Evaluation of a healthy lifestyle intervention among disadvantaged preschoolers

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ABSTRACT

Evaluation is defined as "the process by which we judge the worth or value of something" (Suchman, 1967). Improving nutrition, reducing obesity and increasing the level of exercise were three priority population health objectives identified by the Ministry of Health in the early 2000's. The Healthy Eating – Healthy Action: Oranga Kai - Oranga Pumau Strategy (the HEHA Strategy) (Ministry of Health, 2003b)) and accompanying Implementation Plan (Ministry of Health, 2004b) was the New Zealand Governments response to these issues. In 2005, all District Health Boards (DHBs) were invited to submit proposals to access the HEHA Innovation Fund. The second phase of the successful Southland DHBs proposal was the health promotion programme Healthy Me and You.

A quasi-experimental study measuring the effectiveness of *Healthy Me and You* was conducted between 2008 and 2009 with the recipients of the intervention recruited from within Southland DHB boundary and a matched comparison group obtained from the adjoining Otago DHB. The programme was specifically designed for socially disadvantaged caregivers and their preschool age children in relation to increasing physical activity levels and fruit and vegetable intake.

Healthy Me and You was delivered once a week over six consecutive weeks for two hours in a small group community setting. Twelve programmes were run in six locations during 2008 across Southland. Participants were referred to the study by health and social service agencies in both regions. The content and design of the intervention was informed by conducting five focus groups with parents and health professionals; using the social cognitive theory as a framework to design the content; and finally piloting the programme and amending where necessary.

At baseline, data were collected on 135 caregivers and their child aged three-to-four years (n=67 intervention group; n=68 comparison group). The majority of caregivers were female; a third were from Maori or Pacific origin; with a median age 33 of years. Just under half were in some paid employment; with a third having a tertiary qualification

while a quarter reported having none. Most children lived with at least two adults and another child.

Data were collected a second time after six months, with 113 participants (n=54, intervention group: n=59, comparison group) retained. Information (caregiver and child characteristics and behaviours) were collected using three instruments: NL-1000 accelerometer; fruit and vegetable tick-list; and two interview schedules (core plus supplementary interviews) conducted eight days apart. These included household characteristics; child family food environment; caregiver and child sedentary behaviour, dietary habits and physical activity(PA). Outcome measures investigated were child PA (in minutes), number of fruit offerings to child by caregiver, and number of vegetable offerings to child by caregiver.

In order to gain a better understanding of the participants, predictors of the outcome variables were first explored before examining the effectiveness of the intervention. Regression models (tobit and poisson) were used to model the outcome variables. As these were all obtained from repeated measures, a random participant effect was included. Univariate screening was carried out using $p<0.20$ for inclusion in subsequent models. Results showed children's PA levels reduced as they grew older; were higher for non-Maori/non-Pacific; and increased as the number of caregiver steps increased or if their caregiver was in paid employment. All effect sizes were however small. Likewise several behaviours were shown to increase fruit offerings or vegetable offerings but they were all of limited practical significance due to the large number of additional offerings required to produce an increase of either one *fruit* or *vegetable* offering.

No statistically significant effect of the intervention was found associated with any of the three key outcome variables while controlling for their respective baseline values. Each outcome was then explored further by considering other characteristic-type covariates (caregiver and child) with adjusted models producing the same result. Changes at an individual child level were identified, however these were small and were not of any practical importance. Boys did more PA, as did children with older caregivers or children who had a male caregiver. It was also found that as caregiver education levels

increased, fruit offerings also increased compared to those with no or minimal education. Offerings of vegetables were found to decrease if the child was male.

An investigation into whether there were any subgroups of participants, who benefited more from the intervention, was also carried out. Results showed that there was no statistically significant subgroup effect on child PA or child vegetable offering by the caregiver, while controlling for corresponding baseline values. A very small increase in fruit offerings was however found ($p=0.046$) with respect to increasing attendance rates by caregivers but this was considered to be of marginal practical importance ($RR=1.1$).

These findings show that although health promotion programmes are regularly used to promote healthy lifestyles for children, for socially disadvantaged caregivers with preschoolers in New Zealand, programmes such as *Healthy Me and You* were not found to be as effective as initially thought. As there is currently little evidence available in this area of research further research is recommended to enable researchers and policy makers to be more informed so that our limited resources available can be used effectively to tackle the major public health issue of obesity.

PREFACE

This thesis was born out of the need to prepare a HEHA Innovation Fund proposal for the Southland District Health Board (DHB) in 2005. At the time I was working as a senior policy analyst and together with my colleague Makuini McKercher, we were asked to undertake this activity. During this process, support from DHB management was granted to investigate the inclusion of a doctoral thesis and preliminary discussions were held with the Department of Social and Preventive Medicine. Arrangements were also made between the DHB and Sport Southland (the local Regional Sports Trust) regarding a proposed partnership, should the proposal be funded.

Early in 2006 saw the creation of two key arrangements which helped cement the foundations of the wider research project as well as this thesis. The first was the partnership between the DHB and Sport Southland, both co-funders. This mutually beneficial relationship ensured that project staff were employed within the organization who had the appropriate infrastructure and experience to support the provision of dietary advice (DHB) and physical activity advice (Sport Southland). The second was the supervisory arrangement between the Departments of Preventive and Social Medicine, and Human Nutrition created to ensure I was provided with the expertise and support. This arrangement also at times extended to provide guidance to the management of the larger project and project staff as expertise of this level was not readily available within either host organisation.

In August 2006, I began a part time secondment as the project manager and so began the next chapter in what was to become a long but rewarding journey back into the world of research and health promotion. I had previously worked on two large cohort studies[1] prior to joining the DHB in 2002 and therefore had some understanding and knowledge of what lay ahead. By November 2006, a small team was established and this thesis describes many of the key activities undertaken by this team during the following 30 months.

[1] "Post-Myocardial Infarction Study" based in Christchurch, New Zealand and also the "Families, Children and Child Care Study" based in Oxford and London, England.

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This research would not have been possible without the backing of the Southland District Health Board who facilitated this study together with support and funding from the Ministry of Health and Sport Southland. I am immensely grateful to the wonderful Makuini McKerchar for believing in me, and trusting that I would see our vision brought to life.

To my supervisors, Professor Rob McGee, Associate Professor Winsome Parnell and Andrew Gray, you are simply the best support team a student could have asked for. Thank you for guiding me through a series of challenges over the past five years and for providing me with sound advice and direction. In particular I want to thank Rob for helping me to focus and clarify my thoughts on paper. Winsome, your technical knowledge, adept proof reading and practical advice has been invaluable. Andrew, thank you for being patient and providing me with statistical advice which enabled me to analyse the data collected.

I was incredibly fortunate to have such a dedicated and creative team of Yvette MacKenzie, Stephanie Thurlow, Nikki Willis and Katie Dunn working on this study with me. Yvette and Steph, your efforts sourcing and developing appropriate measures and ideas to create *Healthy Me and You* truly is a credit to you both and your delivery style was always professional. Nikki, your knowledge of the target audience was invaluable, as was your support in the office. Katie, you did an amazing job not only developing a user-friendly database but also successfully tackling the challenging task of recruiting and collecting data from the comparison group. Individually and as a team you were a pleasure to work with and I have many fond memories which I treasure.

My heartfelt thanks are extended to all the organisations throughout Southland and in Dunedin who provided the team with referrals. To the caregivers and their delightful preschoolers, thank you for answering all our questions, wearing the accelerometers and completing the fruit and vegetable tick-lists. Special thanks especially go to the Southland participants who willingly attended *Healthy Me and You*. I am also grateful to

the parents, preschoolers and health professionals who participated in the formative phase studies.

Many thanks also go to the administrative staff of the Department of Preventive and Social Medicine and in particular Nathalie Huston from the Cancer Society Social and Behavioural Research Unit (SBRU), where this research was hosted. Nathalie provided me with invaluable practical assistance, especially during the final twelve months when my visits to the department were infrequent and also for her assistance with managing the endnote library. To past and present staff and students of the SBRU, your support has been appreciated. I would also like to thank my dear friend Dr Rebbecca Lilley and colleagues Dr Rose Richards, Dr Jean Simpson, Dr Richard Egan and Dr Robin Quigg, who have traveled this PhD journey before me and always made time to share their knowledge and wisdom.

On a personal note, I would like to thank my family and friends for their support and encouragement. In particular I am grateful to my husband Mike for allowing me to clock up the many miles traveled between Invercargill and Dunedin and becoming a proficient bachelor during this time. Mum and Dad, thank you for believing in me and providing me with whatever support was needed to make my life easier, especially during the final two years. To my good friends Emma, Kishani, Nick, Rachel and Rebbecca, thank you for keeping me sane. These thanks can also be given to my canine kids, Dan and Lucy, who watched over me from their basket outside the window of my home office. Finally to my two beautiful children Sarah and Sean; what a joy you are to have in my life. Together you have given me the strength and incentive to complete this journey as I know you will both benefit from my involvement in this research.

CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

LIST OF ABBREVIATIONS

BMI	body mass index
CNS02	Children's Nutrition Survey 2002
DHBs	District Health Boards
ECC	Early Childhood Centre
F&V	fruit and vegetables
FFQ	Food Frequency Questionnaire
HEHA	Healthy Eating Healthy Action (Oranga Kai - Oranga Pumau)
MVPA	Moderate to Vigorous Physical Activity
NCDs	non-communicable diseases
NEAT	Nutrition Education Aimed at Toddlers
NNS97	1997 National Nutrition Survey
NZ European	New Zealand European
NZDep Index	New Zealand Deprivation Index
NZHS	New Zealand Health Survey
PA	physical activity
RCT	randomised control trial
SCT	Social Cognitive Theory
SES	socioeconomic status
SHEHAP	Southland Healthy Eating Healthy Action Programme
SPARC	Sport and Recreation New Zealand
TC	total cholesterol
UK	United Kingdom
WIC	Women, Infants, and Children

1 INTRODUCTION

"All too frequently, health promotion programmes have been established on the basis of limited research, and implemented with little or no evaluation. As a consequence, many programmes have been established with poorly conceived and unrealistic objectives, and with no effective mechanism for management, quality control or monitoring." (Foreward by Don Nutbeam in (Hawe, Degeling, & Hall, 1990)

Evaluation is best considered during the planning stage of any health promotion programme. The views of those involved, including researchers, health practitioners, politicians and the participating community, however, will vary in what represents value and how programme success should be defined and measured (Nutbeam & Bauman, 2006). Evaluating a health promotion programme will be easier to set up and do if it is planned at the same time as a programme itself. The evaluation information gathered can be used to improve the programme and inform those making decisions about the programme such as programme development, implementation and effectiveness.

Taking these thoughts into consideration, this chapter provides an overview of the key stages involved in the planning, implementation and evaluation of the health promotion programme *Healthy Me and You*, all of which are described in further details in subsequent chapters. Understanding the need for a programme and potential solutions are key components of programme planning and development, both of which are the focus of this introductory chapter.

1.1 Research context

The New Zealand Health Strategy set the platform for the Government's action on health in the early 2000's (Ministry of Health, 2000). This document also aimed to ensure health services were directed at particular key priority areas thus ensuring the highest benefits for the New Zealand population, particularly focusing on tackling inequalities in health. At that time, the Government identified 13 population health objectives for the Ministry of Health and District Health Boards (DHBs) to focus on in the short to medium term. A DHB has the responsibility in their district of providing, or funding the provision of health and disability services. The Healthy Eating – Healthy Action: Oranga Kai -

Oranga Pumau Strategy (the HEHA Strategy (Ministry of Health, 2003b)) and accompanying Implementation Plan were the Government's integrated response to three of these population health objectives: improving nutrition, reducing obesity and increasing the level of exercise.

In 2005, DHBs were invited to submit a proposal for accessing new funding from the HEHA Innovation Fund aligned to the New Zealand Cancer Control Strategy and Action Plan (Minister of Health, 2003a), He Korowai Oranga: Māori Health Strategy and the Primary Health Care Strategy. The candidate was one of the co-authors for the proposal submitted by the Southland DHB and subsequently funded. Prior to the proposal being submitted, initial enquiries regarding the undertaking of a PhD focusing on programme evaluation were investigated with the University of Otago.

The Southland Healthy Eating Healthy Action Programme (SHEHAP) was divided into two phases with the second phase being the focus of this doctoral study. It was officially launched with a small team of health professionals in November 2006. The overall aim of SHEHAP was to establish a programme focused on improving nutrition and increasing physical activity in low income, Māori and Pacific households with children under five years of age. Throughout this thesis, the target audience is referred to as 'socially disadvantaged' and is categorized as Māori, Pacific peoples[2] and those living in areas of higher deprivation as defined by the New Zealand Index of Deprivation (NZDep Index), (see Appendix A). It is acknowledged that not all individual households identified by this definition will be 'socially disadvantaged' and the definition is used solely to identify a target population from which to source participants in a real-world setting.

A logic model submitted by Southland DHB in March 2006 to the core funder (Public Health Directorate, Ministry of Health) provided the overall direction of SHEHAP, while the programme planning, implementation and evaluation of the phase two programme *Healthy Me and You* was guided by this research and is reported in this thesis. The initial proposal outlined an agreed approach between key community stakeholders and DHB staff. This was small group programmes delivered in a community setting.

[2] Pacific people in New Zealand are represented by at least 13 distinct languages and cultural groups.

At the conclusion of all programme delivery and data collection, sustainable funding was not sought as the effectiveness of the *Healthy Me and You* was unknown. Furthermore the political environment changed with the formation of a new Government in 2009, and the subsequent reorientation of funding within the health sector saw a reduced investment into public health HEHA related programmes.

What I did

After obtaining project funding, the candidate was seconded part-time to manage the team from 2006 to 2009 on behalf of the local funders (Southland DHB in partnership with Sport Southland). During this time, she supervised the staff that helped design and deliver SHEHAP, some of which were activities directly aligned with this PhD. External resources were sought to provide any additional training required. The candidate was not directly involved in any programme delivery or data collection to ensure a robust evaluation process was undertaken. On occasions the candidate was present during sessions to observe staff or to assist with child care. All activities subsequently undertaken after 2009 were directly aligned with the associated PhD.

1.1.1 The burden of obesity

Reducing obesity was chosen as a priority population health objective in the New Zealand Health Strategy as the Government identified obesity as one of the most important avoidable risk factors associated with a large number of life-threatening diseases and also serious morbidity. It was assumed that prevalence rates were likely to increase. There are many health consequences of being overweight or obese, including increased risk of premature death from non-communicable diseases (NCDs) such as some cancers, stroke, diabetes, coronary heart disease and increased risk of various conditions which may have an adverse effect on quality of life such as dyslipidaemia, hypertension, gall bladder disease and psychosocial problems (Ministry of Health, 2003c; World Cancer Research Fund & American Institute for Cancer Research, 2007; World Health Organisation, 2000).

Evidence is now available to show that children who are overweight are liable to remain overweight as adults or to become obese (Deckelbaum & Williams, 2001; Guo, Roche, Chumlea, Gardner, & Siervogel, 1994). As with adults, the prevalence of overweight and obesity in children is increasing and this pattern of increased overweight and obesity prevalence is becoming common in many countries (Deckelbaum & Williams, 2001; Lobstein, Baur, Uauy, & Iaso International Obesity TaskForce, 2004). Unlike adults, the health consequences of childhood obesity have not yet become fully apparent as they may take years or even decades to become clinically evident through the diagnosis of NCDs. Emerging risk factors such as high blood pressure, hyperlipidaemia, or elevated insulin level are being reported earlier (Ebbeling, Pawlak, & Ludwig, 2002; Lobstein, et al., 2004) and, in one study, over half of overweight 5–10-year-old-children were diagnosed with at least one cardiovascular disease risk factor (Erlanson-Albertsson, 2005).

The causes of obesity are not yet fully understood. Figure 1 shows an ecological model to aid the understanding of obesity (Egger & Swinburn, 1997).

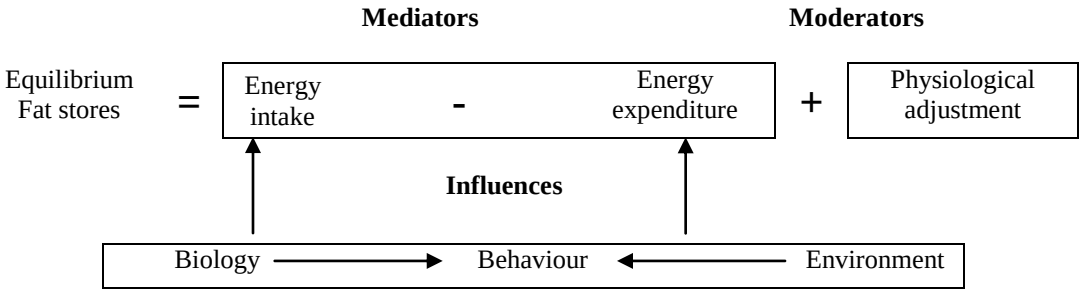


Figure 1: The ecological model of the causes of obesity (Egger & Swinburn, 1997)

This model shows that at a population level, energy expenditure has fallen below energy intake and this is influenced by the physiological adjustments and identified influences. This may be explained by the profound and rapid changes in large parts of the world where unintended environmental influences have caused many people to live in conditions which promote sedentary behaviour and the over-consumption of energy dense food. These issues combined with biological and behavioural influences often make it challenging to maintain a healthy weight. Therefore, if improving nutrition and increasing physical activity, reduces obesity in the population, this change could have a

significant impact on the health and well-being of all populations, including New Zealanders.

There are several ways of defining body fat distribution and quantifying obesity. These include body mass index (BMI), waist to hip circumference expressed as a ratio (WHR) and measures of subcutaneous fat in various skinfolds. BMI is the most common method for measuring obesity rates for population groups, with measurement for children differing from that used on adults and is based on the recommendations of Cole et al. (Cole, Flegal, Nicholls, & Jackson, 2007).

1.1.2 New Zealand obesity statistics

Results from the 2002/03 New Zealand Health Survey (NZHS) showed that over one in three adults (35%) were overweight[3] and further over one in five (21%) were obese (Ministry of Health, 2004a). Males (41%) were statistically significantly more likely than females (28%) to be overweight. Key findings from the National Children's Nutrition Survey 2002 (CNS02) : (Parnell, Scragg, Wilson, Schaaf, & Fitzgerald, 2003) indicated that the majority of New Zealand children (69%) had a weight, in relation to their height, that fell within an acceptable range. Twenty-one percent were overweight and 10% obese.

Socially disadvantaged populations in New Zealand bear a disproportionately high rate of obesity in both adults and children (Ministry of Health, 2004a, 2004c; Salmond & Crampton, 1999). However, obesity levels were similar across the quintiles of the index NZDep2001 for quintiles 1-4, but women's obesity levels are higher for those in quintile 5 (most deprived) (Ministry of Health, 2004a). Results from the 1997 National Nutrition Survey (NNS97) (Russell, et al., 1999) show that obesity and overweight for both Māori and Pacific adults were higher than those for NZ European and Others. Obesity rates for Māori males were 27%, adult Māori females 47% with similar finding for Pacific counterparts; males 26% and females 47%. A further 30% of all Māori are overweight as well as 75% of Pacific adults. Findings from CNS02 (Parnell, et al., 2003) showed that

[3] Classifications of overweight and obesity according to BMI in New Zealand adults differs by ethnicity in the NZHS. European, Asian and other are overweight if their BMI falls between 25-29.9 and obese if BMI ≥30. For Māori and Pacific cut-offs are slightly higher, overweight is classified as a BMI between 26.0-31.9 and obese if ≥32.0 (Ministry of Health, 2004a)

Pacific children had the highest level of obesity (males: 31%; females: 31%) followed by Māori (males: 16%; females: 17%), and then NZ European Others (males: 5%; females: 6%). This pattern was also seen with data describing children who were overweight with Pacific children again having the highest levels (males: 34%; females: 33%) followed by Māori (males: 20%; females: 31%), and then NZ European Others (males: 19%; females: 19%).

Reviewing the findings from the three NZHS's 1996/97, 2002/03 and most recently in 2006/07, suggests the prevalence of obesity for adults is increasing. However, the obesity rate appears to be slowing, with no statistically significant increase from 2002/03 to 2006/07 for both males and females.

1.1.3 New Zealand's public health response

In 1996, the annual cost of obesity in New Zealand was conservatively estimated to be $135 million, however this figure excluded downstream[4] health costs from chronic diseases that result from obesity (Ministry of Health, 2001). Following the development of the HEHA Strategy (Ministry of Health, 2003b) and associated implementation plan (Ministry of Health, 2004b), the 2006 budget saw the Minister of Health committed to a $76.1 million campaign over the next four years in an attempt to counteract the obesity epidemic (Hodgson, 2006). Subsequently, the Ministry of Health commissioned a consortium of researchers to examine the overall effectiveness of the HEHA Strategy at a national level (McLean, et al., 2009), results of which are yet to be published. A key component of this evaluation is the Nutrition and Physical Activity Survey, for which 2011 is the third and final year of data collection.

1.2 The HEHA Strategy and Implementation Plan

"Improving nutrition", "increasing physical activity" and "reducing obesity" were the three population health objectives aligned with the HEHA Strategy (Ministry of Health, 2003b). It is acknowledged that the health sector alone can not produce the outcomes outlined in this strategy and a wide range of government, non-government and private

[4] Medical treatment including secondary prevention measures which may be applied to this high risk population which have the potential to significantly reduce the morbidity and mortality associated with obesity. In this context secondary prevention can include pharmaceuticals, educational and behavioural interventions.

sector agencies are needed to be involved. Education, Sport and Recreation New Zealand (SPARC), local government, social development, transport, non-government agencies and the food and physical activity industries must all have a part to play.

The strategy and implementation plan relies on a cross sectoral approach to addressing issues of nutrition, physical activity and obesity. Table 1 shows the eight key population health messages that underpin the HEHA Strategy and Implementation Plan are derived from the Food and nutrition guidelines for healthy adults: A background paper (Ministry of Health, 2003d); Breastfeeding: A guide to action (Ministry of Health, 2002a); and the New Zealand physical activity guidelines (Hillary Commission, 2001).

Table 1: Key population health messages (Ministry of Health, 2003b)

Eat a variety of nutritious foods	Eat less fatty, salty, sugary foods
Eat more vegetables and fruits	Fully breastfeed infants for at least six months
Aim to maintain a healthy weight throughout life	Add some vigorous exercise for extra benefits and fitness
Be active every day for at least 30 minutes in as many ways as possible	Promote and foster the development of environments that support healthy lifestyles

It was recognized that changing behaviour on the basis of these apparently simplistic key messages was going to be challenging for populations and also for government, non-government and private sector agencies to lead and support successfully. Figure 2 outlines the framework for the implementation plan.

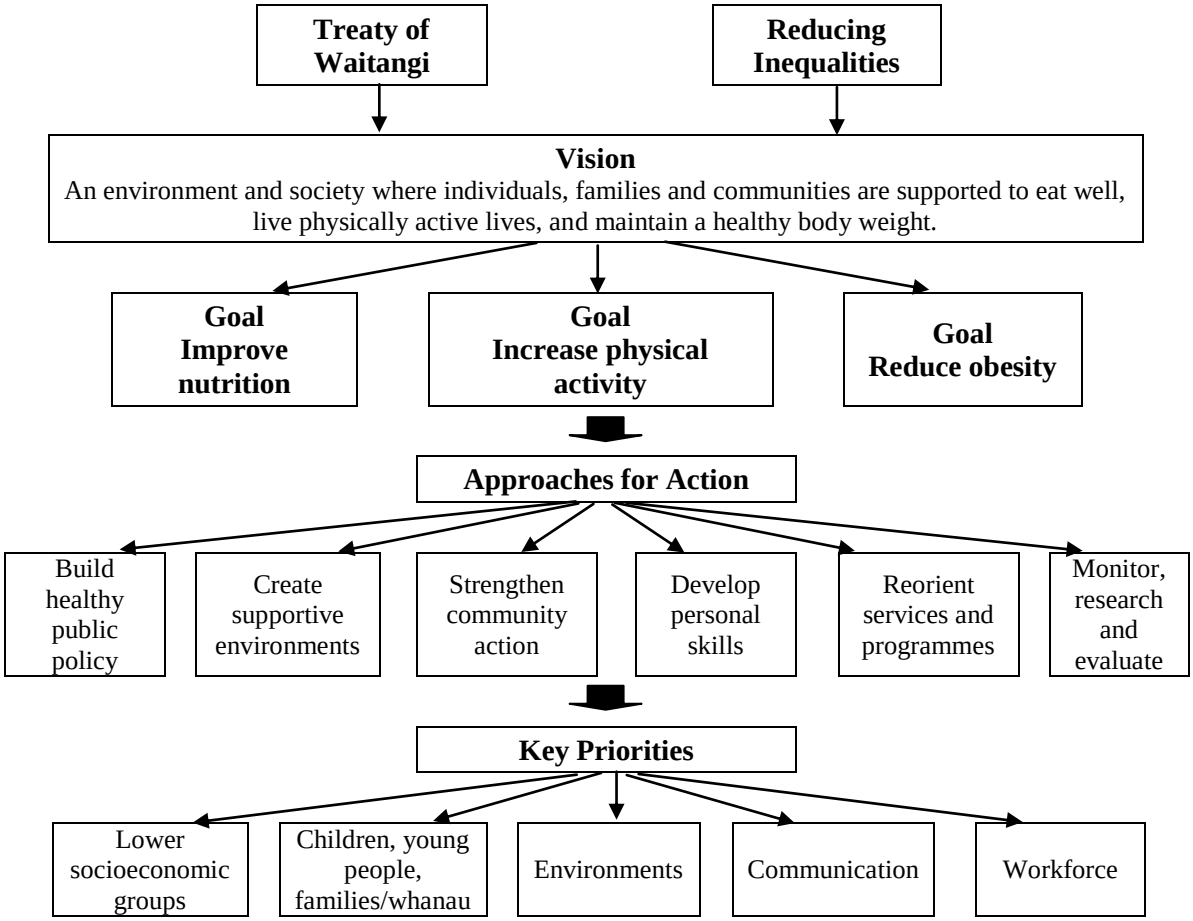


Figure 2: The Healthy Action – Healthy Eating Framework ((Ministry of Health, 2003b))

This framework (Figure 2) was guided by three cross-cutting strands: the Ottawa Charter (World Health Organisation, 1986); key priorities of HEHA (Table 1); and He Korowai Oranga, the Māori Health Strategy (Ministry of Health, 2002b). The HEHA Frameworks' vision recognizes two guiding values, Reducing Inequalities and the Treaty of Waitangi (signed in 1840 between Māori and the Crown and considered to be New Zealand's founding document. Appendix B provides further details about the Treaty). The three principles of the Treaty of Waitangi are partnership, participation and protection, all of which were threaded throughout He Korowai Oranga. The vision then linked directly with each of the three goals. As implementation was expected to vary, individual goals could be focused on in isolation or addressed together. Accordingly only one arrow is shown joining the three goals with the six proposed actions. As with the

three goals, activities undertaken during implementation may use one or all six proposed approaches for action and is represented again by one arrow linking with the chosen five key priority areas.

1.3 Research focus

Funding was obtained in 2006 to establish a programme focused on improving nutrition and increasing physical activity in low income, Māori and Pacific households with children under five years of age as outlined in the proposal submitted by Southland DHB in 2005. Refinements were made to the original target population by selecting preschool aged children only (3 to 4 years olds) and by using the NZDep2006 Index as a proxy for household income or socioeconomic status (SES). The areas of interest were also streamlined using the key population health messages in Table 1, with "improving nutrition" becoming "increasing fruit and vegetable intake".

To evaluate such a programme, a quasi-experimental study design was chosen, with the recipients of the intervention recruited from within Southland DHB boundary and the comparison group obtained from the adjoining Otago DHB. This approach ensured maximum reach for the intervention within the funded DHB region of Southland. The overarching aim of this thesis was therefore to measure the effectiveness of *Healthy Me and You*, a health promotion programme designed for socially disadvantaged caregivers and their preschool age children in relation to *increasing physical activity levels* and *fruit and vegetable intake*.

1.3.1 Why socially disadvantaged caregivers and preschoolers?

This research targets two key priority areas identified in the HEHA Strategy "lower socioeconomic groups" and "children, young people, and their families and whanau" shown in Figure 2. For the first priority area, it is reported that "lower socioeconomic groups" may have difficulties accessing resources, facilities, food and services that help them attain and maintain good health. Furthermore, in New Zealand a disproportionate number of households with Māori and Pacific people live in areas of high deprivation (Salmond & Crampton, 1999). In an attempt to address this priority area, the Strategy promoted the development of policies, programmes and services intended to assist

individuals and families make healthy choices the easy and accessible option as is seen as a key approach to take, given the often limited disposable income available for low socioeconomic households (Ministry of Health, 2003b).

To address the second priority area, "children, young people, and their families and whanau", it is well established that programmes and services which help develop and reinforce healthy food choices and physical activity patterns at a young age can benefit individuals. It is also known that these programmes and services are also likely to impact the behaviours and choices of the wider family and whanau are encouraged to be implemented (Ministry of Health, 2003b, 2003c).

Primary caregivers and their children under five years were identified in the 2005 proposal (see page 1) following the completion of a local needs assessment of programmes offered in Southland. The stock-take showed that programmes which were either being planned or implemented were predominantly delivered in a school setting, with children aged five years and older. A handful of early child care settings were known to receive some healthy lifestyle programmes, however, as in school settings caregivers were generally not present. The authors of the proposal sought to address this gap in service delivery. Engagement with key stakeholders in the local community occurred prior to the proposal being submitted, with feedback indicating that they were fully supportive of the concept (small group programmes delivered in community settings targeting preschool aged children) for the yet to be named health promotion programme H*ealthy Me and You.* No consideration was given to any alternative approach.

