limits of agreement, this could be due to the variability in movements by participants in free-living conditions and continuous undercounting in low intensity activities. In our study the Fitbit recorded consistently higher AEE with a 50% higher average measure (808.1 ± 282.9 calories) compared to the Actigraph (538.9 ± 194.0 calories). This is reflected in the correlation tests between the devices, with the average of the two protocol measures for AEE only having a moderate agreement (ICC = 0.56). The findings in regards to AEE need to be interpreted with caution, due to the differences in measurement equations. As mentioned before, the Actigraph only records AEE, whereas the Fitbit records total energy expenditure based on the sum of the AEE and the BMR. The BMR is calculated using the Mifflin-St Jeor equation, which requires participants' gender, height, and weight.

In contrast to the higher AEE, the average of the MVPA minutes in the Fitbit (35.4 ± 11.8) was significantly lower compared to the Actigraph (54.6 ± 13.9) and the coefficient of variation was greater in the former device (32.7% and 25.5% respectively). Some of the variation in outcome measures may be due to different criteria cutpoints for moderate to vigorous physical activity minutes. Moreover, the Fitbit only records MVPA minutes if the intensity is over 3 METs and, in line with physical activity guidelines [26, 27], only in bouts of at least 10 minutes. In contrast, the Actigraph uses predetermined counts per minute cutpoints to determine activity intensity and duration, including bouts of as little as one-second epochs.

The test-retest reliability analyses in this study indicate the step count estimates produced by the Fitbit over multiple time points would vary more in terms of absolute proportional differences compared to the Actigraph. When compared to direct observation, the Fitbit can overestimate step counts for jogging, but also underestimate the number of steps for walking. While both devices had moderate reliability for estimating flat walking steps in the laboratory environment based on ICCs, only the Actigraph produced reliable incline walking step estimates. Neither device provided reliable stair walking steps estimates, however, even by direct observation there was variation in step count between sessions on this activity, which indicates that participant performance may have been responsible for at least some of the variation. The intraclass correlations were not reported for the free-living outcome measures as there may have been variations in the participants' routine over the duration of the two days of assessment.

The placement of the devices is important as recent research indicates that wrist worn accelerometers might not be as accurate as waist worn devices in counting steps [28, 29]. For example, in activities such as washing dishes, the body can be in a fixed position, but arm movements are occurring. On the other hand, there is the potential for error as activities may also require steps to be taken, but the arms having minimal movement, for example carrying a box [30]. A recent study reported that the wrist worn Fitbit Flex and Nike Fuelband undercounted steps compared to devices worn on the waist or worn in the pockets of the participants' pants [29]. However, wrist worn devices can avoid decreases in wear time compliance as the burden of having to continually remove equipment for water-based activities and to sleep would not be an issue [31].

The Fitbit's accuracy in the measurement of jogging and stair stepping has been confirmed by this research, but more work is needed to validate lower intensity activities, such as walking. Consumer level devices allow for monitoring of health behaviours by providing immediate feedback via displays and internet-based applications. Participant reactivity needs further examination when using fitness monitors that provide immediate feedback to users. A study from van Hoye et al. [14] found reactivity with the use of pedometers caused a significant increase compared to baseline assessments in step counts during the first week of an intervention. There were no significant increases in step count after the first week of the intervention, which suggests that there is a ceiling effect in regards to device reactivity and step count [14]. A systematic review of 26 studies found that with the use of feedback from a pedometer users increased their activity levels by 27% compared to baseline levels [13]. This was primarily achieved by using the pedometer for rapid feedback to inform goal setting and realistic daily physical activity targets. However, reactivity to feedback is a consideration for short term interventions that allow users to access their data online [14]. As mentioned previously, in the present study the participants did not have access to detailed online data on their activity from the Fitbit website. The only feedback they got were the five LED lights on the Fitbit Flex that represent quintiles of the target step count, which would have limited reactivity. However, the provision of multiple measures, such as step counts, activity intensity and duration, might assist laypersons in becoming aware of their own physical activity levels, and allow comparisons against the current physical activity guidelines [32].

Limitations

In order to ease participant burden, the wear time was limited to the study protocol and several hours of free-living. As mentioned previously, in order to have the same wear times, the participants were asked to remove both devices during water based activity. This could be considered as a theoretical limitation as participants might have forgotten to put the devices back on immediately after water-based activities, although unlikely in this study due to the short wear time. The data on AEE and MVPA from the laboratory session were carried over into the free living conditions, which may have impacted the results, as it was not a true representation of only free-living activity. Device compatibility was another issue that potentially limited this study as both devices utilise different equations and cutpoints for the data outputs.

Conclusions

Our findings suggest that the Fitbit Flex has moderate validity for measuring physical activity relative to direct observation and the Actigraph. The test-retest reliability between the two sessions indicated greater variation with the Fitbit relative to the Actigraph. Poor test-retest reliability could have been a result of the inaccuracy of the Fitbit with low intensity activities. The Fitbit might be more suitable in studies in which immediate feedback through detailed data online is needed and where cost is an issue, but not necessarily in clinical settings. For selecting the appropriate physical activity monitor for research projects investigators should consider the activity domains involved, sample sizes, as well as the budget and participant burden [33]. Physical activity surveillance studies using the Fitbit Flex should consider the potential effect of measurement reactivity and undercounting of steps.

Supporting Information

S1 File. Dataset. Sections: 1 Device output step count, 2 Direct observation, 3 Activity minutes & energy output. (XLSX)

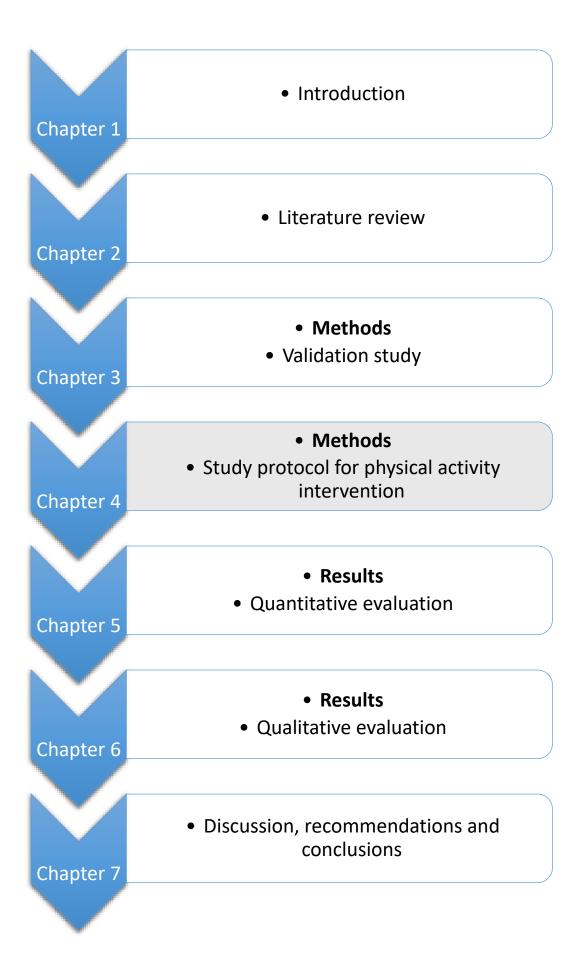
Author Contributions

Conceptualization: AS AE KG Data curation: AS FT Formal analysis: AS FT AE Funding acquisition: KG RM Investigation: AS Methodology: AS AE KG Project administration: AS Resources: KG RM Supervision: AE KG RM Validation: FT AE KG Visualization: AS FT Writing – original draft: AS KG FT AE RM Writing - review & editing: AS KG FT AE RM.

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Chapter 4: Study protocol

Study protocol: A pragmatic trial of an 8-week physical activity program for Indigenous Australians.

Abstract

Indigenous and non-Indigenous Australians have a 10-year difference in life expectancy, mainly due to disproportionately higher rates of chronic disease. There is substantial evidence for the health benefits of physical activity in chronic disease prevention. However, Indigenous Australians have low physical activity levels and there is little evidence on best practice to ensure physical activity programs are effective. The objective of this study is to evaluate the effectiveness of a community-tailored 8-week physical activity program on health outcomes in Indigenous adults in regional communities.

Methods and analysis

The free program will consist of 60 minutes of group-based physical activity four times per week. The trial is pragmatic and will be implemented with two Indigenous communities in Far North Queensland. Data will be collected at baseline, immediately post and three months post program. To qualify for inclusion participants must be Indigenous, aged 18-45 years and have a chronic disease or a risk factor for chronic disease. The primary outcome measure is change in functional capacity from baseline to immediately post program, measured by a six-minute walk test. Additional outcomes include changes in physical activity (objectively measured by a Fitbit Flex), quality of life (SF-12), smoking status, alcohol consumption and fruit and vegetable intake. Metabolic markers that are indicative of chronic disease, such as HbA_{1c} and cholesterol levels, will also be assessed. Semi-structured interviews will be conducted with participants to explore experiences with the program.

Ethics and dissemination

Letters of support were received from peak local Aboriginal and Torres Strait Islander organisations prior to the ethics submission. Approval was obtained from the James Cook University Human Research Ethics Committee in October 2015 (approval number: H5942). The study methodology and results will be disseminated through presentations to both supporting community organisations and community members and will be published in peerreviewed journals.

Trial registration number: ACTRN12616000497404

Strengths and limitations of this study

- This trial is designed to increase physical activity levels of Aboriginal and Torres Strait Islander adults.
- The mixed-methods design of this study will enable a rigorous evaluation of the program and provide evidence for future practice.
- The study will be evaluated using objective measures of physical activity, biomedical markers, a quantitative questionnaire and qualitative interviews
- The intervention is standardised, but the delivery and form will be adapted to the community.

Introduction

There is a 10-year difference in life expectancy between Indigenous and non-Indigenous Australians,¹ and in Queensland half of all reported deaths for Indigenous Australians were at a median age of 58 years old, compared to 81 years for non-Indigenous people.² It is estimated that up to 80% of premature deaths of Indigenous Australians are caused by preventable chronic diseases such as type 2 diabetes and heart disease.³ Nationally, the age-standardised mortality rate for diabetes in Indigenous Australians is nearly five times higher than in other Australians,⁴ and the age-adjusted death rate from cardiovascular disease for adults is almost twice as high.⁵

There is substantial evidence for the health benefits of physical activity for the prevention and management of chronic disease in the general population⁶ and also specifically for Indigenous Australians.⁷⁻¹² Physical activity can reduce body fat and improve cardiovascular function, lower blood sugar levels and increase insulin sensitivity both acutely and long term.¹³ Moreover, physical activity has been shown to decrease depression, social isolation and improve quality of life.^{14, 15} Current Australian guidelines recommend that adults aged 18 to 64 should accumulate 150-300 minutes per week of moderate physical activity or 75-150 minutes of vigorous activity or an equivalent combination of both.¹⁶ However, only 38% of Indigenous people in non-remote locations meet the physical activity recommendations.¹⁷ Compared to non-Indigenous people (adjusting for age differences) Aboriginal Australians and Torres Strait Islanders are less likely to be sufficiently active for health (rate ratio 0.8), and less likely to do any physical activity (rate ratio 0.9).^{17, 18} Excess body fat, which is associated with physical inactivity, is a modifiable precursor of type 2 diabetes and cardiovascular disease.¹⁹ Currently, 66% of Aboriginal and Torres Strait

Islander people over 15 years are overweight or obese, higher than the rates in non-Indigenous Australians (rate ratio 1.1).²⁰

Despite recognition of physical inactivity and obesity contributing to the development of chronic diseases in Indigenous people,^{21, 22} little research has been undertaken to evaluate interventions to encourage physical activity with Aboriginal and Torres Strait Islander people. Our recent systematic review identified only nine such studies from Australia.²³ A limitation of most studies was insufficient reporting of methodological details. The inclusion of sustainability plans and information on community feedback about factors such as barriers to attendance would be beneficial for future research. Cost-benefit analyses would provide useful information on economic feasibility, scalability, and sustainability, which can help inform best practice for future studies that aim to address the needs of vulnerable populations.²⁴ In theory, investments in prevention of chronic diseases are more costeffective compared to the burden through their treatment to the health care system, the community, and to individuals.²⁵

Study aim and objectives

The aim of this study is to evaluate the effects of a community-tailored 8-week physical activity program on physical activity and health outcomes for Aboriginal and Torres Strait Islander adults in regional communities. The effectiveness will be assessed by measuring change in functional capacity, step counts and overall levels of physical activity, metabolic markers, perceived quality of life and other health behaviours and outcomes before, immediately after and 12 weeks after the program. The intervention was co-designed with the Indigenous mentors, where the intervention duration, number of sessions, and exercise types were chosen by the mentors. The free program will include 60 minutes of aerobic and resistance type training, four times per week for an eight-week period. Training sessions will include a variety of exercise modalities such as small sided games and circuit training. Semi-structured qualitative interviews will be conducted with participants to explore barriers to and motivation for physical activity. Additional questions will be included to explore participants' experiences with the program and suggestions for future activities.

Methods and analysis

Trial design

The intervention is an 8-week physical activity program to be conducted in two communities in Far North Queensland, using a pragmatic study design. For various reasons, previous studies conducted in Indigenous communities have moved away from using a traditional randomised controlled trial (RCT), including ethical concerns over allocating half the participants to the control group that will not receive the intervention²⁶ and information sharing among the small communities.²⁷ Consultations with Indigenous mentors and community members in the respective communities concluded it would be inappropriate to utilise an RCT design. An attempt will be made to use a wait-listed control group, however, this will require a relatively large minimum sample size (n=42) for sufficient statistical power. Due to the regional setting with relatively small communities of Indigenous Australians, and after consultation with the local health centres it was deemed it may not be feasible to recruit a sufficient number of participants for a wait-listed control group. Therefore, we may need to revise the study protocol to a pre/post intervention design with two communities which requires a smaller sample size (n=15) for sufficient power. Another barrier to using a wait-listed control group is that one of the communities expressed that they may not be able to commence the intervention at the required time due to staff availability, and a replacement site may need to be obtained later. In our recent systematic review of

physical activity interventions for Indigenous people in Australia and New Zealand only three out of the 13 identified studies were RCTs,²³ which emphasises the difficulties of applying an RCT design in Indigenous communities.

Furthermore, there have been examples where the implementation of RCT designs were not logistically feasible. Sibthrope and colleagues²⁸ implemented an RCT in an urban Aboriginal Medical service, with the aim of assessing the effectiveness of brief interventions on alcohol misuse. There were demising factors, such as the attitudes to the random allocation of participants and low recruitment to the intervention, which lead to the program not being implemented as intended. Ultimately the researchers asked to terminate their funding from Australia's peak funding body for medical research (National Health and Medical Research Council) as the study protocol could not be implemented in full capacity. Ideas and concepts for this program were drawn from a previous study,²⁷ which implemented a similar program with a Maori population in New Zealand. This trial was registered with the Australian New Zealand Clinical Trial Registry (ACTRN12616000497404).

Settings

The two collaborating communities are in Far North Queensland, Australia. The population of one community is estimated to be 1,700 people, with 21% of the residents identifying as Indigenous and the second site has a population of approximately 10,000 residents, with less than 1,500 identifying as Indigenous. Known factors that may affect attendance to exercise programs include the logistics, such as transport to and from the site, personal health and competing obligations such as caring for children.²⁹ In regards to family and income, the communities' unemployment levels were 20 and 54% and jobless single parent families represent 25% and 54% respectively.³⁰ Considering these factors may affect

attendance to the program, it was deemed inappropriate to have participants pay any fees towards activities and to keep activities flexible for family participation such as allowing children to attend the walking groups at the parents' discretion.

Recruitment

Participants will be recruited through community information sessions. Working in conjunction with the Indigenous mentors, flyers will be posted around the community at different sites such as the supermarket and local sporting facilities. A facebook page will also be created to recruit people into the program.

Sample size

A sample size of 15 participants is estimated to achieve more than 90% power to detect a significant difference in the six-minute walk test distance with a level of significance of 0.05. The calculation of the sample size was based on an expected minimum increase in the primary outcome measure of the six-minute walk test of 50 metres, which is considered clinically relevant.³¹ We aim to recruit 30 participants to account for attrition.

Participants

Inclusion criteria

- 1. Aged 18-45 years at recruitment;
- 2. Identify as Aboriginal and/or Torres Strait Islander;
- 3. Have a diagnosed chronic disease or a risk factor for chronic disease. Risk factors are based on the definitions in the guidelines of the Australian Institute of Health and Welfare,³² such as having a BMI of/or greater than 30, waist circumference of/or greater

than 94 centimetres for men and 80 centimetres for women, and/or less than 150 minutes of physical activity per week.

Exclusion criteria

- 1. Pregnancy at baseline or during the study period;
- 2. Advised by a medical professional not to participate in physical activity or physically unable to partake in activities due to injury or illness.

Intervention

This is considered a 'complex intervention' due to a large number of discretionary behaviours and actions required between the sites. Flexibility and tailoring of the program in the delivery and reception will be important factors for success.³³ As described by Hawe et al.,³⁴ the function of the intervention is standardised, but the form varies across the context, which in this case is the community. During discussions with the participating communities, the program was standardised through the agreement of the number of sessions provided per week. However, the physical activity sessions would be determined by the mentor to suit the facilities and resources available in the community.

The duration of 8 weeks of the program is based on previous evaluations of physical activity programs with Indigenous Australians lasting 8 weeks or less which reported significant reductions in weight, BMI and/or a significant increase in fitness,^{9, 10, 35} and improvements in blood lipids.^{35, 36} The effectiveness of the program will be assessed through measures of step counts and overall levels of physical activity, metabolic markers, perceived quality of life and other health behaviours and outcomes before, immediately after and 12

weeks after the intervention.

The program will be delivered through one-hour face-to-face group sessions, four times per week for eight weeks. Participants will be encouraged to attend at least one session per week. Each week there will be two sessions with vigorous and two with moderate intensity activities, delivered by a qualified sport and exercise scientist (principal investigator). The vigorous intensity sessions will include small sided team sports (small number of players per side), such as soccer and touch football, and circuit training with adaptations made to account for individual fitness levels. The remaining two sessions will be self-paced moderate intensity walking sessions (male and female groups) and will be conducted by community leaders. Involving community leaders is important to assist with the eventual changeover and sustainability of the program. Moderate and vigorous intensity sessions will be alternated during the program period and all sessions will include a warm up prior to exercise and cool down after the activity. Each session will have a sign-in sheet to monitor the program dose-response and implementation fidelity. Field note reflections will be taken at the end of every session to report any adverse events or participant feedback. If there are any medical concerns during an exercise activity, participants will be requested to provide a doctor's certificate before they can return to the program. The activities will be conducted at free community facilities, such as walking tracks and football fields, where there will be no cost to participants. Semi-structured qualitative interviews will be conducted after the intervention to explore participants' motivation and barriers with the program and explore suggestions for future physical activity programs.

Participants will be asked to provide informed written consent after a hard copy and verbal explanation of the information sheet is given to them, prior to any baseline

assessments. A plain English verbal explanation will also be provided and Indigenous mentors will be available for those whose first language is not English.³⁷ The explanation will include the purpose of the research, reassurance on the confidentiality and de-identification of information and disclosure of the working relationship with the Indigenous mentors. Participants will be informed that they can withdraw from the study at any time without reason or consequence.

Timeline

The study design is a pragmatic trial with two communities in Far North Queensland. Data collection time points will include before, immediately after and 3 months after the program. One of the communities that agreed to participate in this project was known through an existing relationship from a previous research project.³⁸ An additional community contacted the principal investigator to express their interest in taking part in the intervention as a wait-listed control group. The second site was not an existing research partner of the University and has since had a research agreement in place.

Indigenous mentors

The project will be guided by the principal investigator (AS) in conjunction with local Indigenous mentors from collaborating organisations. The mentors are health workers who live and work in the communities and have extensive knowledge of local culture. The mentors provide advice and information on the appropriate procedures for individuals in that community. Adaptations of survey tools, such as the SF-12,³⁹ were critical as the questions were not always appropriate for the community. For instance, one question on the SF-12 asks participants about time spent doing moderate intensity activities and uses the examples of "moving a table, pushing a vacuum cleaner, bowling, or playing golf". Keeping in mind the

locations and socio-economic status of the communities, activities such as playing golf and bowling would not be common due to lack of facilities for such activities and due to different preferences for activities, including team sports such as touch football. Therefore, these activity examples in the SF-12 were modified to "brisk walking, or moderate exercise".

For the intervention to become sustainable after the initial 8-week program, the Indigenous mentors were asked to provide assistance during the exercise activities. This was to ensure the mentors have established relationships with the participants and will be able to run the program without external help from the researchers.

Data collection

Once a participant has received and had a verbal explanation of the information sheet, they will be asked to sign an informed consent form if they wish to continue with the program. All participants will receive a copy of their data and all organisations that are involved will receive a non-identifying report highlighting the intervention results. Participants will be provided with the option to have results of any health outcomes measured in this study added to their existing medical clinic health record. Participants will be given a Pre-Medical Questionnaire, which has additional questions around possible confounding variables such as medical history, alcohol consumption, education and household income.

The SF-12 will be administered to participants during the session. After the forms are completed, participants will have anthropometric measures objectively assessed such as height, weight, body fat, and waist and hip circumference. Following the assessment, a six-minute walk test (6MWT) will be conducted.^{40, 41} The participants will then receive a wrist worn Fitbit Flex activity monitoring device to wear during the program, in addition to

wearing the device for seven days pre and post program. Participants will be given a pathology form to take to a clinic for the relevant tests. This form needs to be taken to the designated pathology clinic where participants will have a fasting venous blood sample taken. All participants will have the option to send the pathology results to their preferred doctor if they wish for the results to be added to their personal medical records.

The original study forms will be stored in a locked filing cabinet on the University campus. The data will be de-identified and entered into a password protected electronic database. A subset of the forms will be selected for quality control of data entry purposes and cross examined against the values in the database.

1. Blood pressure and anthropometric assessments

- Blood pressure will be measured using an electronic monitor with an upper arm cuff
- (Omron HEM-907). To standardise the measurement of blood pressure, all participants will be seated for at least 5 minutes prior to the readings in line with the guidelines of the American College of Sports Medicine.⁴² Three measurements will be recorded and the mean value for the second and third will be used.
- Height will be measured using a stadiometer. Participants will be asked to remove their shoes and socks for the assessment. Values will be measured to the nearest 0.1cm, with two measures being taken and averaged.
- Weight and body fat will be measured using a segmental bioelectrical impedance Tanita body fat monitor/scale (BF-545, Tanita Corporation, Tokyo, Japan). Participants will be asked to remove their shoes and to remove anything from their pockets. It is advised that participants who are fitted with an electronic pacemaker do not have their measurement taken on these scales due to the bio-electric impedance.

- Waist and hip circumference will be measured preferably by having participants lift their shirts above their hips. However, if they are uncomfortable or unable to (wearing a dress for example), the measurements will be taken over clothing with a note to repeat this at the follow up for consistency. Measurements will be taken to the nearest 0.1cm.
- Physical activity will be measured with a wrist worn Fitbit Flex over a period of seven days prior to the program and seven days after the program. The Fitbit Flex has moderate validity for measuring physical activity relative to direct observation and the Actigraph accelerometer,^{43, 44} and was deemed to be more cost-effective and had a potentially reduced participant burden and better compliance in wearing time as the device is waterproof and can be worn 24 hours a day. The Fitbit Flex is capable of measuring step count, minutes of moderate to vigorous physical activity, sleep patterns, and daily calories burnt (kcal). The data from the Fitbit Flex will be expressed as mean daily steps and energy expenditure (kcal), and weekly minutes of moderate-to-vigorous physical activity.
- Functional capacity to exercise will be measured using the 6MWT. This test measures the distance travelled over the duration of six minutes and was originally designed as an exercise tolerance test, but can also be used as a performance-based measure of functional capacity to exercise.^{40, 41} The 6MWT has been used in a variety of different populations such as in chronic heart failure patients,³¹ chronic obstructive pulmonary disease,⁴⁵ healthy populations,⁴⁶ with Indigenous Australians adults,^{7, 9, 38} and with different age groups from children and adolescents to older adults.^{47,49} An increase of 50 meters will be accepted as a clinically significant improvement.³¹ This field-based measurement requires minimal equipment, is cost effective, non-invasive and self-paced which makes it applicable to people with varying fitness levels and health conditions.³⁸

2. Clinical assessments:

Fasting venous blood samples will be collected from participants by an accredited pathology service in the Far North Queensland region. For consistency in measurements, the same laboratory service will be utilised for both communities.

- Fasting blood glucose levels will be analysed using Hexokinase BSL: Abbott c16000 (Hexokinase – enzymatic)
- HbA_{1c}: Biorad D-100 (HPLC Ion Exchange)
- Liver function: Abbott c16000 (Enzymatic/colorimetric)
- Total cholesterol (LDL, HDL): Abbott c16000 (Enzymatic/colorimetric)
- Triglycerides: Abbott c16000 (Enzymatic/colorimetric)
- C-reactive protein: Abbott c16000 (Immunoturbidimetric)

3. Surveys

Participants will be asked to complete a pre-medical questionnaire, a lifestyle behaviour survey and the Quality of Life SF-12 questionnaire.³⁹ The surveys will be conducted at each data collection point. Although the Indigenous mentors were not present when the participants completed the questionnaires, they were in the immediate vicinity and available to assist in person if needed.

- The SF-12 survey will be used to assess self-rated health, mental health, and physical function.
- The pre-medical questionnaire includes questions about participants' current state of health, such as illness and injuries, family medical history, their own medical history and if they had been told not to participate in exercise. We added questions on socio-economic status, education level and number of dependent children in the household. Health behaviour questions, such as fruit and vegetable and alcohol intake, were taken from

national surveys such as the National Aboriginal and Torres Strait Islander Nutrition and Physical Activity Survey 2012-13⁵⁰ and the 2013 National Drug Strategy Household Survey.⁵¹ The survey questions will allow for more comparable results of the community data against national averages.

The questionnaires will be filled out while the principal investigator is present, in case questions need clarifying. During negotiations with the local health care centres it was agreed that the principal investigator will provide individuals with the results of their assessments. The report will include baseline anthropometric, physical activity and pathology results. Post-intervention reports will have all results included with a personalised summary of what changes they have made and how it will impact their health. Participants will also be provided with a printed copy of their pathology results to provide to their doctor if they wish. Alternatively, participants will have the option to have their reports forwarded (by the researcher) to the relevant doctor/s on their behalf.

Data analysis

Statistical analysis

Although this is a prospective before and after comparison trial, statistical analysis and reporting will follow the SPIRIT guidelines.⁵² Numerical data will be described using mean and standard deviation (SD) if symmetrically distributed and median and inter-quartile range (IQR) if skewed; categorical data on health behaviours will be described using absolute and relative frequencies. Numerical data will be compared pre- and post-intervention using paired Student's *t*-tests if data are symmetrical and paired Wilcoxon signed-rank tests if the data are skewed. The main outcome measure is the paired difference in the 6MWT distance. If the differences in the outcomes of the 6MWT do not fit assumptions of normality, the data will be log transformed for the linear regression analysis. Multiple linear regression analyses will be used to examine associations between demographic variables, health behaviours and differences in the 6MWT. Examples of potential predictor variables include program attendance, health behaviours, such as smoking and alcohol consumption, and employment status. Dummy variables will be created for categorical variables in preparation of the regression analysis. Assumptions of linearity will be checked for numerical factors; which will be categorised if assumptions are violated. Throughout the analysis, statistical significance will be assumed when *p*-values are less than 0.05. The statistical analyses will be undertaken using Stata release 13 (StataCorp LP, College Station, Texas, USA).

Qualitative evaluation

This study is an explanatory sequential design, where the quantitative data will be collected and analysed first, to help inform the qualitative aspect of the study.⁵³ At the completion of post-exercise intervention testing, individual interviews will be conducted. Participants will receive a letter at their post testing session and letters will be sent to those who did not attend the follow-up data collection. The interviews will be conducted in a private space and guided as a semi-structured interview using open-ended questions. The interview questions will be based on the components of the Health Belief Model,^{54, 55} as it is one of the most widely recognised conceptual frameworks for health behaviours.⁵⁵⁻⁵⁷ Questions will be directed to identify perceived barriers and motivations to engage in physical activity. Additional questions will be included to explore the participants' experiences with the program, where improvements could be made and what the perceived

long-term consequences are if their current behaviour continues/discontinues. All interviews will be audiotaped and later transcribed in order to conduct a thematic analysis.

Contingency plan

There were some challenges with the program. The original site to begin the intervention was unable to commit due to a variety of reasons. This easily accessible community already had a research agreement in place and several projects were being conducted at the time of approach, which made members of the community feel 'over-researched'. Originally, a wait-listed control group was agreed upon, but unable to be implemented due to the sample size required and the small population size of the communities. As a contingency plan, a pre/post study design will be implemented instead.

Another concern is the weather conditions might pose a problem to the program as it will be run outdoors. In case of bad weather it has been arranged with the community health workers to use an air-conditioned indoor location to run activities. Access to transportation to attend activity sessions is also a risk factor, however, carpooling will be encouraged.

Discussion

This community-based physical activity program is designed to provide a standardised, but community-tailored approach to a physical activity program. The aim of the study is to evaluate the effectiveness of an 8-week physical activity program in improving physical activity and health outcomes among Indigenous Australian adults in regional communities. The primary outcome of the study is change in functional capacity to exercise, measured by the six-minute walk test. Whilst the population of interest includes young to middle-aged adults (18-45 years old), the early onset of chronic disease is common in this

population group.⁵⁸ The six-minute walk test is primarily used for middle-aged and older adults and more severe health conditions,^{31, 45} but has also been used with Indigenous Australians adults^{7, 9, 38} and younger populations.⁴⁷ The six-minute walk test is appropriate for use in this study as all participants will have identified risk factors for, or an established chronic disease. Chronic diseases are burdensome, debilitating and potentially fatal.⁵⁹ Physical inactivity has detrimental effects on wellbeing and functional capacity,⁶⁰ and regular physical activity is a direct causal pathway to increased fitness levels, which improve the capacity to exercise. The 8-week physical activity program will be run in two Indigenous communities and will include 60 minutes of face-to-face group aerobic and resistance type training, four times per week. The intervention will be evaluated using both qualitative and quantitative approaches to assess the effectiveness. The long term aim will be to investigate the sustainability of the project through the handover of the activity sessions to the partnered community health centres. The program will be conducted and designed to meet the needs of the community and to change health behaviour and health outcomes through increased interaction with the community health centre and through the provision of free physical activity sessions. The evaluation of the intervention program will provide information on best practice and effectiveness of a physical activity program with Aboriginal people and Torres Strait Islanders with a risk factor for, or established chronic disease.

Study limitations

The study has a number of limitations. The intervention is going to use a nonrandomised and uncontrolled study design. A true RCT was not possible given the population size of the communities and the number of participants required to meet the minimum sample size. A wait-listed control group design was examined for feasibility and scalability, but was not possible due to the sample size required and the timeframe and availability of staff. The

follow up length is limited to three months due to timeframe restrictions. Ideally, this would be longer than 12 months to evaluate the sustainability of the intervention effects.

Plans for dissemination of findings

The results of the physical activity program will be disseminated through peerreviewed journal publications and presentations. Study participants will receive a copy of their own results which include the pre and post program anthropometric outcome measures and the results of the six-minute walk test. The supporting community organisations will each receive an overall report detailing the main findings, including a summary of overall pre and post anthropometric outcomes, data on health behaviours (such as physical activity, diet and smoking) and self-rated health. The organisations will also receive a summary of the results from the qualitative aspect of the study for feedback and planning purposes. Copies of all subsequent peer-reviewed publications from the intervention will be sent to collaborating organisations. Presentations on overall results will be given at an open community forum and for all staff members of the supporting organisations. Access to full datasets will only be available to the principal investigators and will not be made available to the public. Collaborating organisations may receive access to pathology reports if prior written consent is received from the study participants.

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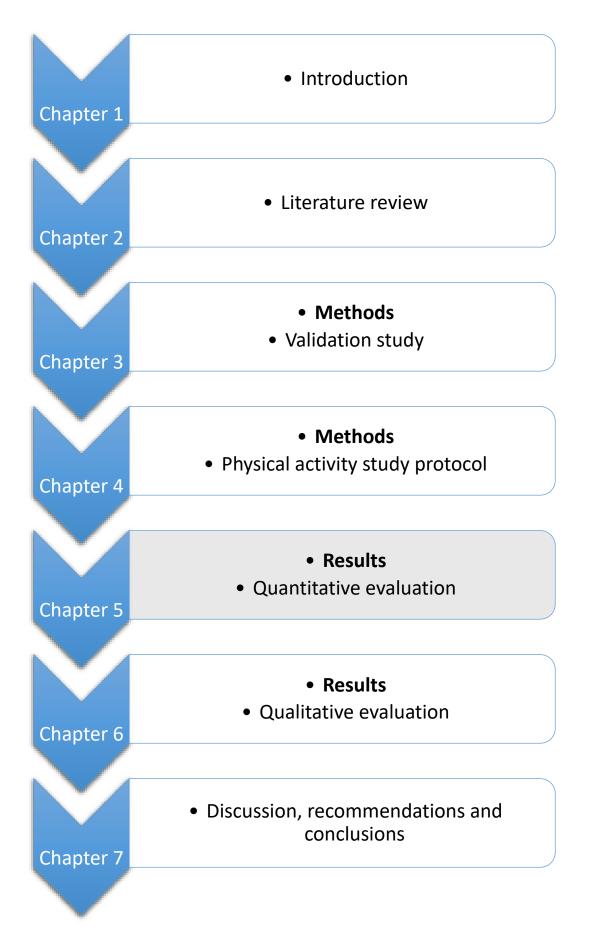
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Chapter 5: Quantitative evaluation

Sushames, A., McDermott, R., Thompson, F., & Gebel, K. (2018). Evaluation of a pragmatic community-tailored 8-week physical activity program with Indigenous Australians in a regional and rural setting (submitted for publication).

Abstract

Objective

To evaluate the effectiveness of a community-tailored 8-week physical activity program on activity levels and health outcomes in Indigenous adults with a risk factor for, or an established chronic disease.

Methods

The intervention was implemented in a rural (N=12) and regional (N=22) setting in Far North Queensland. The free program consisted of 60 minutes of group-based physical activity four times per week. Outcome measures included change in functional capacity for exercise, measured by a six-minute walk test (6MWT), physical activity, anthropometric data and pathology markers.

Results

The rural community members had significant increases in the 6MWT distance from 467 metres±56 to 557 metres±108 (p=0.01) and decreases in body fat (34.98±6.6% to 30.61%±6.92, p=0.009) and hip circumference (106.6cm±4.0 to 104cm±5.3, p=0.005). In the regional city, there were significant reductions in waist circumference (99.11cm±11.95 to 96.07cm±11.46 (p=0.006), hip circumference (105.41cm±11.32 to 101.97cm±8.83, p=0.019) and systolic (p<0.001) and diastolic blood pressure (p<0.001). Self-reported physical activity increased in both communities, but not significantly (p=0.09).

Conclusions

The evaluation of the physical activity program showed promising improvements in

functional capacity for exercise and health outcomes, however, the challenge is to better understand how to increase participation rates.

Introduction

In Australia there is a ten-year gap in life expectancy between Indigenous and non-Indigenous people,¹ and in the state of Queensland this gap is more than 20 years.² It is estimated that 80% of this difference is caused by chronic diseases, such as type 2 diabetes and cardiovascular disease,³ and there is substantial evidence for the health benefits of physical activity in the prevention and treatment of chronic disease.⁴ Australian guidelines recommend that adults aged 18 to 64 should accumulate 150-300 minutes per week of moderate physical activity or 75-150 minutes of vigorous activity.⁵ Based on self-reported data, more than half of all Australian adults (56%) are not sufficiently active, while adults in regional and remote areas are even less active (62% and 61% respectively).⁶ Indigenous Australians have even lower rates of physical activity, with 38% of Indigenous people in nonremote locations meeting the physical activity recommendations.⁷

Nevertheless, little research exists on physical activity and health outcomes among Indigenous Australians.⁸ The aim of this study was to implement and assess the effectiveness of an 8-week physical activity program with Aboriginal and Torres Strait Islanders in Far North Queensland. Outcome measures included functional capacity for exercise and several anthropometric measures and pathology markers. We hypothesised that the program would improve the participants' functional capacity for exercise and health outcomes.

Methods

The trial was registered with the Australian New Zealand Clinical Trials Register (ACTRN12616000497404). Ethical approval was obtained from the James Cook University Human Research Ethics Committee in October 2014 (approval number: H5942). The additional site-specific approval for the regional city was obtained in July 2016. The two

collaborating communities are located in Far North Queensland. The population of the rural community is 1,700 people, with 21% identifying as Indigenous. The regional city is located 100 kilometres from the rural community and has a population of approximately 160,000, with 8% identifying as Indigenous. To be included in the study, participants had to be Aboriginal and/or Torres Strait Islanders, be aged between 18-45 years, and have a diagnosed chronic disease or a risk factor for chronic disease. Risk factors are based on the definitions of the Australian Institute of Health and Welfare,⁹ such as having a body mass index (BMI) of/or greater than 30, waist circumference of/or greater than 94 centimetres for men and 80 centimetres for women, and/or undertaking less than 150 minutes of physical activity per week. The exclusion criteria were pregnancy at baseline or during the study period or advice by a medical professional not to participate in physical activity or being unable to partake in activities due to injury or illness. In conjunction with an Indigenous mentor, a facebook page was created and flyers were posted around the community to recruit participants. The program commenced in January 2016 in the rural community where shortly after the waitlisted control group withdrew. A second convenience site was recruited in a regional city where the project commenced in July 2016.