1.3.2 Why physical activity?

Physical activity is defined as "any bodily movement produced by skeletal muscles that results in energy expenditure" (Caspersen, Powell, & Christenson, 1985). This movement can be further classified as vigorous, moderate, light, or sedentary intensity based on the amount of energy or effort expended in performing the activity (Caspersen, et al., 1985). It is the combination of frequency, intensity, and duration that determines total physical activity levels and this physical activity can also be further defined as incidental, occupational or recreational. The urbanisation and industrialisation of

countries has caused general levels of physical activity to decline and reducing sedentary behaviour is an alternative and complimentary approach to increasing physical activity.

Physical activity has been shown to be protective against some cancers (colon, post-menopausal breast and endometrial) (World Cancer Research Fund & American Institute for Cancer Research, 2007), cardiovascular diseases and diabetes (Ministry of Health, 2004b; U.S. Department of Health and Human Services, 1996; World Health Organisation, 2000). Regular physical activity can also reduce: the risk of obesity; high blood pressure, falls in older adults; levels of stress. It can promote psychological well-being, help people achieve and maintain a healthy weight and positively affect cholesterol levels (Kolt, et al., 2005; U.S. Department of Health and Human Services, 1999).

Two of the HEHA Strategy population health messages shown in Table 1 relate to physical activity, "be active every day for at least 30 minutes in as many ways as possible"; and "add some vigorous exercise for extra benefits and fitness". SPARC also recommends these guidelines (Hillary Commission, 2001). There are no specific recommendations for children under five. However SPARC do promote "*Active Movement*" which assists brain and motor skill development. Guidelines for children 5-18 years promote at least 60 minutes of moderate to vigorous physical activity throughout each day in as many ways as possible (Kolt, et al., 2005).

Results from the 2002/03 NZHS showed that one half of all adults were regularly active participating in at least 30 minutes of physical activity per day on five or more days of the previous week. Men were statistically significantly more likely to achieve this (57%) compared to women (49%), adjusted for age (Ministry of Health, 2004a).

Findings from the CNS02 relevant to this thesis (Parnell, et al., 2003) indicated that young males (29%) were more likely than young females (16%) to be in the highest activity quartile. European/other children were more likely to be in the least active group (males 28%, females 13%) and less likely to be in the most active group (males 23%, females 38%). Pacific children had the lowest proportion in the least active group (males 17%, females 31%) while Māori children had the highest proportion in the active group (males 33%, females 22%).

1.3.3 Why fruit and vegetables?

"Eat more fruit and vegetables" was identified as one of the eight key population health messages of the HEHA Strategy, shown in Table 1. Fruit and vegetables have been shown to protect against cardiovascular disease and some common cancers (Joshipura, et al., 1999; Joshipura, et al., 2001; World Cancer Research Fund & American Institute for Cancer Research, 2007). This is due to their protective effects on cholesterol, blood pressure, homocysteine, blood lipid profiles and also their anti-carcinogenic activities (Ministry of Health & University of Auckland, 2003e). Some of this evidence is linked to various nutrients including antioxidants (e.g. vitamins A, C and E), folate, magnesium and potassium, as well as their high level of dietary fibre and low energy density.

It has been estimated that up to 2.7 million lives worldwide could be potentially saved if intakes of fruit and vegetables were sufficiently increased to meet recommended guidelines (World Health Organisation, 2003a). In New Zealand, six percent of deaths in 1997 were attributed to a low intake of fruit and vegetable consumption. Based on New Zealand historical trends, Tobias created a model which predicted that approximately 334 deaths could be prevented annually from 2011 by increasing population mean fruit and vegetable intake by 40g/day or half a serve (Tobias, et al., 2006).

New Zealand recommendations are for adults to eat at least three servings of vegetables and at least two servings of fruit each day, which may be fresh, frozen or canned (Ministry of Health, 2003d). This target is comparable to the World Health Organisation (WHO) recommendations of a daily total intake of 400g to provide protection against chronic conditions (World Health Organisation, 1990). International comparisons of fruit and vegetable intake are difficult to ascertain, as measurement and definitions of fruit and vegetable often differ between countries. Potatoes and other starchy vegetables are often excluded due to their lower health benefits (World Cancer Research Fund & American Institute for Cancer Research, 2007; World Health Organisation, 2003b) and Australia also excludes fruit juice (McLennan & Podger, 1998). Current recommendations for preschoolers are to eat at least two serves of vegetables and two serves of fruit each day, while guidelines for school aged children (five and older) are identical to adults (Ministry of Health, 1997).

The NNS97 (Russell, et al., 1999) indicated that two out of three adults (67%) ate the recommended three or more servings of vegetables every day, and just under half (46%) of the adults ate the recommended two or more servings of fruit every day. Females were more likely (56%) to eat the recommended number of servings than males (34%).

Results from the 2002/03 NZHS showed that the proportion of adults achieving the daily vegetable consumption recommendation was 69% and 55% of adults achieved the daily fruit intake recommendation. In both males and females, the proportion of adults eating three or more servings of vegetables each day was higher in NZDep2001, quintile 1 (least deprived) than in quintile 5 (most deprived), although the difference was only statistically significant for females. This pattern was also seen with fruit intakes for females, however no differences were found between quintiles for fruit intake for males (Ministry of Health, 2004a).

Relevant findings from the CNS02 (Parnell, et al., 2003) showed that only 43% of children met the recommended number of serves of fruit and 57% of children met the recommended number of serves of vegetables per day. Children aged 5-6 years ate at least two serves of fruit daily more frequently (males 46%, females 55%) than older children[5] (males 39%, females 36%). A higher proportion Pacific children (males 51%, females 50%) ate fruit at least twice a day of fruit than Maori (males 40% vs males , females 43%) or European/other children(males 41% vs males , females 44%).

1.4 Analyses aims

Figure 3 shows the three aims which are examined in this thesis by evaluating the effectiveness of *Healthy Me and You*. Aim one examines three outcomes prior to the intervention at baseline: *child physical activity in minutes; number of fruit offerings to child by caregiver; and number of vegetable offerings to child by caregiver*. The second aim focuses on these three outcomes and compares behaviour change between the intervention group and the comparison group at the conclusion of the study to determine whether *Healthy Me and You* was effective. The third aim focuses only on the

[5] 11-14 year olds.

intervention group to determine if any particular sub-group gained more benefit from participating in *Healthy Me and You.*

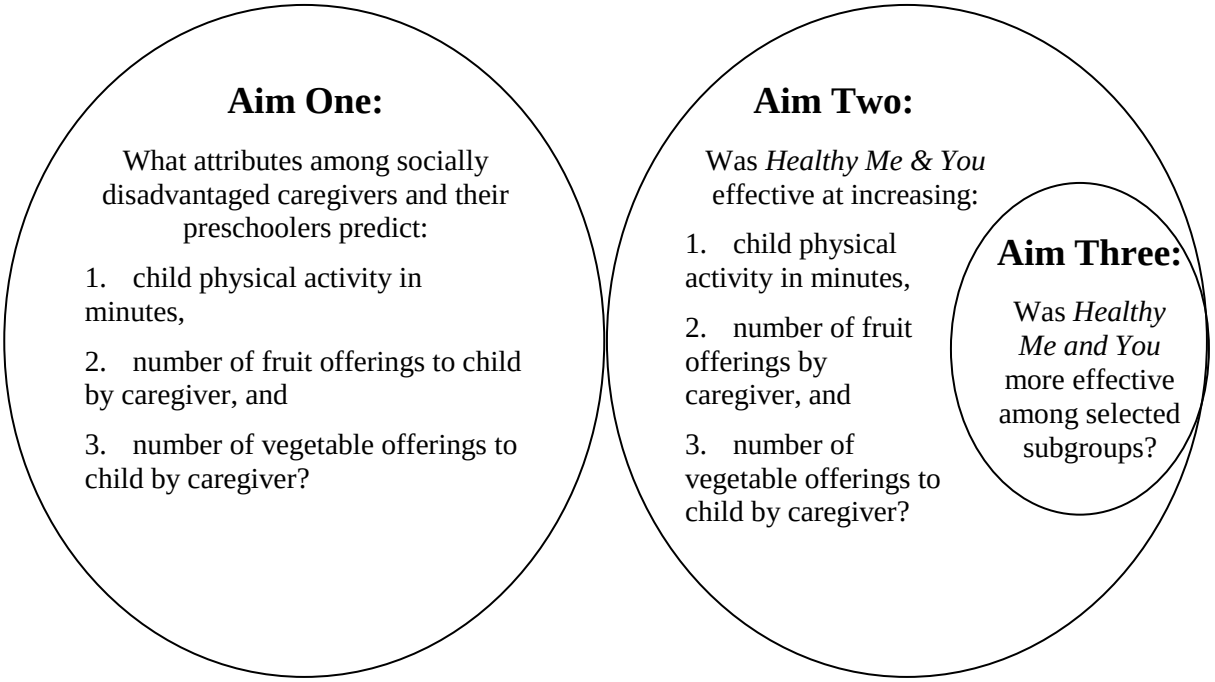


Figure 3: Overview and relationship of the three aims

1.5 Thesis structure

This thesis is structured into three volumes. The core document is organized into a series of seven chapters:

- Chapter one provides an overall context to this research project and describes the analyses aims.
- Chapter two examines the existing literature that supported the design and development of this evaluation.
- Chapter three explains how the intervention *Healthy Me and You* was developed (including application on the chosen theory and formative evaluation studies undertaken). It also provides details of the actual programme.

- Chapter four details the methods used to evaluate the programme including study design, the sample, measurement instruments and statistical methods applied.

- Chapter five reports results from analysis of baseline data (aim one).

- Chapter six reports results from analyse performed on follow-up data (aims two and three), and considers other intermediate outcomes and the validity of the evaluation in light of "loss of follow-up" data.

- Chapter seven interprets the results and discusses these findings in the context of programme effectiveness and future application. The limitations and strengths of this research are also identified together with overall conclusions.

Two additional volumes accompany this thesis. The first contains supplementary information identified as appendices. The second is the *Healthy Me and You* Teachers Guide, which is on compact disc, located on the inside back cover in a pocket.

2 PHYSICAL ACTIVTY AND DIETARY INTERVENTIONS THAT TARGET PRESCHOOLERS

This chapter provides a review of the literature available prior to January 2008[6] on the effectiveness of health promotion programmes targeting preschool age children in relation to increasing *physical activity* levels and/or *fruit* or *vegetable* intake.

2.1 The search for published literature

There was a lack of information on the effectiveness of interventions promoting physical activity and/or fruit and vegetables among preschoolers (Campbell & Hesketh, 2007; Flynn, et al., 2006; van Sluijs, McMinn, & Griffin, 2007), in particular, those in a community or family based setting (Flynn, et al., 2006; van Sluijs, et al., 2007). This review aimed to identify studies which had begun to address this gap including those identified in systematic reviews.

Interventions were identified encouraging healthy lifestyles for preschoolers specifically focused on measuring any one of three outcomes: *physical activity*, *fruit consumption* or *offerings* and *vegetables consumption* or *offerings*. Study inclusion was conditional on a comparison group being present as well as a follow-up period of at least three months.[7] Interventions needed to be run in community settings and include children who were not enrolled in school (i.e.: preschoolers). A further requirement was that papers were to be published in English, up to and including December 2007.

2.1.1 Search strategy

The retrieval of published studies involved a structured search of 6 electronic databases (Scopus, Science Direct, Web of Science, CINAHL, PubMed and the Cochrane database) looking at studies published up to and including December 2007. The search strategy focused on four key elements: study design (e.g. intervention studies), programme evaluation (e.g. health education, health promotion), population (e.g. preschool children, under fives), and the three outcomes or behaviours being measured (physical activity,

[6] Programme implementation commenced in February 2008.
[7] Follow-up time comparable to the 12 week duration used by (Summerbell, et al., 2005) in the Cochrane Database of Systematic reviews.

fruit, and vegetables). Appendix C outlines the search strategy developed for use in Scopus and then adapted to the other databases.

A two phased approach was then taken to identify the relevant studies. Phase one included reviewing all titles and abstracts identified. All potentially eligible articles were then reviewed in their entirety against the inclusion criteria to determine whether they would be included in the review (phase two). Reference lists of these articles were then checked to identify other relevant studies published, which appeared to be appropriate to the review against the inclusion criteria. At the conclusion of this process, eligible articles were included in the final selection. Figure 4 outlines the results of this search process.

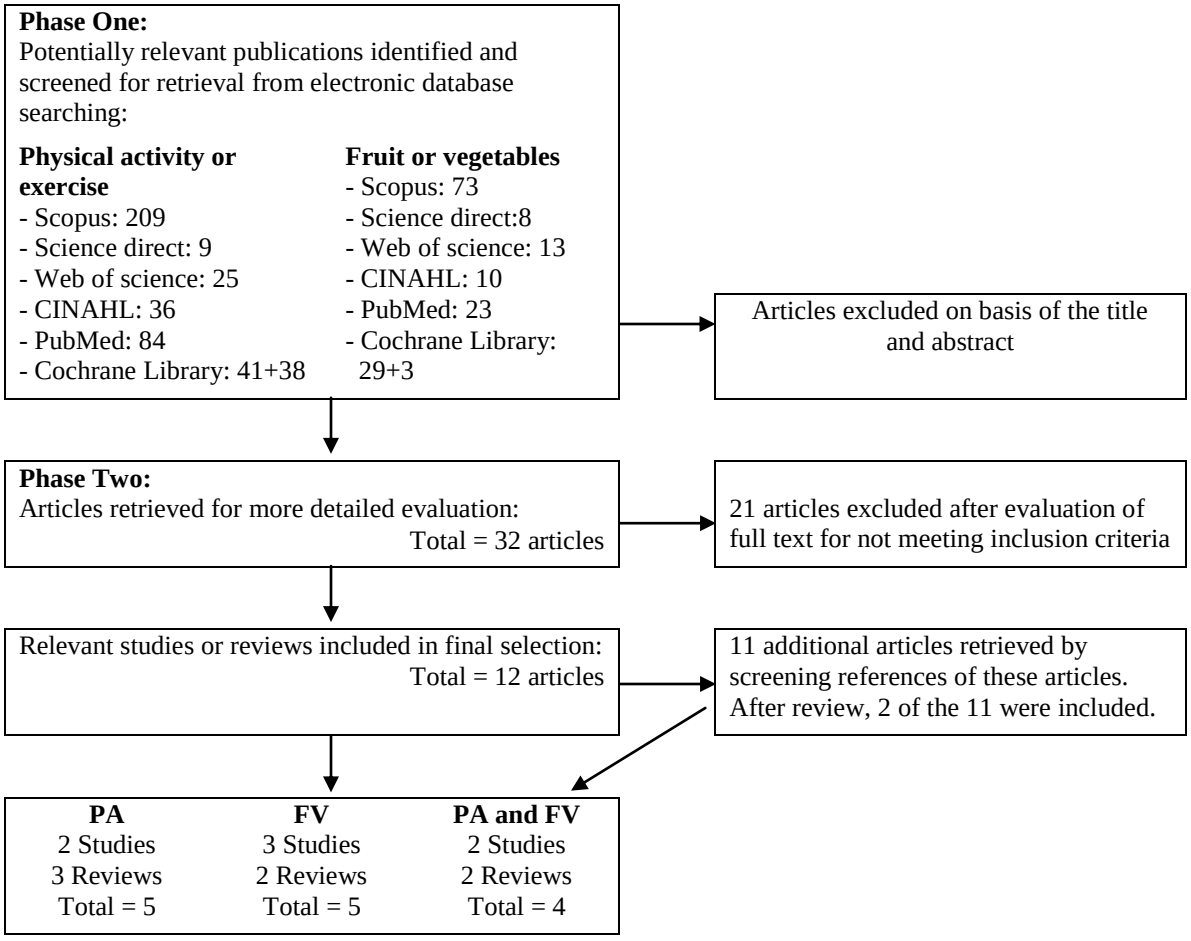


Figure 4: Flow chart of study selection process

2.2 Findings from the literature

Phase one saw over six hundred papers identified (includes duplications) from the search results for *physical activity or exercise* and *fruit or vegetable* respectively. Thirty two were actually retrieved as they met the initial screening criteria based on their title and abstract. Of these, 12 were identified as relevant to the literature review. These articles were then screened and another 11 papers were identified from their references, retrieved and reviewed. An additional 2 studies met the inclusion criteria and were included in the final total of 14.

Reviews and studies have been described under three headings physical activity, fruit and vegetables, and physical activity and fruit and vegetables. Of the seven reviews two each were conducted in Australia, United Kingdom (UK) and United Sates of America, with one a combined effort between the UK and Australia. Table 2 shows all interventions identified in this literature review and are described in further detail together with relevant reviews under each respective heading.

2.2.1 Physical activity

Reviews

Best practice recommendations focusing on reducing obesity and chronic disease risk in children and adolescents were examined by Flynn et al. (2006). Of the 158 articles they reviewed (147 programmes) only nine articles (6%) focused on children 0-5 years. One met the inclusion criteria of this literature review: a pilot study by Harvey-Berino and Rouke (2003), which is discussed in the following sub-section. The review was very informative in identifying opportunities for future research (upstream[8] and population focused interventions), gaps (including populations such as under fives and community or home settings) and identifying issues relating to the assessment of obesity interventions and prevention programmes (i.e. development of consistent indicators to enable comparisons of programme outcomes).

[8] Upstream interventions refer to social policy change which attempt to intervene at a national or community level whereas downstream interventions are curative at an individual level (McKinlay, 1993).

The promotion of physical activity participation among children and adolescents was examined by Salmon et al (2007) based on a settings approach (school, family, primary care and family). Participants were children aged 4-12 years. Of the 90 studies reviewed, 51 involved children with most implemented in school settings or included children aged older than five. From this review only one study was identified; a three year Finnish intervention by Sääkslahti (2004) which is discussed in the following sub-section. Due to the large number of studies based in school settings, the review concluded that the evidence regarding strategies outside this setting was very limited. Further evidence of the efficacy of interventions promoting physical activity was recommended before critiquing family and community settings comprehensively. Furthermore it was noted that many of the studies had a number of study design flaws (e.g. no comparison group, no baseline data) as well as poor quality measures and poor reporting.

The third review by van Sluijs et al. (2007) was similar to that undertaken the same year by Salmon et al. Thirty-three studies (from the 57 identified) promoted physical activity in children, with the majority (n=31) excluded due to the setting and/or age of children. The two remaining studies (Harvey-Berino & Rourke, 2003) and (Sääkslahti, et al., 2004) had both been identified in the two reviews above. This review assessed the level of evidence of each study (accounting for methodological quality) and considered various settings, targeted populations and types of interventions for children (<12 years) and adolescent age-groups. Again limitations in study design and subsequent reporting were identified as issues of concern by the authors together with the lack of precision of the physical activity outcome measures used (i.e. 55% of studies used either self report or parent report measures). The review questioned the usefulness of family based or community based interventions as most reviewed did not report positive results. However, these findings may reflect various study limitations. It also concluded that more focus is needed on areas such as preschoolers and outside school settings to address the gaps.

Studies

A pilot randomised control trial (RCT) conducted by Harvey-Berino and Rourke (Harvey-Berino & Rourke, 2003) involved 40 children (aged 9 months to 3 years)

randomized into a 16 week intervention or control group 'parenting support programme'. Eleven sessions were carried out in the participants' homes, run by an indigenous peer educator. The intervention focus was exclusively on parenting skills for improving eating and exercise behaviours in children. Control participants received the standard parenting support programme which excluded discussing child or parent eating and exercise behaviours. The outcomes measured were obesity levels, dietary intake (3-day food records), physical activity (accelerometer), parental feeding style (Child Feeding Questionnaire) and various maternal outcome expectations. Measurements were collected at baseline and at the conclusion of the intervention (16 weeks).

The study appeared to have limitations in methods as no theoretical framework was discussed and although not a real limitation of the study, potential mediating variables were not measured. At the end of the intervention there were no time or group differences found between the two groups for child or mother accelerometer data. The only other reported outcomes were obesity levels and energy intakes. Results specific to fruit and/or vegetables were not mentioned.

The Finnish intervention (Sääkslahti, et al., 2004) was a three year longitudinal project which aimed to determine how much time children spent in different activities during the weekends and whether it was possible to influence this activity through a family-based intervention. Participants (n=228) were a randomly selected sub-sample from the wider Special Turku Coronary Risk-Factor Intervention Project (STRIP). Intervention group parents received an annual one hour intensive session with other intervention-group parents. Sessions covered the importance of sensory integration, provision of information regarding health, findings from other intervention studies and the promotion of various child-orientated physical activity type activities in the area they live. Printed material was also sent to them twice yearly including board games and review articles. The control group received nothing. Parents completed a physical activity diary twice annually for an entire weekend recording five-minute time units and nine activity categories. Two key results showed that children in the intervention group played outdoors more and indoors less than the control group; and that the amount of time spent in high-activity play in the intervention group increased with age. These results indicated

that interventions based on the Social Cognitive Theory (SCT) which involve repeated intervention doses via parents may be enough to effect children's physical activity behaviour change.

2.2.2 Fruit and vegetables

Reviews

There were very few systematic reviews found which focused on interventions promoting fruit and vegetable consumption among children. The 2006 review conducted by Knai and colleagues was described as "the first systematic review of worldwide evidence of interventions to promote children's fruit and vegetable consumption", with many reviews prior to theirs being limited in scope or geographical setting. Unfortunately this review did not include studies with children less than five years.

An earlier review undertaken by Ciliska et al. in 2000 was identified. It described community based interventions aimed to increase fruit and vegetables including three studies which targeted parents with young children (preschoolers). All inclusion criteria for these studies were met, however data were only collected on parents. Therefore the effectiveness of the interventions on child fruit and vegetable outcomes were unknown for these studies.

The only other systematic review obtained analysed various evaluation measures used in nutrition education intervention research (Contento, Randell, & Basch, 2002). This was an extension of a 1995 review which examined the effectiveness of nutrition education intervention research undertaken, also criticized by Knai. Despite the 2002 review focusing primarily on evaluation methods used, it did utilise study characteristics to describe their findings. From these details it was found that of the 11 preschool studies which measured behaviour, none specifically measured fruit and vegetable intake or offerings.

Studies

Three studies were identified via the search strategy described in Section 2.1.1. None were identified in the above reviews as fruit and vegetable intakes were either secondary or intermediate outcomes.

The Children's Health Project involved 303 children aged between 4-10 years and the primary aim was to promote lower dietary fat intake in order to improve overall diet quality (Dixon, Tershakovec, McKenzie, & Shannon, 2000). Study design involved included three "at risk groups" groups of children (elevated plasma total cholesterol (TC) and low-density-lipoprotein cholesterol and one "not-at-risk" control group (plasma TC not elevated). Children with elevated TC were randomized into one of the two intervention groups or categorized as the "at risk" control group. Intervention participants either received nutritional counseling or a 10-week home-based self-instruction nutrition education programme. Both control groups did not receive any nutrition education and were instructed to maintain typical eating habits. Three 24 hour dietary recalls were conducted with each child and primary caregiver before and after the three month intervention together with fasting plasma samples. Information obtained from the dietary recalls was then converted into a Diet Quality Index which consisted of eight dietary variables, one being fruit and vegetables.

Study results specific to fruit and vegetable intake showed that children who received nutrition education (both intervention groups), did not improve their fruit and vegetable intake. These results were partially explained as the programme encouraged low fat dietary choices rather than promoting overall increased intake of fruit and vegetables; approximately 25% of vegetable intakes reported by children were french fries. Another finding from the study was that across all groups, the percentage of children who initially met fruit and vegetable recommendations did not change over 3 months.

The second study was a home gardening programme that had been integrated into a community-based growth-monitoring programme in a rural village in South Africa, which aimed to improve access to provitamin A-rich food via yellow and dark-green leafy vegetables (Faber, Phungula, Venter, Dhansay, & Benade, 2002). One hundred and

twenty six gardens were established which involved 129 children. A neighbouring village acted as the control. It also received the existing community-based growth-monitoring programme. Baseline and follow-up data at 20 months were collected on the children via questionnaires, plasma samples, anthropometric measurements assessing habitual intake of specific food items such as fruit and vegetables rich in provitamin-A.

Results relating to children's habitual dietary intake showed that statistically significantly more children in the intervention group consumed carrots, pumpkin/butternut squash, spinach and imifino[9] at follow-up than in the control group. Other benefits were also shown relating to improved knowledge of and attitudes towards fruits and vegetables promoted in the intervention as well as improved levels of serum retinol concentration. A limitation of the study was the perceived improved buy-in from control parents at follow-up because they were aware that the programme would soon be extended into their village.

The final study identified was the Nutrition Education Aimed at Toddlers (NEAT) pilot study which was a programme for rural, low-income families (Horodynski, Hoerr, & Coleman, 2004). A convenience sample of 38 families was used whereby all were invited to attend education classes. Nineteen attended (intervention group) and the remaining 19, who chose not to attend, became the control group. Three lessons were delivered and designed to increase caregiver knowledge; awareness of healthy eating and age appropriate feeding practices. Baseline and six-month follow-up data were collected including caregiver interview and 24-hour dietary recall.

Study findings showed that dietary intake for both mother and toddler were less than optimal, with no statistically significant differences found for toddler fruit or vegetable intake between groups (intervention and control). When considering food groups for the combined child groups, over two-thirds consumed at least one piece of fruit daily. However, if fruit juice was excluded then levels not only dropped to one-third but also became lower than recommended guidelines. Toddlers did not eat the recommended guidelines for vegetables; only one-in four consumed at least one vegetable daily. It is

[9] Leafy green vegetable which can be cooked and eaten similar to spinach.

widely accepted that poverty places children and their families at risk of poor health and nutrition and this study supports the notion that knowledge alone is inadequate for caregivers of toddlers to change healthy eating habits and mealtime practices.

2.2.3 Both physical activity, fruit and vegetables

Reviews

A 2001 Cochrane Library systematic review "Interventions for preventing obesity in children" (Campbell, Waters, O'Meara, & Summerbell, 2001) was updated in 2005 (Summerbell, et al., 2005). In the more recent review, only one of the 22 studies met the inclusion criteria for this literature review (Harvey-Berino & Rourke, 2003). Despite the 2005 review focusing predominantly on older children and/or non-community settings, the authors provided some useful commentary about the studies they critiqued which is relevant to this review.

As with the 2007 Salmon and van Sluijs reviews, quality issues were identified as providing some context to intervention findings (with the majority not statistically significantly improving BMI), due to underpowered and/or poorly designed studies. Small positive impacts on BMI status were found in some studies which focused on either diet or physical activity behaviour change. It was also noted that the more recent studies included in the updated review involved more comprehensive evaluations. However details regarding the background and context in which the interventions occurred were still found to be lacking. Another important observation was that many of the studies conducted interventions with populations who were well educated. Interventions with socially disadvantaged groups and "hard to reach" populations were rare. Targeting already advantaged populations not only widens existing inequalities but also limits the generalisation of study findings.[10] Recommendations from the review included improved use of appropriate intervention methods (development, design, duration and intensity) together with comprehensive reporting (also recommended by Salmon and van Sluijs). Review conclusions also state that behavioural change interventions were unlikely to be sustainable or effective unless interventions provided a more supportive environment for participants.

[10] Targeting disadvantaged populations also limits the generalisation of study findings.

The final review sourced was by Campbell and Hesketh (2007) and was the only review which specifically focused on 'under fives'. In the introduction, the authors described the manuscript as the first review of obesity prevention interventions in younger children and that the majority of the studies reviewed had been published between 2003 and 2006. Prior to this time; the emphasis had been on interventions which targeted school-age children. It was noted that the lack of literature reporting the effectiveness of programmes seeking to change dietary, physical activity and/or sedentary behaviour in this age group were currently being conducted or had yet to be published in peer-reviewed literature.

The review identified nine studies, two of which met the inclusion criteria of this review, including Harvey-Berino (2003) previously discussed on page 19 and McGarvey, et al. (2004). The review included the subsequent intervention of the previously described NEAT pilot (Horodynski, et al., 2004) but despite collecting dietary data, these findings were not reported. This NEAT intervention study however reaffirmed the NEAT pilot's conclusion in stating that changes in knowledge did not necessarily result in changes in targeted behaviour (Horodynski & Stommel, 2005).

As with many of the previous reviews discussed, a number of issues which made interpreting the impact of the studies challenging were identified (Campbell & Hesketh, 2007). Specifically identified was the lack of reporting for sample size calculations; limitations of measures used; generalisability of studies; and also cost-effectiveness of interventions.

Studies

Of the two studies identified via the search strategy, the "Fit WIC" programme was a non-randomised control group design promoting targeted parental behaviours to prevent obesity in children of clients' participating in the Special Supplementary Nutrition Program for Women, Infants, and Children (WIC) (McGarvey, et al., 2004). Both groups (intervention n=121; comparison n=65) received two education sessions per month and six-monthly individual session with a nutritionist. Those in the intervention group also received education regarding physical activity, mealtime behaviour, television viewing,

drinking water rather than sweetened beverages, fruit and vegetables and family activities which promote fitness. These six key dietary and physical activity behaviors were modelled by WIC staff and reinforced with promotional messages by collaborating organisations in their local community. Pre and post measures were recorded at baseline and one year which included parental report of a child's activity for either the previous 24 hours or previous seven days and frequency of five other behaviours using a five-point scale including offering of fruits and vegetables daily and engaging in active play with the children.

Results showed that intervention parents were statistically significantly more likely to report that they were involved in active play with their child. However, no effect was found with regards to increasing fruit and vegetable offerings. Limitations of the study included the use of non-validated instruments and the level of engagement staff with participants from different sites, with reports that staff were more efficient in contacting parents at follow-up in the intervention group.

The final study sourced described the development of the Healthy Children, Strong Families (HCSF) study, an obesity prevention intervention for American Indian families (LaRowe, Wubben, Cronin, Vannatter, & Adams, 2007). This was a family based intervention consisting of 12 nutrition and physical activity lessons delivered over a year with the first six lessons delivered in the first three months and the remainder evenly spread over the time. The intervention families received these lessons at home by a trained mentor while those in the comparison group had these lessons mailed to them. Intervention families also received three group-activity lessons. Baseline and 12 month follow-up data were captured prior to the intervention commencing and included anthropometric measurements, non-described measurements for child and caregiver of fruit and vegetable serves, sweetened beverages and candy serves, television watching and percentage of day in sedentary activities in addition to several other caregiver characteristic type outcomes and biochemical markers. No results for outcomes measures were reported in this paper.