This program is described as a 'complex intervention' due to a large number of discretionary behaviours and actions implemented by the communities. Hawe et al.¹⁰ described interventions as complex when the function of the intervention is standardised, but the form varies across the context. The project was implemented by the principal investigator (AS) in partnership with local Indigenous mentors from collaborating organisations. The mentors were health workers who lived and worked in the communities, have extensive knowledge of the local culture and provided advice and information on the appropriate engagement procedures for individuals. The program was delivered through one-hour face-

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to-face group sessions, four times per week for eight weeks. Participants were encouraged to attend at least one session per week. Each week there were two sessions with vigorous and two with moderate intensity activities delivered by an exercise scientist (AS). The vigorous intensity sessions included small-sided team sports, such as soccer and touch football, and circuit training with adaptations made to account for individual fitness levels. The remaining two sessions were self-paced moderate intensity walking.

A verbal explanation of the information sheet was given by the principal investigator before written consent was obtained. Participants were given the opportunity to decline participation in the study or to withdraw at any time. There was no financial cost involved with participation in the project. Participants completed a pre-medical and lifestyle behaviour questionnaire, including physical activity levels.

Anthropometric measures were taken by the chief investigator, including height, weight, body fat (BF-545, Tanita Corporation, Tokyo, Japan), mean blood pressure (Omron HEM-907) and waist and hip circumference. Functional capacity for exercise was assessed with the six-minute walk test and was the primary outcome measure.¹¹ The 6MWT measures the distance an individual is able to walk in six minutes, where the goal is to walk as far as possible within that time. The 6MWT has been used in different populations such as in chronic heart failure patients,¹² chronic obstructive pulmonary disease,¹³ healthy populations,¹⁴ and Indigenous Australian adults.¹⁵ The participants then received a wrist worn Fitbit Flex^{16, 17} accelerometer to wear during the program, and for seven days pre and post program to objectively assess physical activity. The pathology tests included blood glucose, cholesterol, liver function and C-reactive protein.

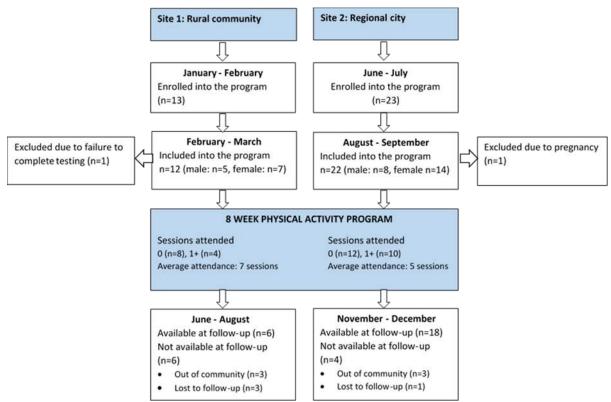
A sample size of 15 participants was estimated to achieve more than 90% power to detect a significant increase (p<0.05) in the primary outcome of the 6MWT distance. The sample size calculation was based on an expected 50-metre increase in the 6MWT, which is regarded as clinically significant.¹² The minimum number of participants to be recruited was estimated to be 30, to account for an expected attrition rate of 50%.

The statistical analyses were undertaken using Stata release 13 (StataCorp LP, College Station, Texas, USA). Only participants who completed pre and post testing were included in the analysis, with separate analyses for each community required due to differences in baseline health status and regional variation. Since participation in the intervention was low, an intention to treat analysis¹⁸ was undertaken (details on the attendance rate are provided in the Results section). Further analyses were conducted to measure the effect of the intervention, based on participants who did and did not attend the program. Numerical data is described using mean and standard deviation (SD) if symmetrically distributed and median and inter-quartile range (IQR) if the data were skewed. Pre and post intervention anthropometric data were compared using a paired *t*-test. Pathology results were analysed using a paired Wilcoxon signed-rank test as the data were not normally distributed. Categorical data on health behaviours is described using absolute and relative frequencies as nominal values and data are compared using a Fisher's exact test or a McNemar's test if the variables are dichotomous.

Results

Descriptive statistics are provided in Table 1. Six men and seven women enrolled into the program (N=13) in the rural community. One participant was later excluded after failing to show up to complete a baseline six-minute walk test. A flowchart of participants is

provided in Figure 1. The mean age of the participants was $36.5 \text{ years} \pm 6.3$ and the average weight and BMI at baseline for all participants was $85.43 \text{kg} \pm 14.71$ and $32.18 \text{kg/m}^2 \pm 3.06$ respectively. BMI classifications were overweight (n=1), obese (n=9) and morbidly obese (n=2). The mean for functional capacity to exercise, assessed with the 6MWT, was



467.33m \pm 56.58. Prior established health conditions of the participants included diabetes (n=5), high cholesterol (n=3), high blood pressure (n=4) and asthma (n=2).

Figure 1: Study flow diagram for evaluation of physical activity intervention for Indigenous Australians, Far North Queensland, 2016.

In the regional city, 23 participants enrolled in the program (eight males and 15 females). One woman was later excluded from the evaluation due to pregnancy, but was still invited to participate in the walking groups. The mean age of the participants was 29.27±6.0 years, with a mean weight and BMI of 88.61kg±16.44 and 30.66kg/m²±5.07 respectively. BMI classifications were normal (n=3), overweight (n=7), obese (n=11) and morbidly obese

(n=1). The mean distance for the 6MWT was 509.8 \pm 52.07m. Pre-existing medical conditions included high cholesterol (n=2), type 2 diabetes (n=3), rheumatic heart disease (n=1) and asthma (n=2).

In the rural community, six participants completed both the pre and post anthropometric assessments (Table 2). There was a significant increase in the primary outcome of the 6MWT distance from 467.3m to 557.8m (p=0.01) and small reductions in BMI, waist circumference, and systolic blood pressure, but these were not significant. The mean weight of the participants only decreased slightly from 85.4kg to 84.6kg (p=0.59), however, there were significant reductions in body fat and hip circumference from 34.9% to 30.6% (p=0.009) and 106.6cm to 104cm (p=0.005) respectively. In the rural community, despite being aware of the pathology collection requirements, participants declined to have a second pathology test taken which resulted in missing data (Table 5).

In the regional city, 18 of the 22 participants attended the post-program assessments. There were no significant changes in the primary outcome measure of the six-minute walk test. However, there were significant reductions in waist circumference from 99.11cm to 96.07cm (p=0.006) and hip circumference (105.41cm to 101.97cm (p=0.019) and in systolic (p<0.001) and diastolic blood pressure (p<0.001). There were no significant changes in weight, BMI, bodyfat percentage or the pathology markers (Table 2).

Program attendance was low. In Table 3, the anthropometric outcomes are displayed for all participants in the communities, grouped by those who attended the program and those who did not, but had follow-up assessments. In the rural community, eight participants did not attend a single training session, and four attended an average of seven sessions. In the regional city, twelve participants did not attend a single training session, while the remaining ten participants attended an average of five sessions. There were significant differences between those who attended the classes and those who did not for the 6MWT (p<0.01) and waist circumference (p=0.022) (Table 3). Those who were exposed to the intervention had significant reductions in waist (p<0.001) and hip circumference (p=0.003), as well as systolic (p=0.005) and diastolic blood pressure (p=0.031). Functional capacity to exercise was also increased significantly (p=0.002) for those who attended, but not for those who did not attend (p=0.75) (data not tabled). Reasons for non-attendance and withdrawal included working outside the community, travelling to visit family members in hospital and relocating to find employment.

Changes in self-rated health and health behaviours for participants who attended the follow-up assessments are displayed in Table 4. For participants who had data for both outcome measurements (n=9), the baseline self-reported daily MVPA minutes (28.4 \pm 13.7) were almost the same as the objectively measured MVPA (29.5 \pm 20.1). After the intervention, there was an increase in self-reported daily minutes of MVPA for those who reported doing regular physical activity at baseline, and who were also available at follow-up (n=10), from 28.2 \pm 13.3 to 40 \pm 20.2 (*p*=0.09) (data not tabled). As a result of poor compliance to wearing the Fitbit Flex, and some participants losing the device, no objectively measured physical activity data post-intervention were available.

Discussion

The aim of this study was to implement and evaluate the effectiveness of an 8-week physical activity intervention in a rural and a regional Indigenous group in Far North Queensland. There were several barriers to program implementation, however, improvements in health outcomes were evident. In the rural community, there was a clinically significant increase in the 6MWT distance and significant reductions in body fat and hip circumference. In the regional setting there was a non-significant increase in the 6MWT distance. However, significant reductions were evident in waist and hip circumference and systolic and diastolic blood pressure. There were no significant changes in weight, BMI or pathology markers for either community.

The findings from this study are consistent with other evaluations of physical activity programs for Indigenous Australians.^{15, 19} One 8-week program¹⁹ evaluated the uptake and effects on lifestyle and cardiovascular risk factors of a cardiac rehabilitation program at an Aboriginal Medical Service in a metropolitan area of Western Australia. The program involved twice weekly, supervised, one hour exercise sessions with stationary cycling and dumbbell exercises as well as education sessions. Dimer et al.¹⁹ reported significant reductions in BMI, waist circumference and in blood pressure. In addition, there was a significant increase in the distance walked during the 6MWT, consistent with our results from the rural community. In the regional city in the present study there were also significant reductions in blood pressure and waist and hip circumference, but no significant changes in weight and BMI. Another similar study¹⁵ in Tasmania with two one-hour exercise sessions and a one hour education class each week reported significant reductions in weight, waist circumference in the 6MWT distance.

In contrast to two other studies with similar duration,^{20, 21} in the present study there were no significant changes in pathology markers. An Australian study²⁰ with a duration of seven weeks reported reductions in plasma insulin, cholesterol and glucose in 14 Indigenous participants who were taken to a remote location in Western Australia to revert to a

traditional hunter and gatherer lifestyle. However, the volume of physical activity in this intervention would have been extremely high. A four week RCT in New Zealand²¹ involved small sided team sports three times per week and the participants attended 10-12 training sessions. There were significant increases in V0₂ peak, leg strength and HDL cholesterol which would suggest that eight weeks are long enough to detect significant changes in pathology markers if the physical activity program is intensive and has a good attendance rate.

The participants in our study had no significant changes in weight or BMI. Evidence suggests that even without weight loss, changes in exercise and diet can improve cardiometabolic risk profiles in overweight or obese individuals.²² In the rural community, there were no significant reductions in weight or BMI, but reductions in waist and hip circumference and bodyfat indicate an increase in muscle mass. Reductions in blood pressure like in our study can also reduce cardiovascular morbidity and mortality,²³ particularly in hypertensive patients where the more aggressive the blood pressure reduction, the greater the benefit.²⁴ The significant reductions in waist and hip circumference in our study are also likely to have a positive impact on the participants' health as irrespective of overall body fat central obesity is a mediating variable to hypertension, type 2 diabetes and hyperinsulinemia.²⁵

A strength of this study is the 'complex intervention' design, which allowed for the physical activity program to be tailored to each community. During the discussions with the Indigenous mentors they decided what activities for the intervention would be most appropriate and well-received by the community. Although the attendance to the program was low, the participants had not identified the type of exercise as an issue, but rather external factors that influenced their attendance, such as lack of transport. This resulted in different types of physical activity being conducted across both sites, and using different training locations such as gyms, local parks and walking tracks. Small-sided team sports were only possible to conduct in the regional city, due to accessibility to an oval with equipment (such as soccer goals), and a larger population size. Other strengths of the program delivery were that all the training sessions were free to the participants and that sustainability of the program was achieved in the rural community. The continuation of the program beyond this study was only possible in the rural community as it had a collaborative approach with a local community health centre which had an Indigenous mentor who was also a fitness instructor and who after the program was allocated working hours towards continuing to run free physical activity classes for the community.

The key limitations related to the study design, implementation fidelity and missing data. Conceptually, the ideal study design would have been a randomised controlled trial or the inclusion of a wait-listed control group. However, in reality this was not possible. Initially, a wait-listed control group was recruited in another rural community, but they unexpectedly withdrew. Instead, we used a pre/post design which is not as strong as an RCT or controlled trial. Previous studies conducted in Indigenous communities have moved away from using traditional RCTs for various reasons, including ethical concerns over allocating half the participants to the control group that will not receive the intervention and information sharing among the small communities.⁸ In our recent systematic review of physical activity interventions for Indigenous people in Australia and New Zealand, only three out of the 13 identified studies were RCTs, which emphasises the difficulties of applying an RCT design in Indigenous communities.⁸

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Missing physical activity data due to poor compliance with the Fitbit Flex accelerometer and missing pathology tests limited the data analysis. The missing data for some participants limited the statistical power for some of the pre/post outcome comparisons and restricted subgroup analysis. Only six participants had pathology markers assessed at baseline and post-program. The majority of the participants failed to have their blood tests taken even though free transportation to a clinic was offered. The fear of needles and the frequency of blood tests (three times during the program) were all barriers to obtaining pathology samples.

While the lack of objective measures of physical activity at follow-up due to poor participant compliance with wearing the Fitbit Flex was a limitation, the baseline data for self-reported and objectively measured MVPA were almost identical which would suggest a high validity of the self-reported minutes of MVPA at follow-up. We are only aware of two evaluations of physical activity interventions with Indigenous people in Australia and New Zealand that used objective measures of physical activity (pedometers).^{26, 27} Most similar interventions rather focused on health outcomes.⁸ In the context of this study, the 6MWT was a more practical indicator of the change in exercise levels rather than data from the Fitbit Flex, as regular physical activity is a direct causal pathway to increased fitness levels, which improves the capacity to exercise.⁴

Conclusion

The 8-week physical activity program was implemented in both a rural and regional city in Far North Queensland. There were several barriers to implementation, however, improvements in multiple health outcomes were evident in both communities. The low attendance to sessions suggests that more work is needed before program implementation to investigate perceived barriers and facilitators to physical activity programs within Australian Aboriginal and Torres Strait Islanders communities.

	Rural com	nmunity n (%)	Regional city n (%)			
	Baseline (n=12)	Follow-up (n=6)	Baseline (n=22)	Follow-up (n=18)		
Gender	Female (n=7)	Female (n=4)	Female (n=14)	Female (n=13)		
	Male (n=5)	Male (n=2)	Male (n=8)	Male (n=5)		
Age (mean (SD))	36.5 (6.3)	38.66 (3.6)	29.27 (6.0)	29.88 (5.6)		
Employment status						
Full time	6 (50)	4 (66.6)	4 (18.1)	3 (21.4)		
Part time/casual	3 (25)	2 (33.3)	8 (36.3)	6 (42.8)		
Not employed	3 (25)	0 (0)	10 (45.4)	5 (35.7)		
Education						
<year 12<="" td=""><td>2 (16.6)</td><td>0 (0)</td><td>6 (27.2)</td><td>6 (33.3)</td></year>	2 (16.6)	0 (0)	6 (27.2)	6 (33.3)		
Year 12	0 (0)	0 (0)	6 (27.2)	6 (33.3)		
TAFE	5 (41.6)	4 (66.6)	8 (36.3)	5 (27.7)		
University	3 (25)	2 (33.3)	2 (9.1)	1 (5.5)		
Unanswered	2 (16.6)	0 (0)	0 (0)	0 (0)		
Gross household income						
Less than \$20,000	0 (0)	0 (0)	7 (31.8)	6 (33.3)		

Table 1. Characteristics of the participants in each community at baseline and follow-up.

\$20,000-\$59,999	4 (33.3)	3 (50)	9 (40.9)	7 (38.8)
\$60,000+	3 (25)	3 (50)	5 (22.7)	4 (22.6)
Unanswered	5 (41.6)	0 (0)	1 (4.5)	1 (5.5)
No. of adults in the house	hold			
1	2 (16.6)	2 (33.3)	8 (36.3)	7 (38.8)
2	5 (41.6)	2 (33.3)	7 (31.8)	6 (33.3)
3+	3 (25)	2 (33.3)	7 (31.8)	5 (27.7)
Unanswered	2 (16.6)	0 (0)	0 (0)	0 (0)
No. of children in househo	bld			
0	2 (16.6)	1 (16.6)	7 (31.8)	6 (33.3)
1	2 (16.6)	2 (33.3)	6 (27.2)	4 (22.2)
2	3 (25)	2 (33.3)	3 (13.6)	3 (16.6)
3+	2 (16.6)	1 (16.6)	6 (27.2)	5 (27.7)
Unanswered	3 (25)	0 (0)	0 (0)	0 (0)
Main carer				
Yes	7 (58.3)	4 (66.6)	11 (50.0)	10 (55.5)
No	4 (33.3)	2 (33.3)	11 (50.0)	8 (44.4)
Unanswered	1 (8.3)	0 (0)	0 (0)	0 (0)

Table 2. Pre and post anthropometrie	c and physical activity outo	comes for participants who at	tended follow-up.

		Rural Community					Regio	nal city	
		n	Pre mean (SD)	Post mean (SD)	P-value	N	Pre mean (SD)	Post mean (SD)	<i>P</i> -value
Functional capacity for exercise	6MWT (m)	6	467.33 (56.58)	557.83 (108.21)	0.01	18	509.83 (52.07)	526.19 (60.72)	0.287
Anthropometrics	Weight (kg)	6	85.43 (14.71)	84.61 (13.27)	0.59	18	88.61 (16.44)	88.01 (16.23)	0.250
	BMI (kg/m²)	6	32.18 (3.06)	31.92 (2.80)	0.63	18	30.66 (5.07)	30.43 (4.88)	0.197
	Bodyfat (%)	6	34.98 (6.66)	30.61 (6.92)	0.009	18	35.25 (9.26)	35.48 (7.70)	0.859
	Waist (cm)	6	105.33 (8.40)	101.5 (6.71)	0.069	18	99.11 (11.95)	96.07 (11.46)	0.006
	Hip (cm)	6	106.66 (4.08)	104 (5.32)	0.005	18	105.41 (11.32)	101.97 (8.83)	0.019
Blood pressure	Systolic BP (mmHg)	6	123 (5.01)	121 (12.99)	0.706	17	124.23 (12.20)	111.76 (11.43)	<0.001
	Diastolic BP (mmHg)	6	83 (10.99)	83.6 (9.47)	0.827	17	82.35 (7.65)	74.17 (8.99)	<0.001
Physical activity ¹	Daily step count	5	8,373 (3218)	-	-	12	7,117 (1841)	-	-
	Daily distance walked (kilometres)	5	5.71 (2.19)	-	-	12	5.25 (1.56)	-	-
	Daily minutes of MVPA	5	30.8 (18.53)	-	-	12	26.9 (16.38)	-	-

Daily minutes of MVPA	2	23.9 (1.51)	60.7 (25.25)	-	8	29.37 (14.92)	35.22	0.327
(self-reported)		()	(()	(17.0)	

1 Follow-up data for objectively measured physical activity were not available due to poor compliance with wearing the accelerometer and some participants losing the device.

		Treated				Untreated (0 sessions)				Difference between groups
		n	Pre mean (SD)	Post mean (SD)	Change	Ν	Pre mean (SD)	Post mean (SD)	Change	<i>P</i> -value
Functional capacity for exercise	6MWT (m)	14	498.42 (48.25)	562.64 (72.64)	64.21 (60.31)**	10	500.3 (66.62)	494.15 (57.51)	-6.15 (59.18)	0.009
Anthropometrics	Weight (kg)	14	88.85 (12.35)	87.55 (11.61)	-1.3 (2.36)	10	86.38 (20.29)	86.62 (20.14)	0.24 (2.44)	0.134
	BMI (Kg/m ²)	14	32.28 (3.38)	31.82 (3.22)	-0.45 (0.85)	10	29.29 (5.71)	29.36 (5.61)	0.069 (0.81)	0.143
	Bodyfat (%)	14	38.18 (7.13)	36.15 (6.49)	-2.03 (4.90)	10	30.99 (8.91)	31.64 (8.74)	0.65 (5.64)	0.227
	Waist circumference (cm)	14	102.60 (6.97)	97.82 (7.49)	-4.77 (3.39)**	10	97.95 (15.62)	96.87 (14.35)	-1.08 (3.96)	0.022
	Hip circumference (cm)	14	107.82 (5.55)	103.82 (6.15)	-4 (4.02)**	10	102.8 (13.82)	100.6 (10.19)	-2.2 (5.96)	0.385
Blood pressure	Systolic BP (mmHg)	13	121.38 (6.76)	114.53 (8.55)	-6.84 (7.08)**	10	127.2 (14.04)	113.7 (16.43)	-13.5 (16.02)*	0.193
	Diastolic BP (mmHg)	13	82.69 (7.88)	76.69 (9.30)	-6 (8.83)*	10	82.3 (9.40)	76.6 (11.07)	-5.7 (7.11)*	0.931

Table 3. Pre and post results for the communities combined, analysed by those who did and did not attend.

* *p*≤0.05

***p*≤0.01

Table 4. Self-rated health and health behaviours for participations who attended follow-up.

	Rura	I Community (n=6)		Regional city (n=18)				
	Baseline n (%)	Follow-up n (%)	P-value	Baseline n (%)	Follow-up n (%)	P-value		
In general, would you say your	health is:							
Good-excellent	4 (66.6)	6 (100)	-	10 (58.8)	13 (76.4)	0.250		
Poor-fair	2 (33.3)	0 (0)		7 (41.1)	4 (23.5)			
Do you engage in regular phys	ical activity?*	· · ·			·	·		
Yes	4 (66.6)	6 (100)	-	12 (70.5)	11 (64.7)	1.000		
No	2 (33.3)	0 (0)		5 (29.4)	5 (29.4)	-		
Compared to your physical act	ivity in the past three m	onths, was last week's	physical activ	ity more, less or about	the same?	•		
More	1 (16.6)	5 (83.3)	0.333	1 (5.8)	9 (52.9)	0.878		
Less	1 (16.6)	0 (0)		4 (23.5)	5 (29.4)	-		
About the same	4 (66.6)	1 (16.6)		12 (70.5)	3 (17.6)			
Are you currently making any o	changes to your diet?							
Yes	2 (33.3)	5 (83.3)	1.00	6 (35.2)	10 (58.8)	0.219		
No	4 (66.6)	1 (16.6)		11 (64.7)	7 (41.1)			
How many pieces of fruit do yo	ou usually eat per day?				• • •	1		
0-1 piece of fruit per day	1 (20)	1 (16.6)	0.333	11 (68.7)	9 (56.2)	0.106		
≥2 pieces of fruit per day	4 (80)	5 (83.3)		5 (31.2)	7 (43.7)	_		
How many serves of vegetable	s do you usually eat pe	r day?						
0-2 serves per day	4 (66.6)	1 (16.6)	-	10 (62.5)	6 (37.5)	0.307		
≥3 serves per day	2 (33.3)	5 (83.3)		6 (37.5)	10 (62.5)	1		
Do you drink alcohol regularly	?*			-	•			
Yes	1 (20.0)	4 (66.6)	1.000	11 (68.7)	8 (50.0)	0.250		

4 (80.0)	2 (33.3)		5 (31.2)	8 (50.0)	
often did you have an a	alcoholic drink of a	ny kind?		•	
1 (33.3)	2 (50.0)	0.067	3 (25.0)	3 (25.0)	0.236
1 (33.3)	2 (50.0)		9 (75.0)	8 (66.6)	
1 (33.3)	0 (0)		0 (0)	0 (0)	-
d drinks you have					
0 (0)	0 (0)	0.100	0 (0)	1 (8.3)	0.524
3 (100)	4 (100)	- -	5 (50.0)	4 (40.0)	
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* Data are dichotomous and compared using a McNemar's test.

Table 5. Pre and post pathology markers for each community.

		Rural community		Regional city		
Outcome	n	Pre median (range)#	n	Pre median (IQR)	Post median (IQR)	<i>P</i> -value
Glucose (mmol/L)++	5	4.9 (4.8-6.4)	6	5.25 (4.6-5.7)*	5.4 (4.8-5.5)	0.687
Cholesterol (mmol/L)	5	4.3 (4.2-5.4)	6	5.85 (5.4-5.9)	5.6 (5.0-5.9)	0.625
Triglycerides (mmol/L)	3	1.8 (1.5-14.7)	6	2.2 (1.7-3.4)	2.4 (1.9-2.8)	1.000
HDL (mmol/L)	3	1.05 (0.73-1.06)	6	0.96 (0.9-0.99)*	0.95 (0.74-0.98)	1.000
LDL (mmol/L)	3	2.5 (2.4-13.7)	6	3.75 (3-3.9)	3.15 (3-4.1)	0.687
Total cholesterol/HDL	3	4.1 (4-12.6)	6	6.05 (5.6-6.2)	5.7 (5.1-7.6)	1.000
HbA1c NGSP (%)	5	6.2 (5.2-6.2)	6	5.5 (5-5.8)*	5.5 (5.2-5.6)	0.625
C-Reactive protein (mg/L)	0	-	6	3.5 (1-6)	3.5 (2-6)	1.000
Total protein (g/L)	4	79 (75-81)	6	75.5 (75-78)	75.5 (74-80)	1.000
Albumin (g/L)	4	42.5 (39.5-64)	6	39.5 (37-41)	39 (37-40)	0.625
Globulin (g/L)	4	35 (34-36.5)	6	37 (35-40)	37.5 (35-40)	1.000
Bilirubin (umol/L)	4	4 (4-6)	6	8.5 (8-10)	7.5 (6-8)	0.218
Alkaline phosphatase (U/L)	4	88 (76.5-118.5)	6	84.5 (59-99)	83.5 (58-95)	1.000
AST (U/L)	3	17 (16-48)	6	21 (14-25)	18.5 (15-27)	1.000

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ALT (U/L)	4	39 (30.5-53.5)	6	31 (15-39)	31 (16-46)	0.687
Gamma GT (U/L)	4	47 (39-56.5)	6	29 (21-52)	28 (24-48)	0.218
Haemolysis Index	4	8.5 (1-63.5)	5	4 (3-5)	5 (5-5)	1.000

No follow-up data is available to present

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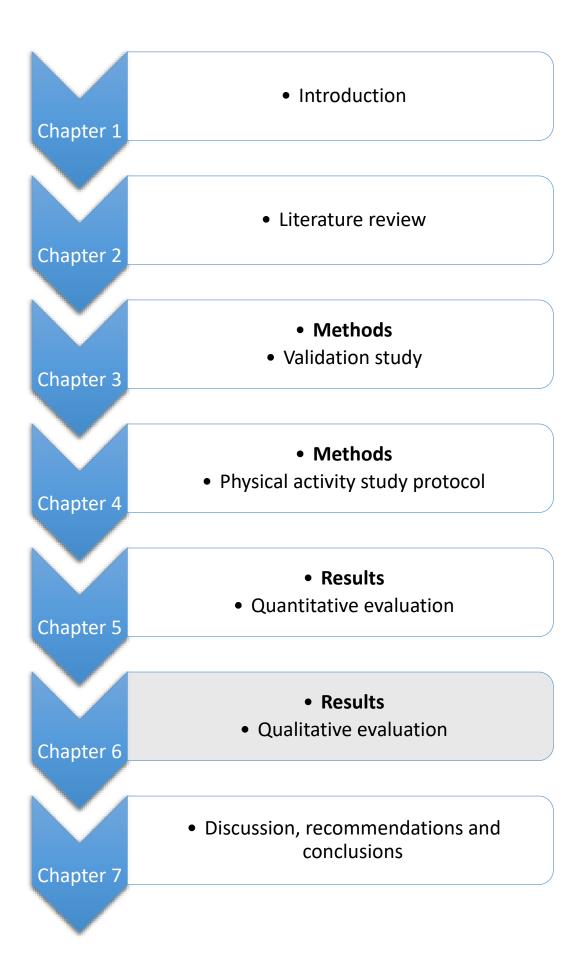
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Chapter 6: Qualitative evaluation

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RESEARCH

International Journal for Equity in Health



Perceived barriers and enablers to participation in a community-tailored physical activity program with Indigenous Australians in a regional and rural setting: a qualitative study

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Abstract

Background: Aboriginal and Torres Strait Islander people have higher rates of chronic disease and a lower life expectancy than non-Indigenous Australians. In non-urban areas these health disparities are even larger. The aim of this qualitative study was to explore perceived barriers and enablers to attending an eight-week physical activity program in a rural and regional setting which aimed to improve health outcomes, but had a low attendance rate.

Methods: Thirty-four Indigenous Australians participated in the intervention from the rural (n = 12) and the regional (n = 22) community. Qualitative semi-structured individual interviews were conducted at the follow-up health assessments with 12 participants. A thematic network analysis was undertaken to examine the barriers and enablers to participation in the program.

Results: Overall, there were positive attitudes to, and high levels of motivation towards, the physical activity program. Enablers to participation were the inclusion of family members, no financial cost and a good relationship with the principal investigator, which was strengthened by the community-based participatory approach to the program design. Barriers to program attendance were mostly beyond the control of the individuals, such as 'sorry business', needing to travel away from the community and lack of community infrastructure.

Conclusions: More consideration is needed prior to implementation of programs to understand how community-specific barriers and enablers will affect attendance to the program.

Trial registration: ACTRN12616000497404. Registered 18 April 2016.

Keywords: Indigenous, Physical activity, Intervention, Chronic disease, Australia

Background

Indigenous Australians have a lower life expectancy compared to non-Indigenous Australians, mainly due to higher rates of preventable chronic diseases [1-3]. Chronic diseases, such as type 2 diabetes and cardiovascular disease, are the leading cause of death for Aboriginal and Torres Strait Islander people [1]. Inequalities in health are further exacerbated by the location in which people reside, as rural and remote communities do not have the same opportunities to access services, education and employment [4]. The location and accessibility to Indigenous communities can also prove to be challenging when undertaking research into the health inequalities with Indigenous Australians [5].

There is a limited amount of research conducted with socially disadvantaged groups [6, 7], fundamentally attributed to the continuous struggle for researchers to access, engage with and retain participants [7]. Indigenous Australians are unique in this regard as they are considered to be socially disadvantaged, however, there are



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concerns of being over-researched without corresponding health improvements [8]. Reasons for poor participation rates in 'hard-to-reach' populations can include mistrust in research and fear of exploitation [7], lack of education [9] and generally low population numbers compared to non-Indigenous people [10]. Conducting physical activity research with Indigenous Australians is challenging, but not impossible and the potential benefits could be significant.

A recent systematic review investigated the effects on health outcomes of physical activity programs for Indigenous people in Australia and New Zealand [11]. While there was some evidence to suggest these programs improved health outcomes, most of the 13 studies in the review reported issues with recruitment, retention and adherence to the programs. For instance, several studies had less than 60% of participants complete the program, or failing to have complete data sets [12-16]. A randomised controlled trial by Biddle et al. [17] had an attendance rate of more than 80% to a physical activity intervention which involved small sided (small number of players) games over a four week period. Biddle and colleagues collected written feedback from the participants about their reasons for attending the program in which they stated that they had fun and enjoyed doing the exercise program.

In addition to a quantitative evaluation, one of the studies in the review, a 12-week fitness program for Aboriginal and Torres Strait Islander women [13], also had a qualitative component to identify perceived barriers and facilitators to the attendance of the program [18]. Identified barriers included personal health, access to transport and competing obligations. In regards to logistics and attendance, transportation has also been recognised by Davey et al. [19] as a potential barrier to participation in an Indigenous cardiopulmonary rehabilitation program. The 8-week rehabilitation program involved twice weekly training sessions which were delivered at a gym in a private physiotherapy practice. Free transport to the practice was organised for the participants who would otherwise have had difficulties attending. Additional factors that are known to affect attendance to programs in rural areas are the need to travel away out of the community for work, medical appointments and education, as potential participants would be away for a substantial duration of the week [14].

Understanding the barriers and enablers to participation in physical activity programs can assist researchers in interpreting contextual factors that influence the implementation of and attendance to a program [20]. Thus, the aim of this study was to explore the barriers and enablers to participate in a community-tailored physical activity intervention for Indigenous Australians in a rural and regional setting in Far North Queensland.

Methods

Settings and recruitment of participants

The two intervention sites were located in a rural and regional setting in Far North Queensland, Australia. The communities are not identified in this paper to protect the participants' anonymity. To be included in the study participants had to be Aboriginal or Torres Strait Islanders aged 18–45 who have a chronic disease or a risk factor for chronic disease. Based on the definitions by the Australian Institute of Health and Welfare Guide-lines [21], risk factors for chronic diseases include a BMI of or greater than 30, a waist circumference of or higher than 94 cm for men and 80 cm for women and less than 150 min of physical activity per week. Participants were excluded if they were pregnant or advised by a doctor not to engage in physical activity.

The program commenced in January 2016 in the rural community and in July 2016 in the regional location. At the commencement of the study, 34 participants were enrolled. A flowchart of participant recruitment and attendance is provided in Fig. 1.

Interview guide development

Interviews were conducted at the post-program assessments. The interviews were loosely based on the Health Belief Model [22], as it is one of the most widely recognised conceptual frameworks for health behaviours [22– 24]. The Health Belief Model was selected as it was theorised that individuals would be more likely to voluntarily engage in the physical activity program if their current behaviour is perceived as a threat to their health. An interview guide was created to assist in the delivery of semi-structured interviews and included open-ended questions, which were designed to prompt responses relating to experiences with physical activity, the program delivery and future directions for interventions. The interview guide included the following themes:

- 1. What was your experience with the program?
- 2. What could have been made better about the program?
- 3. What would you like to see happen in the future?
- 4. Is there anything else you would like to comment on?

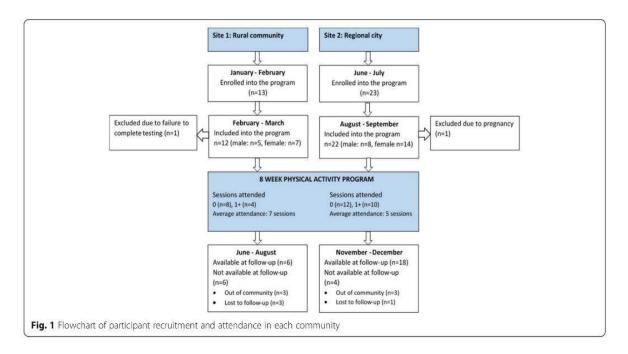
Due to the complexity of a non-Indigenous researcher working with an Indigenous population group, the interview guide had limited questions to allow a better exploration of previously unidentified themes that may arise.

Procedure

An 8-week physical activity program was implemented in two communities. The free program was delivered

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through one-hour face-to-face group sessions, four times per week for eight weeks. Each week there were two sessions with vigorous activities and two with moderate intensity activities, delivered by a qualified sport and exercise scientist (principal investigator). The vigorous intensity sessions included small-sided team sports (small number of players per side), such as soccer and touch football and circuit training with adaptations made to account for individual fitness levels. The remaining two sessions were self-paced moderate intensity walking sessions. After the program, participants were invited to partake in one-on-one interviews, regardless of their attendance to exercise sessions. Interviews were mostly conducted at the participants' house by the principal investigator (PI) who already had established relationships with the participants.

Data treatment and analysis

All interviews were digitally recorded by the PI and transcribed professionally by an external transcription service. Transcription files were presented in Microsoft Word and later uploaded into NVivo 11 (QSR International, Australia) for analysis. Interview transcriptions were read by the PI while listening to the corresponding audio file to cross-validate the content and to ensure the context was captured accurately. The interviews were coded and examined independently by a second person (CM) for a thematic analysis. The thematic network analysis was aimed at identifying global, organisational and basic themes [25], which were also compared between the two communities. The analysis involved coding the raw material into specific topics or words, such as 'money', 'time' and 'work' in order to reduce the data. The next step of the analysis involved clustering the codes to identify the organizing themes. The three themes were labelled as 'barriers', enablers', and 'suggestions for future programs'. Finally, the thematic networks were constructed and arranged for further exploration and interpretation. To compare the findings between the rural and regional communities, the codes within the themes were reviewed and highlighted in two distinct colours to examine the frequency of appearance. The global theme of the data was named as 'participation in physical activity' as it best described the overall context of the findings.

Results

Participants

Table 1 provides the baseline anthropometric measures for all participants of the intervention. Many participants were unemployed (n = 12) and annual gross household income was frequently less than \$20,000 (n = 7) or less than \$60,000 (n = 12). Seven participants had not completed year 12 and 17 participants had completed a TAFE or university degree. Twenty-seven of the 33 respondents (missing n = 1) rated their general health either good (n = 16), fair (n = 9) or poor (n = 2). Only two participants rated their health as excellent. Quantitative results from the program will be provided elsewhere in an additional publication.

Overall, attendance to the program was low. In the rural community, eight people who enrolled in the program did not attend a single training session, and four attended an average of seven sessions during the eight Sushames et al. International Journal for Equity in Health (2017) 16:172

		Rural community ($N = 10$)	Regional community ($N = 22$)	Combined ($N = 32$)
		Mean (SD)	Mean (SD)	Mean (SD)
Age		36.6 (6.89)	29.27 (6.0)	31.56 (7.07)
Anthropometrics	Height (cm)	162.5 (9.14)	169.86 (9.10)	167.28 (9.77)
	Weight (kg)	85.81 (12.05)	88.12 (15.61)	87.4 (14.44)
	BMI (kg/m ²)	32.73 (2.55)	30.53 (4.81)	31.21 (4.32)
	Bodyfat (%)	34.14 (7.99)	34.07 (9.15)	34.09 (8.67)
	6MWT (m)	455 (95.45)	509.72 (65.54)	492.62 (78.86)
	Waist circumference (cm)	104.2 (6.77)	98.59 (11.75)	100.34 (10.67)
	Hip circumference (cm)	105.45 (3.93)	105.15 (10.49)	105.25 (8.89)
Blood pressure	Systolic BP (mmHg)	126.8 (9.30)	124.66 (11.36) ^a	125.35 (10.63)
	Diastolic BP (mmHg)	84.1 (10.22)	81.33 (7.40) ^a	82.82 (8.34)

Table 1 Baseline anthropometric measures of the communities separately, and combined, Queensland, Australia, 2016

6MWT 6 Minute Walk Test, BMI body mass index, BP blood pressure, a Data was not available for one participant

weeks. In the regional city, twelve participants did not attend a single training session, while the remaining ten participants attended an average of five sessions.