Limitations of the study included not conducting a pilot due to time constraints relating to funding and the desire from the community to begin the intervention sooner rather than later. The second major limitation was that the curriculum was developed with little involvement from the community and none from the mentors who were employed to deliver the lessons.

Table 2: Included studies

Study	Theory	Participants	Intervention	Measures used	Outcomes
Physical activity only					
Harvey-Berino 2003 Obesity prevention plus parenting support (OPPS) intervention. *USA & Canada*	Not reported	Native-American children; 9m-3yrs. n=20 intervention; n=20 comparison.	Participants randomly assigned to parenting support (PS) or obesity prevention plus parenting support (OPPS) groups. 16-week programme conducted in the home of each participant.	Accelerometer (child & adult)	There were no time or group differences in any of the determinants of maternal or child exercise behaviors (p=ns).
Saakslahti 2004 Part of STRIP (Special Turku Coronary Risk-Factor Intervention Project). *Finland*	Social Cognitive Theory	Children 2-4 yrs; n=116 intervention; n=112 control	Parents of intervention-group children received information and concrete suggestions on how, when, and where to encourage their child's physical activity. Follow-up 3 years.	Physical activity diary	Children in the intervention group spent more time playing outdoors ($p = 0.041$); and play in the high-activity category increased with age ($p < 0.001$) compared to the control group.
Fruit & vegetable only					
Dixon 2000 Children's Health Project. *USA*	Not reported	Children 4-10 yrs. n=71 & n=77 intervention; n=79 & n=76 control	3 month intervention, two different nutrition education interventions. Controls received no education.	24 hour dietary recall	Children who received nutrition education were less likely to meet fruit and vegetable recommendations (p=ns). In all four study groups, the percentage of children who met fruit and vegetable recommendations did not differ over time.
Faber 2002 Home gardening programme. *South Africa*	Not reported	Children 2-5 yrs. n=129 intervention, n=85 control	Demonstration gardens with education promoting yellow & dark-green leafy vegetables in intervention villages. Follow-up 20 months.	Food frequency questionnaire	Statistically significant increase in consumption of carrots, spinach & imifino within intervention group (baseline verses follow-up) and including pumpkin between groups at follow-up (p=0.001)
Horodynski 2004 Nutrition Education Aimed at Toddlers (NEAT) *USA*	Not reported	Low-income, rural families with toddlers aged 12-36 months. n=19 intervention, n=19 comparison.	6 month follow-up, small group education to intervention group only.	24 hour dietary recall	No statistically significant differences found between fruit and vegetable consumption. Overall participants had inadequate fruit intakes.

Table 2 (continued)

Study	Theory	Participants	Intervention	Measures used	Outcomes
Both physical activity and fruit & vegetable					
McGarvey 2004 Women's Infant and Children (Fit WIC), *USA*	Social Cognitive Theory	Children 2-4yrs. n=185 intervention; n=151 comparison	1 year prospective study. Promotion of 6 targeted behaviours through education programme, not received by comparison group.	Parental report of 6 key messages	Significant change in engaging in active play with child (p=0.009): no effect found with offering fruit and vegetables (p=ns).
La Rowe 2007 Healthy children, strong families (HCSG). *USA*	Social Cognitive Theory	American Indian children 2-5yrs. n=92 assigned to intervention or control groups.	12 month randomised trial. Intervention group received home visits with education plus extras, control receive same education material by mail only.	Not reported.	Secondary outcomes included serves of fruit and vegetable & percentage of day in sedentary activities for child. Results not reported.

2.3 Summary

The literature indicates a lack of information about the effectiveness of interventions in preschool aged children which promote the increase of physical activity and/or fruit and vegetables in community settings. Of those studies published prior to 2008, the evidence appears to be inconsistent and this conclusion may be partially explained by the small number of publications. Authors of systematic reviews also identified several key issues which have hindered the overall quality of studies reported during this time. These included poor study design, underpowered designs, no pilot study, no comparison group, no baseline data, poor quality measures/instruments, insufficient follow-up and poor reporting of results. Generalisability of studies was also questioned as it is known from international data that there are differences in the prevalence levels of overweight and obesity by socioeconomic backgrounds. Consequently the use of well-educated population groups and families as target populations may widen existing inequalities within a population. To further complicate this issue, studies that have attempted to address this issue and have targeted low SES populations have concluded that providing families with knowledge may not be sufficient enough to change and sustain behaviour.

3 THE HEALTHY ME AND YOU PROGRAMME

3.1 Developing the *Healthy Me and You* programme

Understanding the needs of the target audience, using appropriate and accepted intervention methods and materials are all key components to the development and design of an effective health promotion intervention (Nutbeam & Bauman, 2006). Developing an evaluation plan in parallel with programme development is recommended and for the *Healthy Me and You* programmes, three different types of evaluation were used, formative, process and impact. Data was collected before, during and after the programme was implemented and both qualitative and quantitative methods were used.

Section 3.1 describes the three activities carried out as part the formative evaluation component of the evaluation plan for *Healthy Me and You*. The purpose of these activities was to develop and pretest programme materials and methods. This process commenced with the development of the programme framework through the application of a theoretical background. Following this, a series of focus groups were undertaken to determine the programme content and then the programme was piloted.

Process evaluation documents what happened during the course and context of the programme; activities undertaken, programme quality and who it is reaching. This thesis does not describe the activities undertaken as they sit outside the scope of this document.

Impact evaluation measures the immediate effect of the programme in relation to the three outcomes measured (child PA in minutes, number of fruit offerings to child by caregiver, and number of vegetable offerings to child by caregiver), whereas outcome evaluation (if undertaken)[11] would measure the long term effects of the programme in relation to obesity levels in children. Chapters 4 to 6 describe the methods used and results associated with the impact evaluation carried out.

[11] Outcome evaluation was not possible due to time and funding constraints.

3.1.1 Theoretical background: Social Cognitive Theory

SCT was chosen as an appropriate theoretical framework to apply to the design and implementation of *Healthy Me and You* as this framework addresses the psycholosocial factors that determine health behaviour as well as strategies to promote behaviour change (Bandura, 1986). The SCT blends concepts and processes from cognitive, behavioural, and emotional models of behaviour change and is based on the premise that people learn not only through their own experiences, but also by observing the actions of others and the results of those actions (Glanz & Rimer, 1997). The interaction between the individual and the social environment is also emphasized in this theory (Neumark-Sztainer & Story, 1996). Figure 5 shows a schematic drawing of the concepts and illustrates how they interrelate.

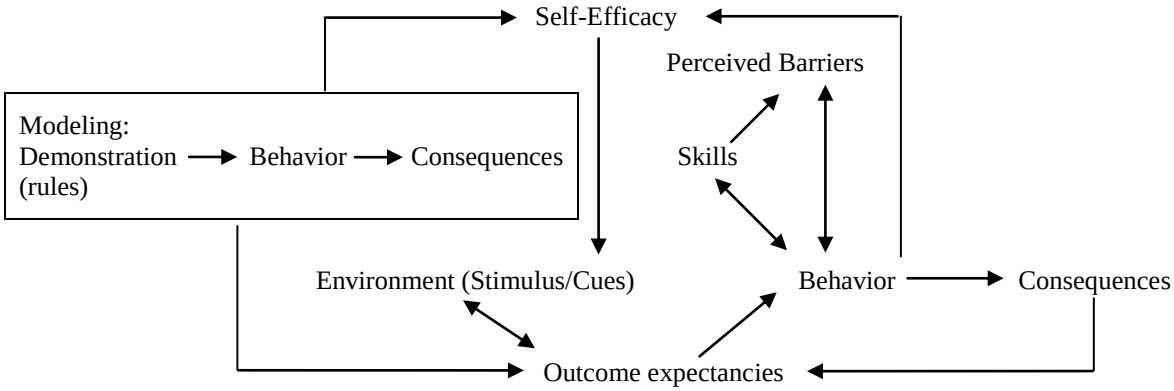


Figure 5: Social Cognitive Theory schematic (Baranowski, Cullen, & Baranowski, 1999)

Applying the SCT to Healthy Me and You

When *Healthy Me and You* was designed, two matrices were created using the SCT to assist the programme planning phase. Table 3 provides a definition and approach taken for each of the SCT constructs and shows how this framework was intended to be used to increase fruit and vegetables (F&V) intake among preschoolers.

Table 3: Social Cognitive Theory constructs for increasing fruit and vegetable intake

Construct	Definition	Approach	Aim: increase F&V	Parent specific activity	Parent/child activity
Environment	Factors physically external to the person	Provide opportunities & social support	Increase availability and accessibility of F&V at home	Budgetary activity (making F&V go further)	Garden preparation activity
Situation	Person's perception of the environment	Correct misperceptions & promote healthful norms	To promote increased consumption of F&V to 5+ a day	Cost benefit activity of increased F&V consumption	Simulated shopping with plastic F&V
Behavioural capability	Knowledge & skill to perform a given behaviour	Promote mastery learning through skills training	C/g[12] to develop skills on how to prepare & incorporate F&V into snacks/meals	C/g's to brainstorm F&V snacks and meal incorporation	Preparation and tasting of F&V snack
Expectations	Anticipatory outcomes of a behaviour	Model positive outcomes of healthful behaviour	C/g to learn about being a positive role model for F&V re snacks and meals	C/g to role model tasting of F&V snacks	C/g and child to complete taste testing activity
Expectancies /Incentives	The values that the person places on a given outcome, incentives	Present outcomes of change that have functional meaning	C/g to identify and develop F&V preference for self & family	C/g to discuss eating and feeding strategies (positive parenting) re F&V intake	Parents to shop with child and purchase novel F&V to taste test
Self-control	Personal regulation of goal directed behaviour or performance	Provide opportunities for self-monitoring, goal setting, problem solving, & self-reward	C/g set goals to eat more F&V at all meals & snacks. To develop the skills to be able to problem solve ways to increase F&V intake of themselves and for their children	C/g to role model positive F&V eating behaviours and set SMART[13] goals for F&V intake	Preparation and tasting of F&V snack

[12] Caregiver.
[13] Specific, Measurable, Attainable, Realistic and Timely.

Table 3 continued

Construct	Definition	Implications	Aim: increase F&V	Parent specific activity	Parent/child activity
Observation-al learning	Behavioural acquisition that occurs by watching the actions & outcomes of others' behaviour	Include credible role models of the targeted behaviour	Dietitian provides education and instruction on F&V preparation and portion size/ garden preparation	C/g to observe dietitian preparing meal incorporating F&V	C/g and child to complete taste testing activity
Reinforce-ments	Responses to a person's behaviour that increase or decrease the likelihood of reoccurrence	Promote self-initiated rewards & incentives	C/g receive incentives for participation/achieving goals set (positive feedback)		
Self-efficacy	The person's confidence in performing a particular behaviour	Approach behavioural change in small steps to ensure success; seek specificity about the change sought	C/g to develop confidence to eat & incorporate 5 plus serves of F&V for themselves and their family	C/g to discuss eating and feeding strategies (positive parenting) re F&V intake	Activity on F&V "where do these come from"
Emotional coping responses	Strategies or tactics that are used by a person to deal with emotional stimuli	Provide training in problem solving and stress management; include opportunities to practice skills in emotionally arousing situations	C/g to develop the skills to be able to problem solve how to increase daily fruit and vegetable intake to 5 plus per day	C/g to discuss eating and feeding strategies (positive parenting) re F&V intake	
Reciprocal determinism	The dynamic interaction of the person, the behaviour and the environment in which the behaviour is performed	Consider multiple avenues to behavioural change including environmental, skill, & personal change	C/g purchase/grow more F&V; child exposed to more F&V; increased exposure increase preference for F&V for entire family	C/g purchases more F&V, C/g has skills to prepare more F&V, child eats more F&V, child increases taste preference for F&V	

Table 4 shows how the SCT was intended to be used to increase physical activity (PA) levels of preschoolers. Both tables differ slightly in their format [14] but contain information which the facilitators (dietitian and PA advisor) used to design their respective modules of the intervention.

Table 4: Social Cognitive Theory constructs for increasing physical activity

Construct	**Aim: Increase PA levels ie: to be active for at least 30 minutes a day**
Environment	• Promote more opportunities in the physical home environment • Develop emergent family characteristics promoting PA in the home • More opportunities in the local community • Social support through buddy system/walk and talk group or with other people
Situation	• Correct perceptions of PA: Fun, easy, for everyone, different reasons to be active • Promote 30mins a day as a guideline • Correct perceptions of the PA physical environment • Increased awareness of support systems for PA
Behavioural capability	• C/g[15] to develop skills on how to be more active with their child, at home and in the community • Forms of activity and how to perform • Know-how for PA equipment, facilities, venues • Learn how to master skills needed, then perform during session • Learn what, how, when to be active then perform between sessions as homework
Expectations	• C/g to learn about being a positive role model with respect to being active • Encourage change in outcome expectations of C/g • For PA: Negative to Positive • For sedentary behaviour: Positive to Negative
Expectancies / Incentives	• C/g to identify outcomes of PA that have functional meaning to the C/g and child • C/g to identify outcomes of inactivity/sedentary behaviour e.g. screen-time that have functional meaning to the C/g and child
Self-control	C/g to develop: • PA problem solving skills • Set PA goals • Self monitor PA • Self reward
Observational learning	• PA advisor provides education & instruction on how to be more active at home & in the community • Invite credible role models that the audience relates to as a guest speakers at a session • PA advisor role models PA experience that the audience relate to (i.e. achievable for them, nothing too 'hard core') and shows the rewards e.g. fit, healthy, happy, energetic (even when not feeling like those things)

[14] Developed independently by the two facilitators.
[15] Caregiver.

Table 4 continued

Construct	Aim: Increase PA levels ie: to be active for at least 30 minutes a day
Reinforcements	• Vicarious through child and others enjoying PA (see 'observational learning' above) • Direct – positive feedback during performance (see 'behavioural capability' above) • C/g receive incentives for participation/achieving goals set (positive feedback) • Also see self control: self reward for achieving goal • Necessary to emphasise intrinsic reinforcement, will depend on 1) motivations for PA session 2) listing observed benefits after performance either in the session or as homework
Self-efficacy	• C/g and child experience specific positive PA successes in supportive group environment and develop confidence in continuing PA • Repeated positive experiences, possibly with task simplified into several simple steps • C/g to learn then perform steps to overcome barriers • Provided with resources to make the behaviour change easier eg active toys
Emotional coping responses	• Provide training in problem solving and stress management; include opportunities to practice skills in emotionally arousing situations
Reciprocal determinism	• Consider multiple avenues to behavioural change including environmental, skill, & personal change • C/g and child have more PA resources & opportunities in home and community, positive attitude to PA and developed skills to enjoy PA

The tables above do not include a description of the process and impact evaluation aligned to each construct as some methods employed were outside the scope of this thesis. Also it was assumed that increasing F&V offerings was an intermediate step (or mediator) to increasing F&V intake for children (Bere & Klepp, 2005), therefore a second matrix specific to increasing F&V offerings and replacing Table 3 was not created.

In summary, better understanding of environmental, personal and behavioural characteristics through the alignment of appropriate theories such as the SCT should enable health promotion programmes (such as *Healthy Me and You*) to be designed and implemented in such a way that influence behavioural change (Baranowski, Perry, & Parcel, 1997).

3.1.2 Community perception vs theoretical background: The development and implementation of *Healthy Me and You* focus groups

Focus groups provide crucial input to the early development of any programme development and can be helpful in gaining understanding of an issue through the eyes of

a target audience (Krueger & Casey, 2000). This methodology was used during the development stage of designing *Healthy Me and You*.

Four focus groups were arranged with parents or caregivers of children aged 3 or 4 years, and one with members of the Southland HEHA Network (a local network of health and education professionals who actively support and promote HEHA initiatives in the region). The aim of the focus groups was to gain a better understanding of the barriers parents of young children face with regard to healthy eating and being more active. It was also hoped that participants would be able to provide SHEHAP staff with practical suggestions and ideas to be incorporated into the design of the pilot programme *Healthy Me and You*.

Methods

Ethical approval was obtained at a Departmental level from the University of Otago (May 2007) and University of Otago ethics guidelines were adhered to during all stages of the study. Informed consent was obtained from participants (see Appendix D) and information regarding participant ethnicity, age group, and household characteristics (for parent or caregiver focus group participants only) were recorded. Focus groups were conducted during May and June 2007.

Participants were recruited from an Early Childhood Centre (ECC) and were offered a $5 grocery voucher and provided with afternoon tea as an incentive. Invitations were via a flyer distributed by participating ECCs. Centres were identified by SHEHAP staff using the following four criteria: range of urban and rural; target higher deprivation areas;[16] target those with higher enrolment of Māori and Pacific ethnicity children and those where existing relationships between SHEHAP staff and ECC staff existed.

Participants from the Southland HEHA Network group were recruited via a flyer distributed to this network and the focus group was held after one of their scheduled bimonthly meetings.

[16] Defined as deciles 6-10 from the 2006 NZDep Index of deprivation.

Each focus group was conducted by two facilitators and a standardised procedure was followed which included 13 key questions (see Appendix D). Amendments were made to the key questions for the Southland HEHA Network focus group as they were not the target audience of *Healthy Me and You*, but their opinions and ideas were sought given their knowledge and understanding of the target community. Information for each focus group was captured in the form of note taking by the facilitators as well as being recorded by a dictaphone for later transcription.

Results

Twenty-eight participants from ECCs and five from the Southland HEHA Network participated in five focus groups (minimum n=5, maximum n=8). The majority of the ECC focus group attendees had preschool aged children (n=26). Siblings included newborns to teenagers. The median number of children in a household was two, the maximum six. ECC participants were predominately aged 31-35 years, with 10% (n=3) identifying as Māori. Identical ages were found with the Southland HEHA Networking group however all participants identified themselves as NZ European. All four ECC locations had been identified as potential programme delivery sites for *Healthy Me and You* in 2008.

Opinions by participants of what constitutes healthy activity and healthy eating among preschoolers were consistently expressed within ECC focus groups. All ECC groups felt it was important to encourage children to be active and most said that parental role modelling was important but that varying levels of activity were performed because of balancing parental responsibilities. The weather was consistently identified as a barrier to family or personal activity.

The Southland HEHA Network focus group identified similar barriers to those identified by parents/caregivers but PA was not necessarily seen as a priority for the intervention as children in general were thought to be active whether or not their parents were involved in their activity. They believed more emphasis was needed on reducing sedentary behaviour and that parents were often not aware that they were role models to their children. They recommended building parents self esteem so they could see themselves

as active people, be involved in their children's activity and become active role models for their children.

Issues identified as barriers to healthy eating included preference for Southland food patterns,[17] fussy eating and easy access to takeaway foods. Parental role modelling was identified by ECC groups as an area of importance however parents discussed the multiple challenges they face trying to provide healthy foods to their families while keeping within budgets and finding time to prepare meals.

Feedback from Southland HEHA Network group indicated that promoting healthy eating with participants would probably not be a priority for them because of issues such as lack of money for food or inconsistent educational material. Some ethnic traditional foods and associated ethnic traditional cooking methods were also believed to be "unhealthy", however this area was identified as challenging and recommended not to be addressed in the intervention.

Desirable practical skills suggested by all groups included food label reading, back-to-basics cooking and healthy substitutes for recipes which could either expand or reinforce participants existing knowledge and skills. All food preparation education was recommended to be undertaken using basic household equipment so that participants could easily replicate meals and snacks at home.

3.1.3 Development and implementation of a Pilot, *Healthy Me and You*

The aim of the pilot study was to test the programme content and delivery on a sample of people similar to the target audience of the final intervention. Participant feedback generated practical and theoretical amendments required prior to finalising the programme. SHEHAP staff invited six caregivers who had children between two and five years to participate in the *Healthy Me and You* pilot, were the primary caregiver for the child in the home setting and were able to attend a six week pilot. Duration of the programme was informed by focus group discussion, existing local health education

[17] Southland traditional cooking methods were based almost exclusively on British eating habits for European/other ethnicities. Diets were typically high protein, high fat and low fibre.

programmes[18] and influenced by the study design. Programmes were intended to be delivered during the school terms in 2008 which were 9-10 weeks blocks and it was thought to be logistically impractical to deliver programmes longer than six-weeks in duration.

Methods

Ethical approval for the pilot was obtained from the University of Otago and the Royal New Zealand Plunket Society in October 2007. Ethical consent together with the pilot information sheet and consent form are in Appendix E and Appendix F respectively. Consent was obtained from all participants during the pilot enabling photos to be taken and used in the dissemination of results or the promotion of *Healthy Me and You*.

The pilot was conducted in November and December 2007 at a community venue, similar to that intended to be used in the intervention. Each session was led by two facilitators (dietitian and PA advisor) with support from two health professionals and a qualified ECC teacher who was invited specifically to assist with child care. Table 5 outlines each session of the pilot intervention.

Participants were invited to give feedback during the delivery of each session, at the conclusion of sessions and were also contacted by phone within a month of the course finishing. Feedback and advice was also sought from the ECC teacher prior to commencing the pilot, during delivery and prior to formal implementation.

[18] Healthy Eating For Life, a healthy lifestyle programme for people at risk or with diabetes and/or coronary heart disease

Table 5: Session outlines for the pilot

	Healthy Eating	**Healthy Action**
Week 1	Theme: Child development Activity: 1) Matrix grid 2) food practical	Theme: Health benefits of PA and other benefits Practical: Bush walk/Pool
Week 2	Theme: Fussy eating Activity: 1) NEAT scenario; 2) cartoon scenarios 3) food practical	Theme: Incidental activity Practical: Local Park
Week 3	Theme: Fruit & vegetables Activity: 1) Planting/growing F&V for children; 2) incorporating F&V into mealtimes (practical)	Theme: Overcoming barriers, local PA opportunities Practical: Main Park
Week 4	Theme: Meal times Activity: 1) Child friendly meal times	Theme: TV time Practical: Fun at home #1
Week 5	Theme: Budget Activity: 1) Takeaway's vs homemade; 2) minimize F&V wastage; 3) cheap recipes 4) food practical	Theme: Self monitoring, goal setting Practical: Fun at home #2
Week 6	Theme: Celebration Activity: 1) healthy treat food incorporating F&V	Theme: Celebration Practical: Fun at home #3

Results

Seven caregivers, (1 male and 6 females) participated with eleven (7 boys and 4 girls) of the 13 children attending with them aged between two to four years. Most of the children attending had siblings, of which the majority under the age of five years, participated in the pilot, with the exception of the two infants. Three families identified as Māori or Pacific (n=4 children) and two families lived in a rural setting (n=5 children). One participant attended only the first two sessions and was subsequently unable to be contacted. All others attended at least five to six sessions.

At the conclusion of the first session, the facilitators had gained experience of delivering the programme and so made modifications prior to subsequent sessions. These included reducing the number of activities and components of some sessions to an achievable level. This allowed extra time to allow for late arrivals, ensuring the programme was delivered in a relaxed format and not rushed. Flexibility of not only the programme content but also how the facilitators operated was essential to ensure sessions flowed well and so that activities did not to finish abruptly before the next component commenced.

Indirect feedback was also gained through participants' body language and the interaction they had with their children during practical activities. Participating children were very vocal about the activities they enjoyed or disliked and, where multiple activities were initially offered during the pilot (PA components only), the final selection was based on those which were identified as popular by children and limited to no more than three options per session. A selection of quotes obtained from the telephone follow-up at the conclusion of the pilot are shown in Table 6.

Table 6: Feedback from participants

- It was a good programme that made us think differently. It was good to have issues addressed as they arose.
- It was a pretty good, beneficial programme. I can see the benefits for the target groups. Felt it was hard for the programme time to be divided fairly between Healthy Eating and Healthy Action.
- It was a really good programme. The programme will be able to be modified to different group situations. We've been more active and played a lot of games. The kids love the ice-blocks and fruit smoothies. It was well run and person A and person B listened well to suggestions.
- It was good. Picked up some things and have used some of the recipes. Good reminder/reinforcement of what I already knew.

Facilitators modified the content of some sessions. This included reducing the number of off-site excursions to two (session 4 and 6) and making these predominantly healthy activity focused. The healthy eating session structures remained similar to the original design with the only major change being the combining of content from session four with session five.

In addition to the amendments of the programme content and delivery, two additional decisions were actioned. The first was the employment of an experienced child care advisor who could also undertake some of the administration duties for programme delivery in 2008. The second change was the availability of transport, with age appropriate child care seating for each session, enabling participant with no transportation to attend sessions. This service was intended to reduce some of the barriers which some participants faced when considering whether they wanted to attend future *Healthy Me and You* programmes.

Measures were not tested with pilot participants as during the development or validation of each, they had undergone testing, as had their accompanying instructions.

3.2 Description of the *Healthy Me and You* programme

The Southland Healthy Eating Healthy Action Programme comprised of two phases: a workforce development programme (phase one) and *Healthy Me and You* (phase two). The programme was originally intended to be completed over a 30 month period however this was lengthened to three years to enable all data required for the impact evaluation to be collected. This section provides information about both phases.

3.2.1 Phase two: *Healthy Me and You* (the intervention)

Each *Healthy Me and You* programme was delivered by a team of a dietitian,[19] physical activity adviser and childcare advisor that comprised six two-hour sessions delivered weekly over successive weeks. To comply with early childhood regulations, additional adults were employed casually to ensure appropriate adult to child ratios were observed.[20] A health promoter was employed in Dunedin to undertake all work aligned to recruitment and engagement with the comparison group.

Transport and childcare was offered (see Section 3.3) and a free-calling 0800 number was made available to enable all participants to contact staff if problems occurred during the data collection period. Participants were invited to bring a support person with them to the programme sessions. Sessions were delivered in the morning at a community venue. Caregivers were contacted the day before each session (text or phone call) to confirm their availability. Transportation was also confirmed (if required) and collection times arranged.

Each session included a theory and practical component within the healthy eating and physical activity modules except for weeks four and six sessions. These were "off-site", therefore all food was prepared in advance, by *Healthy Me & You* programme staff. The theory component involved only the caregivers with the respective health professional

[19] Due to staff changes, the healthy eating components of courses run in the later stages of 2008 were delivered by three different dietitians.

[20] Additional children such as siblings or other children being cared for by the caregiver were able to attend. Child to adult ratio was based on 4:1 assuming that most infants present would be cared for by their mother.

(dietitian or physical activity advisor), while all practical components involved all children and adults present. At the conclusion of each session, children were provided with take-home gifts such as a skipping rope, chalk, vegetable peeler, drink bottle or ice block maker which related to the activities for that day. For some sessions, caregivers were given homework. Volume B of this thesis contains a Teacher's Guide for the programme, providing detailed instructions for the various modules as identified in Table 7.

Table 7: Programme modules for *Healthy Me and You*

	Healthy Eating module	**Physical activity module**
Week 1	Title/Theme: Child development Relating child development to eating skills and behaviours plus an introduction to the parent/child feeding relationship and the roles that children can play in food preparation according to age.	Title: Introduction of physical activity Theme: Benefits of PA Personalising the benefits of PA, health benefits and other benefits, and fun novel physical activity with the group including caregivers and children together: Increases intrinsic motivation to be active and enhances outcome expectancies.
Week 2	Title/Theme: Fussy eating Identification and discussion of meal time behaviour problems and management strategies.	Title: Child development and physical activity Theme: Incidental activity Review benefits of PA via case study. Introduce the concept of incidental activity as a first step towards increasing their physical activity levels. Practical component: active play opportunities for children accounting for perceived barriers, and highlight critical aspects of physical activities for child development.
Week 3	Title/Theme: Fruit and vegetables Practical F&V activities involving both parents and children and discussion of how to incorporate F&V into daily eating.	Title: Increasing PA Theme: Overcoming barriers and local PA opportunities Build knowledge of ways to overcome barriers to PA – increases self efficacy to be active. Includes 'PA Buddy' activity linking participants with supportive partner. Activity diary encourages moving from incidental activity to also planned regular PA. Overview of PA opportunities in local area especially free/low cost activities.
Week 4	No formal module delivered Focus of this session was entirely on PA however a healthy picnic was provided but food prepared in advance.	Title: Maintaining physical activity (Park session)[21] Theme: Goal setting and self monitoring Visit to fun PA venue eg. Park, changing attitudes to PA and experiencing the benefits of PA. Building on last session (regular PA, self monitoring) through goal setting and self reward.
Week 5	Title: Marvellous meal times Theme: Mealtimes / Budget Practical ways of making mealtimes enjoyable and child friendly. Budgetary cost activity and demonstration of practical budget related food skills.	Title: TV time Theme: Reducing screen time Strategies for reducing screen time and why families may need to reduce their screen time. Participants individually state which strategies they will adopt.
Week 6	No formal module delivered Practical and fun demonstration of healthy celebration food, incorporating F&V.	Title/Theme: Celebration session (at swimming pool)[22] Participants receive personalised Screen Time 'Contract' to sign. Celebrate with fun PA e.g. pool, enhances outcome expectancies of PA and intrinsic motivation.

[21] Gardening session offered as wet weather alternative to park session.
[22] Teddy bears picnic offered if a swimming pool was not available for celebration session.

Programme locations

Healthy Me and You programmes were offered only during the four school terms to maximise attendance rates of participants. Communities were identified based on their NZDep2006 Index score (see Appendix A). There were insufficient numbers for programmes to be offered in some areas[23] so instead a condensed "one-off" half-day programme was offered in early 2009 to families from these areas, together with one in Invercargill. In term one courses were held in Queenstown, Invercargill and Ohai/Nightcaps. Two courses were held in Invercargill in term two along with one in Mataura/Wyndham. One course in both Invercargill and Riverton were held in term three, while term four courses consisted of two in Invercargill, one in Otautau and a second course in Queenstown. Staff were based in the city of Invercargill and for all programmes (except Queenstown) they travelled to each rural community township the day of the session (up to an hour away).