Motivations to participate in the program

The motivations to join the physical activity program were different between the rural and regional community. During the analysis, the regional community had a sub-theme develop in regards to motivations of healthrelated outcomes such as weight loss and fitness. For example, reasons to join included 'To lose weight, get fit and be more active' (Female 6, Regional) and 'Weight loss and to get more into physical activity' (Male 1, Regional). For one participant, weight loss was a means of controlling the progression of her chronic disease: 'Well, with the current condition I'm under it is very important that I control my weight...I've got diabetes' (Female 5, Regional). The rural community members more explicitly stated motivations to participate were due to chronic diseases. One participant stated 'I'm determined not to be a [chronic disease] statistic... I'm pretty determined to break the cycle' (Female 1, Rural), and another explained 'she [another participant] wanted to do it ... her chronic disease wasn't looking good so she had to start making changes' (Female 4, Rural).

Barriers to attendance

Many of the men who enrolled in the program stated that their main reason for non-attendance to activities was work commitments. Two of the participants who worked in the rural community stated 'I do work away, all the time up the Cape' (Male 2, Rural) while another often did shift work: 'Yes, well, at that time I was doing all day shifts at work and the timing was sort of out' (Male 3, Rural). Both men were highly motivated to participate and attended the follow-up data collection, despite not attending a single training session. The men acknowledged their disappointment that they did not get any benefit from the program. One of the men in the regional community, who was also a university student, found it hard to attend as his work required him to travel away regularly, 'I think the biggest barriers for me are work, study and travel' (Male 1, Regional).

There were logistical barriers identified in the interviews, which were unique to the communities. In the regional community, logistical problems were mainly the timing of the class (despite being suggested by the participants), whereas the rural community members experienced problems with access to transport. The rural community also had issues with access to facilities. During the first four weeks of the program, no indoor facilities were available and classes were regularly cancelled due to rain. 'You've got to take into consideration that a lot of outdoor activities can't be run on a regular basis sometimes, due to - obviously we live in the tropics, the wet tropics. That's why it's called wet, as - it can set in for days, months sometimes' (Female 4, Rural). Despite being able to access a secondary facility five kilometres away, there were barriers in regards to access to transport to attend the classes. 'But organising stuff, even when there is wet [weather], we don't have indoor facilities...You've got to go in town or you've got to access a facility - fitness facilities, and then they cost money. Every time you want to do something, it costs money' (Female 4, Rural). There was a lack of public transport services and 'not everybody has access to a car' (Female 4, Rural).

There were other barriers to program implementation and attendance in the rural community, such as 'sorry business', which is a term used by Indigenous Australians that refers to a time of mourning in the community, following the death of a person. The process of mourning can take place over extended periods, and the intensity of the mourning is reflective of the importance of the individual that has passed away, respectively the importance of his or her family. 'We run a program - we've always tried to start it with a start date. Obviously because of the weather, obviously because of sorry business or something, we can never start it when we want to start it. It got put off as much as we could. Then when it got up and running, by the time it was finishing, that's when they started walking in the door' (Female 4, Rural). An identified sub-theme in the rural community was menstruation being a barrier to female participation. 'Sometimes women won't participate if they're menstruating. I know quite a few say they can't' (Female 4, Rural). Although there was no further elaboration from other participants in the interviews on this particular issue, several personal communications received prior to program sessions indicated that the reason for non-participation was menstruation. Specific concerns reported included feeling uncomfortable exercising, cramping and fatigue and concerns regarding hygiene in the rain.

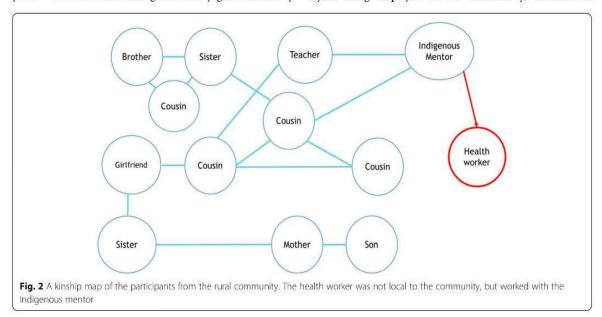
A lack of family and peer support were identified as a barrier to participating in physical activity. One of the participants who had a young family and a partner that worked away explained: 'I think the only thing, sometimes I feel depressed there is not enough support from my partner, which is something that I'm wanting more is his support' (Female 6, Regional). A male participant explained his hardship of needing to take control of his health conditions and the effect it has on his family. 'I suppose the receptive of the rest of the family is probably your key stumbling block if there's one ... see I've got a wife and four kids so it's like I've got to have a separate meal'. He also expressed his feelings toward the impact that health choices have on his children: 'because I think she's borderline [his daughter] – at the age of 20, borderline diabetic, and we try to do that with her, but yeah - sort of heartbreaking when they get emotionally

upset because they're not allowed to go and enjoy what they want to enjoy' (Male 3, Rural).

The lack of peer support and family also transitioned into themes of shame and stigma around undertaking physical activity. There were previous negative experiences in regards to people wanting to exercise for their health. 'Now or prior to the last five years, exercise was deemed as people who wanted to look good. There was always this negative attitude. Because I think obesity has become a norm in most – in the cultures now. You either need to look fat, so everyone stays fat, and if you want to lose fat, you're deemed as being sick. If you want to look good for the sake of being healthy, people think that you're better than anybody else. Whereas I think the culture is shifting a little bit now, or the mentality is shifting' (Male 1, Regional).

Enablers to participation

Several participants mentioned finances and money during the interviews as barriers to participate in physical activity and that having a free program acted as an enabler. Reasons for joining were because 'it is good that it doesn't cost money. Everything else costs money' (Female 7, Regional). Unemployment was as a financial barrier to undertaking exercise as 'Money is a major barrier for myself. Only because you're still looking for work' (Female 3, Regional) and 'it was free ... Yeah, I couldn't afford it, no money, no job' (Female 2, Regional). An identified enabler to joining in the physical activity program was the inclusion of family members into the activities. Figure 2 provides a kinship map of the participants in the rural community. Before the program, only the Indigenous mentor was known to the principal investigator. Despite flyers being displayed in the community, recruitment



tended to occur via snowballing methods through family members. In the regional community, five members from the same family participated in the program. One of the family members stated 'It just made it all the better that it was family involved... And yourself of course. You're family' (Female 3, Regional).

Aside from family participation, peer support and guidance also assisted with facilitating participation. One person admitted to feeling uncomfortable when exercising on her own due to embarrassment: 'It's just if I'm by myself in public and I'm going for a jog on the road, I feel very self-conscious ... Look at this fat chick she's jogging, what the hell' (Female 2, Regional). Another participant stated they needed support and guidance from a qualified person, 'I tend to do things alone, and I don't know if I'm doing it right or not. Whereas if you've got somebody there who can guide you, you sort of have a better understanding of the process ... most of the time I go to the gym, and one of the fears I have is not knowing if I'm actually doing it right. You know that as you're probably aware, you can hurt yourself ... so I tend to do a lot of jogging' (Male 1, Regional).

Themes of resilience also emerged in regards to the lack of peer support. It was encouraging to hear statements such as: 'You have, yeah, those kind of people that would think [exercising is a disconnecting activity] like that, but, you know, just got to ignore them and do what's best for you, I guess ... Turn around and tell them where to go, say this is my life, I'm not going to end up with a chronic disease, are you going to look after me when I'm on dialysis or whatever?' (Female 4, Rural) and 'I think for me that's what I'd like to see, is that exercising becomes the norm for our people ... my mum comes from the dormitory [stolen generation] [26], so exercising for her was never the norm. I hope I've broken the cycle now, my kids will start to see it as more normal' (Female 1, Rural).

An enabler to participation in the physical activity program was the participants' relationship with the researcher. Many primary concerns to program implementation in the rural community revolved around the principal investigator being an 'outsider', female and non-Indigenous. When participants were asked about whether having a non-Indigenous female run the program could have been an issue, many positive responses were received. One of the male participants explained his thoughts on the principal investigator, focusing on the relationship and level of comfort: 'Of course, because you really need to have a good relationship and it eliminates the shame factor. Because sometimes you're a bit too embarrassed, even though if you can't – if you don't have the strength or the capacity to do what you want to do or achieve' (Male 1, Regional).

For one of the female participants, having a female principal investigator was seen as an enabler to participation: 'Not really, when I met you, I was like yeah this

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you are' (Female 2, Regional). Although there was not a negative reaction to the principal investigator being a non-Indigenous female, the need for a male role model was evident, particularly in the rural community. The principal investigator felt comfortable and welcome in the community, however, there were suggestions for future research. For instance, one of the men responded by saying there was a need for male role models: 'To some extent yeah, a possibility. I mean it doesn't matter ... especially in communities, having a male would benefit, because a lot of the times, when you use girls, the girls always turn up to a lot of your stuff. But the blokes won't because there's too many women there. But if there was a bloke there and he sort of did it together, maybe they might turn up' (Male 2, Rural). In agreement, another male participant also offered his suggestion to increase attendance: 'Just that it could have been a lot more user friendly in regards to that. I mean, I'm not saying that you're an uncomfortable person to talk to. You're very comfortable. But that's just me. Other people might find it uncomfortable and it's like role modelling too. So, if you've got an - even not so much of a young male or an older male who's got some problems, health problems, they can actually role model or they've come from a background where there's bad health in the families and so forth' (Male 3, Rural).

The need for male role models was further emphasised by higher program attendance by women. One woman suggested 'I think maybe it needs to have a male and a female, because it seemed to have worked more so for the women, than for the men' (Female 1, Rural) whilst another believed 'Culture is still focused on the men's and women's stuff ... we did have a men's group, but they do a lot of social outings. That's something we could've tapped into' (Female 4, Rural). It would have been ideal to have a male involved in the program, as this was an issue discussed during the study design, it was extremely difficult to involve a male Indigenous role model. This was due to the lack of male Indigenous health workers and qualified people to run physical activities.

Discussion

This study sought to explore Aboriginal and Torres Strait Islander participants' perceived barriers and enablers to attending a community-tailored physical activity program implemented in a rural and a regional setting. There were unique themes identified within the communities in regards to the barriers to attendance, however, the motivations to participate were similar across both sites. Firstly, the rural community had a lack of provisional infrastructure and access to resources.

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This impacted the program delivery and attendance due to inadequate access to an undercover facility during wet weather events.

Barriers to participation

There was a contrast between the logistical barriers between the communities where participants in the regional community were unable to attend due to poor timing, as opposed to those in the rural setting for whom lack of access to transport was a major barrier. The rural participants also expressed the importance of having both female and male role models for community members. For many their main motivation to participate in the program was that they saw physical activity as a means for prevention and management of chronic disease. In the regional community motivations were more centred on physical activity-related outcomes of weight loss and increased fitness. Participants from both communities highlighted the importance of support from their family and peers with their journey to becoming more active.

Evaluations of physical activity interventions with Indigenous populations have reported several barriers to participation, which include the transient nature of the population, logistic issues and *shame* [27]. The Indigenous Australian population is more mobile than the remainder of the Australian population, as they often need to leave their homes to access medical services or for cultural obligations such as to attend funerals [28]. Particularly in smaller communities Indigenous people often need to relocate to larger cities to find employment opportunities [14]. For the rural community in this study, the need to travel to a larger city for personal, or family medical reasons was a frequent reason for non-attendance.

Logistical issues, mainly in regards to transportation, are also known barriers to attendance to research programs [18]. Davey et al. [19] recognised access to transportation as an issue and included free transportation to exercise sessions, which was used by the majority of the participants and consequently attributed to retaining participants. In the context of this study, access to free transport was offered at both sites, but car-pooling was more common in the rural community due to the lack of public transportation. In the regional community, the provision of free transport was difficult due to the geographical spread of participants and due to the principal investigator also needing to conduct the exercise sessions. There were some participants who did use public bus services to attend the program.

The concept of *shame* refers to embarrassment in certain situations and is often due to attention or circumstance, rather than the action by oneself [29]. The most prominent example of *shame* occurring was during a walking group in the rural community, where the principal investigator was

asked to walk on the opposite side of a participant to block her from the view of men who were sitting across the road. Thompson et al. [30] examined the cultural and social context of physical activity in an urban Aboriginal population in Melbourne. A finding was that the Aboriginal people tended to view physical activity in three different aspects of everyday activities, sports and exercise. Everyday activities are described as necessary and performed for the benefit of the family and community, such as mowing the lawn or playing with children. Sporting competitions which can include individual and team disciplines are highly valued as the player represents the community and is a source of community pride and esteem. However, exercise is viewed as something conducted individually and specifically for personal fitness and health. In this context, the desire to personally improve oneself through exercise can be looked upon as a shameful and disconnecting experience by the community as it is often undertaken separately from family and community. Similar to our findings, Thompson et al. [30] reported that there were some elements of shame around exercising to improve health. The involvement of family in the exercise sessions may have reduced the shame associated with participation and acted as an enabler to participation.

Enablers to participation

Enablers to participation in the physical activity program primarily revolved around relationships to the other participants and with the principal investigator. In the rural community, all participants had a kinship connection with at least one other member of the program. It became evident that recruitment to the project was largely through kinship connections, rather than through the wider advertisement throughout the community. In the regional community, kinship connections were also an obvious factor in recruitment. One family had five family members involved, while another family had three sisters participate. The flexibility in the program delivery was also well-suited to participants who were the primary carer for children or dependant adults. It was often observed that participants would bring their children to training sessions, and in one instance a participant brought her dependant adult mother to a class. During the walking groups, some women would bring prams or bikes for their children to join in with the activity. There were also several community members who were not part of the program, but who began to attend training with the encouragement of the existing participants.

The fact that the principal investigator who ran the physical activity intervention in the two communities was a non-local, non-Indigenous female was seen as a potential barrier to conducting the research. However, positive feedback was received and participants often 'vouched' for the principal investigator during the recruitment of their family members. The only barrier with the principal investigator conducting classes was the lack of mentorship for the men who were involved in the program. This was highlighted during the interviews with the members of the rural community. There was an understanding that it is challenging to find Indigenous men to assist with the program, especially in a voluntary role as it would have been with this project. It is important to be aware of the cultural ideas of men's and women's business which refers to certain customs and practices in Indigenous communities that need to be undertaken by men and women separately [31]. Therefore, researchers should aim to have mentors from both genders.

Strengths

The 8-week physical activity intervention lead to significant improvements in health outcomes, however, attendance was low across both communities. The research project utilised a participatory action research approach [32] and was guided by local Indigenous mentors, in conjunction with a local Aboriginal health organisation. The support from Indigenous mentors was invaluable as they provided a more in-depth understanding of the broader constructs of the community and the cultural ideologies to perform culturally appropriate research. Another strength of the research was the relationship between the principal investigator and the participants. Although the attendance rate was low, the responsiveness of participants was high in terms of availability for follow up assessments and interviews. Originally, there was no qualitative evaluation component planned for the physical activity program. However, after low recruitment and attendance rates were observed during the first few weeks of the program, the qualitative component was added to create a better understanding of the factors that lead to the low participation rates. This allowed for a better interpretation of the study results, as the interviews offered a rich source of data and new information in regards to improving the implementation of physical activity programs in Far North Queensland.

Limitations

The theoretical model utilised for the qualitative evaluation is a somewhat limiting model for a complex topic. The Health Belief Model was useful to identify barriers and enablers to program participation, but there are suggestions for future research. A limitation of this model is the lack of focus on external factors, such as access to transport, as opposed to individual factors, which can influence health behaviours [33]. A suggestion for future research would be to include the use of an ecological approach [34], as it could have been useful in this context.

Conclusion

The aim of this qualitative study was to explore perceived barriers and enablers for a rural and regional Indigenous community to participate in an eight-week physical activity program. Overall, there were positive attitudes and high levels of motivation towards the program. Enablers to participation were the inclusion of family members, no financial cost and a good relationship with the principal investigator. Barriers to program attendance were mostly beyond the control of the individuals, such as cultural obligations, the transient nature of communities and lack of community infrastructure. In conclusion, more consideration is needed before program implementation to understand community-specific barriers and enablers to physical activity programs. Furthermore, more work is needed to better understand how to improve participation rates.

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Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available as participants may be easily identified in their respective communities, but are available from the corresponding author on reasonable request.

Authors' contributions

Conception or design of the work: AS, KG, TE. Data collection: AS. Data analysis and interpretation: AS, TE. Drafting the article: AS, TE, KG. Critical revision of the article: AS, TE, KG. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The trial was registered with the Australian New Zealand Clinical Trails Register (ACTRN12616000497404). Ethical approval for the study was obtained from the James Cook University Human Research Ethics Committee in October 2014 (approval number: H5942) and the additional site-specific approval for the regional city was obtained in July 2016.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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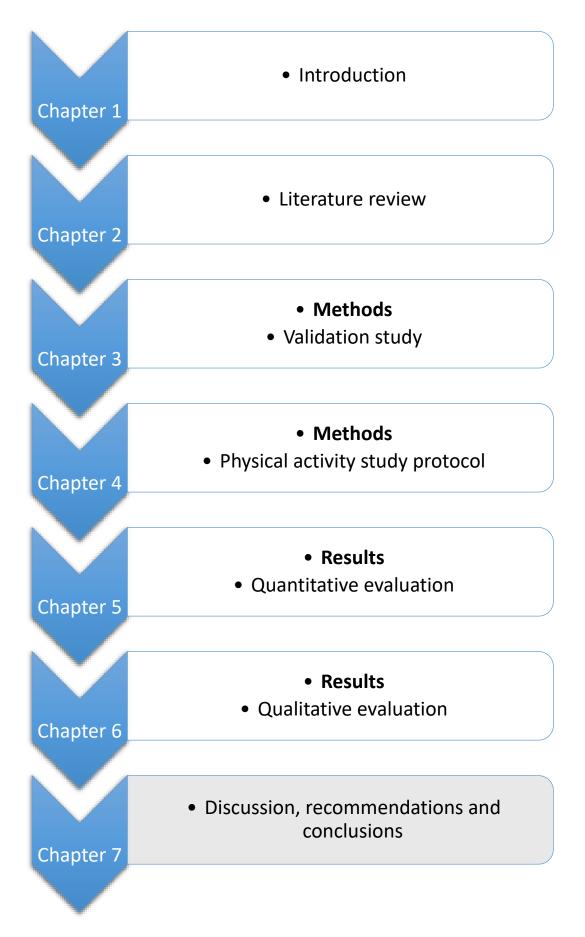
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Chapter 7: Discussion, recommendations and conclusions

Discussion of the research and key findings

This thesis aimed to design, implement and evaluate a community-tailored physical activity program for Aboriginal and Torres Strait Islander people in Far North Queensland. Most of the findings from this study were consistent with previous evaluations of other physical activity programs with Indigenous people residing in Australia and New Zealand. There are two other studies which implemented an 8-week physical activity program with Indigenous people in Australia or New Zealand^{9, 14} and two additional studies that were conducted with the same population group, but with a duration of seven¹⁵ respectively four weeks.¹⁶

One of the 8-week programs¹⁴ evaluated the uptake and effects on lifestyle and cardiovascular risk factors of a cardiac rehabilitation program at an Aboriginal Medical Service in a Metropolitan area of Western Australia. The program involved twice weekly, supervised, one-hour exercise sessions which consisted of stationary cycling and dumbbell exercises. Once a week there were education sessions which include topics on diet, nutrition, risk factor modification, and medication usage. There were 28 participants that completed the eight weeks of exercise and education sessions. Dimer et al.¹⁴ reported significant reductions in BMI (34.0kg.m²± 5.1 vs 33.3 kg.m² ± 5.2), waist girth (113cm ± 14 vs 109cm ± 13) and in blood pressure (135/78 mmHg ± 20/12 vs 120/72 mmHg ±16/5). In addition, in the study from Western Australia there was a significant increase in the distance walked during the 6MWT (296 metres ± 115 vs 345 metres ± 135) which is consistent with our results from the rural community. The regional community in our study also reported significant reductions in blood pressure and waist and hip circumference, but no significant change in weight or BMI. Another similar study⁹ evaluated a physical activity program for Aboriginal people in Tasmania. The 8-week program was designed to create an ongoing sustainable program to promote the benefits of physical activity to participants and the wider Aboriginal community. The program involved two one-hour exercise sessions and a one hour education class each week which covered topics such as nutrition, self-management approaches to health and smoking cessation. Participants had significant reductions in weight (-0.8kg), waist circumference (-3.6cm) and improvements in generic quality of life domains (measured by the SF12). There were also clinically significant improvements in the 6MWT distance (+55.7metres, 95% CI 37.8 to 73.7) and the incremental shuttle walk test (+106.2 metres, 95% CI 79.1 to 133.2). Overall, the program increased participation in the rehabilitation program for Aborigines with, or at high risk of established disease, and improved exercise capacity and health-related quality of life.

Two evaluations of physical activity programs of shorter duration conducted with Indigenous people in Australia and New Zealand also had positive health outcomes.^{15, 16} An Australian study¹⁵ with a duration of seven weeks reported health improvements for 14 Indigenous participants who reverted to a traditional hunter and gatherer lifestyle in remote Western Australia. There were marked improvements in carbohydrate and lipid metabolism in the diabetic participants, with reductions in plasma insulin, cholesterol and glucose. However, the results may be due to the intensive type of the intervention where participants were taken to a remote location for the study period and had to actively hunt and gather their own food sources. The other short study was a four-week RCT conducted in New Zealand by Biddle et al.,¹⁶ which involved small sided team sports games three times per week. There were significant increases in the fitness assessments of V0₂ peak and leg strength (maximal concentric force of the quadriceps at 60°/second) and an increase in HDL cholesterol.

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Overall, improvements in blood lipids have been reported in these shorter duration studies (8 weeks or less),^{15, 16} whereas this was not evident in the evaluation which is part of this thesis. These findings would suggest that a duration of eight weeks is long enough to detect significant changes in pathology markers if the physical activity program is more intensive and has better attendance.

Additional physical activity studies identified in the systematic review (Chapter two),¹⁷ have also reported decreases in blood pressure and waist circumference. Eight out of the 13 studies included in the systematic review assessed blood pressure. Significant reductions in blood pressure were reported in four studies, which had a duration of 8 weeks,¹⁴ 16 weeks¹⁸ or six months or longer.^{2, 19} Similar to our findings in this thesis, significant reductions in waist circumference and blood pressure were reported in two previous studies of the same duration,^{9, 14} as well as significant increases in the 6MWT.

Study strengths

The physical activity study conducted in this thesis had four key strengths related to the collaboration between communities, delivery of the program, program sustainability and qualitative evaluation. One of the main strengths of this study was the interaction between the mentors from the two original communities who participated in several three-way discussions with the principal investigator, where the program design was discussed in full detail. The two mentors collaboratively decided upon the program inclusion criteria, the number of days to run activities and the types of activities that were best suited for their local community. Specifically, the mentors expressed the program should be offered to those who will benefit the most, which was identified as people with risk factors or an established chronic disease. Another notable example of positive interactions between communities was at a local fun run in the regional community. Between myself and one of the Indigenous mentors, we organised to enter in a free local fun run to give participants the chance to meet each other while undertaking a community event. Seven participants turned out for the event, and positive feedback was received in regards to the social interactions and the event.

The pragmatism and delivery of the physical activity program were one of the other strengths of this study. This program is described as a 'complex intervention' due to a large number of discretionary behaviours and actions implemented by the communities. Complex interventions, as described by Hawe et al.,⁴ are when the function of the intervention is standardised, but the form varies across the context. During the discussion with the Indigenous mentors they decided what activities would be most appropriate and well-received by the community. This resulted in different physical activities being conducted across both sites, using different training locations types such as gyms, local parks, and walking tracks. Another strength of the program delivery was that all of the training sessions were free to the participants.

Sustainability of the program was another strength of the research. The continuation of the program was only possible in the rural community as it had a collaborative approach with a local community health centre. The Indigenous mentor, despite working in a clinical role, had several additional qualifications which included being a personal training and fitness instructor. The program delivery was shared between the Indigenous mentor and the principal investigator, and after the 8-week period, the health centre reviewed the mentor's job description. This review was conducted approximately five weeks after the program finished and resulted in the allocation of working hours towards continuing to run free

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physical activity classes and activities for the community.

The final strength of the study was the inclusion of the qualitative evaluation. The original study design was limited to a quantitative evaluation, however, after experiencing the difficulties in the fieldwork and hearing anecdotal evidence about barriers to attending from participants, a qualitative component was included. The depth and richness of the findings allowed for a greater understanding of the internal and external factors that acted as barriers and enablers to physical activity. Despite the belief that a complex intervention would eliminate many of the barriers to implementation, the qualitative component established that it was not sufficient to tailor the activities to the communities, but researchers need to account for the cultural and social differences within and between communities.

Study limitations

There are limitations to the physical activity intervention program that need to be acknowledged when interpreting the results. The key limitations related to the study design, implementation fidelity, and missing data. These elements are discussed in greater detail throughout the thesis (specifically in Chapter four), but are discussed in more detail in the section below. It should also be noted that due to the small sample size the results of the study may be unique to the nature and location of the sample, namely Aboriginal and Torres Strait Islander people living in Far North Queensland and may not be generalisable to the wider Indigenous Australian population. In addition, the participants in the rural community were closely related which means there may be a self-selection bias among the participants. Conceptually, the ideal study design for this research topic would have been a randomised controlled trial or the inclusion of a wait-listed control group. However, because of challenging circumstances, in real life this was not possible. Instead, a pre/post design was used which is not considered as strong as an RCT or controlled trial. An attempt was made to get a control group on board, but it was not possible in this context and setting due to a small population size and the withdrawal of the intended wait-listed control group. Furthermore, our systematic review identified that many studies do not have control groups and often are cohort studies.

Randomised controlled trials (RCTs) are viewed as the definitive study design for assessing the effectiveness of interventions.²⁰ In the context of Indigenous health research, the implementation of RCT designs is challenging, and even well-designed studies can falter when faced with the reality of the community context. The literature demonstrates that barriers to RCTs in small population groups in regional, rural and remote settings include the need for relatively large sample sizes and the ethical considerations of control groups not receiving treatment.

Our experiences in the design, implementation and evaluation of a physical activity program with Australian Aboriginals and Torres Strait Islanders in a rural and regional setting highlight some of the challenges. Originally, an RCT with a wait-listed control group was planned for this physical activity intervention, which would have also allowed for a costbenefit analysis. However, the actual implementation of the proposed study design was challenging due to a range of factors. A revised approach to the study plan was required. The sample size calculation was based on an expected clinically significant increase in the

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Chapter 7: Discussion, recommendations and conclusions

primary outcome measure of functional capacity to exercise, assessed by a six-minute walk test. Because of the population sizes and staff availability, including Indigenous mentors, the four communities approached for the project expressed concerns about the recruitment of a minimum of 50 participants for sufficient statistical power.

During the months of negotiations, there were many staff changes in the communities, and this was ultimately one of the main barriers to accessing the communities. One community undertook baseline assessments and a wait-listed control group was identified from a second community, with the intention of assessments being conducted two weeks post the initial group. However, program commencement was delayed in the first community due to the passing of an elder. On advice from the Indigenous mentor, the researcher did not visit the community until permission was granted from Indigenous elders to return. Additionally, testing in the waitlisted community was also delayed several times at the request of the collaborating staff members who had other prioritised projects, before eventually this community apologetically withdrew from the study.

Despite this withdrawal, the program continued in the first community. There were three rural communities initially interested in the project and after a total of 18 months of negotiations, only one community was able to commence. A project redesign was required and a cohort pre/post design was chosen, utilising a convenience site in the local area regional city as the new secondary site. The sample size at the secondary site was also small and not sufficiently powered to act as a control group. Despite the challenges, qualitative feedback demonstrated that the project was well received by the community²¹ and clinically optimistic outcomes were observed.

Ethical practice and pragmatism should be considered above the idealism of RCTs when conducting research with Australian Aboriginals and Torres Strait Islander communities. The idea that evidence-based practice can only be obtained through rigorous designs limits the development of shared empirical knowledge between researchers and communities. It is undisputed that RCTs are important for research, however, conforming to the idea that it is the only credible way to gain evidence-based practice limits research opportunities when engaging with Aboriginals and Torres Strait Islander populations.

The implementation fidelity and missing data also influenced the results of the study. The lack of undercover facilities in the rural community was a major barrier to implementation and several times during the first four weeks sessions had to be cancelled, which may have influenced the motivation to participate. This was a factor that could not be controlled as there was no alternate solution available until the fourth week. Missing data due to poor compliance with wearing the Fitbit Flex and pathology tests was also a limiting factor. The missing data limited some of the pre and post outcome measurements from being sufficiently powered and restricted from any subgroup analysis. Many participants failed to have their blood tests done. Free transportation to a clinic was offered by the principal investigator, but this was not utilised as much as expected. The fear of needles and the frequency of blood tests (three times in 20 weeks) were all barriers to obtaining pathology samples.

The mixed-methods design of the research in this thesis was pragmatic, but could have been improved by using a convergent design instead of an explanatory sequential

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design. An interactive approach where qualitative and quantitative data are collected and analysed simultaneously would have allowed more flexibility in the intervention delivery to help increase attendance. Flexibility to the data collection methods would have also improved compliance to testing, where pathology testing was not viewed positively in one of the communities and being able to seek for an alternative solution (such as finger prick blood samples) could have potentially reduced the missing data and participant dropout. In future studies, having a focus on intervention mixed methods frameworks would allow data to be collected prior to the development of the interventions, to assist researchers in understanding the contextual factors that could affect the outcomes of the intervention.^{22, 23}

Guidelines and recommendations

Key guidelines for the translation of physical activity research into practice.

The following ten principles are a summary of guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research, created by Jamieson et al.²⁴ The summary is based on documents relating to working and researching with Indigenous Australians, such as the National Health and Medical Research Council (NHMRC) ethical guidelines for research among Aboriginal and Torres Strait Islander people.²⁵ In the following section, the original principals created by Jamieson et al.²⁴ are explained in the context of my own research to assist with the understanding of the translation of my research into practice:

1. Respect communities' past and present experience of research.

Australian Aboriginals and Torres Strait Islanders have had a history of forced assimilation, sustained social disadvantage and experiences of poor research practices. Trust

and respect are essential, and a mindset 'to do no harm' are critical to establish prior to conducting research. Most importantly, researchers need to respect the communities' right to decline to participate in the project.

2. Recognise the diversity of Indigenous Australian populations.

There are distinct cultural differences in the values, attitudes and beliefs of Indigenous people in Australia. The inclusion of an Indigenous mentor will provide guidance on how to maintain the community values while doing research. The diversity in cultural differences was identified during the qualitative component of this thesis. An example is the rural community requesting for a male and female role model and essentially wanting to have separate exercise sessions for genders. In the regional community, the gender of the trainer/researcher was not as important, and the emphasis was focused on the relationship and personality of the principal investigator.

3. Address a priority health issue as determined by the community.

Essentially, research into physical activity should be conducted in communities where there is a recognised issue to be addressed. Priorities should be determined through discussions with the Indigenous mentors and key stakeholders to ensure the desired research is a suitable project and is wanted by the community.

4. Conducting research within a mutually respectful partnership framework

Building trust within a community and the key stakeholders will take time and having an open and transparent relationship is a key to success. Communities are more likely to work with researchers whom they are familiar with, as opposed to someone unfamiliar, regardless of the sophistication of study design and availability of funding.

5. Capacity building.

Capacity building is essential for research translation into practice. The lack of sustainability with research projects may be due to the absence of appropriately qualified staff to take over the project. Physical activity programs should be conducted by a qualified professional such as a sport and exercise scientist, exercise physiologist or a personal trainer/group fitness instructor. Additionally, some form of first aid training is ideal for risk management.

If there is a sufficient budget allocation, capacity building could take the form of assisting a staff member to gain a minimum qualification needed to conduct exercise classes and pre-screening assessments. In the rural community, the physical activity program has been continued beyond the intervention that was part of this thesis as the local Indigenous mentor had the appropriate qualifications to conduct exercises classes.

6. Flexibility in study implementation while maintaining scientific rigour.

An important factor that may influence the study outcome is the implementation fidelity. Implementation fidelity is the degree to which an intervention is delivered as intended and is imperative to the translation of evidence-based interventions into practice.²⁶ In Chapter four, the modifications to the study are described in detail, where pragmatism and flexibility in the program delivery were essential. Consideration must be given to program fidelity and modifications over time, and more recognition is needed to understand the external factors that may influence these elements, such as community infrastructure, and how they all interact to influence the program and quality of the results.²⁷

7. Ensure extended timelines do not jeopardise projects.

Before conducting any research, a sufficient amount of time should be spent in the community to build a relationship of trust and respect. In my experience, the timeline of the project was extended due to 'sorry business', which lasted for several weeks and delayed the start of the program. Capacity building to mentor the nominated person to take over the project will also extend the timelines. In the rural community, the program ran for 8 weeks, however, the principal investigator continued to return to the community to assist with the transition process for almost two months after the program finished.

8. Prepare for Indigenous leadership turnover.

The leadership turnover among key stakeholders can be high, and was evident in my research project. Although it can be frustrating and inconvenient, researchers need to be aware that they cannot rely on individuals alone, nor on the goodwill of volunteers to assist with their research projects. We need to be mindful of the burden and pressure that environments with high staff turnover place on the remaining Indigenous mentors and accept the reality of the situation at hand. Community, family and personal priorities will almost always take precedence over a research project.

9. Support community ownership.

Research aimed at improving health in Indigenous Australians should have community ownership and input, not only for success, but for sustainability. Short-term

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projects may have immediate benefits, but will not be maintained without long-term planning and capacity building. Supporting community ownership is a method to assist with the transition of short-term projects becoming a part of routine practice. Supporting community ownership can also take place in the form of assisting the nominated person to take over. In my research, this was done by preparing, assisting and conducting classes with the Indigenous mentor to help build their confidence.

10. Develop systems to facilitate partnership management in multicentre studies.

Collaborating partnerships should ensure there are equitable and transparent processes for all aspects of management, recruitment, implementation and evaluation. People considering doing research with Indigenous Australians should review notable recommendations by organisations, such as the National Health and Medical Research Council (Australia). The Research Council has provided a "Road Map" in regards to working with Indigenous populations and the cultural factors that researchers need to consider before designing programs.²⁸

Key recommendations for the design of future research programs on physical activity with Aboriginal Australians and Torres Strait Islanders.

These recommendations are based on the experience of implementing a physical activity program in a rural and regional community. Based on the learnings from the research for this thesis the following six suggestions are for people planning to do research within Indigenous communities.

- 1. Do not discount the value of a small community by sample size.
- 2. Be pragmatic with the study design.
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- 3. Collaborate and form alliances for ethical research and sustainability.
- Use a measurement of fitness in conjunction with objective physical activity monitoring.
- Coincide pathology testing with community health checks in rural/remote communities.
- 6. Consider a qualitative component within studies.

1. Do not discount the value of a small community by sample size.

Research projects aimed at improving health outcomes for Indigenous Australians should not be discriminative of small communities. Communities that seek out opportunities to be part of research projects should be given a fair chance to be considered as study sites. Ignoring an appeal for help from at-risk communities somewhat defeats the purpose of doing research to close the gap in life expectancy.

2. Be pragmatic with the study design.

A wait-listed control group is an ideal alternative to traditional RCT designs. If researchers can obtain control groups, an economic cost-benefit analysis would be viable which could provide a financial perspective on whether the programs are 'value for money' and if the prevention is more cost-effective than the progression and treatment of the disease/illness of interest. Information on cost-effectiveness could provide evidence that would support the acquisition of further funding to create sustainability in these types of projects. However, when faced with adversity in the field, alternative study designs should be considered.

3. Collaborate and form alliances for ethical research and sustainability.

As discussed in the section on research translation into practice, collaborations are essential for good research practice. Alliances and collaborations also allow researchers to be mentored by Indigenous leaders, gaining knowledge which can be critical for successful program implementation and ensures ethical practice. The physical activity program in this thesis was co-designed with Indigenous mentors and supported by a peak local Aboriginal and Torres Strait Islander organisation. We were able to achieve sustainability of the program in the rural site because of the support and alliances within the community. At the completion of the eight weeks, the local Aboriginal and Torres Strait organisation reviewed the Indigenous mentor's job description and modified her contract to allow her to continue to run the program during her paid working hours. Without this support, it would not have been possible to continue the program unless it was facilitated by volunteers.

4. Use a measurement of fitness, in conjunction with objective physical activity monitoring.

Objective measures of physical activity are ideal, but are not always feasible. The participant burden, cost of equipment and reactivity to non-research grade accelerometers are all potential issues that are associated with objective measures of physical activity in small scale studies with limited access to resources. In my project, there was a perception of the Fitbit Flex to be more user-friendly, however, there was poor compliance with wearing the device which resulted in missing data. Missing data at follow-up from non-compliance or loss of the accelerometer resulted in incomparable pre and post measures for objective physical activity levels. Furthermore, since the publication of the validation study, the Fitbit Flex has been superseded by at least seven new Fitbit devices, with some including heart rate monitoring components. The evolving technology of novel accelerometer devices may prove

difficult for future studies to evaluate physical activity programs due to reliability and validation issues. The evolving technology trends are also evident with the Actigraph devices, which are now available as a water-resistant wrist worn device with a display and heart rate monitoring. However, unlike novel devices, the Actigraph is well known for being a valid and reliable accelerometer and the new enhancements improve data accuracy and increase the user-friendliness of the device. In this instance, fitness-related measurements, such as aerobic capacity, anaerobic threshold or timed exercise activities, should be assessed in conjunction with physical activity monitoring devices.