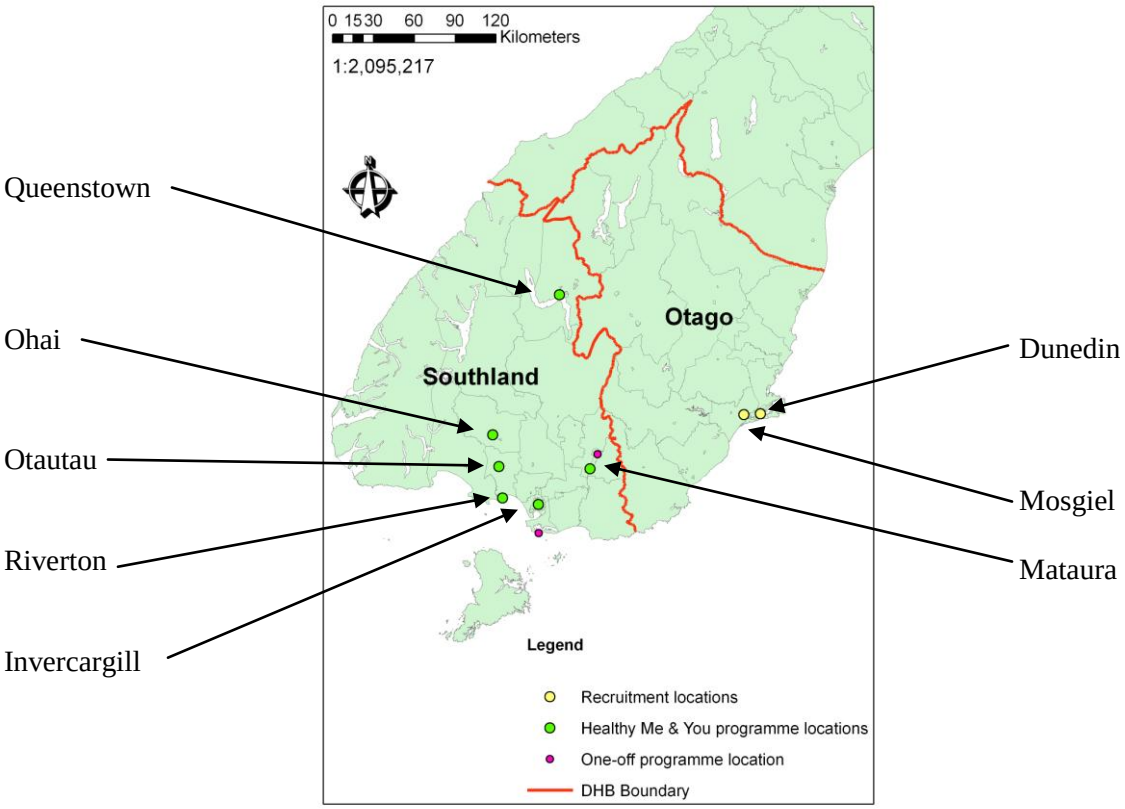


Figure 6: Map of programme locations (intervention group) and recruitment locations (comparison group)

[23] Bluff (20 minutes south via car from Invercargill) and Gore (10 minutes north via car from Mataura).

3.2.2 Phase one: Workforce development

The aim of the workforce development programme was to provide agencies and their employees with knowledge and transferable skills to ensure a consistent message was presented by agencies working with children under five and their caregivers. Each programme consisted of four three-hour sessions which covered the eight HEHA population key messages (Table 1) together with Motivational Interviewing and Cultural Sensitivity modules. Appendix G contains two logic models including one aligned to the HEHA Innovation Fund minutiae as described in Section 1.2).

Six courses were offered in mid 2007. Twenty-three health and social service agencies were approached and invited to attend the workforce development courses. Twenty initially indicated that they were interested in having their staff attend but only nine were able to release staff. From these nine agencies, 75 registrations were received but not all attended all four sessions. Overviews of each session delivered were available on the SHEHAP website and were promoted to all agencies. These details included key messages, some notes and adapted presentations from guest speakers.

All participants were asked to complete an initial questionnaire of their knowledge of the HEHA messages and this was repeated at the conclusion of the training. A third questionnaire was circulated to participants four months after attending the workforce development training which focused on the benefits gained from attending the course. Findings from all three questionnaires are not reported in this thesis because they were outside its scope.

4 METHODS FOR EVALUATION

This chapter describes the process followed to measure the effectiveness of *Healthy Me and You* and was achieved by using impact evaluation to answer the three aims described in Figure 3.

4.1 Study design

The study design was of a quasi-experimental nature with participants from Southland assigned to the *Intervention Group* and those recruited from Otago assigned to the *Comparison Group*. Approval was provided by the University of Otago Human Ethics Committee 07/186 (25 September 2007) and the Royal New Zealand Plunket Society Ethics Committee (28 September 2007) for the study (see Appendix E).

4.1.1 Sample size

Initial sample size calculations were based on information from existing New Zealand datasets (NNS97 and 1996/97 NZHS). In order to detect a 0.75 difference in the number of servings of fruit and vegetables assuming a 1.25 serving standard deviation,[24] and using a two-sided test at the 0.05 level, 44 caregivers were required in each group. To detect a 15 minute daily difference in exercise in the same way assuming a 35 minute standard deviation, [25] 86 caregivers were required in each group. These calculations were based on the number of adults required and assumed 80% power to detect these effects. Based on these estimates, four programmes were planned to be delivered during each of the four school terms in 2008. Each programme was to include, on average, six primary caregivers. This equated to 96 primary caregivers in the intervention group which would then be appropriately matched to a comparison group and would allow for up to ten percent dropout or missing data. Data on the comparison group were, wherever possible, collected within four weeks of the corresponding data from the intervention group to minimise confounding from external environmental factors. It was further assumed that any design effects introduced from delivering the intervention via these programme groups would be negligible and not affect the sample size calculations.

[24] Based on the 1997 National Nutrition Survey data.
[25] Based on results from the 1996/97 New Zealand Health Survey.

4.2 Sample

The sample was drawn from socially disadvantaged populations within the Southland DHB catchment area. This was defined for this study as households with Māori or Pacific preschool aged children (three to four years) or households living in greater than average deprivation areas[26] (Salmond, Crampton, & Atkinson, 2007). A comparison sample from the neighbouring DHB Otago was matched at an individual level by the sex and ethnicity of the child as well as the corresponding household NZDep2006 Index score. For practical reasons,[27] the area identified for the comparison group was the Dunedin metropolitan region including Mosgiel, shown in Figure 6.

Table 8: Key characteristics of the 2006 census of population and dwellings by DHB

	Otago DHB n (%)	Southland DHB n %
Sex		
Male	87,363 (49)	53,346 (50)
Females	92,034 (51)	53,481 (50)
Age group		
0-4	9,846 (5)	6,924 (6)
5-19	37,890 (21)	21,93 (21)
20-39	47,922 (27)	29,199 (27)
40-64	57,876 (32)	34,980 (33)
65+	25,866 (14)	13,800 (13)
Ethnic group[28]		
NZ European	138,873 (77)	80,886 (76)
Māori	11,466 (6)	11,319 (11)
Pacific peoples	3,018 (2)	1,584 (1)
Asian	6,876 (4)	2,070 (2)
Middle Eastern/Latin America/African	963 (1)	468 (0)
Total, other ethnicity	24,642 (14)	15,822 (15)
Missing information	5,322 (3)	3,777 (4)
Areas by New Zealand Deprivation Index (NZDep2006 Index)		
Deciles 1-5 (lower deprivation)	96630 (54)	67530 (63)
Deciles 6-10 (higher deprivation)	82764 (46)	39273 (37)

Source: (Statistics New Zealand, 2007) (Southern District Health Board, 2010)

Both Otago and Southland DHBs have similar key population characteristics, shown in Table 8 with the exception of a proportionately higher population of Māori (11%) and

[26] NZDep2006 deciles 6-10 inclusive.
[27] Proximity to Dunedin (where health promoter was based) and balancing role expectations in relation to hours employed.
[28] Individuals could identify with more than one ethnic group therefore percentages add to more than 100 percent.

63% of Southlanders residing in decile areas 1-5 compared to Otago (Māori 6%; decile areas 1-5, 54%). Figure 1 identifies the two DHB area's. The remainder of New Zealand is divided into 19 other DHB area's (boundaries not shown in figure).

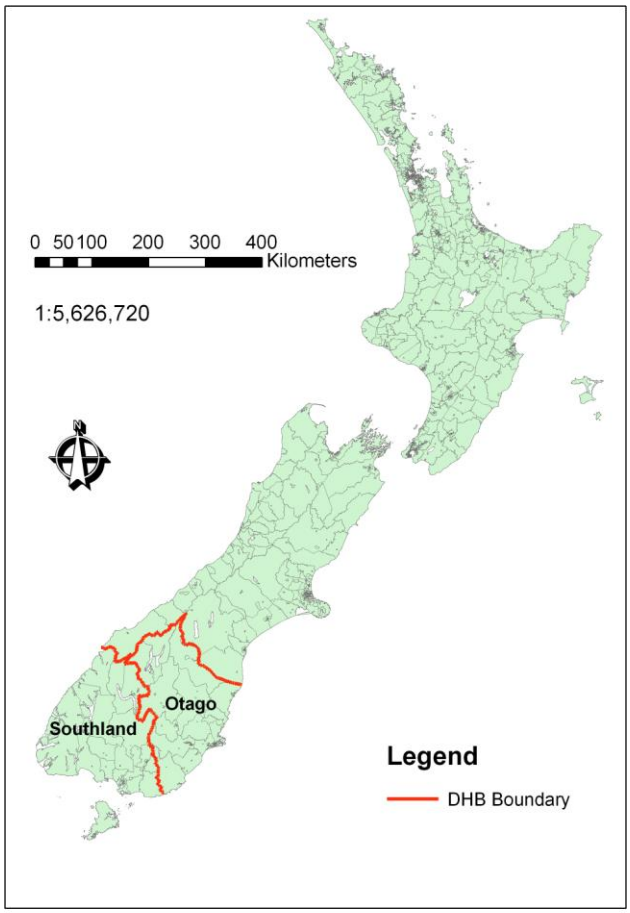


Figure 7: Map of New Zealand and study populations

4.2.1 Recruitment of study participants

For the intervention group, health and social service agencies were asked to identify clients who met the study's entry criteria (Table 9) and, in their opinion, would benefit from attending *Healthy Me and You.* Referral pathways were developed and copies of printed materials sent to community agencies outlining the study entry criteria (including maps of eligible areas). Contact details for programme staff and study timeframes are found in Appendix H.

Table 9: Study entry criteria

	Inclusion Criteria
1	Have a relationship with the referring agency
2	Child is three or fours years
3	Households reside in NZDep2006 Index deciles 6-10 for non-Māori or non-Pacific families , or child is identified by their caregiver as Māori or Pacific
4	The caregiver is the primary caregiver for the child when in the home

In addition to the identified caregiver meeting the entry criteria, referred participants were only recruited if they were interested in participating in the study. Self-referrals were not accepted. Recruitment took place during January to October 2008.

A similar process was followed in Otago to obtain the comparison sample. However, some recruitment hurdles were anticipated, including less interest due to not having an incentive such as participating in a health promotion programme, and also difficulty matching at an individual level. Due to theses anticipated challenges, it was agreed prior to recruitment commencing, to widen the scope of community agencies outside health and social service agencies to include preschool educational facilities and child orientated community events which attract the study's target audience. This approach also assisted with ensuring adequate numbers and/or matching was obtained. Recruitment from both the intervention and comparison participants commenced in February 2008 and concluded 12 months later. Figure 8 illustrates the overall referral pathway followed to obtain both samples.

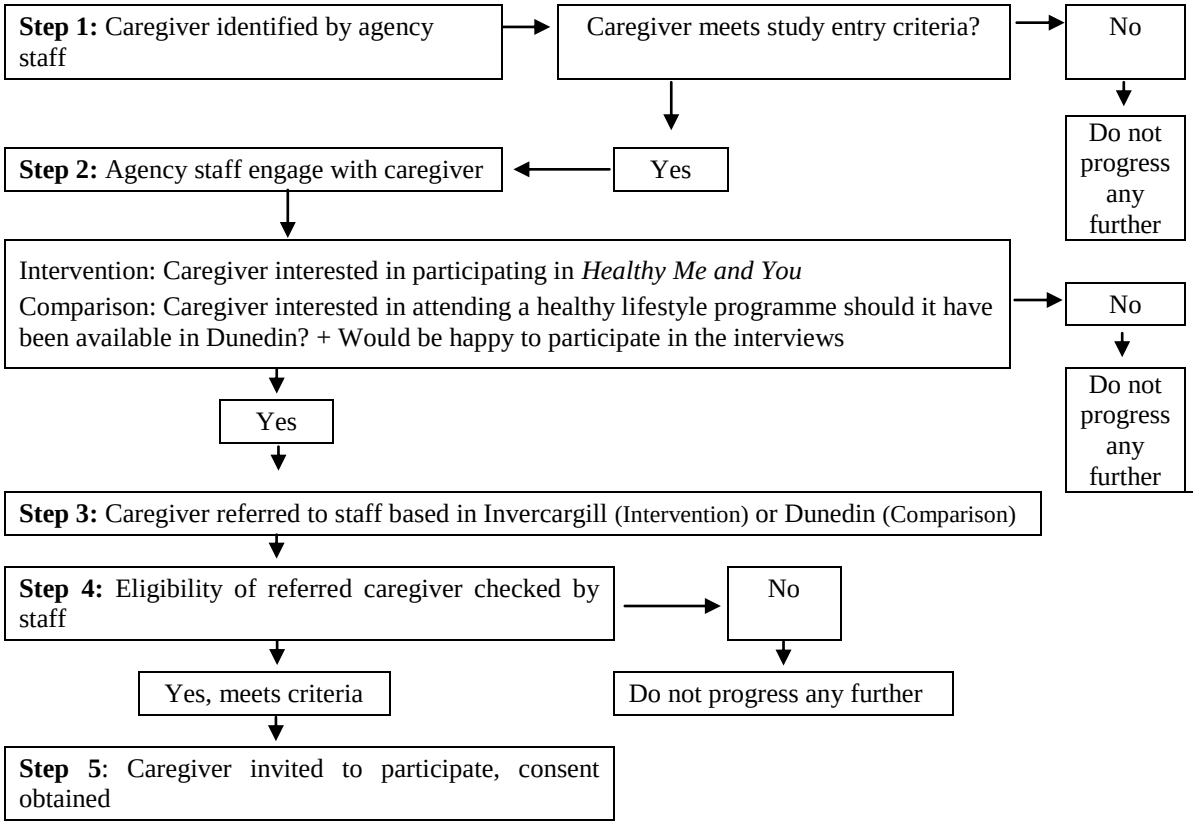


Figure 8: Referral pathways for both samples

SHEHAP staff observed that Southland agency staff were more likely to refer their clients to *Healthy Me and You* if they had attended the workforce development sessions (phase one SHEHAP) offered in 2007 (N. Willis, personal communication, 12 March 2009).[29]

4.3 Measurement instruments

Details describing the process followed to measure the three outcomes of interest: child physical activity in minutes; number of fruit offerings to child by caregiver; and number of vegetables offerings to child by caregiver are described below.

[29] Workforce development courses were not offered in Otago.

4.3.1 Assessing physical activity of the child (in minutes)

Objective measures, such as accelerometers, are increasingly being used to measure physical activity (PA) levels in children, and the use of validated and reliable instruments is desirable when measuring the effectiveness of programmes. The New Lifestyles NL-1000 accelerometer is affordable (approximately US$50 in 2010), it can measure time spent being active at given intensities, and it has a seven day memory, shown in Figure 9. It has previously been validated on adults (Ayabe, et al., 2006; McLean, et al., 2009) and more recently in children aged 10-13 years (modifying the manufacturers settings for measuring moderate to vigorous physical activity (MVPA)) (McMinn, Rowe, Stark, & Nicol, 2010). This device was identified as an appropriate instrument to measure PA but a study to determine the validity and reliability of the New Lifestyles NL-1000 accelerometer among preschoolers using a modified version of the Children's Activity Rating Scale (CARS) was required (Liggett, Gray, Parnell, McGee, & McKenzie, 2012) (see Appendix I). Participant information sheet and consent forms are found in Appendix J.

Results from this study showed that within subject reliability (measured using intra-class correlation coefficients), were similar, 0.58 for CARS and 0.59 for NL-1000. A clear linear association between the standardized datasets were also found, with most of the variation in CARS (95.4%, 95% Confidence Interval 92.6-97.5) explained by variation in the NL-1000 measurements, with 2.4% of the variation being participant-specific. These findings demonstrate that the NL-1000 is a valid means of measuring PA as it provides a comparable a level of reliability to the modified CARS.

Figure 9: New Lifestyles NL-1000 accelerometer

Caregiver and child PA was assessed by the NL-1000 with MVPA activity duration in minutes and corresponding steps measured. All participants were assigned the same NL-1000 device at both data collection periods unless the device was either lost or no longer operational. In such cases a new device was assigned.

4.3.2 Assessing fruit and vegetable offerings to child

Many factors make assessing food intake in preschoolers difficult. They include a high number of eating events and variable eating patterns, challenges recording information due to multiple caregivers and ever changing food intakes due to rapid growth and development for children in this age group (Hertzler, Bowens, & Hull, 1993; Stein, Shea, Basch, Contento, & Zybert, 1991, 1992). Dietary Assessment tools for use with preschool children were reviewed (Andersen, Lande, Trygg, & Hay, 2004; Bollella, et al., 1999; Iannotti, et al., 1994; Klohe, et al., 2005; Metcalf, et al., 2003; National Cancer Institute, 2007; Parrish, Marshall, Krebs, Rewers, & Norris, 2003; Serdula, Alexander, Scanlon, & Bowman, 2001; Ziegler, Briefel, Clusen, & Devaney, 2006) and particularly those for the assessment of F&V intake in children (Cade, Frear, & Greenwood, 2006; Cox, Skinner, Carruth, Moran, & Houck, 1997; Haraldsdóttir, et al., 2005; Linneman, et al., 2004). There were no published data in 2007 of standard portion sizes for F&V in preschoolers (3-4 years) suitable for the *Healthy Me and You* study. It was therefore decided to measure the number of offerings of F&V to the child by the caregiver as a surrogate for F&V intake because total dietary assessment was not being sought and we weren't in a position to visually measure intake. This decision assumed that there would be moderate to strong correlation between caregiver offerings and child consumption, a theory supported by (Dhingra, Sazawal, Menon, Dhingra, & Black, 2007). It was understood that some underestimation of offerings would occur, such as when the child was offered F&V by other caregivers e.g. at a child care centre. It was also assumed that parental reporting would be representative of the caregiver's normal F&V offering to that the child and would not be adjusted by caregivers due to their study participation.

Development of the Fruit and Vegetable tick-list

Table 10 outlines the process followed to determine the final instrument in *Healthy Me and You*, the F&V tick-list.

Table 10: Development of the F&V tick-list

Steps followed	Description
1. Methods identified	Food Frequency Questionnaire (FFQ), diet recall, food record
2. Instruments trialed (n=3), all captured types of F&V offered and number of offerings	Option A: 3 day prospective F&V check-list (FFQ) Option B: 3 day F&V record (self report with daily reminder phone calls) Option C: 3 day F&V diet recall (phone interview)
3. Review of instruments, modifications and additions made	3 days increased to 5 days for all options Option A: renamed as the F&V tick-list Development of Option D: telephone administered F&V FFQ
4. Development of evaluation included layout, readability and understanding questions	Options tested on mothers with preschool aged children (Option A n=2 ; Option B n=1; Option C n=1, Option D n=3)
5. Review feedback and identify preferred option	Participant feedback showed preference for Option A (F&V tick-list). It was noted by caregivers that daily reminder texts were helpful.

The F&V tick-list collected information about four food groups: fruits; fruit and vegetable juices; vegetables; and dishes with vegetables including soups. Data were collected by the caregiver on five separate days in a seven day period.[30] If fruit or vegetables were offered to the child when the caregiver was not present, data were not recorded. Examples of a complete day of data and subsequent scoring, are found in Appendix K.

Inclusion criteria: Juice and soup

Caregivers recorded juice or soup offerings on the F&V tick-list. Inclusion criteria (i.e. whether these contained sufficient fruit or vegetables to be counted as a 'fruit' or 'vegetable' offering) were developed (see Appendix L). They depended on the additional information obtained from the supplementary interview (visit 2 or 4). This information was used to enable a coder[31] to determine whether the offering could be counted.

[30] Days were not required to be consecutive and may or may not include a Saturday or Sunday.
[31] All coding was undertaken for both groups by one individual. The coder was one of the SHEHAP staff therefore was not blinded to the intervention group.

4.3.3 Interview schedules

This section details all measures collected from the interview schedules (core and supplementary) at both time points (baseline and follow-up). The core interview schedule included socio-demographic data and behavioural questions, while the supplementary interview schedule collected information on PA behaviour and additional information required to code juice and soup offerings. Follow-up interview schedules were similar to those used at baseline. Some socio-demographic questions were not repeated. Most questions had been specifically designed for *Healthy Me and You*. Copies of all schedules and show cards are found in Appendix M.

Caregiver, child and household characteristics

Caregiver characteristics included age, sex, highest level of education, current employment status and relationship with the participating child. Highest level of education was coded based on 2006 Census coding: None, NCEA1, NCEA2, NCEA3, Vocational and University equivalent. NCEA [32] levels one to three are levels of secondary school education achieved with NCEA1 being equivalent to the UK GCSE[33] and NCEA3 equivalent to the UK GCE A levels[34]. Caregivers were asked to describe their current employment status as full time, part time or other.

Child characteristics included age, ethnicity (as defined by the caregiver) and childcare arrangements. The 2006 New Zealand Census ethnicity question was used (Ministry of Health, 2004d). However Chinese and Indian options were combined as Asian, due to the small numbers in the study regions (Table 8). If caregivers identified their child belonging to more than one ethnic group, ethnicity was prioritised (Māori taking priority over Pacific which took priority over all remaining ethnicities).

The weekly amount of daily childcare[35] with someone other than the study caregiver was determined in both the core interview and supplementary interviews. The core interview detailed what was a typical or normal week for the child while the supplementary interview determined arrangements "over the previous week". The child's household

[32] National Certificate of Educational Achievement.
[33] General Certificate of Secondary Education which replaced GCE O-Levels in 1988.
[34] General Certificate of Education Advanced Level.
[35] Paid or unpaid.

environment was described including the number of adults and children (under 18 years) in the household, and whether the caregiver resided in the household all or some of the time.

Dietary habits of caregiver and child

Assessing F&V intake of caregivers was undertaken by using key questions from "Your usual food intake" questionnaire, a qualitative FFQ designed for the NNS97 (Russell, et al., 1999).

Two food habit questions adapted from the CNS02 (Parnell, et al., 2003) were used to identify if there were any foods which the child did not eat. Category options included: All meats, Red meat, Chicken, Fish, Dairy product, Eggs and Others.

Family food environment of child

Two questions assessing meal preparation practices (child involvement in food preparation and food shopping) and one question assessing family meal structures were asked. Questions were adapted from a Family Food Environment study with children aged 5-6 years (Campbell, et al., 2002).

Physical activity of caregiver and child

Caregiver and child PA was assessed by the NL-1000. Caregivers were also asked to report any *extra PA* undertaken over the past seven days (MVPA for caregivers, any for children). This was self-reported activity which was unable to be captured by the NL-1000 such as swimming[36] and cycling, and, for caregivers only, strength type activities[37]. Questions used were based on the Short Form, New Zealand Physical Activity Questionnaire (NZPAQ-SF) (Sport and Recreation New Zealand, 2004).

To aid with implementation of *Healthy Me and You*, all participants were asked to identify "Anything which limited either their activity or their child's activity".

[36] Also including aqua jogging or aerobics; water polo or canoe polo; surfing or body boarding; diving; water skiing or wakeboarding; canoe, kayak, or rowing.
[37] For example muscle toning exercises; yoga or pilates; weight training; indoor rowing; shoveling, for example in the garden; chopping wood.

Sedentary behaviours of caregiver and child

The daily average time caregivers watched or looked at a small screen (ie home computer, video games) excluding work[38] was sought using a modified version of questions from the World Health Organisations Global Physical Activity Questionnaire (GPAQ) (Armstrong & Bull, 2006). Caregivers were also asked to report child's daily viewing habits using a question from the Be Active Eat Well Project (Sanigorski, Malakellis, Kremer, & Swinburn, 2008b).

Caregivers were asked to report TV watching habits of their child when eating main meals or snacks. Questions originated from The FLAME Study (Taylor, et al., 2009). Responses available included: ≥5 times a week, 3-4 times a week, 1-2 times a week, 1-3 times a month, <1 a month, Never and Not applicable.

4.4 Data collection procedure

Figure 10 outlines the data collection process. Participants from the intervention group were asked to attend the six week programme *Healthy Me and You*. Participant information sheets and consent forms are provided in Appendix N.

Where there was more than one eligible child in the household (i.e. twins) interviewers were provided with a list of random numbers to assist with selecting one study child from the household.

Data were collected between January 2008 and August 2009. Information was collected at baseline and follow-up using three instruments: NL-1000; F&V tick-list; and the interview schedule (core plus supplementary interviews). Show cards were provided for most questions, enabling caregivers to easily identify their answers.

[38] The GPAQ instrument uses a separate question to assess sedentary behaviour at work. This was not included as it was assumed that the study child would not be present during this time and therefore not reflective of active role-modeling behaviour.

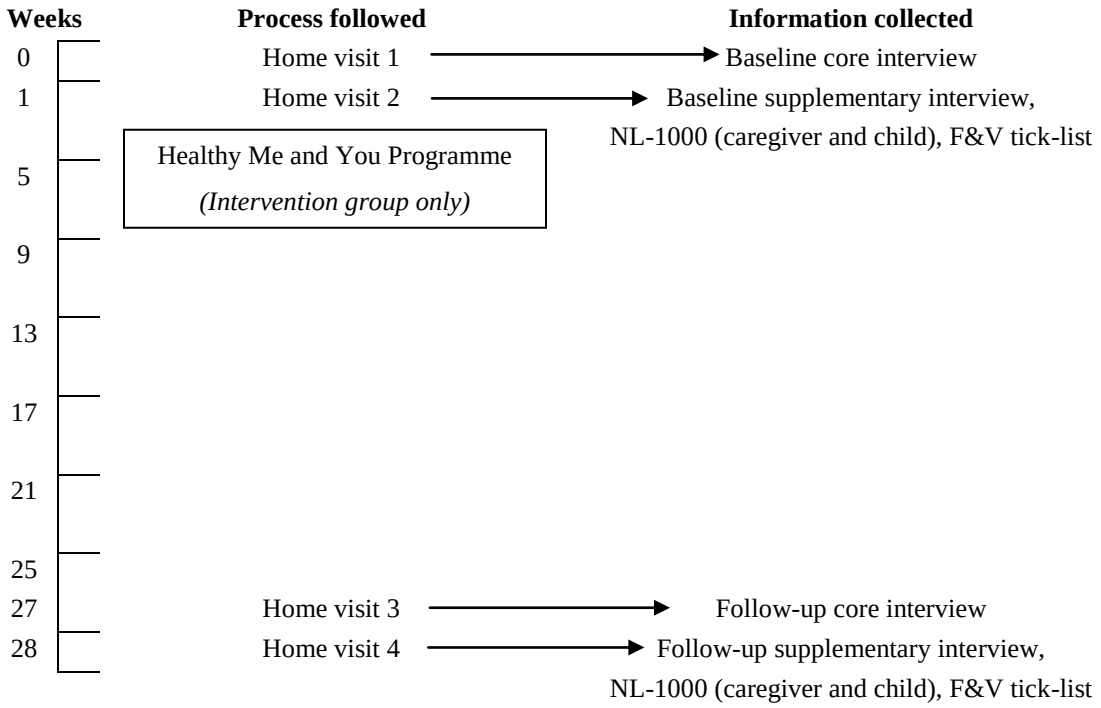


Figure 10: Study flow-chart and timeframe

Baseline interviews were undertaken on day zero with instructions given on how to use both the NL-1000 and F&V tick-list (see Appendices N and O.) Participants (caregiver and child) were then each asked to wear the NL-1000 for the next seven days (days 1-7 inclusive) and the caregiver was asked to fill out the F&V tick-list on five[39] of those seven days. Daily reminders via text were sent to caregivers reminding them to complete the F&V tick-list and wear the NL-1000. Caregivers were then visited at home by the interviewer on day 8 where the caregiver answered the supplementary interview questions and the interviewer collected the F&V tick-list and both NL-1000's. When data were collected on day 9, only 6 days of data from the NL-1000 (days 2-7 inclusive) would be recorded as the device had a seven day memory. The same timeframes and processes were repeated for follow-up data collection at six months. Participants were, where possible, given the identical device at follow-up to minimise external validity.

All caregivers were rewarded with a $20 grocery voucher (from a supermarket of their choice) on the completion of both the second and the fourth home visits.

[39] Days were not required to be consecutive and may or may not include a Saturday or Sunday.

4.5 Statistical methods

All analyses were performed using Stata Statistical Software (version 10, Stata Corporation, Texas, USA, 2003) using two-sided tests with $p<0.05$ considered to be statistically significant.

4.5.1 Data cleaning

Data collected from all interview schedules (NL-1000 data were recorded directly into the supplementary interview schedules) and F&V tick-list were entered into a Microsoft Access (version 2003 database), specifically designed for the study. All data entry was verified by an independent data entry operator by means of blinded duplicated double entry. Consent forms were removed from all records to ensure anonymity for participants.