5. Coincide pathology testing with community health checks in rural/remote communities.

The feeling of being 'over-researched' in the rural community was evident and was amplified by the need for regular pathology testing. Communities that have regular health screenings should coincide testing dates with health screening events as this would reduce the need for another visit to the clinic. In regional communities it may be more appropriate to have a nurse or other qualified personnel onsite during baseline testing or to have the option to have pathology samples collected in the participants' home.

6. Consider a qualitative component within studies.

Poor attendance may not be due to disinterest in the program, and assessing quantitative outcomes alone will not capture additional internal and external factors that influence attendance. A finding of the project was that the baseline health status of the people in the rural community was poorer compared to those in the regional city, and the barriers and enablers to physical activity are unique to the location. Indigenous research

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methodologies suggest that prior to program implementation it is essential to understand the Indigenous experience through appropriate qualitative methods including yarning circles and story-telling. Evaluations of the participants' experiences are a valuable form of feedback and should not be overlooked. Qualitative methods, such as yarning circles, are needed to engage with Indigenous mentors, elders and community members to successfully achieve recommendation three (collaborate and form alliances for ethical research and sustainability). A yarning circle is an important process within Aboriginal and Torres Strait Islander culture, and has been used by Indigenous Australians to learn from a collective group, build respectful relationships, and to preserve and pass on cultural knowledge.²⁹ In qualitative work, a yarning circle can be used as a teaching and learning strategy to assist researchers with understanding the Indigenous perspective. In addition, yarning can facilitate the building of relationships by allowing a collaborative way to have respectful and honest interactions between people.

Conclusion

This thesis describes the process of implementing and evaluating a physical activity program for Aboriginal Australians and Torres Strait Islanders in Far North Queensland. The effectiveness of the 8-week community-tailored program is also examined both quantitatively and qualitatively. The results of the program suggest that those who participated in physical activity during the study period had significant improvements in clinical health outcomes.

There was a low attendance to the physical activity program. Barriers and enablers to participation were explored in a qualitative part of the study. Participants from the regional community were unable to attend due to poor timing, opposed to those from the rural community who were unable to participate due to lack of access to transport. The rural participants also expressed the importance of needing both female and male role models for community members, and their motivation to engage in physical activity and exercise was for chronic disease prevention and maintenance. The motivation of the people in the regional community was more centred on physical activity-related outcomes of weight loss and increased fitness. In conclusion, more consideration in program design and barriers is needed to ensure physical activity programs are implemented as intended and the participants' experiences can be explored.

Acknowledgment

Despite my previous experiences with Indigenous communities and having formal training, potential issues with the research included misunderstandings, misinterpretations, and biases. It is important to address the constraints and possible biases of this project in regards to the principal investigator being a non-Indigenous person researching with Indigenous people. I would like to express my sincere gratitude for the leadership and guidance provided to me by my Indigenous mentors and for the review of my work by my Indigenous colleagues. I offer my sincere apologies if any offence is caused by the language or the research methodology in this thesis.

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Appendices

Appendix 1: PROSPERO registration used for the systematic review in Chapter 2.

PROSPERO

International prospective register of systematic reviews

Systematic review

Please complete all mandatory fields below (marked with an asterisk *) and as many of the non-mandatory fields as you can then click *Submit* to submit your registration. You don't need to complete everything in one go, this record will appear in your *My PROSPERO* section of the web site and you can continue to edit it until you are ready to submit. Click *Show help* below or click on the icon to see guidance on completing each section.

1. * Review title.

Give the working title of the review, for example the one used for obtaining funding. Ideally the title should state succinctly the interventions or exposures being reviewed and the associated health or social problems. Where appropriate, the title should use the PI(E)COS structure to contain information on the Participants, Intervention (or Exposure) and Comparison groups, the Outcomes to be measured and Study designs to be included.

Do physical activity interventions in Indigenous people in Australia and New Zealand improve activity levels and health outcomes? A systematic review

2. Original language title.

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3. * Anticipated or actual start date.

Give the date when the systematic review commenced, or is expected to commence.

01/02/2015

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

28/11/2015

5. * Stage of review at time of this submission.

Indicate the stage of progress of the review by ticking the relevant Started and Completed boxes. Additional information may be added in the free text box provided.

Please note: Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. Should evidence of incorrect status and/or completion date being supplied at the time of submission come to light, the content of the PROSPERO record will be removed leaving only the title and named contact details and a statement that inaccuracies in the stage of the review date had been identified.

This field should be updated when any amendments are made to a published record and on completion and publication of the review.

The review has not yet started: No



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NHS

National Institute for

Health Research

PROSPERO International prospective register of systematic reviews	National Institute for Health Research		
Review stage	Started	Completed	
Preliminary searches	Yes	Yes	
Piloting of the study selection process	Yes	Yes	
Formal screening of search results against eligibility criteria	Yes	Yes	
Data extraction	Yes	Yes	
Risk of bias (quality) assessment	Yes	Yes	
Data analysis	Yes	Yes	

Provide any other relevant information about the stage of the review here (e.g. Funded proposal, protocol not yet finalised). Accepted for publication in a peer reviewed journal.

Accepted for publication in a peer reviewed journal.

6. * Named contact.

The named contact acts as the guarantor for the accuracy of the information presented in the register record. Ms Sushames

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:

7. * Named contact email.

Give the electronic mail address of the named contact. ashleigh.sushames@my.jcu.edu.au

8. Named contact address

Give the full postal address for the named contact.

Cairns, QLD Australia, 4870

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code. +61 488 214422

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

Centre for Chronic Disease Prevention, James Cook University, Cairns, Australia

Organisation web address:

11. Review team members and their organisational affiliations.

Give the title, first name, last name and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong.

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Miss Ashleigh Sushames. James Cook University, Australia Dr Klaus Gebel. Australian Catholic University, Australia Dr Jannique van Uffelen. University of Leuven, Belgium

12. * Funding sources/sponsors.

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Include any unique identification numbers assigned to the review by the individuals or bodies listed.

None

13. * Conflicts of interest.

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

None

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members.

15. * Review question.

State the question(s) to be addressed by the review, clearly and precisely. Review questions may be specific or broad. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS where relevant.

To synthesise the literature on the effects of physical activity interventions for Indigenous people in Australia and New Zealand on activity levels and health outcomes. What were the most common study designs?

Which measures were used to evaluate interventions?

16. * Searches.

Give details of the sources to be searched, search dates (from and to), and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.

The Cochrane Library, MEDLINE, SPORTSDiscus and PsycINFO will be searched for physical activity interventions for Indigenous people in Australia and New Zealand.

Search terms will include 'Oceanic ancestry group' OR 'Indians, North American' OR 'population groups' OR 'aborig*' OR 'Indigenous*' and will be combined with 'intervention*' and physical activity related terms. We will also undertake forward and backward citation tracking from the identified papers. No language restrictions will be applied. Government websites and databases will be searched for grey literature. Health departments will be e-mailed in search of programs that may not have been identified. Experts in the field will be contacted to search for additional references. No restrictions will be placed on publication years. Search results and screening outcomes will be presented in a flow-diagram.

17. URL to search strategy.

Give a link to the search strategy or an example of a search strategy for a specific database if available (including the keywords that will be used in the search strategies).

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Yes I give permission for this file to be made publicly available

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18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

It is undisputed that Indigenous people suffer a lower life expectancy due to higher rates of chronic disease compared to non-indigenous populations. The life expectancy gap of Indigenous Australians exceeds other Indigenous populations as recent data estimate there is still an approximate 10 year difference. In New Zealand, the life expectancy gap with Maori and the non-Indigenous populations is considerably less as it is estimated to be 7.1 years. A variety of complex social, emotional and environmental factors can attribute to the lower life expectancy. Particularly obesity related manifestations of chronic disease, such as type 2 diabetes and cardiovascular disease have a substantial impact on morbidity and mortality of Indigenous populations.

The domains and conditions that will be examined are physical activity and health outcomes in Indigenous people residing in Australia and New Zealand.

19. * Participants/population.

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

Inclusion criteria: Indigenous people residing in Australia and New Zealand who are 18 years or over. Exclusion criteria: Studies that did not specifically target Indigenous people, but included Indigenous individuals as subgroups. This is because Indigenous populations are minority and diverse groups that need special consideration when designing programs due to cultural differences. Recommendations have previously been made by organisations, such as the National Health and Medical Research Council (Australia), with regard to working with Indigenous populations and the cultural factors that researchers need to consider before designing programs.

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the nature of the interventions or the exposures to be reviewed.

Physical activity is defined as body movement produced by skeletal muscle that results in energy expenditure above resting levels. Exercise is a subset of 'leisure time physical activity' that is often structured, planned, repetitive which is done with the purpose of recreation, improving or maintaining physical fitness or enhancing other components of health.

Physical activity and exercise interventions in Indigenous populations are defined as those applied to identified Indigenous people residing in Australia or New Zealand with the aim to increase physical activity levels. Studies with multi-component interventions will be included if physical activity was a core component of the intervention.

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

Ideally the interventions would have used a non-exposed control group. However, in Indigenous communities it is difficult to recruit participants for control groups. Therefore, uncontrolled studies with rigorous protocols will also be included.

22. * Types of study to be included.

Give details of the types of study (study designs) eligible for inclusion in the review. If there are no restrictions on the types of study design eligible for inclusion, or certain study types are excluded, this should be stated. The preferred format includes details of both inclusion and exclusion criteria.

All interventions will be included that aimed to increase physical activity levels either as a primary or secondary outcome measure in Indigenous people in Australia or New Zealand. As in the past researchers have found it difficult to recruit Indigenous participants for control groups, studies that did not have a control

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group will also be included.

23. Context.

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

To be included in the review studies have to evaluate an intervention with a physical activity component for Indigenous people residing in Australia or New Zealand aged 18 years or over. Indigenous groups include Aboriginal people and Torres Strait Islanders in Australia and the Maori people in New Zealand. While it is acknowledged that Pacific Islander people are not Indigenous to New Zealand, there are historical and cultural connections with Maori people. Therefore, studies conducted in New Zealand with Pacific Islander communities will be considered eligible for inclusion into the review.

24. * Primary outcome(s).

Give the pre-specified primary (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

Changes in objectively measured or self-reported levels of physical activity.

Timing and effect measures

No specified time limits.

25. * Secondary outcome(s).

List the pre-specified secondary (additional) outcomes of the review, with a similar level of detail to that required for primary outcomes. Where there are no secondary outcomes please state 'None' or 'Not applicable' as appropriate to the review

Secondary outcome measures will include anthropometric measures and metabolic changes such as weight, body fat percentage, waist circumference, blood pressure, glucose measures, C-reactive proteins, Hb1AC, liver function and total cholesterol. No specified time limits.

Timing and effect measures

Measures will need to take place immediately pre and post intervention. No specified time limits will be applied to a secondary follow up period.

26. Data extraction (selection and coding).

Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted.

Two team members will independently review the articles found in the literature search and will exclude those that do not meet the inclusion criteria based on title, abstract and full text. Differences in reviewers' decisions will be resolved through discussion and consensus. Data will be extracted by one author and will be examined by the second author. A standardised abstraction procedure based on Zaza et al. (2000) will be used to extract data from the included studies. Information to be extracted will include: study population, study setting (such as remote/rural) and demographic and baseline characteristics of participants. Details of the intervention and control conditions along with the study methodology, recruitment strategy and compliance rates will also be examined. The studies will also be assessed on the outcomes measured, the timing of measurements, acceptability of the program to the Indigenous community and the risk of bias. The data extraction process will be conducted independently and examined for discrepancies; any disagreements will be resolved through discussion and consensus. Information that was not provided in the studies will be requested from study authors.

27. * Risk of bias (quality) assessment.

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State whether and how risk of bias will be assessed (including the number of researchers involved and how discrepancies will be resolved), how the quality of individual studies will be assessed, and whether and how this will influence the planned synthesis.

Independent appraisal of study quality and risk of bias will be conducted by two reviewers using the Quality Assessment Tool for Quantitative Studies. The data supplied will be examined for selection bias, consistency, randomisation, missing data and adherence to follow up. Summary tables of appraisal tools will also be viewed by two authors and differences in ratings of study quality will be resolved through discussion and consensus with a third person. In the synthesis appropriate weight will be given to more rigorous studies.

28. * Strategy for data synthesis.

Give the planned general approach to synthesis, e.g. whether aggregate or individual participant data will be used and whether a quantitative or narrative (descriptive) synthesis is planned. It is acceptable to state that a quantitative synthesis will be used if the included studies are sufficiently homogenous.

Data synthesis for the systematic review will utilise aggregated data and follow a quantitative synthesis. The data synthesis will contain findings from the included studies such as type of intervention, target population characteristics, types of outcomes that were assessed and the intervention content. The effect of the intervention in each study will be summarised according to how the data are presented (e.g., effect size, p-value and/or 95% CI where provided), and what is appropriate to the study design and variable type (e.g., mean/median between group differences for numerical variables, % change or relative risks for dichotomous variables). If there is sufficient consistency between studies, intervention effects will be summarised (e.g., meta-analysis). If there are heterogeneity of study designs and outcome variables, a narrative (descriptive) synthesis will be conducted.

29. * Analysis of subgroups or subsets.

Give details of any plans for the separate presentation, exploration or analysis of different types of participants (e.g. by age, disease status, ethnicity, socioeconomic status, presence or absence or co-morbidities); different types of intervention (e.g. drug dose, presence or absence of particular components of intervention); different settings (e.g. country, acute or primary care sector, professional or family care); or different types of study (e.g. randomised or non-randomised).

Subgroup analysis may be conducted (e.g. between Aboriginal and Torres Strait Islander groups). Where necessary data are available, subgroup analyses will be done between males and females, diabetics and non-diabetics and BMI classifications. It is not possible to specify all groups that may be used to subgroup analysis in advance.

30. * Type and method of review.

Select the type of review and the review method from the lists below. Select the health area(s) of interest for your review.

Type of review Cost effectiveness No Diagnostic No Epidemiologic No Individual patient data (IPD) meta-analysis No Intervention Yes Meta-analysis No Methodology

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No

Network meta-analysis No Pre-clinical No Prevention No Prognostic No Prospective meta-analysis (PMA) No Qualitative synthesis No Review of reviews No Service delivery No Systematic review Yes Other No

Health area of the review

Alcohol/substance misuse/abuse No Blood and immune system No Cancer No Cardiovascular No Care of the elderly No Child health No Complementary therapies No Crime and justice No Dental No Digestive system No Ear, nose and throat No Education No Endocrine and metabolic disorders No Eye disorders

National Institute for Health Research

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NHS National Institute for Health Research

No General interest No Genetics No Health inequalities/health equity No Infections and infestations No International development No Mental health and behavioural conditions No Musculoskeletal No Neurological No Nursing No Obstetrics and gynaecology No Oral health No Palliative care No Perioperative care No Physiotherapy No Pregnancy and childbirth No Public health (including social determinants of health) No Rehabilitation No Respiratory disorders No Service delivery No Skin disorders No Social care No Surgery No **Tropical Medicine** No Urological No Wounds, injuries and accidents No

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NHS National Institute for Health Research

Violence and abuse

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error. English

There is an English language summary.

32. Country.

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved.

Australia

33. Other registration details.

Give the name of any organisation where the systematic review title or protocol is registered (such as with The Campbell Collaboration, or The Joanna Briggs Institute) together with any unique identification number assigned. (N.B. Registration details for Cochrane protocols will be automatically entered). If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

This review protocol will not be registered with other organisations.

34. Reference and/or URL for published protocol.

Give the citation and link for the published protocol, if there is one

Give the link to the published protocol.

Alternatively, upload your published protocol to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Yes I give permission for this file to be made publicly available

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

35. Dissemination plans.

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

The target journal for this paper is the International Journal of Behavioral Nutrition and Physical Activity. The review will also be presented at national and international conferences.

Do you intend to publish the review on completion?

Yes

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords will help users find the review in the Register (the words do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

Indigenous Physical activity

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NHS National Institute for Health Research

Health

37. Details of any existing review of the same topic by the same authors.

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

38. * Current review status.

Review status should be updated when the review is completed and when it is published.

Please provide anticipated publication date

Review_Completed_published

39. Any additional information.

Provide any other information the review team feel is relevant to the registration of the review.

40. Details of final report/publication(s).

This field should be left empty until details of the completed review are available.

Sushames A, van Uffelen JGZ, Gebel K. Do physical activity interventions in Indigenous people in Australia and New Zealand improve activity levels and health outcomes? A systematic review. Int J Behav Nutr Phys Act. 2016. Dec; 13(1):129-145. doi:10.1186/s12966-016-0455-x

Give the link to the published review.

https://ijbnpa.biomedcentral.com/articles/10.1186/s12966-016-0455-x

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Appendix 2: Information sheet for the validation study in Chapter 3.

INFORMATION SHEET

Title:

Validation of a novel accelerometer device

Study Aim

The main aim of this study is to investigate the reliability and validation of a novel activity monitoring device against a widely utilised and accepted standard accelerometer device. This information will assist in providing the most accurate and consumer friendly device for participants to wear during a physical activity intervention.

The Researcher

The study is being conducted by Ms Ashleigh Sushames (Bachelor of Sport and Exercise Science - Honours) and will contribute to her PhD projects in Sport and Exercise Science at James Cook University.

You are invited to:

 Attend two sessions of testing a week apart and two sessions to return the device and to debrief in a confidential room at a time convenient for you. The first session will include a medical screening questionnaire, baseline measurements and activity protocol and will take approximately 30-45 minutes.

Session 1: This session will request for you to complete and address the following:

- Medical History Questionnaire
- Informed Consent Form
- General health details
- Smoking and alcohol consumption information
- A Quality of Life Survey

Complete a pre-screening health assessment with the following measurements:

- Height
- Weight
- Waist and hip circumferences
- Body fat percentage measured using electronic scales
- Participate in a physical functional assessment a six-minute walk test
 - You will be required to walk for six minutes in a safe indoor environment
 - The final distance will be recorded
 - Perceived level of exertion will be monitored and recorded on an 11point scale of 0-10
 - 0 = minimum level of exertion and 10 = maximum level of exertion
 - Please note:
 - The six-minute walk test cannot be completed in a confidential room
 - The six-minute walk test can be used for most population types and is considered appropriate for various health conditions

- Participate in an activity protocol which is comprised of the following six-minute activities:
 - Walking at a self-determined speed with an incline of 0% (Rated Perceived Exertion RPE 4)
 - Walking at the same speed with an incline of 5% (RPE 4)
 - A slow jog at a self-determined speed with an incline of 0% (RPE 7)
 - Stair stepping at a comfortable pace (RPE 4)

For the duration of the protocol and remainder of the waking day you will need to:

- Be fitted with electronic devices after you complete the six-minute walk test.
- You are expected to wear the devices for the remainder of the day or at least 10 hours.
- Provided with verbal and written instruction regarding device use, protection and removal will be provided
 - One device will be worn around the wrist on a bracelet
 - The other device will be worn on the hip on an adjustable elastic belt
 - The device on the adjustable elastic belt may be removed when sleeping
 - The devices will be positioned to cause the least amount of discomfort and to allow you to continue with normal daily activities
- Session 2: This session will request for you to complete and address the following:
 - You will be requested to attend a brief interview session in a confidential room at a time convenient for you. The interview is expected to take approximately 15-20 minutes. During this time:
 - The devices will be removed
 - You will be required to complete a questionnaire on the devices regarding user compliance
 - Discuss use of the devices (e.g. when they were removed, how comfortable they were, suggestions for improvement, etc.)
- Session 3: This session will request for you to complete and address the following:
 - You will repeat the same physical tests that were utilised during the first session and wear the accelerometers as previously advised.
- Session 4: In this session you will be requested to complete and address the following:
 - Return the devices to the laboratory.