Minor modifications were made to data records prior to any analysis being performed. This included excluding daily step counts and corresponding activity minute data if the data recorded for daily step counts was under 1000 steps (Rowe, Mahar, Raedeke, & Lore, 2004), as they were deemed not to have followed wearing instructions correctly. NL-1000 data were also excluded if someone else other than the participants (caregiver or child) wore the device for one or more days.[40]

4.5.2 Statistical analysis

Descriptive statistics were used to describe all measures collected or created and are reported for the total study population for both baseline (Chapter 7) and follow-up for each group (Chapter 8). Following data collection and prior to any analyses performed, nine variables were either recoded or modified as shown in Table 11.

[40] The spouse of one caregiver wore the NL-1000 at both data collection points.

Table 11: Variables requiring recoding or modification

Covariates	Description
Highest Education	The six categories were collapsed ie: none/NCEA1, NCEA2, NCEA3/Vocational, University equivalent.
Employment	Information collected on employment status was recoded to determine whether caregiver was in paid employment or not. Paid employment was defined as full time, part time, causal, seasonal work or being self-employed.
Child ethnicity	Ethnicity was later collapsed into Māori /Pacific and non-Māori/non-Pacific.
Child care hours	Collected information on normal arrangements (core interview) and actual arrangements (supplementary interview) over seven days. Details were then modified to identified children whose actual care arrangements were 25% different to their normal arrangements and then to determine the hours of care which child spent with caregiver.
Child resides with you	The scale was amended to include the option mostly, allowing responses for caregivers with regular custody arrangements to be more accurately categorized.
Food habits questions	A composite variable entitled dislikes anything was created from the food categories (all meats, red meat, chicken, fish, dairy product, eggs and other) for both child and caregiver and collapsed into yes or no if any of the eight categories were answered yes.
5+ a day	This variable was created from combining individual answers from the 1996 NNS Qualitative FFQ, questions 2 and 3.
Family food environment questions	The five point scale used for these questions was collapsed due to small numbers into never/seldom, sometimes, mostly/always.
Location	*Healthy Me and You* programme locations was recoded into rural and urban locations based on the presence or absence of a hospital.[41]

4.5.3 Statistical processes followed

Attributes predicting baseline outcome variables

Model design: Tobit regression (Amemiya, 1984) was used to model child PA minutes due to the truncated nature of the NL-1000 activity minutes data with a daily ceiling level of 199 minutes and 56 seconds.[42] Similarly, the numbers of *fruit* or *vegetable* offerings to the child by the caregiver, as count variables were modelled using Poisson regression (Frome & Checkoway, 1985). As all outcome variables were obtained from repeated measures (ie: 7 days PA minutes, 5 days offerings of *fruit* or *vegetables* to child by caregiver), a random participant effect was included. Effects reported are coefficients for continuous (untransformed) outcomes (tobit), ratio's of geometric means for continuous

[41] Travel time greater than 15 minutes.
[42] The NL-1000 was unable to display activity minutes greater than 199 minutes and 56 seconds therefore daily activity minutes for the wearer was capped at this value.

(transformed) outcomes and rate ratios (RR) for count outcomes (poisson). All regression models were checked by performing residual diagnostics including histograms and scatter-plots to determine whether the assumptions required for the regression models were satisfied. For tobit regression models, histogram of the residual was checked to ensure it was normally distributed and if not, a log transformation was investigated.

For all tobit regression, a scatter-plot was used to check the linearity of associations for continuous independent variables, (i.e. residual plotted against predictor). For any continuous covariates, scatter-plots of the residuals against these variables were also examined. Levene's test was performed on any categorical covariates to examine identify cases where residuals had non-constant variances.

Analysis plan: Figure 11 and Figure 12 show the analysis plan for each outcome variable. For all plans, four identical steps were followed. Step 1 to 3 were initial analyses which used $p<0.2$ as the cut-off criteria for each of the explanatory measures progressing to the next model. The first step was univariate regression. Step 2 was multivariate regression involving covariates with $p<0.2$ from step 1 from five initial blocks (Characteristics: child, caregiver and household; Behaviours: child and caregiver). The third step included all covariates with $p<0.2$ from step 2 into combined characteristics and combined behaviours. The final regression model was generated by merging the covariates with $p<0.2$ from step 3.

Effectiveness of Healthy Me and You

Model design: As described in aim one.

Analysis plan: Figure 13 shows the analysis plan for each outcome variable. For each, three identical steps were followed, the example provided being child PA minutes, outcome variable 1. Step 1 considers the effect of the programme on each outcome variable while controlling for the baseline data of the outcome variable of interest. Step 2 then extends on the first model including a series of characteristic variables (covariates), initially individually. Step 3, combines the covariates with $p<0.2$ from step 2.

Subgroup analysis of Healthy Me and You participants

Model design: As described in aim one.

Analysis plan: The analysis plan for each outcome variable is shown in Figure 14. Two steps were followed for each. Step 1 considers the three intervention subgroups of interest (urban or rural location; level of caregiver attendance; and presence of a support person), each subgroup is considered separately while controlling for the baseline data of the outcome variable being investigated. Step 2, combines those covariates with $p<0.2$. Due to the small sample size, no further variables were considered in these models.

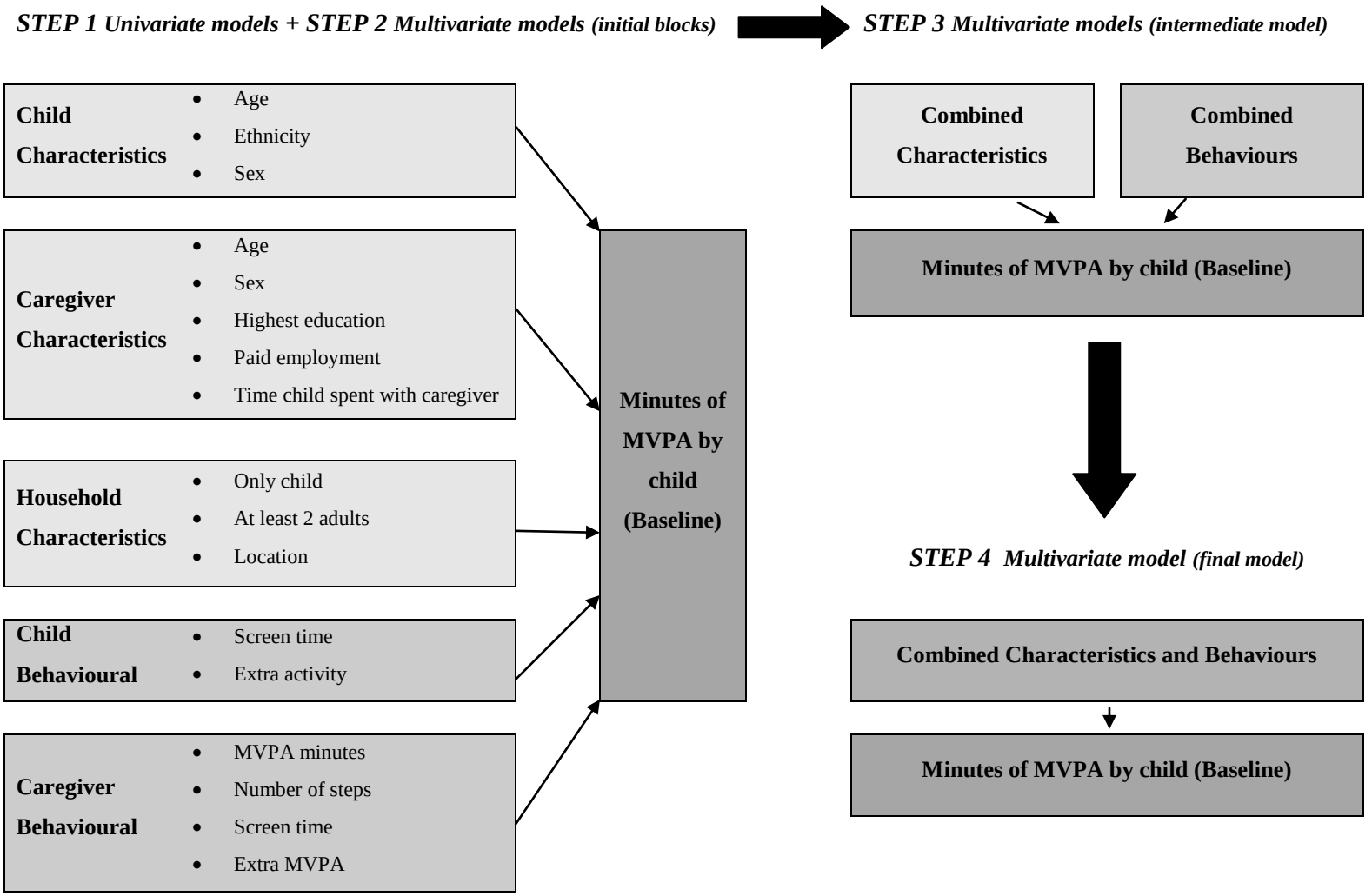


Figure 11: Analysis plan for covariates of Child Physical Activity (Outcome variable 1)

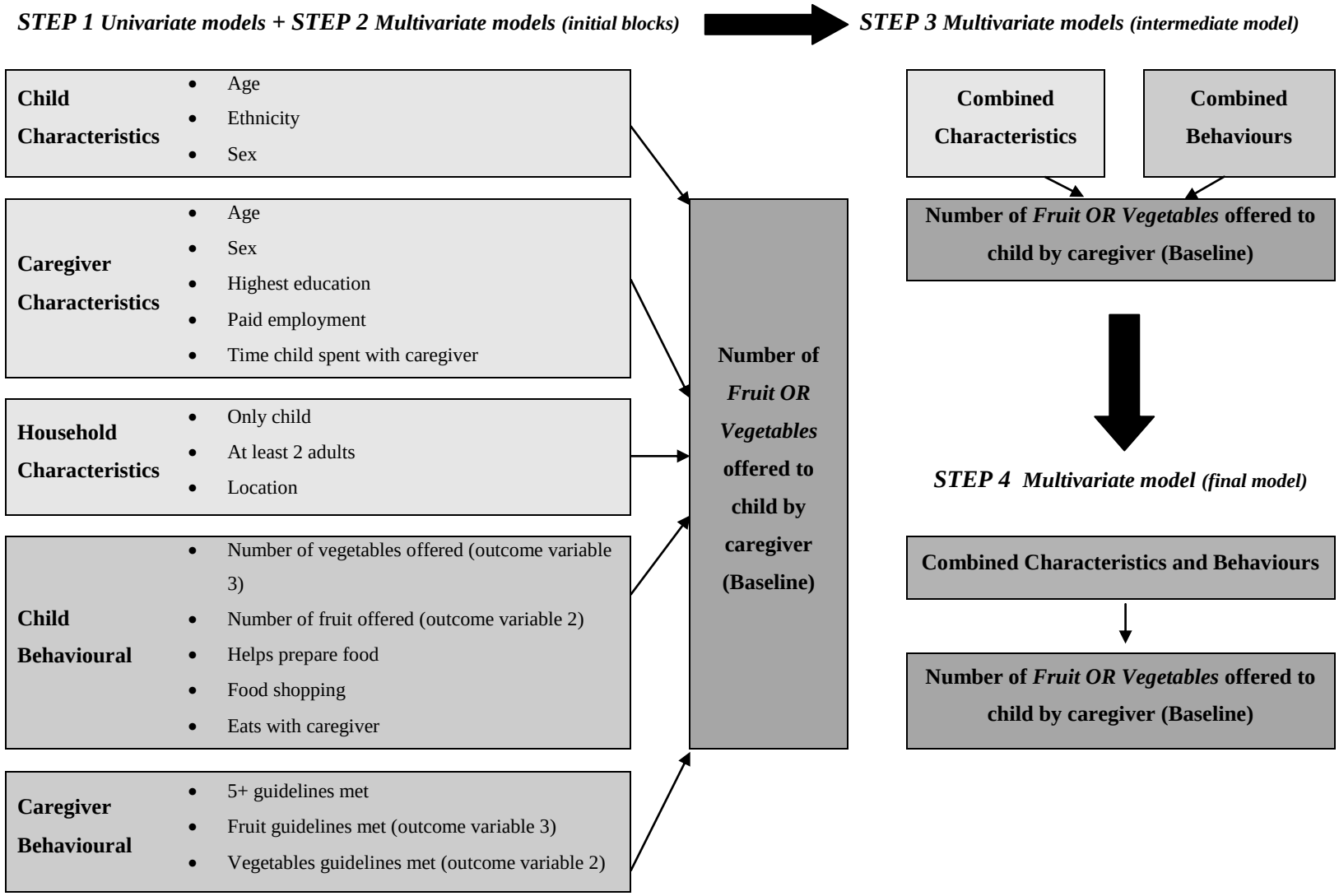
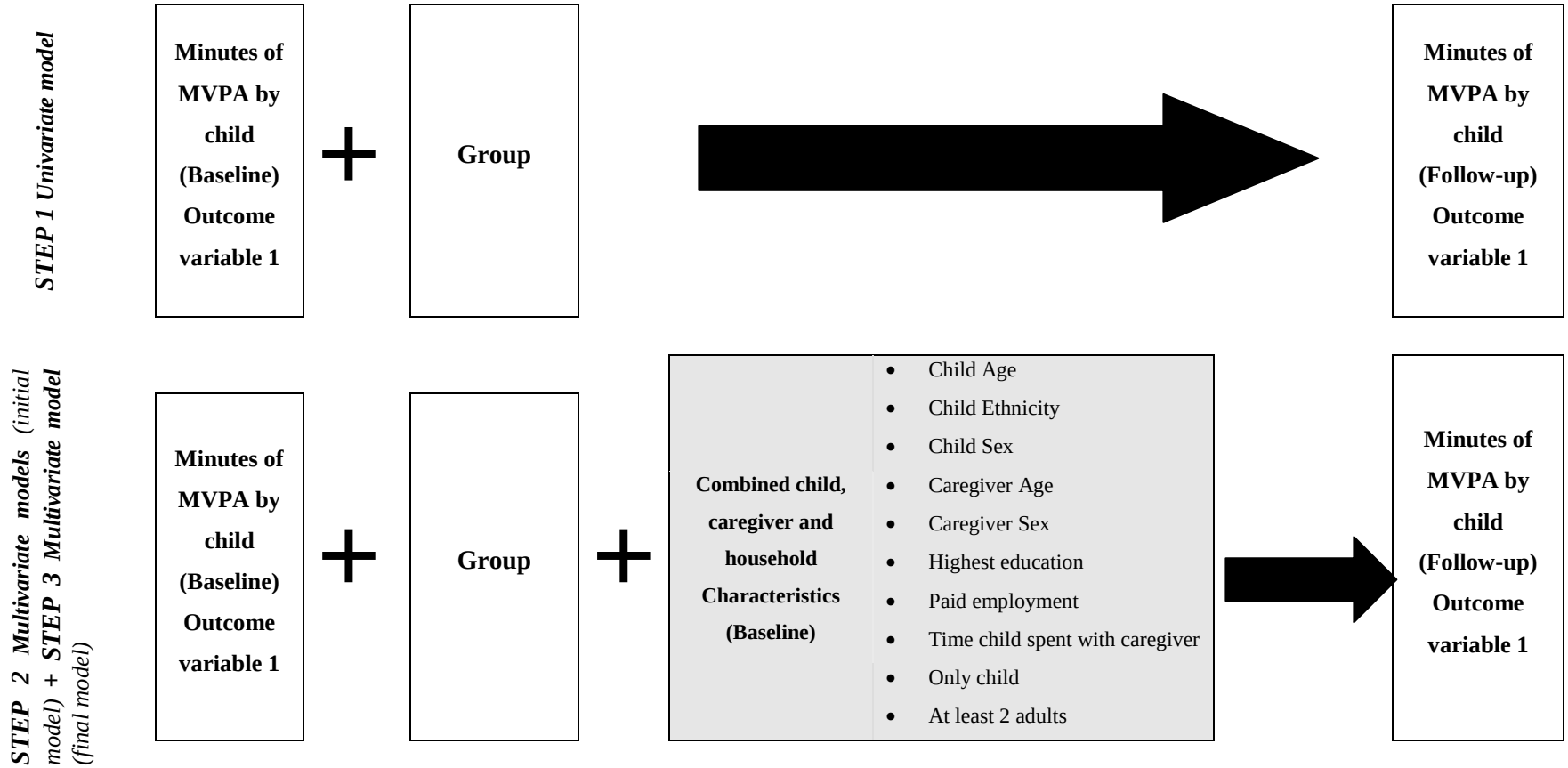
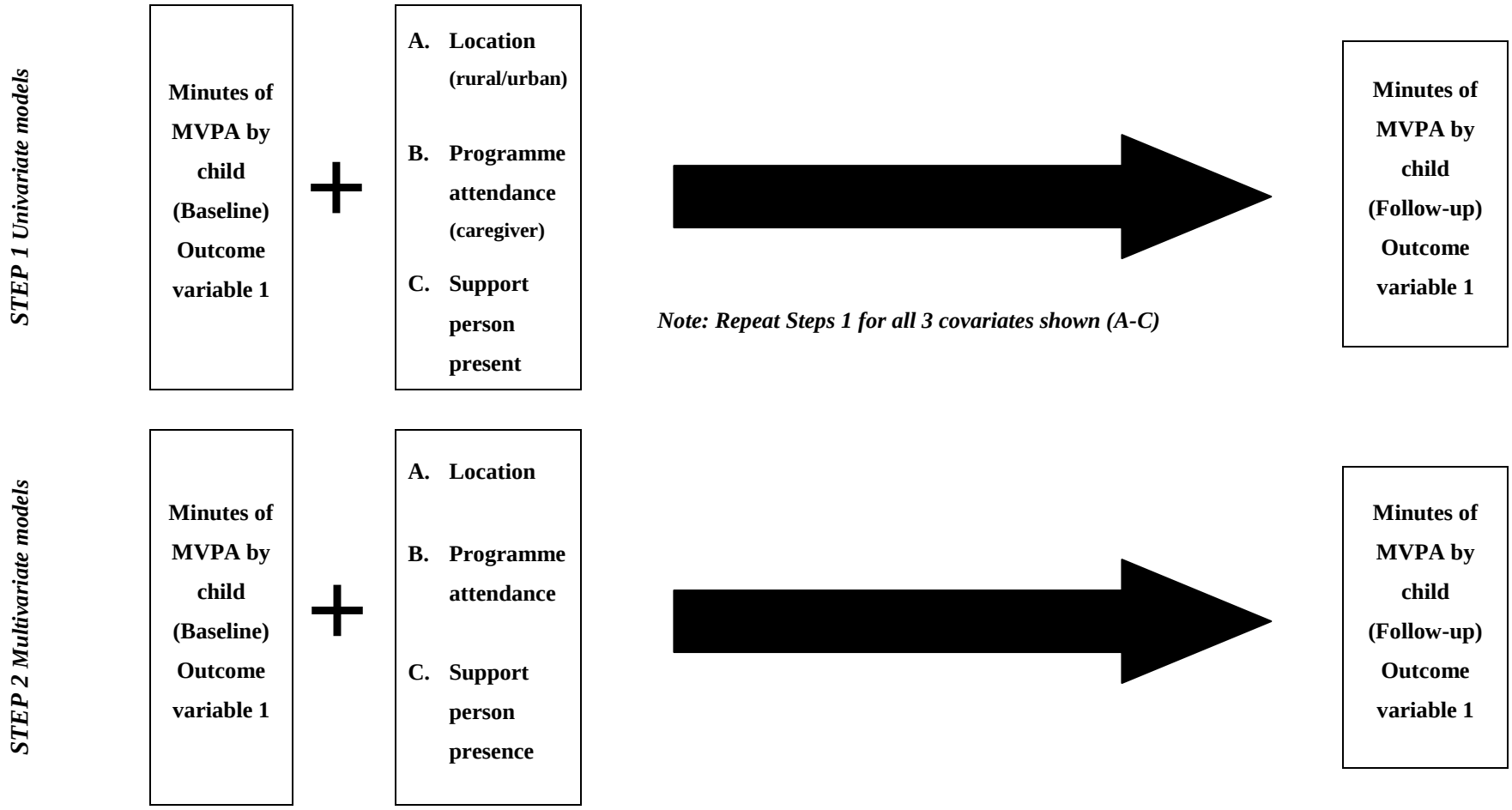


Figure 12: Analysis plan for covariates of Fruit OR Vegetable Offerings (Outcome variable 2 and 3)



Note: *Repeat Steps 1-3 for outcome variables 2 (number of fruit offerings) and 3 (number of vegetable offerings)*

Figure 13: Analysis plan for examining the effectiveness of *Healthy Me and You* on each outcome variable (Outcome variable 1 shown as an example)



Note: *Repeat Steps 1-2 for outcome variables 2 (number of fruit offerings) and 3 (number of vegetable offerings)*

Figure 14: Analysis plan for examining the effectiveness of *Healthy Me and You* for sub-groups for each outcome variable (Outcome variable 1 shown as an example)

5 BASELINE RESULTS

5.1 Overview

The results described in this chapter relate to baseline information and commences with a description of the sample and matching process. Descriptive information for the entire sample is reported. This includes dietary habits, family food environment, physical activity and sedentary behaviours. No statistical comparisons between the two groups were undertaken, as this analyses sat outside of the scope of this thesis and associated research questions. Baseline descriptives of the groups are found in Appendix Q. The chapter concludes by analysing separately the association between each of the outcome variables (child PA in minutes, number of fruit offerings to child by caregiver, and number of vegetable offerings to child by caregiver) and the covariates identified as shown in Figure 11 and Figure 12.

5.2 Description of sample

Of the 101 referrals received from health and social service agencies for the intervention, only eleven were ineligible and one was unable to be contacted. Of the 89 eligible referrals, all agreed to participate. Data were only collected on 67 of them, however, because: consent was withdrawn prior to the intervention beginning (n=10); participants lived in areas where numbers were not large enough to make programme delivery viable in that area (n=11) and baseline data collection had not occurred prior to attending the programme (n=1). The numbers of participants needed for the comparison group was therefore 67 with 72 referrals required to obtain appropriate numbers. All comparison group referrals met the study inclusion criteria but four were later excluded due to baseline data not being obtained.

5.2.1 Baseline data collected

Among the 135 participants, data were collected at baseline from: interviews (n=135); supplementary interviews (n=133); caregiver NL-1000 data (n=129); child NL-1000 data (n=129) and F&V tick-list (n=133). Figure 15 shows an enrollment flow chart combined with information collected at baseline.

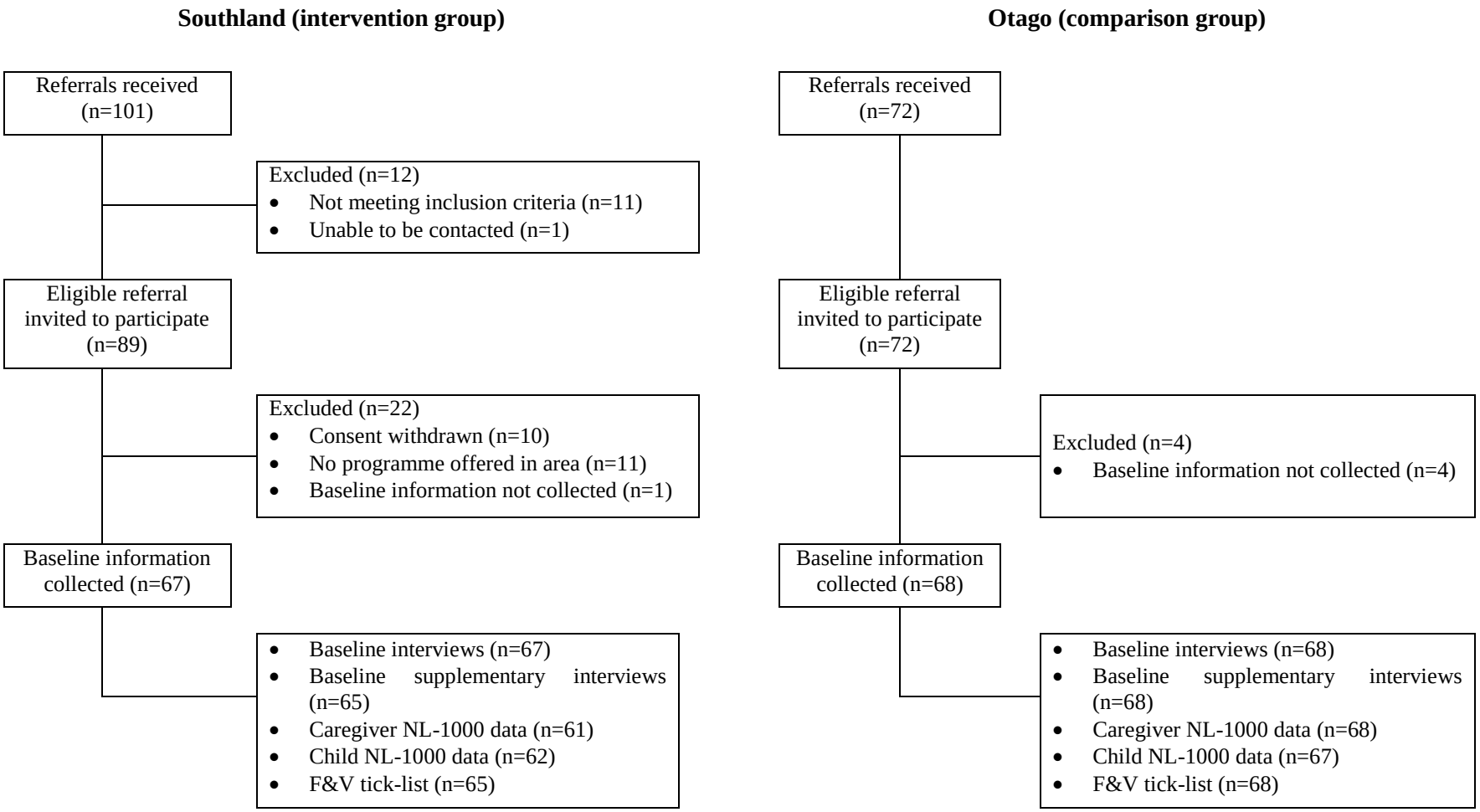


Figure 15: Enrolment flowchart

5.2.2 Matching process

The comparison sample was matched at an individual level by sex, child ethnicity and NZDep2006 Index. Table 12 shows the distribution of these three variables.

Overall, the comparison group was more 'advantaged' with 43% of households located in high deprivation areas compared with 30% in the intervention group. A more detailed table showing NZDep2006 Index quintiles is found in Appendix R.

Table 12: Participant matching, examining NZDep2006 Index levels and child sex by group and ethnicity (n=135)

	Māori/Pacific		Non-Māori/Non-Pacific		Total	
	Intervention Group n (%)	Comparison Group n (%)	Intervention Group n (%)	Comparison Group n (%)	Intervention Group n (%)	Comparison Group n (%)
Areas by New Zealand Deprivation Index[43]						
Deciles 1-5 (lower dep)	5 (19)	3 (15)	15 (37)	26 (54)	20 (30)	29 (43)
Deciles 6-10 (higher dep)	21 (81)	17 (85)	26 (63)	22 (46)	47 (70)	39 (57)
Child sex						
Males	16 (62)	10 (50)	24 (59)	26 (54)	40 (60)	36 (53)
Females	10 (38)	10 (50)	17 (41)	22 (46)	27 (40)	32 (47)

5.3 Baseline descriptions

5.3.1 Caregiver, child and household characteristics

Key characteristics of the 135 participants are shown in Table 14. Forty-four percent of the preschoolers were girls and the median age of all children was 3 years 8 months. The majority of caregivers were women (93%) and most of them mothers (97%) with the median caregiver age of 33 years (range 19-54 years). Just under one third of the caregivers had tertiary qualifications; 29% had completed high school[44] or vocational training. Just under a quarter[45] stated they had either no or minimal qualifications while approximately one in six had only completed some high school. Slightly less than half the caregivers were in paid employment. Thirty eight of these paid employees were

[43] 2006 NZDep Index.
[44] NCEA3.
[45] This differs from the sum of the percentage in due to rounding.

working part time (57%), 19 were paid work full time (29%) and the remaining nine (14%) were either self employed or had casual/seasonal employment.

Caregivers could identify their child in more than one ethnic group. Using total response ethnicity (Ministry of Health, 2004d) the majority of children were identified as NZ European (78%), followed by Māori (30%), Pacific peoples (10%), Asian (2%) and all others (6%). To enable ethnicity to be used as a covariate, prioritised child ethnicity[46] was determined with approximately a third of the children classified as either Māori or Pacific.

In most families (73%) two adults aged 18 years and over lived in the household with the child. However for 22 households had only one adult and 11 percent reported that there were three or more adults. The majority of households had three or more children (44%),[42] whereas 52 households had two children and only 17 percent had a single child. The majority of participating caregivers always lived with the child (93%), or mostly had the child in their home (5%). The exceptions were two caregivers, one a grandmother and the other a godmother, who was also employed as a live-out nanny.

The median daily number of hours that the participating child spent with the caregiver was 22 hours 17 minutes (IQR three hours 26 minutes). Twenty-three caregivers were the sole primary caregiver over the previous seven days. A participating father and also the godmother/nanny spent on average less than 12 hours with the child on a daily basis as the primary caregiver for that child. When comparing normal childcare arrangements against actual arrangements, for the majority of children (72%) their care arrangements did not differ by more than 25%.

[46] Child ethnicity was priorotised as Māori over Pacific over NZ European.

Table 13: Characteristics of study participants at baseline (n=135)

	Total n (%)		Total n (%)
Sex of caregiver		Sex of child	
Men	9 (7)	Boys	76 (56)
Women	126 (93)	Girls	59 (44)
Age of caregiver (years)		Age of child (years)	
<20	1 (1)	Three	92 (68)
20-29	46 (35)	Four	34 (32)
30-39	73 (56)		
40+	11 (8)		
Highest education		Child ethnic group (total response)	
None	11 (9)	Māori	40 (30)
NCEA1	21 (16)	Pacific	13 (10)
NCEA2	22 (16)	Asian	3 (2)
NCEA3	7 (5)	Other	8 (6)
Vocational	33 (24)	NZ European	105 (78)
University equivalent	41 (30)		
Employment status		Children in household (includes child)	
Paid, full time	19 (14)	One	23 (17)
Paid, part time	38 (28)	Two	52 (38)
Other, paid	9 (7)	Three	42 (31)
Other, unpaid	69 (51)	Four	13 (10)
		Five or more	5 (4)
Child lives with you		Adults in the household (18+)	
Always	126 (93)	One	22 (16)
Mostly	7 (5)	Two	99 (74)
Sometimes	1 (1)	Three	11 (8)
On occasions	0	Four or more	3 (2)
Never	1 (1)		
Relationship with child		Actual childcare arrangements at least 25% different from normal	
Mother	122 (90)		
Father	9 (7)	No	97 (72)
Other (includes other family)	4 (3)	Yes	38 (28)
Average daily time child spent with caregiver over past week			
Median hrs:mins (IQR)	22:17 (3:26)		

5.3.2 Dietary habits of caregiver and child

Forty percent (n=54) of children had no food dislikes while the comparable figure was 60% (n=81) among caregivers.[47] Table 14 shows caregiver daily fruit and vegetable serve consumption. The New Zealand recommendations for adults are to eat at least three serves of vegetables and at least two serves of fruit each day including fresh, frozen or canned (MOH 2003). Over 60% of caregivers met their daily fruit serves recommendations (n=83) however this was reversed for vegetables (n=50). The proportion of caregivers meeting the 5+a day guidelines was 42%. Meeting 5+a day guideline could not be determined for two caregivers.

Table 14: Dietary habits of participants at baseline (n=135)

	Total n (%)		Total n (%)
Caregiver - Daily fruit serves		Caregiver - Daily vegetable serves	
I don't eat fruit	5 (4)	I don't eat vegetables	1 (1)
<1 serve	15 (11)	<1 serve	0
1 serve	32 (24)	1 serve	9 (7)
2 serves	39 (29)	2 serves	75 (55)
≥ 3 serves	44 (32)	3 serves	50
		≥ 4 serves	0

Each caregiver completed all five days of the F&V tick-list. One child was not offered any fruit or vegetables on two consecutive days and the interviewer verified these details at the baseline supplementary interview. There were another six instances where no offerings in any of the four categories were recorded on one particular day, all of which were confirmed during the supplementary interview. Results reported in Table 15 show the total five day offerings to the child by the caregiver for fruit and vegetables, while Appendix S shows results relating to juice and mixed dishes offered.

[47] A composite variable entitled dislikes anything was created from the food categories (all meats, red meat, chicken, fish, dairy product, eggs and other) and collapsed into yes or no if any of the eight categories were answered yes.

Table 15: Descriptive statistics for five day total offerings by F&V tick-list categories at baseline (n=133)

	n	Median	IQR[48]	Min	Max
Total number of fruit offerings over 5 days	133	16	11	4	47
Total number of vegetable offerings over 5 days	133	15	10	0	39

5.3.3 Family food environment of child

Half of all caregivers (n=68, 51%) reported that their preschooler sometimes helped to prepare food, while 40 (29%) never or seldom were involved and the remaining 27 (20%) were highly involved in this activity (Table 16). A similar number of children were regularly involved in food shopping with 77% of caregivers (n=104) reporting that the child either mostly or always was involved in this activity. The majority of caregivers (n=121, 90%) either mostly or always ate with their child.

Table 16: Family food environment data at baseline (n=135)

	Never n (%)	Seldom n (%)	Sometimes n (%)	Mostly n (%)	Always n (%)
Does the child help prepare the meals	18 (13)	22 (16)	68 (51)	24 (18)	3 (2)
The child goes food shopping with caregiver	3 (2)	12 (9)	16 (12)	44 (33)	60 (44)
Caregiver sits down with the child for a meal	1 (1)	4 (3)	9 (7)	37 (28)	84 (62)

5.3.4 Physical activity of caregiver and child

Thirty caregivers and eight children were identified, via parental or self report, as being 'limited in some capacity' with their activity over the previous three months. The majority of explanations provided for caregivers related to a current or recent pregnancy, with some minor ailments also mentioned, such as previous skeletal injuries and asthma. Asthma was also identified as the prominent limitation for children together with constipation and skeletal deformities.[49]

Nine percent of caregivers (n=11) and children (n=12) had more than two days of data excluded from analysis. Data were collected but excluded on eight caregivers and nine children due to: low step counts (n=5); supplementary interviews unable to be completed

[48] Inter-quartile range.
[49] Percentages observed were representative of those expected.

(n=2); the NL-100 had been worn by another family member (n=1); the device being lost or malfunctioned due to exposure to water (n=9). Table 18 shows that as the number of days retained for analyses increased, so did the number of participants.

Table 17: NL-1000 data collected at baseline (n=129)

	Total n (%)		Total n (%)
Caregiver - Number of days retained for analysis		Child - Number of days retained for analysis	
0	2 (2)	0	3 (2)
1-2	9 (7)	1-2	9 (7)
3-4	10 (8)	3-4	22 (17)
5-6	40 (31)	5-6	31 (24)
7	68 (52)	7	64 (50)

Table 18 shows the weekly averages for step counts and MVPA minutes for both caregivers and children. Due to the truncated nature of the data,[50] median and inter-quartile ranges are shown. Individual day-by-day results are in Appendix T.

Table 18: Descriptive statistics of participants seven day MVPA assessment averages at baseline (over and up to one week)

	n	Median	IQR[51]	Min	Max
Caregiver - Number of steps measured	127	7206	4642	2477	17185
Caregiver - MVPA measured (mins:sec)	127	14:55	13:30	0:37	80:58
Child - Number of steps measured	126	10561	4813	1855	18663
Child - MVPA measured (mins:sec)	126	110:16	48:37	21:02	176:50

The baseline median step counts for children are approximately a third higher (10500) compared to the median step counts results of 7200 for caregivers. Corresponding median weekly MVPA minutes for caregivers were 14 minutes 55 seconds and for preschoolers 110 minutes 16 seconds.

Acknowledging that not all activity undertaken by participants is able to be captured by NL-1000, additional information was sought regarding activities such as swimming (including water sports), cycling and strength type activities and results are shown in Table 19.

[50] The NL-1000 was unable to display activity minutes greater than 199 minutes and 56 seconds therefore daily activity minutes for the wearer was capped at this value.
[51] Inter-quartile range.

Table 19: Any extra activities performed by participants at baseline not captured by NL-1000 (n=133)

	Caregiver (MVPA)		Child	
	Yes n (%)	No n (%)	Yes n (%)	No n (%)
Any extra cycling	4 (3)	129 (97)	67 (50)	66 (50)
Any extra swimming	18 (13)	115 (87)	34 (26)	99 (74)
Any extra strength	52 (39)	81 (61)		
Any extra	62 (47)	71 (53)	79 (59)	54 (41)

Four caregivers (3%) participated in moderate-to-vigorous type cycling during the week while 18 caregivers (13%) went swimming at moderate-to-vigorous levels. Fifty-two caregivers (39%) were involved in some type of moderate-to-vigorous strength activity. When combining these activities, just under half the caregivers (n=62, 47%) did at least one of these types of activities at moderate-to-vigorous levels during the week.

Participation at any level was recorded for children, with half of all children (n=67, 50%) riding a bike at least once during the week and one in four children swimming (n=34, 26%). Combining these two activities indicated that three in five children participate in swimming or biking type activities during a normal week (n=79, 60%).

5.3.5 Sedentary behaviours of caregiver and child

Table 20 shows that the daily median for TV or small screen viewing was 30 minutes more for caregivers than children with the inter-quartile range being wider for caregivers also.

Table 20: Daily small screen time of participants at baseline (hh:mm)

	n	Median	IQR[52]	Min	Max
Caregiver – daily small screen time (hr:mins)	134	2:00	1:31	0:00	10:00
Child – daily small screen time (hr:mins)	133	1:30	1:18	0:00	7:00

Table 21 shows the frequency of children watching TV while eating their main meals or snacks. Approximately half (52%) are not allowed to watch any TV while eating breakfast (n=70) or the main evening meal (n=71). Of the remaining 48% (n=65), the

[52] Inter-quartile range.

frequency of TV watching is higher at breakfast time with one in three children eating breakfast at least three times a week with the TV on (n= 45, 33%) with this reducing to one in four children (n=35, 26%) for their evening meal.

When considering lunch and other snack times, caregivers were able to answer 'not applicable' if either a TV was not present (i.e. child in centre-based care) or the meal/snack is not offered. Afternoon tea was the only time of the day when a larger proportion of children were offered snacks while the TV was on (n=63, 47%; TV never on n=55, 41%). For all other times when snacks were offered the proportion of children watching TV while snacking was less than 30% (morning tea n=28, 21%; lunch n=39, 29%; bedtime snack n=18, 13%).

Table 21: Exposure to TV while eating main meals and snacks at baseline (n=135)

	Breakfast n (%)	Dinner/Tea n (%)	Morning tea n (%)	Lunch n (%)	Afternoon tea n (%)	Bedtime snack n (%)
5+ days/week	31 (23)	26 (19)	-	-	-	-
3-4 days/week	14 (10)	9 (7)	-	-	-	-
1-2 days/week	14 (10)	19 (14)	-	-	-	-
1-3 days/month	2 (2)	8 (6)	-	-	-	-
< once/month	4 (3)	2(2)	-	-	-	-
Ever	-	-	28 (21)	39 (29)	63 (47)	18 (13)
Never	70 (52)	71 (52)	72 (53)	77 (57)	55 (41)	40 (30)
Not applicable	0 (0)	0 (0)	35 (26)	19 (14)	17 (12)	77 (57)

5.4 Attributes predicting outcome variables at baseline

Results are presented as: coefficients for child PA in minutes or rate ratios for number of *fruit* or *vegetable* offerings to child by caregiver along with 95% confidence interval (CI), and the associated p-value. Groups are identified by location for all models, Southland (intervention group) and Otago (comparison group).

5.4.1 Outcome variable 1: Child physical activity in minutes

Table 22 shows associations obtained from steps one and two using Tobit regression models of prior selected covariates with baseline child PA minutes. All variables with $p<0.2$ were entered into the next model. However caregiver MVPA minutes ($p=0.049$) was not selected for step 2 multivariate models (initial blocks) based upon the

assumptions that step counts were more likely to represent active role modelling with the child.[53] This was supported by a statistically significant correlation between MVPA minutes and step counts for caregivers, r=0.59, p<0.001.

Seven variables (5 characteristics and 2 behaviours) identified in step 1 progressed to step 2. Of these, children who were either Māori or Pacific compared with non-Māori/non-Pacific showed lower PA minutes, while children whose caregivers were in paid employment showed higher PA minutes, (p<0.050). Higher levels of caregiver education were almost statistically significant in step 1 (p=0.054) but the effects generally attenuated after controlling for other caregiver characteristics which progressed to step 2. The number of caregiver steps was positively associated with child PA minutes and was the only behaviour-type variable to progress to step 3, multivariate models (intermediate models). Caregiver daily small screen levels were again almost statistically significant in step 1 (p=0.056), however, this association did not strengthen after controlling for other caregiver behaviours and the p-value increased to 0.605. All other variables child (age) and caregiver (age) were not found to be associated with child PA minutes (all p-values >0.050).

[53] It is assumed that the majority of MVPA minutes undertaken by the caregiver were performed in isolation from activity undertaken with the study child and therefore would represent passive role modelling.

Table 22: Results of STEP 1 Univariate models + STEP 2 Multivariate models (initial blocks) using Tobit regression: characteristic and behavioral covariates of MVPA in preschool children

Potential covariates	STEP 1: Univariate models Coefficient (95% CI)	p-value	STEP 2: Multivariate models Coefficient (95% CI)	p-value
Child Characteristics			**Child Characteristics model**	
Age of child *[6mth units]*	-5.39 (-12.04-1.27)	0.113	-4.72 (-11.26-1.82)	0.157
Ethnicity of child *(reference non-Māori /non-Pacific)*				
Māori /Pacific	-16.59 (-28.65-4.53)	0.007	-15.76 (-28.14--3.39)	0.013
Sex of child *(reference female)*				
Male	2.74 (-9.34-14.82)	0.657		
Caregiver Characteristics			**Caregiver Characteristics model**	
Age of caregiver *[5yr units]*	3.40 (-1.72-8.53)	0.193	1.63 (-3.70-6.96)	0.549
Sex of Caregiver *(reference female)*				
Male	4.57(-18.09-27. 23)	0.693		
Caregiver level of education *(reference none/NCEA1)*		0.054		0.216
NCEA 2	17.33 (-2.03-36.69)		17.53 (-1.13-36.19)	
NCEA 3 / vocational	20.52 (3.93-37.11)		15.08 (-1.30-31.46)	
Tertiary	20.63 (4.39-36.88)		10.95 (-6.40-28.30)	
Caregiver in paid employment *(reference no)*				
Yes	17.66 (6.04-29.28)	0.003	17.75 (5.89-29.62)	0.003
Time spent with caregiver over past week *[1hr units]*	-0.53 (-2.52-1.45)	0.599		

Note: p<0.2 to progress to the next model

Table 22 continued

Potential covariates	STEP 1: Univariate models Coefficient (95% CI)	p-value	STEP 2: Multivariate models Coefficient (95% CI)	p-value
Household Characteristics			**Household Characteristics model**	
Only child in household *(reference no)*				
Yes	6.54 (-9.42-22.50)	0.422		
Two or more adults living in household *(reference no)*				
Yes	9.87 (-6.38-26.13)	0.234		
Location of child *(reference Otago)*				
Southland	-7.62 (-19.28-4.04)	0.201		
Child Behaviours			**Child Behaviours model**	
Average daily small screen time by child *[10mins units]*	-0.51 (-1.29-0.27)	0.201		
Any Extra MVPA done by child over past week [swim/bike] *(reference no)*				
Yes	4.89 (-7.35-17.14)	0.434		
Caregiver Behaviours			**Caregiver Behaviours model**	
MVPA minutes done by caregiver	0.21 (0.00-0.42)	0.049	Not selected	
Number of steps done by caregiver *[500step units]*	1.51 (1.04-1.98)	<0.001	1.52 (1.052.00)	<0.001
Average daily small screen time by caregiver (excludes work) *[30mins units]*	-1.95 (-3.95-0.05)	0.056	-0.53 (-2.55-1.48)	0.605
Any Extra MVPA done by caregiver over past week [swim/bike/strength] *(reference no)*				
Yes	5.52 (-6.48-17.52)	0.368		

Four covariates therefore progressed to step 3. Age and ethnicity of child, and employment status of caregivers were considered in the combined characteristic model, while caregiver step count was the only behaviour-type variable analysed. Results from these models showed that associations from step 2 were still present in step 3 and all four covariates progressed to step 4, the adjusted final multivariate model. Appendix U provides the results from step 3.

Table 23: Results of STEP 4 adjusted multivariate model (final model) using Tobit regression: characteristic and behavioral covariates of MVPA in preschool children

	STEP 4: Multivariate model	
Potential covariates	**Coefficient (95% CI)**	**p-value**
Age of child [6mth units]	-7.66 (-13.62—1.70)	0.012
Ethnicity of child *(reference non-Māori /Non-Pacific)*		
Māori /Pacific	-13.22 (-24.64—1.80)	0.023
Caregiver in paid employment *(reference no)*		
Yes	14.59 (3.79-25.38)	0.008
Number of steps done by caregiver *[500step units]*	1.45 (0.99-1.92)	<0.001

Results from the adjusted final multivariate model are presented in Table 23 and show that the number of child PA minutes was higher (approximately 14 minutes more) if caregivers were in paid employment (p=0.008). A positive association was also found with increasing levels of caregiver step counts (p<0.001) with approximately 90 seconds more child PA untaken for every 500 step units. However the 95% CI was very narrow representing the range of plausible effect sizes (1-2 minutes). Increasing age of child was negatively associated with child PA minutes (p=0.012; a reduction of approximately 8 minutes as age increases in six monthly intervals), while lower levels of child PA minutes (approximately 13 minutes) was association with child ethnicity (Māori or Pacific; p=0.023).

5.4.2 Outcome variable 2: Number of fruit offerings to child by caregiver

Table 24 shows associations obtained from steps one and two using Poisson regression models of prior selected covariates with number of fruit offerings to child by caregiver recorded at baseline. All variables with $p<0.2$ were entered into subsequent models. As with the caregiver MVPA from the previous set of models, caregiver daily vegetable serve guidelines achieved were also not selected because it was considered that caregivers achieving their daily fruit serves would more likely represent active role modelling to the child and thus offer more fruit. There was also found to be a correlation between daily vegetable serves and daily fruit serves for caregivers, $r=0.24$ ($p=0.005$). Caregiver 5+ a day guidelines achieved was also not selected as this variable represented information captured by both daily vegetable serves and daily fruit serves for caregivers.

Six variables (3 characteristics and 3 behaviours) identified in step 1 progressed to step 2. Children with older caregivers were offered more fruit than those with younger caregivers ($p<0.05$). Caregivers in paid employment initially indicated that they offered children more fruit than those not in paid employment, however, this association was attenuated after controlling for other caregiver characteristics and the p-value increased from 0.167 to 0.439. Initial screening also indicated that children living in Southland were offered more fruit that their Otago counterparts ($p<0.020$) with this variable progressing through to the final model.

When examining child and caregiver behaviours, the number of vegetable offerings was positively associated with the mean number of fruit offerings by the caregiver over five days ($p<0.001$) and higher levels of fruit offerings to children was associated with their involvement in helping to prepare food ($p=0.005$). Both associations were retained after controlling for the other and progressed to the step 3. The only other behaviour found to met the screening selection was caregivers achieving guidelines for daily fruit serves ($p=0.064$).

Table 24: Results of STEP 1 Univariate models + STEP 2 Multivariate models (initial blocks) using Poisson regression: characteristic and behavioral covariates of fruit offerings in preschool children

Potential covariates	STEP 1: Univariate models Rate ratio (95% CI)	p-value	STEP 2: Multivariate models Rate ratio (95% CI)	p-value
Child Characteristics			**Child Characteristics model**	
Age of child *[6mth units]*	0.02 (-0.08-0.11)	0.742		
Ethnicity of child *(reference non-Māori /non-Pacific)*				
Māori /Pacific	1.08 (0.90-1.30)	0.397		
Sex of child *(reference female)*				
Male	0.97 (0.81-1.15)	0.693		
Caregiver Characteristics			**Caregiver Characteristics model**	
Age of caregiver *[5yr units]*	0.09 (0.02-0.16)	0.014	1.09 (1.02-1.17)	0.018
Sex of caregiver *(reference female)*				
Male	1.00 (0.70-1.41)	0.982		
Caregiver level of education *(reference none/NCEA1)*		0.287		
NCEA 2	1.11 (0.84-1.47)			
NCEA 3 / vocational	1.20 (0.95-1.53)			
Tertiary	1.25 (0.98-1.58)			
Caregiver in paid employment *(reference no)*				
Yes	1.13 (0.95-1.34)	0.167	1.07 (0.90-1.27)	0.439
Time spent with caregiver over past week *[1hr units]*	0.01 (-0.02-0.03)	0.622		

Note: p<0.2 to progress to the next model

Table 24 continued

Potential covariates	STEP 1: Univariate models Rate ratio (95% CI)	p-value	STEP 2: Multivariate models Rate ratio (95% CI)	p-value
Household Characteristics			**Household Characteristics model**	
Only child in household *(reference no)*				
Yes	0.91 0.72-1.15)	0.437		
Two or more adults living in household *(reference no)*				
Yes	1.11 (0.88-1.41)	0.390		
Location of child *(reference Otago)*				
Southland	0.88 (0.74-1.05)	0.155	0.88 (0.74-1.05)	0.155
Child Behaviours			**Child Behaviours model**	
Mean number of vegetable offerings to child over 5 days	1.04 (1.02-1.07)	<0.001	1.04 (1.02-1.07)	<0.001
Child helps prepare food *(reference never/seldom)*		0.005		0.005
Sometimes	1.35 (1.11-1.65)		1.34 (1.11-1.61)	
Mostly/always	1.40 (1.10-1.79)		1.38 (1.09-1.74)	
Child helps food shopping *(reference never/seldom)*		0.214		
Sometimes	1.20 (0.82-1.75)			
Mostly/always	1.29 (0.97-1.73)			
Child eats with you *(reference never/seldom)*		0.271		
Sometimes	0.87 (0.49-1.57)			
Mostly/always	0.73 (0.44-1.19)			
Caregiver Behaviours			**Caregiver Behaviours model**	
Daily 5+ guidelines achieved by caregiver	1.15 (0.97-1.37)	0.111	not selected	
Daily fruit serve guidelines achieved by caregiver	1.18 (0.99-1.42)	0.064	1.18 (0.99-1.42)	0.064
Daily vegetable serve guidelines achieved by caregiver	1.20 (1.01-1.44)	0.040	not selected	

Five covariates therefore progressed to step 3. Child age and participant location was considered in the combined characteristic model while mean number of vegetable offerings over 5 days, child helping with food preparation and daily fruit serve guidelines being achieved by caregiver were analysed in the combined behaviour model. Results from these models showed that all five met the $p<0.2$ screening criteria and progressed to step 4, the adjusted final multivariate model. Appendix U provides the results from step 3.

Table 25: Results of STEP 4 adjusted multivariate model (final model) using Poisson regression: characteristic and behavioral covariates of fruit offerings in preschool children

	Multivariate model	
Potential covariates	**Rate ratio (95% CI)**	**p-value**
Age of caregiver *[5yr units]*	1.06 (0.99-1.14)	0.078
Location of child *(reference Otago)*		
Southland	0.92 (0.78-1.09)	0.334
Mean number of vegetable offered to child over 5 days	1.04 (1.01-1.06)	0.003
Child helps prepare food *(reference never/seldom)*		0.038
Sometimes	1.24 (1.02-1.50)	
Mostly/always	1.32 (1.05-1.67)	
Daily fruit serve guidelines achieved by caregiver	1.11 (0.93-1.33)	0.261

Results of the adjusted final multivariate model are presented in Table 25 and show that the number of fruit offerings by the caregiver was statistically significantly associated positively with the mean number of vegetables offered to the child ($p=0.003$). However the RR suggests a very small change. Predicted rates of fruit offerings were found to be larger if the child helped prepare food ($p=0.038$) compared to those who neither or seldom helped. This association existed for both levels of helpfulness (sometimes $p=0.033$; mostly/always $p=0.019$) however no association was found between sometimes helpful and mostly/always helpful; $p=0.519$. All other variables examined in this model were found to be not statistically significant ($p\geq0.078$).

5.4.3 Outcome variable 3: Number of vegetable offerings to child by caregiver

Table 26 shows associations obtained from steps 1 and 2 using Poisson regression models of prior selected with number of vegetable offerings by caregiver recorded at baseline. All variables with $p<0.2$ were entered into subsequent models. As with the previous outcome variable, number of fruit offerings to the child by the caregiver and 5+ a day guidelines were not selected for step 2 based on the same rationale.

For all child, caregiver and households characteristics, only one variable from each block had $p<0.2$ (steps 1 and 2) and therefore progressed directly to step 3. These variables were increasing age of caregiver, location of participant and if the child was Māori or Pacific. No associations were found for all other child (age, sex), caregiver (sex, education, employment status, time spent with child) or household characteristics (household composition).

A similar scenario was seen when examining child and caregiver behaviours, as again only one variable from each block (steps 1 and 2) progressed. A positive association was found between for the mean number of fruit offerings by the caregiver over five days ($p<0.001$) and also if the caregivers achieved daily vegetable serve guidelines ($p=0.003$). All other behaviour-type variables examined were associated with $p>0.2$.

Table 26: Results of STEP 1 Univariate models + STEP 2 Multivariate models (initial blocks) using Poisson regression: characteristic and behavioral covariates of vegetable offerings in preschool children

Potential covariates	STEP 1: Univariate models		STEP 2: Multivariate models	
	Rate ratio (95% CI)	p-value	Rate ratio (95% CI)	p-value
Child Characteristics				
Age of child *[6mth units]*	-0.03 (-0.12-0.05)	0.455		
Ethnicity of child *(reference non-Māori /non-Pacific)*				
Māori /Pacific	1.15 (0.97-1.36)	0.097	1.15 (0.97-1.36)	0.097
Sex of child *(reference female)*				
Male	0.98 (0.83-1.15)	0.821		
Caregiver Characteristics				
Age of caregiver *[5yr units]*	0.06 (-0.00-0.12)	0.066	1.06 (1.00-1.13)	0.066
Sex of caregiver *(reference female)*				
Male	1.02 (0.74-1.4)	0.903		
Caregiver level of education *(reference none/NCEA1)*		0.548		
NCEA 2	1.09 (0.85-1.41)			
NCEA 3 / vocational	0.98 (0.78-1.22)			
Tertiary	0.91 (0.73-1.14)			
Caregiver in paid employment *(reference no)*				
Yes	0.93 (0.79-1.09)	0.373		
Time spent with caregiver over past week *[1hr units]*	-0.01 (-0.04-0.01)	0.272		

Note: p<0.2 to progress to the next model

Table 26 continued

Potential covariates	STEP 1: Univariate models Rate ratio (95% CI)	p-value	STEP 2: Multivariate models Rate ratio (95% CI)	p-value
Household Characteristics				
Only child in household *(reference no)*				
Yes	0.89 (0.71-1.10)	0.269		
Two or more adults living in household *(reference no)*				
Yes	1.05 (0.84-1.30)	0.672		
Location of child *(reference Otago)*				
Southland	1.13 (0.96-1.32)	0.147	1.13 (0.96-1.32)	0.147
Child Behaviours				
Mean number of fruit offerings to child over 5 days	1.06 (1.03-1.08)	<0.001	1.06 (1.03-1.08)	<0.001
Child helps prepare food *(reference never/seldom)*		0.645		
Sometimes	1.04 (0.86-1.25)			
Mostly/always	1.11 (0.88-1.41)			
Child helps food shopping *(reference never/seldom)*		0.281		
Sometimes	1.02 (0.72-1.44)			
Mostly/always	1.18 (0.91-1.55)			
Child eats with you *(reference never/seldom)*		0.940		
Sometimes	0.92 (0.53-1.60)			
Mostly/always	0.92 (0.58-1.47)			
Caregiver Behaviours				
Daily 5+ guidelines achieved by caregiver	1.13 (0.97-1.33)	0.122	Not selected	
Daily fruit serve guidelines achieved by caregiver	0.99 (0.83-1.17)	0.873		
Daily vegetable serve guidelines achieved by caregiver	1.27 (1.08-1.49)	0.003	1.27 (1.08-1.49)	0.003

Five covariates progressed to step 3. Child ethnicity, age of caregiver and participant location were considered in the combined characteristic model while mean number of fruit offerings over 5 days and daily vegetable serve guidelines being achieved by caregiver were analysed in the combined behaviour model. Results from these models mirrored findings from step 2 and all five covariates progressed to step 4, the adjusted final multivariate model. Appendix U provides the results from step 3.

Table 27: Results of STEP 4 adjusted multivariate model (final model) using Poisson regression: characteristic and behavioral covariates of vegetable offerings in preschool children

	Multivariate model	
Potential covariates	**Rate ratio (95% CI)**	**p-value**
Ethnicity of child *(reference non-Māori /Non-Pacific)*		
Māori /Pacific	1.15 (0.99-1.33)	0.064
Age of caregiver *[5yr units]*	1.05 (0.99-1.12)	0.079
Location of child *(reference Otago)*		
Southland	1.16 (1.01-1.34)	0.038
Mean number of fruit offerings to child over 5 days	1.05 (1.02-1.07)	0.001
Daily vegetable serves guidelines achieved by caregiver	1.23 (1.07-1.41)	0.003

Results for the adjusted final multivariate model are reported in Table 27 and show that the number of vegetable offerings to the child by the caregiver was statistically significantly greater for those in Southland (p=0.038), was higher if the caregiver achieved the daily vegetable serve guidelines (p=0.003) and increased with the mean number of fruit they offered the child (p=0.001). However the respective RR were small and indicative of very small changes. All other variables examined in this model were found not to be statistically significant ($p \geq 0.064$).

5.4.4 Summary

Initial univariate models identified various characteristics (child, caregiver or household) and behaviour-type covariates (child or caregiver) which were progressively examined in a step-wise process to determine the final model for each outcome variable. A total of four (from 17), five (from 18) and four (from 18) covariates were retained for each

respective final model (child PA minutes, number of fruit offered and number of vegetables offered).

Despite the same 11 characteristic-type covariates being initially considered, less than half were eligible to be included in any of the final models. Of these child ethnicity, caregiver age and participant location were all present in two of the three models, however, after controlling for all other covariates, only two statistically significant results were found. Māori or Pacific children were found to undertake less PA, (approximately 13 minutes) than their non-Māori/non-Pacific counterparts and levels of PA reduced by approximately 8 minutes as children age (half yearly intervals). However if the caregiver was in paid employment, children undertook approximately 14 extra minutes more than those whose parents who either did not work or were not paid.

The only characteristic-type covariate shown to be statistically significant for F&V offerings was location, where children in the intervention group were offered more vegetables than children from the comparison group.

Behaviour-type covariates available (n=7) were initially similar for either fruit offerings or vegetable offerings with a different six covariates identified for the outcome variable PA minutes. Results show that child PA minutes levels increased by approximately ninety seconds as caregiver daily step counts increased (500 steps blocks), a small but important increase if accumulated. The number of fruit offerings by the caregiver was positively associated with the mean number of vegetables offered to the child however the RR was indicative of a very small change. A similar finding occurred for outcome three, where vegetable offerings were higher if the caregiver achieved the daily vegetable serve guidelines and they also increased with the mean number of fruit they offered the child. Predicted rates of fruit offerings were found to be larger if the child helped prepare food compared to those who neither or seldom helped and were found to be similar for both levels of helpfulness (sometimes or mostly/always). Associated RR's indicate that the level of change was small.