All interactions will be conducted in the Cairns region and will take place at James Cook University, Cairns Campus.

Preparation by Participants for Testing

- Participants should wear comfortable clothing and footwear (e.g. closed in walking/running shoes) for all sessions
- Avoid participating in any strenuous exercise for 24 hours preceding the prescreening health assessment and completion of a physical functional assessment session;
- Maintain a similar dietary intake for the 24 hours immediately preceding each testing session, including refraining from consuming any caffeine or supplements which may affect the results.

Taking part in this study is completely voluntary and you can stop taking part in the study at any time without explanation or prejudice. You may also withdraw any unprocessed data from the study.

Are there any risks involved?

- The six-minute walk test is a physical function test and may result in breathlessness for individuals with
 medical conditions and/or a general feeling of fatigue. This may also happen during the treadmill and stair
 stepping protocol.
- To ensure safety throughout the study, the procedures will be stopped immediately if at any time an individual experiences unusual feelings of illness, pain or discomfort or wishes to discontinue.
- Please advise if you feel discomfort from the device and wish to cease participation, as you are able to withdraw at any time without reason.
- Should participants feel as if they need counselling, the details of local counselling services are provided below. It is recommended that JCU students seek counselling from the JCU counselling services and participants from the community seek counselling from Lifeline Community Care.

	Lifeline Community Care
After hours GP helpline	188 Aumuller St,
Phone: 1800 022 222	Bungalow
	Cairns QLD
	Phone: (07) 4050 4955

Participation in this study may promote awareness of how physically active you are on a daily basis.

Please remember that you are not required to participate in any additional physical activity just because you are wearing the electronic devices.

You are expected to continue with attempting all daily activities and any other tasks that you may normally partake in.

Confidentiality

Any information that is obtained will remain strictly confidential. Anonymous results will be disseminated via publication in peer-reviewed journal articles and seminar/conference presentations.

All participants are free to withdraw from the study or discontinue participation in an activity at any time without reason.

If you have any questions about the study, please contact Ms Ashleigh Sushames or Dr Andrew Edwards.

Principal Investigator: Ashleigh Sushames Institute of Sport and Exercise Science James Cook University Mobile: Email: <u>ashleigh.sushames@my.jcu.edu.au</u>

If you have any concerns regarding the ethical conduct of the study, please contact: Human Ethics, Research Office James Cook University, Townsville, Old, 4811 Supervisor: Name: Dr. Andrew Edwards School: Institute of Sport and Exercise Science James Cook University Phone: Email: andrew.edwards@jcu.edu.au

Phone: (07) 4781 5011 (ethics@jcu.edu.au)

Appendix 3: Informed consent form for the validation study in Chapter 3.

This administrative form has been removed

Appendix 4: Letters of support for the physical activity program in Chapter 4.



16 September 2015

Ashleigh Sushames-BSpExSc (Hons) PhD Candidate Centre for Chronic Disease Prevention Division of Tropical Health and Medicine PO Box 6811 D3: Room 132 Cairns QLD 4870 AUSTRALIA

Dear Ashleigh,

Thank you for your request to include the Mossman Gorge Community as part of your PhD entitled "Physical activity interventions using cultural based activities".

The Apunipima Cape York Health Council's Research Governance Committee have considered your request and I'm pleased to advise that support for your PhD project has been approved.

It is recommended that you work with Ms Julie Salam, Chronic Disease Health Worker at our Mossman Gorge clinic to arrange your community visits.

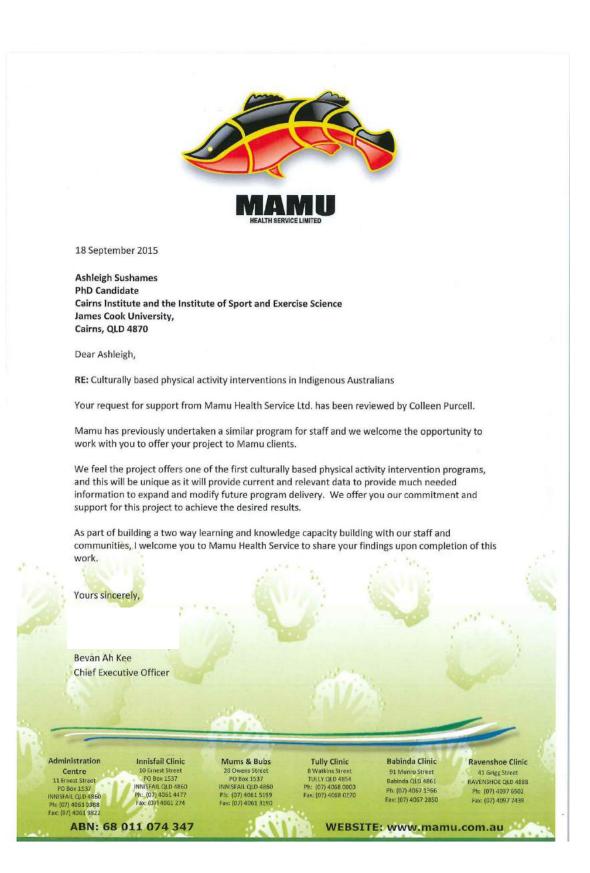
As part of research translation and reciprocity, I invite you to present your findings to our staff and board members at the completion of your work. To do this please be in touch with our, Research Coordinator, on 07 4037 7213 or <u>Rachael.ham@apunipima.org.au</u>. I wish you all the best with your PhD journey.

Yours sincerely.

CLEVELAND FAGAN Chief Executive Officer

> Apunipima Cape York Health Council Aboriginal Corporation ABN 26 089 437 717 PO Box 12045, Cairns DC OLD 4870 (186 McCoombe Street, Bungalow Cairns QLD 4870) Phone: 07 4037 7100 • Fax 07 4038 4100 • Email: reception@apunipima.org.au





Appendix 5: Information sheet for the physical activity program in Chapter 4.

INFORMATION SHEET

Title: Culturally based physical activity intervention for Indigenous Australians **Study Aim:** The main aim of this study is to create, implement and evaluate a cultural based physical activity intervention in regional and rural Indigenous communities in Far North Queensland. The intervention is aimed at reducing the burden of chronic disease, such as type 2 diabetes and heart disease, by increasing physical activity levels through culturally appropriate activities that maintain the communities' values, attitudes and beliefs. The time commitment from participants will include three health screening sessions and participation in physical activity sessions during the week. The duration and the number of activity sessions will vary depending on the type of activity and fitness level of participants. A timetable will be released once your activity preference has been recorded. You will be invited to attend an optional focus group after the 8-week program, to give your feedback on the project.

The Researcher

The study is being conducted by Ms Ashleigh Sushames (Bachelor of Sport and Exercise Science - Honours) and will contribute to her PhD projects in Sport and Exercise Science at James Cook University.

You are invited to:

• Attend some initial health screening before and after the eight weeks of activities. There will be a follow-up screening session three and 12 months after the end of the program. The screening will always be the same and will consist of the following:

All screening sessions: This session will request for you to complete and address the following:

- Informed Consent Form
- Medical History Questionnaire
- General health details
- Smoking and alcohol consumption information
- 12 question Short Form Health Survey
- Nutritional recall survey
- Fasting venous blood sample to measure metabolic markers such as blood glucose and cholesterol

The screening sessions are expected to last between 30-60 minutes with the option of taking some forms home to complete in your own time.

Complete a pre-screening health assessment which will include the following measurements:

- Height
- Weight
- Waist and hip circumferences
- Body fat percentage measured using electronic scales

Participate in a physical function assessment - a six-minute walk test

- You will be required to walk for six minutes in a safe indoor environment
- The final distance will be recorded
- Perceived level of exertion will be monitored and recorded on a scale from 0-10
- The six-minute walk test cannot be completed in a confidential room

You will be asked about your preference of activities which can include the following:

- Bushwalking (men and women in separate groups)
- Traditional dance

- Sporting competition nights
- · Volunteering to help the community

For all health testing sessions:

- You will be fitted with an electronic wristband (Fitbit) which is to be worn for a week to measure your step count and activity levels
- Verbal and written instruction regarding device use, protection and removal will be provided
- The device will be worn around the wrist on a bracelet

For all intervention activities:

- Appropriate footwear is to be worn for outdoor activities
- You have the right not to participate in activities where you feel shame or you are unable to take part due to illness.

All interactions will be conducted in the Mossman region and testing will take place in a private and confidential room at Apunipima Cape York Health Council.

Preparation of participants for testing

- Participants should wear comfortable clothing and footwear (e.g. closed in walking/running shoes) for all sessions
- Please avoid participating in any strenuous exercise for 24 hours preceding the prescreening health assessment and completion of a physical functional assessment session;
- Please maintain your normal dietary intake for the 24 hours immediately preceding each testing session, including refraining from consuming any caffeine or supplements which may affect the results.

Are there any risks involved?

- The six-minute walk test is a physical function test and may result in temporary breathlessness for individuals with medical conditions and/or a general feeling of fatigue.
- To ensure safety throughout the study, the procedures will be stopped immediately if at any time an
 individual experiences unusual feelings of illness, pain or discomfort or wishes to discontinue.

Taking part in this study is completely voluntary and you can stop taking part in the study at any time without explanation or prejudice. You may also withdraw any unprocessed data from the study. Should participants feel that they need counselling, the details of local counselling services are provided below.

After hours GP helpline	Wuchopperen Health Service
Phone: 1800 022 222	13 Moignard Street
	Cairns QLD
	Phone: (07) 4080 1000

Participation in this study may promote awareness of how physically active you are on a daily basis and changes in health by being more active. You are expected to continue with attempting all daily activities and any other tasks that you may normally partake in.

Confidentiality

Any information that is obtained will remain strictly confidential. Anonymous results will be disseminated via publication in peer-reviewed journal articles and seminar/conference presentations. All participants are free to withdraw from the study or discontinue participation in an activity at any time without reason.

If you have any questions about the study, please contact Ms Ashleigh Sushames or Dr Klaus Gebel.

Principal Investigator: Ashleigh Sushames Institute of Sport and Exercise Science James Cook University Phone: Email: ashleigh.sushames@my.jcu.edu.au

If you have any concerns regarding the ethical conduct of the study, please contact: Human Ethics, Research Office James Cook University, Townsville, Qld, 4811 Phone: (07) 4781 5011 (ethics@jcu.edu.au) Supervisor: Name: Dr Klaus Gebel College of Public Health, Medical and Veterinary Sciences James Cook University Phone: Email: klaus.gebel@jcu.edu.au **Appendix 6: Informed consent form for the physical activity program in Chapter 4.**

This administrative form has been removed

Appendix 7: Pre-screening assessment forms used for the physical activity program in Chapter 4.

JAMES COOK UNIVERSITY AUSTRALIA Pre-screening Med	lical and Lifestyle Questionnaire
Name:	Date:
Street Address:	
	Post Code
Home Phone:	Mobile Phone:
Date of Birth	Gender: Male 🗌 Female
Do you identify as: Aboriginal	Torres Strait Islander 🗌 Both 🗌
Emergency contact details:	
Name:Cont	tact number/s:
Relationship to you:	
Past medical history Have you ever had any of the following ar	nd if so, when?
YearRheumatic feverHigh cholesterolHigh blood pressureAny heart troubleDisease of the arteriesVaricose veins	Year Lung disease
Explain:	
12	
Family medical history Have any of your close relatives had any c	of the following?
Age Relative	Age Relative
Heart attack () Co heart disea	ase ()
High blood pressure () Hea High cholesterol () Oth Diabetes() Hea	ner ()

Present Symptoms Review Have you recently had any of the following, if so when?				
Chest pain Coughing of blood Shortness of Breath Back pain Heart palpitations Swollen, stiff, painful joints Cough on exertion (when doing physical activity)				
Explain:				
Females only: Are you pregnant?				
Medication				
Are you currently taking any medications?				
What is this medication for?				
Smoking				
Do you smoke? YES NO If YES, for how long? If YES, how many cigarettes a day?				
If NO, have you ever smoked?				
If YES, for how long?				
If YES, what age did you stop?				

Diet

How many pieces of fresh fruit do you usually eat per d or grapes as one piece)	ay? (count ½ cup of diced fruit, berries Fruit
I do not eat fruit Image: Constraint of the set of th	$ \begin{array}{c} $
How many serves of vegetables do you usually eat per <i>timned</i>)	day? (count all types, fresh, frozen or
1 serve per day 1 2 serves per day 1 3 serves per day 1 4 serves per day 1 5 serves per day 1 6 or more serves per day 1	$ \begin{array}{c} \begin{array}{c} \begin{array}{c} \\ \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \\ \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \\ \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \\ \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} $
Physical Activity Do you engage in any regular physical activity?	YES NO
If YES, please describe the exercise or sport	demodul
How long is the session (minutes)?	<u>10</u>
How hard does it make you work (light/moderate/hard)?
How often do you do the exercise/sport per week?	~
Have you ever been told not to exercise? If YES, for what reason?	YES NO

Compared to your physical activity over the past three months, was last week's physical activity more, less or about the same? More 🗌

Less 🗌 About the same

Alcohol

Do you drink alcohol regu	ılarly?			YES	🗌 NO
In the last 12 months, how	v often di	d you have an	alcoholic	drink of any	y kind?
Everyday					
5 to 6 days a week					
3 to 4 days a week					
1 to 2 days a week					
2 to 3 days a month					
About 1 day a month					
Less often					
No longer drink					

Please record how often in the last 12 months you have had each of the following number of standard drinks in a day? (Mark one response for each row below)

	Everyday	5-6 days a week	3-4 days a week	1-2 days a week	2-3 days a month	About 1 day a month	Less often	Never
20 or more standard drinks a day								
11-19 standard drinks a day								
7-10 standard drinks a day								
5-6 standard drinks a day								
3-4 standard drinks a day								
1-2 standard drinks a day								
Less than 1 standard drink per day								
None								

Employment:

Employed full-time

Employed part-time/casual Not currently employed

Household Income (pre-tax):

Less than \$20,000	\$60,000 - \$79,999	
\$20,000 - \$39,999 🗌	\$80,000 - \$99,999	
\$40,000 - \$59,999 🗌	Over \$100,000	

Highest Level of Education:	
Did not complete Year 12	
Completed Year 12 Certificate	
Completed TAFE course (vocational	education)
Completed an undergraduate universi	ty course
Completed a post graduate university	course

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Household:

Number of adults in my household (aged 18 years and over):_____

Number of children in my household (aged under 18 years):

Are you the main carer for the children, or any dependent adults (such as elderly family members)?

□ YES	□ NO
L ILS	

If yes: what ages are your dependent family members?

- Toddlers 2 years and under
- 3-5 years

Primary school age children

-] High school age children
- Dependent adult

Appendix 8: Information sheet for the interviews in Chapter 6.

INFORMATION SHEET

Title: Physical activity program- Interview

You are invited to take part in an interview to gather feedback on the 8-week physical activity program. The program was aimed at reducing the burden of chronic diseases, such as type 2 diabetes and heart disease, by increasing physical activity levels through culturally appropriate activities that maintain the community's values, attitudes and beliefs. We want to yarn about your experiences, how the program could be improved, and ideas for future programs.

The Researcher

The study is being conducted by Ms Ashleigh Sushames (Bachelor of Sport and Exercise Science - Honours) and will contribute to her PhD projects in Sport and Exercise Science at James Cook University. Ashleigh is based at the Centre for Chronic Disease Prevention of JCU.

You are invited to:

- Attend an interview to talk about your experience of the 8-week program
- Participate in discussions around the program and the future direction of physical activity programs in your community

The interview will take place in convenient and private location. Vocal discussion will be audiotaped and written material will be kept and **de-identified** to review later.

Are there any risks involved?

• You may feel uncomfortable and not willing to share your ideas, in which case you can choose to remain silent or write down your thoughts.

Taking part in this study is completely voluntary and you can stop taking part in the study at any time without explanation or prejudice. You may also withdraw any unprocessed data from the study. Should participants feel that they need counselling, the details of local counselling services are provided below.

After hours GP helpline	Wuchopperen Health Service
Phone: 1800 022 222	13 Moignard Street
	Cairns QLD
	Phone: (07) 4080 1000

Confidentiality

Any information that is obtained will remain strictly confidential. Anonymous results will be disseminated via publication in peer-reviewed journal articles and seminar/conference presentations. All participants are free to withdraw from the study or discontinue participation in an activity at any time without reason.

If you have any questions about the study, please contact Ashleigh Sushames or Dr Klaus Gebel.

Principal Investigator: Ashleigh Sushames Institute of Sport and Exercise Science James Cook University Phone: Email: ashleigh.sushames@my.jcu.edu.au Supervisor: Name: Dr Klaus Gebel College of Public Health, Medical and Veterinary Sciences James Cook University Phone: Email: klaus.gebel@jcu.edu.au

If you have any concerns regarding the ethical conduct of the study, please contact: Human Ethics, Research Office James Cook University, Townsville, Qld, 4811 Phone: (07) 4781 5011 (ethics@jcu.edu.au) **Appendix 9: Informed consent form for the interviews in Chapter 6.**

This administrative form has been removed

Appendix 10: Semi-structured interview sheet for the interviews in Chapter 6.

Semi-structured interview run sheet

Duration: 30 minutes

- 1. Before this program, how would you describe your physical activity levels? [EXPLORE] what were some of your first thoughts when told about the program and why did you decide to participate (or not to participate)? Do you generally enjoy/not enjoy exercise/physical activity?
- 2. What was your experience with the program? [EXPLORE] Would you describe physical activity as a positive or negative experience? Were there any cultural issues or concerns in regards to the research project? Have you seen any changes or benefits from the program, such as with your health or body?
- 3. What could have been made better about the program?

[EXPLORE] Were there any factors that you would consider to be barriers to your participation? (reasons why you were unable to make some sessions). What did you think about the health tests, would you keep them the same or change some? (maybe the bloods?).

- **4. What would you like to see happen in the future?** [EXPLORE] what would you change about the program so it suited you better? How did you find the activities?
- 5. Is there anything else you would like to comment on?