6 FOLLOW-UP RESULTS

6.1 Overview

This chapter focuses on the evaluation of the intervention programme, *Healthy Me and You*. It commences with descriptive statistics on the three outcomes of interest before investigating to see if there was a significant increase in these outcomes (physical activity minutes, number of fruit offerings by caregiver, and number of vegetable offerings by caregiver) for children attending *Healthy Me and You* compared to children in the comparison group. The third aim follows by asking *were there any subgroups for whom Healthy Me and You was more effective?* For both aims, behaviour change was measured by undertaking a series of regression analyses as specified in Figure 13 and Figure 14. The chapter concludes by looking briefly at a selection of intermediate outcomes before investigating whether the evaluation undertaken was compromised by those lost to follow-up.

6.2 Data collection at follow-up

Of the 135 participants (intervention group n=67; comparison group n=68), 113 had follow-up information collected on them. Appendix V contains a series of tables showing the change in participant characteristics and behaviours collected on these 113 participants from baseline to follow-up. Descriptive information for the outcome variables are shown below.

6.2.1 Child physical activity

Baseline data were initially collected on 110 (intervention group n=51; comparison group n=59) of the 113 children who also provided follow-up information. Following the data cleaning process (where steps counts and corresponding activity minutes were excluded should daily step counts be under 1000), these numbers were reduced for children in both groups (baseline n=107; follow-up n=103).[54] Figure 16 shows that there was a small reduction of 4 minutes (comparison group) and 7 minutes (intervention group) of weekly median activity minutes at follow-up.

[54] See Appendix V, Table V-5 for breakdown by group.

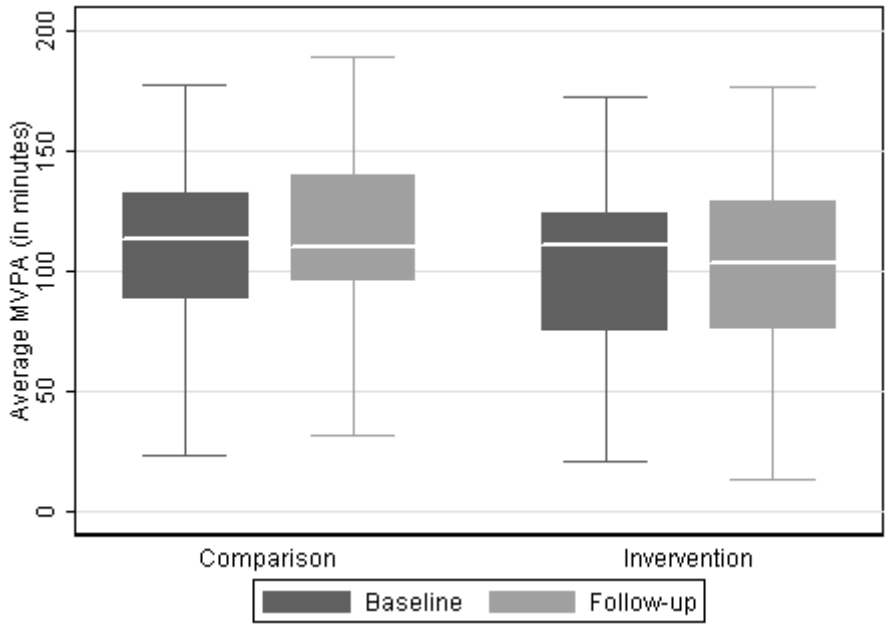


Figure 16: Seven day child MVPA assessment averages (in minutes) collected at baseline and follow-up by group

6.2.2 Child fruit offerings and vegetable offerings by caregiver descriptives

Three F&V tick-lists were not completed by caregivers at follow-up (n=1 intervention group; n=2 comparison group) and one caregiver completed this instrument at either baseline or follow-up. Figure 17 and Figure 18 show that caregiver behaviour appears to be similar across areas for both fruit and vegetable offerings at both data collection times. For the comparison group only, there are between one to three outliers for both *fruit* and *vegetable* offerings at either time point.

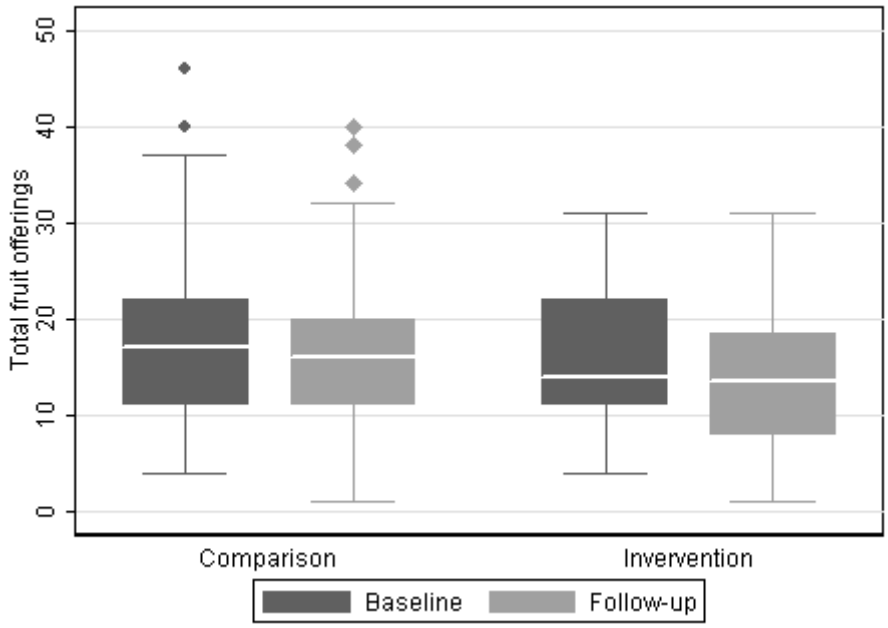


Figure 17: Five day total fruit offerings collected at baseline and follow-up by group

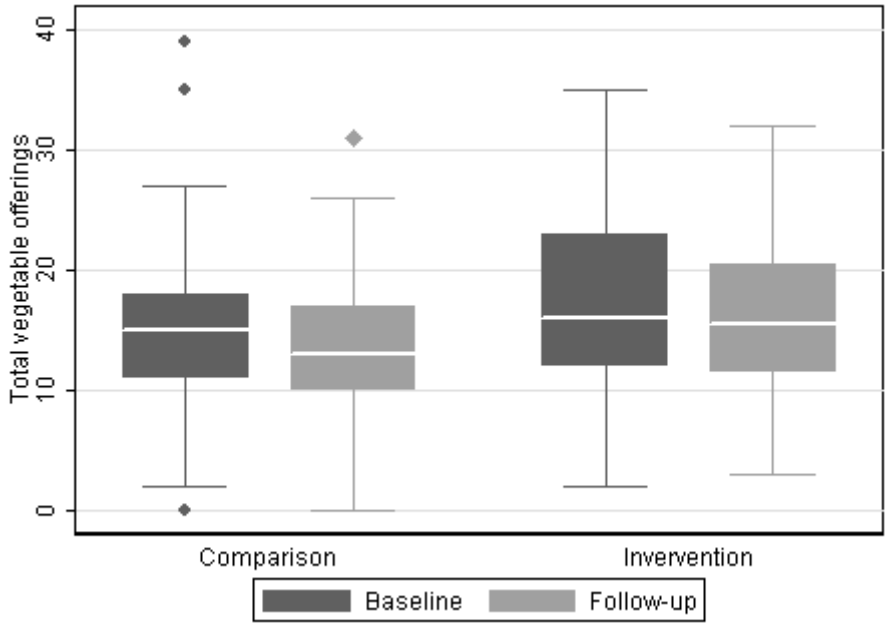


Figure 18: Five day total vegetable offerings collected at baseline and follow-up by group

6.3 Effectiveness of *Healthy Me and You*

Regression coefficients are shown for child PA minutes and rate ratios for number of *fruit* or *vegetable* offerings to child by caregiver, together with 95% CI and associated p-value. As shown in Figure 13, the analysis plan, groups (intervention or comparison) are compared in all models.

6.3.1 Outcome variable 1: Child physical activity in minutes

There was no statistically significant effect of the programme on child PA (Table 22), while controlling for baseline values (p=0.365). Data collected for this outcome variable was shown in Figure 16**.** This result was then explored further by considering other characteristic-type covariates (step 2), with half of the combined baseline characteristics eligible to proceed to step 3 ($p<0.2$, Table 22). Results from step 2 showed that higher PA minutes were associated with being a boy, having a male caregiver or an older caregiver, while lower PA levels were associated with having a caregiver with a lower level of education (all $p\leq0.049$). When considering covariates to include in the adjusted model, the key variable of group status (intervention vs comparision) was still not statistically significant (p=0.686). However the width of the confidence interval (95% CI: -15.2-10.0) was considered narrow. Other results from the step 3 include retaining the positive association between higher PA minutes for boys (p=0.005), those children with older caregivers (p=0.036) and male caregivers (p=0.043). Education level and number of adults in a household were no longer associated with PA minutes ($p\geq0.076$).

Table 28: MVPA in preschool children: Results of STEP 1 and 2 unadjusted models + STEP 3 adjusted model (final model) using Tobit regression: characteristic covariates of at follow-up controlling for baseline MVPA and group

Potential covariates	Unadjusted models Coefficient (95% CI)	p-value	Adjusted model Coefficient (95% CI)	p-value
Group Child belongs to *(reference Comparison)*				
Intervention	-5.3 (-16.8-6.2)	0.365	-2.6 (-15.2-10.0)	0.686
Child, Caregiver and Household Characteristics				
Age of child [6mth units]	3.9 (-2.8-10.6)	0.253		
Ethnicity of child *(reference non-Māori /non-Pacific)*				
Māori /Pacific	6.5 (-5.9-18.9)	0.304		
Sex of child *(reference female)*				
Male	12.7 (1.3-24.0)	0.029	15.3 (4.7-25.9)	0.005
Age of caregiver *[5yr units]*	5.3 (0.2-10.4)	0.042	5.2 (0.4-10.1)	0.036
Sex of caregiver *(reference female)*				
Male	19.3 (0.1-38.5)	0.049	18.4 (0.6-36.2)	0.043
Caregiver level of education *(reference none/NCEA1)*		0.046		0.076
NCEA 2	-12.8 (-33.2-7.6)		-12.8 (-32.1-6.5)	
NCEA 3 / vocational	-19.3 (-37.4-1.1)		-21.6 (-38.5-4.6)	
Tertiary	-2.16 (-21.6-17.2)		-10.9 (-29.6-7.8)	
Caregiver in paid employment *(reference no)*				
Yes	-1.9 (-13.7-9.8)	0.746		
Time spent with caregiver over past week *[1hr units]*	-0.9 (-2.6-0.8)	0.299		
Only child in household *(reference no)*				
Yes	-0.2 (-15.7-15.2)	0.975		
Two or more adults living in household *(reference no)*				
Yes	15.8 (-0.2-31.8)	0.053	12.6 (-2.51-27.8)	0.102

Note: p<0.2 to progress to the final model

6.3.2 Outcome variable 2: Number of fruit offerings to child by caregiver

There was no statistically significant effect of the programme on child fruit offerings. However a tendency ($p<0.100$) associated with programme participation was shown (Table 29). The CI was very narrow (95% CI: 0.8-1.0). Shown in Figure 17 was the data collected for this outcome variable. Further investigations were then performed.

Results from step 2 showed that follow-up fruit offerings were fewer in the intervention group, for older children and children who were male (all $p<0.2$). Fruit offerings were shown to be higher with caregivers who had a higher education. These four progressed to step 3 where the only variable shown to have any statistical association with fruit offerings ($p=0.042$) was caregiver level of education with more offerings given with higher levels of education. Associated RR for each level of education are indicative of very small changes and were also found to be in a positive direction.

6.3.3 Outcome variable 3: Number of vegetable offerings to child by caregiver

No statistically significant effect of participation in the programme was found in relation to child vegetable offerings $p=0.408$ (Table 30). The CI width was similar to that found in the previous model (95% CI: 0.9-1.2). Figure 18 illustrates the data collected for this outcome variable. Further investigation via steps 2 and 3 were then performed with six covariates from step 2 found to have p-values <0.200 (Table 30). Of these, two covariates were shown to have an association ($p<0.05$), where girls and singletons were offered more vegetables than boys or households with two or more children living there.

The adjusted model (step 3) showed that the group the child belonged in, was still not statistically significant ($p=0.122$). The association between offering and sex of child ($p=0.043$) was retained however the calculated RR of 0.9 indicated that the change was very small. The number of children living in the household was no longer associated with vegetable offering ($p= 0.071$). All other covariates were found to be not statistically significant in step 3.

Table 29: Fruit offerings in preschool children: Results of STEP 1 and 2 unadjusted models + STEP 3 adjusted model (final model) using Poisson regression: characteristic covariates of at follow-up controlling for baseline fruit offerings and-group

	Unadjusted models		Adjusted model	
Potential covariates	**Rate ratio (95% CI)**	**p-value**	**Rate ratio (95% CI)**	**p-value**
Group Child belongs to *(reference Comparison)*				
Intervention	0.9 (0.8-1.0)	0.097	1.0 (0.9-1.2)	0.917
Child, Caregiver and Household Characteristics				
Age of child *[6mth units]*	0.9 (0.9-1.0)	0.135	0.94 (0.9-1.0)	0.122
Ethnicity of child *(reference non-Māori /non-Pacific)*				
Māori /Pacific	0.95 (0.8-1.1)	0.535		
Sex of child *(reference female)*				
Male	0.9 (0.8-1.0)	0.181	0.9 (0.8-1.0)	0.086
Age of caregiver *[5yr units]*	1.0 (0.9-1.1)	0.913		
Sex of caregiver *(reference female)*				
Male	0.9 (0.7-1.2)	0.624		
Caregiver level of education *(reference none/NCEA1)*		0.079		0.042
NCEA 2	1.3 (1.0-1.7)		1.3 (1.0-1.7)	
NCEA 3 / vocational	1.1 (0.9-1.4)		1.2 (0.9-1.4)	
Tertiary	1.3 (1.0-1.7)		1.3 (1.1-1.7)	
Caregiver in paid employment *(reference no)*				
Yes	1.0 (0.8-1.1)	0.581		
Time spent with caregiver over past week *[1hr units]*	1.0 (1.0-1.0)	0.889		
Only child in household *(reference no)*				
Yes	1.0 (0.8-1.2)	0.702		
Two or more adults living in household *(reference no)*				
Yes	0.9 (0.8-1.2)	0.607		

Note: p<0.2 to progress to final model

Table 30: Results of STEP 1 and 2 unadjusted models + STEP 3 adjusted model (final model) using Poisson regression: characteristic covariates of vegetable offerings in preschool children at follow-up controlling for baseline vege offerings and sub-group

Potential covariates	Unadjusted models		Adjusted model	
	Rate ratio (95% CI)	p-value	Rate ratio (95% CI)	p-value
Group Child belongs to *(reference Comparison)*				
Intervention	1.1 (0.9-1.2)	0.408	1.1 (1.0-1.3)	0.122
Child, Caregiver and Household Characteristics				
Age of child *[6mth units]*	0.9 (0.9-1.0)	0.197	0.9 (0.8-1.0)	0.116
Ethnicity of child *(reference non-Māori /non-Pacific)*				
Māori /Pacific	0.9 (0.8-1.1)	0.180	0.9 (0.8-1.1)	0.294
Sex of child *(reference female)*				
Male	0.9 (0.7-1.0)	0.034	0.9 (0.7-1.0)	0.043
Age of caregiver *[5yr units]*	1.1 (1.0-1.1)	0.090	1.0 (1.0-1.1)	0.144
Sex of caregiver *(reference female)*				
Male	0.9 (0.7-1.2)	0.638		
Caregiver level of education *(reference none/NCEA1)*		0.502		
NCEA 2	1.1 (0.8-1.4)			
NCEA 3 / vocational	1.0 (0.8-1.2)			
Tertiary	1.1 (0.9-1.4)			
Caregiver in paid employment *(reference no)*				
Yes	1.0 (0.9-1.2)	0.863		
Time spent with caregiver over past week *[1hr units]*	1.0 (1.0-1.0)	0.415		
Only child in household *(reference no)*				
Yes	0.8 (0.6-1.0)	0.029	0.8 (0.7-1.0)	0.071
Two or more adults living in household *(reference no)*				
Yes	1.2 (0.9-1.4)	0.152	1.2 (1.0-1.4)	0.109

Note: p<0.2 to progress to the final model

6.4 Subgroup analysis of *Healthy Me and You* participants

Covariates pre-selected to investigate were: urban or rural location; level of caregiver attendance; and presence of a support person. These are described below. Regression analyses are then performed where coefficients are shown for child PA minutes and rate ratios for number of *fruit* or *vegetable* offerings to child by caregiver, together with 95% CI and associated p-value.

6.4.1 Location and number of participants in each programme

Healthy Me and You was delivered in six locations during 2008, with programmes offered in Invercargill (n=6) and Queenstown (n=2). Both were categorized as urban.[55] In the rural locations, Mataura, Ohai, Otautau and Riverton, each had only one programme delivered. Programme participation numbers are shown in Appendix W.

6.4.2 Programme attendance

For the majority of programmes (83%), all had the designed six sessions delivered. For two programmes (Queenstown B and Otautau), sessions were condensed into five. This change occurred due to a session being cancelled, which caused the programme scheduling to run into the holiday period which was not convenient for participants. Programme content was amended for the remaining sessions with some of the theory and practical components condensed. Celebration sessions for all were held on the final session of each programme.

Attendance at the first session was 76% (n=41), slightly lower than attendance levels at the celebration session 80% (n=43). Eleven children[56] were accompanied by a support person to at least one session. Support people included caregivers partner/husband, other family member, neighbour or their caseworker (the individual who referred them into the study). On six occasions, a child attended without their caregiver but with a support

[55] Based on the presence of a local hospital.
[56] Mataura (n=3), Invercargill A, D and E (n=2), Queenstown B and Ohai (n=1).

person and six caregivers attended a combined total of eight sessions without their child.[57]

Table 31: Descriptive statistics for programme attendance

	n	Median (%)	IQ range (%)	Min (%)	Max (%)
Programme attendance proportion					
Caregiver	54	82	83	0	100
Any adult (caregiver or support person)	54	83	50	0	100
Child	54	67	50	0	100
Any attendance (caregiver/support person/child)	54	83	33	0	100

Table 31 shows the median attendance level for the caregiver was 82%, any adult 83% and child 83%. When the combined programme attendance of any adult or child were measured, levels remained 83% however the inter-quartile range reduced to 33%. There were three participants 6% (one each from Invercargill B, Invercargill D and Ohai) where either the caregiver, support person or child attended only one session, while 100% attendance was recorded for a third of the caregivers and their child (n=18).

6.4.3 Outcome variable 1: Child physical activity in minutes

There was no statistically significant subgroup effects on child PA (Table 32), while controlling for corresponding baseline values. No further investigations were undertaken as outlined in Figure 14 as all p-values did not meet the $p<0.2$ screening criteria.

Table 32: Results of STEP 1 Univariate model using Tobit regression: sub-group covariates of MVPA in preschool children at follow-up controlling for baseline MVPA

Potential covariates	**STEP 1: Univariate model Coefficient (95% CI)**	**p-value**
Rural location *(reference no)*		
Yes	12.3 (-6.6-31.1)	0.202
Caregiver attendance level *[increase of 1 session]*	2.8 (-1.8-7.4)	0.234
Attendance at programme of support person *(reference no)*		
Yes	-4.74 (-28.0-18.5)	0.689

[57] n=3, a father attended three times when the caregiver was unavailable, and on two occasions, a child came with one of the other study caregivers therefore no direct home environmental support was present.

6.4.4 Outcome variable 2: Number of fruit offerings to child by caregiver

Increasing caregiver attendance level was the only covariate in step 1 to meet the criteria level of p<0.2 thus the multivariate model (step 2) was not performed as results produced would not differ (Table 33). The associated p-value of 0.046 showed a statistically significant result indicating that as caregiver participation rates increased, fruit offerings to the child also increased. This increase was however very small (RR=1.1) and the confidence interval was very narrow (1.00-1.14). No evidence was found for an association with programme location or presence of a support person.

Table 33: Results of STEP 1 Univariate model using Poisson regression: sub-group covariates of fruit offerings in preschool children at follow-up controlling for baseline fruit offerings

	STEP 1: Univariate model	
Potential covariates	**Coefficient (95% CI)**	**p-value**
Rural location *(reference no)*		
Yes	0.9 (0.7-1.1)	0.293
Caregiver attendance level *[increase of 1 session]*	1.1 (1.0-1.1)	0.046
Attendance at programme of support person *(reference no)*		
Yes	1.0 (0.8-1.3)	0.973

6.4.5 Outcome variable 3: Number of vegetable offerings to child by caregiver

There was no evidence of a subgroup effect on vegetable offerings (Table 34), when controlling for corresponding baseline results. No further investigations were undertaken as all p-values >0.2.

Table 34: Results of STEP 1 Univariate model using Poisson regression: sub-group covariates of vegetable offerings in preschool children at follow-up controlling for baseline vegetable offerings

	STEP 1: Univariate model	
Potential covariates	**Coefficient (95% CI)**	**p-value**
Rural location *(reference no)*		
Yes	1.2 (0.9-1.4)	0.213
Caregiver attendance level *[increase of 1 session]*	1.0 (1.0-1.1)	0.552
Attendance at programme of support person *(reference no)*		
Yes	0.8 (0.6-1.1)	0.213

6.5 Other intermediate outcomes

Results from the second aim (see Section 6.3) were not statistically significant therefore additional intermediate outcomes were investigated to determine whether the intervention had any effect on these. All categorical intermediate outcomes identified (Table 35) were recoded as binary variables and where possible, the split focused on plausible binary categories. Two different splits were required for the three family food environment outcomes as there were insufficient numbers to retain the never/seldom/sometimes against mostly/always for the outcome variable caregiver sits down with the child for a meal.

Table 35: Intermediate outcomes

PA Intermediate outcomes	**Binary recoding definition**
Weekly average MVPA measured (mins)	Continuous variables – not recoded
Weekly average number of steps measured	Continuous variables – not recoded
Daily small screen time (mins)	Continuous variables – not recoded
Caregiver: Any extra (MVPA)	Yes verses no
Daily small screen time (mins)	Continuous variables – not recoded
Child: Any extra (PA)	Yes verses no
F&V Intermediate outcomes	
Does the child help prepare the meals	Never/Seldom/Sometimes verses Mostly/Always
The child goes food shopping with caregiver	Never/Seldom/Sometimes verses Mostly/Always
Caregiver sits down with the child for a meal	Never/Seldom/Sometimes/Mostly verses Always
TV on when Child eats breakfast	Never verses ever
TV on when Child eats dinner	Never verses ever
Caregiver: Daily F&V serves	Above (≥) and below guidelines (5+ serves)
Caregiver: Daily fruit serves	Above (≥) and below guidelines (2 serves)
Caregiver: Daily vegetable serves	Above (≥) and below guidelines (3 serves)

Logistic regression was then used to generate coefficients, odds ratios, 95% CI and p-values for each (Table 36) while Figure 19 shows the standardized analysis plan used.

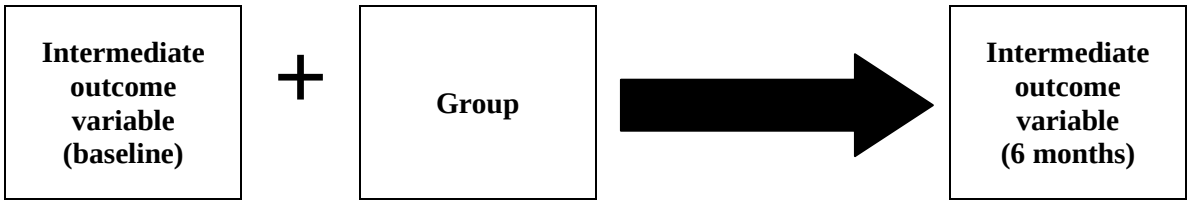


Figure 19: Analysis plan for examining the effectiveness of *Healthy Me and You* on each intermediate outcome

Table 36: Logistic regression results of intermediate outcomes at follow-up, controlling for their baseline values which considers the group the child belong to (reference comparison)

PA Intermediate outcomes	Coefficient	Odd's ratio	(95% CI)	p-value
Caregiver: Weekly average MVPA (mins)	-1.7		-6.5-3.0	0.471
Caregiver: Weekly average number of steps	-200.7		-1119.7-718.2	0.666
Caregiver: Daily small screen time (mins)	17.7		-8.0-43.4	0.176
Caregiver: Any extra (MVPA)		1.6	0.7-3.5	0.251
Child: Daily small screen time (mins)	35.1		9.3-60.9	*0.008*
Child: Any extra (PA)		11.5	0.2-672.5	0.240
F&V Intermediate outcomes				
Does the child help prepare the meals		8.9	0.0-3883.1	0.482
The child goes food shopping with caregiver		1.7	0.7-4.3	0.243
Caregiver sits down with the child for a meal		1.6	0.7-3.8	0.270
TV on when Child eats breakfast [a]				
TV on when Child eats dinner		0.5	0.2-1.4	0.186
Caregiver: Daily F&V serves		0.6	0.3-1.5	0.291
Caregiver: Daily fruit serves		1.0	0.4-2.6	0.983
Caregiver: Daily vegetable serves [a]				

Note: [a] = model didn't converge

As with the original outcomes investigated, Table 36 shows that the programme had no effect on the various intervening behaviours (intermediate outcomes) explored with one exception. Daily small screen time for children was found to be statistically significantly larger in the intervention group (by 35 minutes 6 seconds)[i] at follow-up despite a reduction in this behaviour being promoted in the programme. However baseline levels were initially higher in the intervention group with a wider inter-quartile range (See Appendix Q, Table Q-8).

6.6 Lost to follow-up

Of the 135 participants (intervention group n=67; comparison group n=68), 16% did not have follow-up (six month) data collected (intervention group n=13; comparison group n=9). Reasons included formally withdrawing from the study (n=7), relocating within NZ or overseas (n=6), with the remaining nine participants not able to be contacted via their recorded contact details or from an alternative source such as an emergency contact or the original referring agency. No statistically significant differences were found between those lost from the study compared to those who were retained for the evaluation (Table 37).

Table 37: Comparison between participants with complete data collection and those lost to follow-up

	(n=113) *6 month data collected*		(n=22) *No 6 month data*		
	Intervention Group n (%)	Comparison Group n (%)	Intervention Group n (%)	Comparison Group n (%)	p-value
Areas by New Zealand Deprivation Index[58]					
Deciles 1-5 (low deprivation)	17 (85)	28 (97)	3 (15)	1 (3)	0.291
Deciles 6-10 (high deprivation)	37 (79)	31 (79)	10 (21)	8 (21)	1.000
Sex					
Men	2 (100)	7 (100)	0	0	
Women	52 (80)	52 (13)	13 (20)	9 (15)	0.488
Sex					
Boys	33 (82)	33 (92)	7 (18)	3 (8)	0.310
Girls	21 (78)	26 (81)	6 (22)	6 (19)	0.757
Caregiver age					
<30 years	22 (81)	14 (70)	5 (19)	6 (30)	0.489
≥ 30 years	32 (80)	45 (94)	8 (20)	3 (6)	0.102
Child age					
<4 years	36 (88)	45 (88)	5 (12)	6 (12)	1.000
≥ 4 years	18 (69)	14 (82)	8 (31)	3 (18)	0.480
Ethnicity of child					
Māori /Pacific	19 (73)	15 (75)	7 (27)	5 (25)	1.000
Non-Māori /non-Pacific	35 (85)	44 (92)	6 (15)	4 (8)	0.503
Highest education					
None/NCEA1	19 (70)	3 (60)	8 (30)	2 (40)	0.637
NCEA2	9 (82)	9 (82)	2 (18)	2 (18)	1.000
NCEA3/Vocational	20 (87)	15 (88)	3 (13)	2 (12)	1.000
Tertiary	6 (100)	32 (91)	0 (0)	3 (9)	1.000

Note: Due to rounding percentages do not always add up to 100%.

[58] 2006 NZDep Index.

6.7 Summary of analyses

The effectiveness of *Healthy Me and You* was initially modeled for each outcome variable controlling for baseline information only. Results showed that those receiving the intervention programme *Healthy Me and You* did not demonstrate statistically significant differences from the comparison group for all three outcomes measured. Additional covariates were then included for each outcome for the fully adjusted models, with the same conclusion obtained from each; namely that the intervention was not effective. Results did however show that after controlling for baseline and other characteristic-type covariates, individual children undertook more PA at follow-up if they were a boy; if their caregivers were older and if the caregiver was a male. As caregiver education levels increased, increased fruit offerings also occurred compared to those with no or minimal education. Vegetable offerings were found to decrease slightly if the preschooler was male. Associated correlations and RR associated with these results were suggestive of small changes.

An investigation into three *Healthy Me and You* subgroups (rural location, level of attendance and presence of support person) was undertaken to determine if the programme was most effective in any group. Each outcome variable was modeled while controlling for respective baseline information. The only statistically significant result found was a small increase in fruit offerings if caregiver attendance levels were higher. This result was problematic as a third of the caregivers already had a 100% attendance rate and as the RR was so small, to achieve an extra fruit offering, the usual daily offering would need to be at least ten to be of practical significance.

Intermediate outcomes were then explored. However, as with the original outcomes investigated, the programme had no effect on the various intervening behaviours with one exception. Daily small screen time for children was found to statistically significantly larger in the intervention group at follow-up despite a reduction in this behaviour being promoted in the programme. Baseline levels were however initially higher in the intervention group with a wider inter-quartile range.

Differences between those lost from the study at follow-up compared to those who were retained for the evaluation were examined with no statistically significant differences found.

7 DISCUSSION

Internationally, community-based interventions such as *Healthy Me and You* targeting preschool aged children are uncommon. Furthermore the evidence for the effectiveness of such interventions is inconsistent. *Healthy Me and You*, a well designed and implemented cutting edge New Zealand intervention, did not effectively increase child PA and offerings of fruits and vegetables to children, despite robust programme planning, implementation and evaluation. Such a result may at first be seen as the inability of health promotion programmes to be effective in this complex area. However it is well to remember that childhood obesity is acknowledged as a fledgling area of research. For that reason, it is important to explore and seek to understand the implications of this study's findings rather than automatically dismissing the intervention as a failure or concluding that similar health promotion programmes are not a viable option to pursue.

This chapter examines these topics commencing with the key results from the three analyses aims. A review of the most recent research developments since the evaluation *Healthy Me and You* commenced follows together with a summary of the limitations and strengths of the intervention. This will provide evidence for recommendations proposed for similar research in the future. The chapter concludes with discussing the thesis in the context of international and New Zealand approaches to 'real world' obesity prevention research.

7.1 Review of key results

In order to gain a better understanding of the participants, predictors of *child physical activity levels* and *child fruit and vegetable intake* were first explored before examining the effectiveness of the intervention. Results showed that children undertook lower levels of PA as they grew older and PA levels also shown to higher if they were non-Maori/non-Pacific. Children also participated in more PA as the number of caregiver steps increased or if their caregiver was in paid employment. As the majority of children met the

recommended daily PA levels,[59] estimated effect sizes were considered small and therefore it was unlikely for any of these effects to be of practical importance.

With respect to fruit offering by the caregiver, results showed that while the mean number of vegetables offered over 5 days was found to be statistically significant, the RR is indicative of only a four percent increase. Similarly, statistically significant results with larger RR's were found between fruit offerings by the caregiver and the level of helpfulness exhibited by the child when food was being prepared. The number of vegetable offerings by the caregiver was also found to be statistically significantly greater for those in the intervention group, if the caregiver achieved the daily vegetable serves guidelines and increased the mean number of fruit offering to the child over five days. Associated RR's for both were again very small. Despite these statistically significant results, they were of limited practical significance due to the large number of additional offerings required to produce an increase of either one *fruit* or *vegetable* offering. It is however encouraging that they moved in the desired direction.

These findings provide valuable information for researchers and policy makers with respect to understanding the target population and identify behaviours that may warrant further investigation.

Evaluating the programme was the primary focus of this thesis. No statistically significant effect of the programme was found for any of the three outcome variable of interest while controlling for their respective baseline values. Each outcome was then explored further by considering other characteristic-type covariates with adjusted models producing the same result, namely that the programme was not effective. Results did show that boys did more PA than girls, as did children with older caregivers or children who had a male caregiver. It was also found that as caregiver education levels increased, fruit offerings also increased compared to those with no or minimal education. Offerings of vegetables were found to be lower if the child was male. These changes in offerings could not be deemed of practical importance due to the small RR calculated.

[59] The baseline weekly daily median for child MVPA was 110 minutes, with 75% of participating children doing at least 80 minutes and just over 10% of the study children participating in less than the daily recommended amount of 60 minutes.

As the intervention was shown not to be effective, it was important to investigate whether there were any subgroups of participants, who benefited more from the intervention. Investigations showed that there was no statistically significant subgroup effect on child PA or child vegetable offering by the caregiver, while controlling for corresponding baseline values. A very small increase in fruit offerings was however found with respect to increasing attendance rates by caregivers. However this small change was not considered a real difference and of practical importance.

7.2 Developments since the implementation of the *Healthy Me and You* programme

Since the implementation of the programme a considerable effort has been undertaken to design, develop and evaluate health promotion programmes which target preschool children with the aim to increase PA and improve nutrition. This recent work has begun to address the previously identified gap in knowledge of 'under fives' and interventions, and since 2008 publications indicate that research in the area is increasing.

A Cochrane protocol (Wolfenden, et al., 2010) aimed to review interventions specific to increasing F&V among preschool aged children. The rationale for this new protocol is supported by evidence described in Chapter Two, where previous reviews identified only a few trials with preschool aged children (Ciliska, et al., 2000; Knai, Pomerleau, Lock, & McKee, 2006). This new protocol focuses on RCTs which include children (five years or under), parents/caregivers responsible for the care of these children and professionals responsible for care of the child including childcare staff and health professionals. A complementary review has recently been completed which examined increasing access to or consumption of fruit and vegetables (or both) in five to 18-year olds in community-based settings (Ganann, et al., 2010). As with the Cochrane review, no other previous reviews had been undertaken in their respective areas.

Two systematic reviews (Hesketh & Campbell, 2010; Monasta, et al., 2011) both focus on interventions or RCTs intended to prevent obesity in young children. No new studies since 2008 were identified from these reviews. However they did include three of the studies previously discussed in Chapter Two (Harvey-Berino & Rourke, 2003; McGarvey,

et al., 2004; Sääkslahti, et al., 2004). Both reviews noted that that the majority of interventions targeting preschool children continue to be delivered in centre-based settings such as preschools, early childcare centers or kindergartens. These are settings where primary caregivers are generally not present and inconsistencies within these settings were identified (i.e. duration of session attended – half day versus full day; structured versus unstructured curriculum) making it challenging to generalize results of interventions. There was also a reported lack of focus on social and environmental determinants which are very difficult to address in interventions which use micro-environments such as center-based settings (Monasta, et al., 2011). Other areas highlighted include variable 'evidence' produced from studies with regards to programme effectiveness for some behaviours that contribute to obesity (Hesketh & Campbell, 2010). With respect to PA levels, the results may be explained in part by the low levels of PA typically observed in preschool/childcare settings (Brown, Hume, & ChinAPaw, 2009) despite a relatively robust study design. The low level of preschool PA typically observed in these settings is not new and confirms the need for further action in these settings.

Of the five recent studies identified, three did not have published information about the results of their respective evaluations. Two were study protocols, the Mind Exercise Nutrition Do It! Program[60] (Skouteris, McCabe, Swinburn, & Hill, 2010) and Healthy Toddlers Trial[61] (Horodynski, Baker, Coleman, Auld, & Lindau, 2011), while the other reported baseline data from a new arm of the previously reported Healthy Children Strong Families[62] intervention (LaRowe, et al., 2010; LaRowe, et al., 2007). The fourth is High 5 for Preschool Kids, a randomized nested cohort study which aimed to increase F&V intake (Haire-Joshu, et al., 2008). Participants in this study included 1306 parents and their preschoolers (intervention n=759; control n=899) involved in the Parent As Teachers (PAT), a national education program in rural, South-East Missouri, USA. Programme evaluation examined whether changes in parent behaviour were associated

[60] MEND2-4 is a RCT conducted with 200 parents and their children (2-4 years) in Australia.
[61] HT is a multi-state RCT with disadvantaged mother-toddler dyads (12-36 months) which was based on the NEAT intervention (Horodynski and Stommel 2005)
[62] HCSF is a 2 year randomized trial in the USA. Participants were 150 parents with at least one child (2-5 years who is American Indian).

with improvements of child F&V intake as well as determining whether the intervention taught parents to provide a positive F&V environment for their preschoolers. The intervention included three components: a tailored newsletter, a series of home visits and materials for both parent and child and was guided by the SCT and an ecological framework. Baseline and follow-up information (7 months) was obtained through telephone interviews. F&V intake was assessed by using the validated FFQ (Linneman, et al., 2004). Results showed that when compared to control children, F&V serves increased for those with a normal weight adjusted for parent's age and education and baseline F&V intake. No intervention effect was found for children who were overweight relative to the controls. Parent change in F&V intake was also found to be a positive predictor of improved child F&V intake for participants in the intervention group. This study provides further evidence for the importance of targeting parents in a real-world setting and the potential gains which may be achieved in relation to upstream childhood obesity prevention as parents/caregivers are the gatekeepers of a young child's food environment. The final study is the Family Ties to Health Program, a four month feasibility study of a home-based intervention aimed to improve vegetable intake of preschoolers (Tabak, Tate, Stevens, Siega-Riz, & Ward, 2012). Intervention participants (n=22) received 4 tailored newsletters (informed by the SCT) and 2 motivational phone calls over four months, whereas the control group received 4 non-health/nutrition related children's books. Data was collected in the home at baseline and follow-up. Child vegetable intake was measured using the Block Kids FFQ (NutritionQuest Assessment & Analysis Services). The intervention was shown to be effective in increasing offerings of F&V as snacks (p=0.04) and implied that similar low-resource home-based interventions may be able to increase vegetable intake in children through changing parental feeding practices and the physical home environment. The study was reported by the authors to be underpowered and the generalizeability of the results was limited by the use of a convenience sample obtained from a university list serv.

Numerous interventions were identified during the updated search which did not meet the inclusion criteria used in this thesis (see Section 2.1) but are worth noting such as Be Active Eat Well (Sanigorski, Bell, Kremer, Cuttler, & Swinburn, 2008a), Romp &

Chomp (de Silva-Sanigorski, et al., 2010), CATCH[63] Early Childhood (Sharma, Chuang, & Hedberg, 2011) and Tooty Fruity Vegie (Adams, Zask, & Dietrich, 2009). Engagement with primary caregivers/parents was reported to be included in all of these study designs however they were identified as secondary approaches to influencing child dietary and/or PA behaviours. Techniques used in these approaches included parent education sessions/workshops or parent tip sheets. However the effectiveness of the methods employed were either not measured, yet to be reported or showed trends in the right direction. This shift towards the inclusion of primary caregivers as a meaningful primary audience for interventions, confirms not only the opportunity to influence and potentially reshape adverse eating and activity behaviours that are known to promote obesity but that these behaviours are often learned early in life, within the family context (Birch & Ventura, 2009; Janz, Dawson, & Mahoney, 2000; Livingstone, McCaffrey, & Rennie, 2006; Wardle, 1995).

Other interventions that use different approaches and were shown to be effective in changing F&V intake and/or PA levels in preschoolers include Color Me Healthy (Witt & Dunn, 2012)and EXCEL[64] (Trost, Messner, Fitzgerald, & Roths, 2011). Both were child-care settings-based and although parents were engaged with in Color Me Healthy, change was unable to be successfully measured in the home environment.

7.3 Review of study parameters

Healthy Me and You was initially born out of the HEHA Innovation Fund proposal submitted by Southland DHB in 2005 and as with some funding pools, a framework was provided which identified recommended areas of action and key priorities (Figure 2).

The first aim identified caregiver and child predictors associated with the three outcomes examined (child PA in minutes, number of fruit offerings to child by caregiver, and number of vegetable offerings to child by caregiver). The second and third aims investigated the effectiveness of the intervention *Healthy Me and You* for all three outcomes measured; the results indicated no effect due to the intervention.

[63] Coordinated Approach To Child Health
[64] Excellent Care for Early Learning

Since evidence of the value and effectiveness of similar interventions are also not conclusive there may be a variety of factors which are closely linked to the quality and quantity of published literature. What is known is that influencing the home environment is fundamental when tackling such an issue because for an individual to make healthy choices (for themselves or their family), a supportive environment is essential and requires access to affordable food choices (U.S. Department of Health and Human Services, 2001). This is most apparent in disadvantaged populations (Story, Kaphingst, Robinson-O'Brien, & Glanz, 2008). Therefore, without understanding and addressing the context in which people make such decisions, individual behaviour change will be difficult to achieve (King, Gill, Allender, & Swinburn, 2011). Fortunately process evaluation data was collected during the delivery of the intervention and future examination of this information should help explain why the programme was not effective. The author concludes that despite caregivers identifying that they desired to change their behaviour (and thereby influence their children's practices) they were unable to change because their environment (time and resources) did not allow this. Meanwhile, to enable this study to be comparable with others the limitations and strengths are identified.

7.3.1 Limitations

Intervention development

As with any data collection methods, limitations associated with the use of focus groups and a programme pilot were identified. This is due to the small sample sizes used in conducting both formative studies, together with the opportunity of introducing bias and subjectivity into their development and implementation. Accordingly, when disseminating the study design[65] or associated findings,[66] it has clearly been stated that the primary objective of these formative phase studies was to obtain valuable feedback from members of the target population so that tuning of the programme could be made prior to formal implementation.

[65] Poster presentation at the Population Health Congress Conference in Brisbane, Australia; 9 July 2008.
[66] Poster presentation at the International Society of Behavioural Nutrition and Physical Activity Scientific Meeting in Melbourne, Australia; 18 June 2011.

Programme description

Programmes were only offered during the four school terms of the 2008 calendar year which restricted the number of courses able to be delivered. This determined final participation numbers. A maximum of three were able to be offered each term due to the practicalities of running multiple courses, associated travel time and other study commitments (i.e. data collection). Additional ad-hoc courses were not an option. Because of these limitations, eleven participants (caregiver and child) recruited into *Healthy Me and You* were unable to attend one of the programmes as courses were not run in the area they lived.

Methods

Because Healthy Me and You was conducted as part of a larger health promotion programme (SHEHAP), a true experimental design in which participants were randomized to an intervention or comparison group was not feasible. Consequently, a pragmatic evaluation design in which participants from Southland (the funded DHB region) by default were allocated to the intervention group and a similar sample obtained from the neighbouring region of Otago. The study design allowed the collection of data at baseline and follow-up at six-months to determine whether behaviour change was sustained in the short to medium term. The duration of follow-up would ideally be longer (Salmon, Booth, Phongsavan, Murphy, & Timperio, 2007; Summerbell, et al., 2005; van Sluijs, et al., 2007). As with many studies which use similar or shorter follow-up periods, funding and timeframes are often key factors influencing the evaluation design. In the case of *Healthy Me and You*, a conscious decision was made to invest resources into the formative evaluation of the study to ensure optimal methodology.

The power calculations undertaken used results from national studies of adults. This was a limitation as only child outcomes were investigated in this research. This approach was taken as there were no reliable age-appropriate national statistics available at the time and assumptions were made that each participating adult would attend a programme with a preschooler and be the mediator of behavioural change for that child. However this scenario did not occur for all adult-child dyads. On six occasions, a child attended without their caregiver but instead with a support person and also six caregivers attended

a combined total of eight sessions without their child. Therefore for advice provided to the support adult was not guaranteed to be disseminated to the caregiver and if it was, the quality of the information may be questionable.

The recruitment of study participants was intended to be similar for both areas. However there were minimal incentives for recruiting agencies and participants in the comparison area so recruitment was slower and more challenging. Allowances were made and the health promoter based in Dunedin widened the scope of agencies that could refer. Participants were matched by child ethnicity and sex as well as the household deprivation index score however area scores are often not homogenous and therefore may not accurately represent the SES of an individual household (Salmond & Crampton, 1999). Accordingly, this population based indicator was not used as a covariate for any of the regression models analysed in this thesis.

The instrument used to measure PA levels was the NL-1000. Prior to analysis, information was first 'cleaned' by excluding activity minute and steps data where corresponding daily steps were <1000 (Rowe, et al., 2004). The NL-1000 was not able to capture all possible PA undertaken by participants such as water-activities, cycling and for caregivers only, strength-type activities. Accordingly additional information was gathered on such activities then intensity and duration if deemed to be of MVPA. As with all subjective measures, the accuracy of this information is of a lower standard and therefore this information was not combined with data obtained from the NL-100 to create a combined total of daily MVPA minutes for participants.

The F&V tick-list used to measure F&V offerings was developed specifically for this study as no appropriate validated instruments were available at the time to accurately measure F&V intake. This meant that comparisons with other studies was challenging. However the focus of this study was to measure programme effectiveness via assessing change therefore the substitution made should not affect this activity. This instrument was not validated prior to use but a thorough development process was followed prior to finalizing the F&V tick-list. This measure was deemed to be a good surrogate for F&V intake and it was assumed that there would be some correlation between caregiver

offerings and child consumption. However the substitution of F&V intake to offerings by the caregiver may have created a wider margin of variance. This is because children may be offered fruit or vegetables by people other than the participating caregiver and therefore daily offerings could be underestimated. Also the size of the offering may vary from one caregiver to the next. Food lists contained within the F&V tick-list originated from the National Children's Nutrition survey of 5-15 year children (Parnell, et al., 2003) and some adaptations were made. The classification of mixed vegetable dishes, soups and juices was challenging. Examples of what could be classified as mixed vegetable dishes were provided to caregivers. Detailed information was sought from caregivers when collecting the F&V tick-lists which assisted with the classification of both juices and soups. Data collected were analysed as a five day total rather than individual days as young children regulate their energy intake over a 24-48 hour period compared to adults who tend to regulate meal by meal.[67]

Questions chosen for use in the interview schedules were, wherever possible, taken from a previously validated instrument. This was not always possible and some new questions were developed while approximately half of the questions required slight modifications of existing questions.[68] Comparisons between results found in this study can not be made against studies using the original question because of these modifications.

7.3.2 Strengths

Healthy Me and You was the first known community based intervention to be implemented in New Zealand that targeted socially disadvantaged caregivers and their preschoolers and aimed to increase child PA and improve F&V intake. The quasi-experimental design allowed determination of whether or not *Healthy Me and You* was effective when delivered in real-world conditions (Robson, 2002).

The initial proposal and funding was obtained by a DHB, which subsequently sought assistance from a university to assist with design, development and evaluation of the programme. This arrangement is not common but it allowed a comprehensive evaluation of a DHB implemented HEHA initiative (HEHA Strategy Evaluation Consortium, 2010).

[67] Random effects modeling does allow each days data to be used if required.
[68] Modifying existing questions can also be identified as a strength of the study.

Engagement with key community stakeholders occurred from the outset and it was at their request that the SHEHAP phase one 'workforce development programme' was created and preceded *Healthy Me and You*. All referring agencies were eligible for ongoing support from the SHEHAP team during the 3 year operational period and relationships between the staff delivering the *Healthy Me and You* and these agencies were both developed and strengthened (where existing relationship were present).

Intervention development

The HEHA Strategy's key population health messages pre-determined the primary outcomes for this research (Section 1.3). The combination of the theoretical framework (SCT (Bandura, 1986)) which is based on the premise that people learn by watching others and is influenced by the environment, behaviour and personal factors and combined with two formative-type evaluations (focus groups followed by programme piloting) is seen as one of the strengths of this intervention. A recent article by Baranowski et al. (Baranowski, Cerin, & Baranowski, 2009) identified four sequential types of formative evaluation steps recommended to improve intervention effectiveness in obesity prevention-related behavior change trials. Examples identified in this article and used to develop *Healthy Me and You* included a theoretical framework, focus groups and programme pilot.

The application of the SCT to *Healthy Me and You* provided a valuable framework so that the programme could have clearly identified aims, activities and implications for each of the different constructs. This process ensured that the programme was designed and implemented at an appropriate level compatible to a participant's behaviour and intended to cognitively affect their future behaviour. An example relating to increasing F&V is the construct environment (shown in Table 3, page 33), where the aim was to increase the availability and access of F&V in the home. Associated activities included budgetary activities so that purchased products would go further, for example minimise wastage and purchasing and growing options. Activities with both caregiver and child focused on garden preparation activities. These approaches intended to provide opportunities and social support relating to factors physically external to the person. The

content of the programme also conformed to best practice guidelines used and promoted in New Zealand at the time of implementation.

The quality of the data collected was considered 'very good' from all three instruments by the author, despite the limitations described above. To summarise, the NL-1000 had been previously validated for adults (Ayabe, et al., 2006; McClain & Tudor-Locke, 2009) and was validated for use by preschoolers before use (Liggett, et al., 2012). The F&V tick-list had been developed for the region and tested prior to use. Participants conformed well to instructions (wearing of NL-1000 and completion of F&V tick-list) and very little data were lost from either. If problems occurred during the data collection period, caregivers rang a free-call number and seek advice from one of the programme staff. Participants were, where possible, given the identical device at follow-up to minimise external validity. Participants also received daily reminders via text to complete the F&V tick-list and wear the NL-1000. Additional process evaluation data, which was beyond the scope of this thesis, was collected with the intent to assess the success of the programme implementation.

Methods

The model used for recruiting participants was fully supported by health and social service agencies as they felt they knew their population and were better placed to identify disadvantaged families. Alternative approaches often used in studies such as advertisements seeking study participants were more likely to attract the traditional 'well-educated population groups'. Guidance was however provided to these agencies based on residential maps outlining areas which were identified at a population level to be deemed high deprivation areas.

7.3.3 Research implications

This study examined the effectiveness of the health promotion programme *Healthy Me and You.* While no positive results were found in this study, further research into prevention of childhood obesity is still important given the huge public health gains which could potentially be made. The growing obesity epidemic justifies why it is important to intervene as early as possible therefore it is appropriate to target preschool

aged children. As such it is noteworthy to stress that preschooler's food preferences are largely dependent on their parents/caregivers (Benton, 2004; Birch, 1999) and that the home environment, which emulates parental behaviours is associated with preschool children's physical activity, sedentary behaviour and dietary patterns (Spurrier, Magarey, Golley, Curnow, & Sawyer, 2008). The evidence-base is growing and while researchers are predominantly still focused on center-based settings such as schools and childcare facilities there has been a recent shift of focus towards targeting preschool aged children in their homes. This shift is important as although many preschool aged children spend time away from the home in a child care setting, the family home remains one of the principle environments with family rules and preferences largely determining food availability (and thus offerings) together with opportunities for physical activity (Booth, et al., 2001).

Encouraging positive behaviour change is known to be challenging (Rollnick, Mason, & Butler, 1999) and as with other areas of research which aspire to improve the health and well-being of individuals at a population level, there is no "silver bullet" or "magic pill" available and this task is considerably more challenging when targeting disadvantaged populations. The environment for which we now live in no longer favours a balance between physical activity and food intake energy expenditure (Egger & Swinburn, 1997), therefore it may be challenging for some to make healthy choices. Ideally educational interventions such as *Healthy Me and You* should be accompanied by environmental and policy changes which motivate and enable people to obtain healthful foods and use opportunities for physical activity (Booth, et al., 2001; Story, et al., 2008). The HEHA Strategy from which this intervention is derived from does take this ecological approach however major policy change did not occur during programme implementation nor since then. Existing macro-level environmental factors which operate within the wider society (such as food marketing and social norms) also hinder behaviour change adoption and maintenance.

A number of methodological design, implementation and evaluation issues have been identified which warrant consideration in future research being carried out. These issues should also be shared with policy makers and funding agencies so that they can be fully

informed prior to making future decisions in this area. In New Zealand, this also means that programmes should recognize two guiding values: *Reducing Inequalities* and the *Treaty of Waitangi*. Despite best intentions, not all involved have the necessary skills, knowledge and resources to do so and would benefit from attending appropriate training to up-skill and/or refresh their knowledge. Real world research is challenging due to the complexities of the environment in which people live, combined with striving to obtain a representative study population. This is due to most researchers using the more traditional well-educated population, which may inadvertently widen existing inequalities and have little effect on those who would benefit the most with respect to improved health status.

7.4 Recommendations and future research

These are specific to methodological improvements which should be considered prior to the design, implementation and evaluation of future research in this area.

1. When developing an intervention, ensure an appropriate framework/theory is applied. Invest resources into formative phase studies which include engaging with the target population to inform programme content and pilot test adequately.
2. Ensure that a comparison group is recruited in a similar manner to that of the intervention group.
3. Aspire to undertake real-world research. Be aware that the use of well-educated population groups and families as target populations may widen existing inequalities within a population.
4. Should this approach be taken, be mindful that behavioural change interventions in isolation are unlikely to be sustainable or effective unless interventions provide a more supportive environment for participants.
5. When identifying study outcomes and associated measurement instruments, select outcomes which have ideally been used elsewhere so that comparisons with existing results and the pending research findings are possible.
6. Measurement instruments should be both reliable and validated for the target population.

Even with the best implementation, this study has shown that in New Zealand, education-style interventions such as *Healthy Me and You* may not work. For many disadvantaged

families, there are just too many other priorities, more important than improving nutrition and increasing physical activity of their children. At a household level these priorities (or barriers) will vary. However they can be considered under three broad headings: social barriers for example stress reactions in response to economic adversity; environmental barriers such as access to resources; and countervailing forces around accessing unhealthy food and sedentary behaviour. These areas were determined from information obtained from the focus groups and also indirectly from programme staff.

To help counteract these social and environmental barriers, future interventions similar to *Healthy Me and You* are recommended to be linked with a parallel initiative. Research could therefore be undertaken to determine which of these provide the best synergistic effect on fruit and vegetable intake and physical activity levels of the child. Excellent measures have been developed that could be used in such research and combined with the measures capturing these nutrition and physical activity levels. Some suggested examples are identified below.

Research suggests that living in low SES environment for prolonged periods may deplete emotional reserves which in turn leads to poorer relationships with family and friends. This has a direct effect on parenting behaviour of their children and consequently on their health (Bradley & Corwyn, 2002).

Children are also found to be healthier when they are living in insulated homes (Howden-Chapman, et al., 2007). Financial constraints may limit access to preventive health care and the timeliness of care and treatment for sick children (Grant, et al., 1998). A low SES in childhood has also been shown to be associated with adverse health outcomes in adulthood (Poulton, et al., 2002). In the PhD thesis by Smith (2011), the Spend study examined the effect of providing supermarket vouchers to food insecure households and demonstrated that most of this additional money is spent on food. Research has shown that inadequate dietary intake is associated with a number of adverse outcomes in children (Engle & Black, 2008). This approach might support and complement the intervention, enhancing the desired behavioural change. However little is known about using such incentives in New Zealand but a recent published article indicated that

economic incentives may be a viable option to promote healthier household purchases (Ni Mhurchu, et al., 2011).

In summary, these barriers are thought to distract caregivers from parenting practices which provide their children with an increased amount of healthy foods or promote increased levels of activity. It may be that if these barriers are changed and caregivers attend an intervention such as *Healthy Me and You*, their discretionary money will increase and they will spend this additional money on promoting a healthy lifestyle for them and their preschoolers (as taught in the intervention). This new research would not only enable the health status of children to be measured (for example through doctor's and hospital visits) but new measures of fruit and vegetable use and physical activity could also be factored into these social and environmental changes.

7.5 Relationship to international evaluation efforts

This research has confirmed that there was little evidence for the effectiveness of health promotion programmes aiming to increase PA levels and improve F&V intake for socially disadvantaged caregivers and their preschoolers in a community-based setting. Interventions of this nature are rare, with the majority of similar studies predominantly targeted towards older children or well educated populations, and delivered in center-based settings such as schools, kindergartens and early childhood centers. Therefore a comprehensive comparison between the results from this work and similar studies was not possible.

A recent global projection of the burden of obesity based on 2005 data through to 2030 indicates that the proportion of people overweight or obese will increase from 33% up to 57% with increases found in both developed and developing countries (Kelly, Yang, Chen, Reynolds, & He, 2008). These figures together with the knowledge that more than 20% preschool children are either overweight or obese before they attend school (Ogden, et al., 2006) heightens the need for further research in this area. The prevention of childhood obesity is a rapidly developing area and there has been an increasing awareness of the potential health gains to be made by preventing or delaying obesogenic behaviours in early childhood (Reilly, 2008). A shift towards tackling this issue in children under

five has recently occurred but it is acknowledged there is much work still to be done specifically regarding methodological issues in the design, delivery and evaluation of such programmes (Livingstone, et al., 2006; Salmon, et al., 2007; Summerbell, et al., 2005; van Sluijs, et al., 2007).

In the absence of an existing approach to intervention design, data collection and outcome measures, the approach taken in this thesis to develop, implement and evaluate *Healthy Me and You* may offer some guidance to those considering establishing a similar intervention. Populations will vary internationally. However some commonalities exist. This New Zealand intervention offers an example of an approach to study design and evaluation methodologies used to examine upstream early childhood obesity interventions.

7.6 Relationship to New Zealand obesity prevention research and evaluation

Research in New Zealand in relation to PA continues to expand. The inception of the HEHA Strategy enabled new funding from the government to be invested alongside traditional existing funding avenues such as HRC,[69] DHB Research Fund, NGO's[70] (i.e. Cancer Society, Heart Foundation, Stroke Foundation) and FRST.[71] The majority of published research with preschool aged children has been prospective, for example The FLAME Study (Taylor, et al., 2009). There are no other known New Zealand interventions published.

It has recently been reported that more emphasis needs to be placed on rigorous evaluation of the large number of government and community-based programmes currently underway in New Zealand, with very few of the HEHA Strategy funded initiatives having evaluation components attached to them (HEHA Strategy Evaluation Consortium, 2010). This HEHA Strategy Evaluation Consortium report emphasised the importance of evidence-based health promotion, specifically outcome evaluation (behaviour and health change) as without this it is challenging to justify continued investment from the government. Should outcome or impact evaluation not be included

[69] Health Research Council.
[70] Non Government Organisations.
[71] Foundation for Research Science and Technology.

into the design of a programme, programme delivery can be improved though information gained through the formative, and process evaluation undertaken. Dissemination of all evaluation is critical to enable researchers, health promoters, funders and policy decision-makers to inform future decisions. While New Zealand continues to grapple with the obesity problem, whether it is addressing potential cures through primary and secondary prevention or the complex multiplicity of probable causes, sharing this type of information may help fight the "battle of the bulge". Lessons learnt in New Zealand may be applicable in other developed countries.

New Zealand is fortunate to have several studies using nationally representative samples with which to measure PA and nutritional status of the country. The latest of these is the Nutrition and Physical Activity Survey which is currently in the final years of data collection (McLean, et al., 2009) [72] and the recently published 2008/09 New Zealand Adult Nutrition Survey (University of Otago and Ministry of Health, 2011). However all of these studies lack information on preschool aged children. To fully understand how active our population is, the use of robust, objective measurement data in future studies using nationally representative samples, is recommended. Without this information, individual results can not be compared against national statistics.

7.7 Conclusion

Healthy Me and You was a carefully run, soundly developed and managed intervention. Despite this, no changes occurred in outcomes measured or intervening behaviours. There was no change evident in intermediate behaviours which were explored given that the overall intervention was not found to be effective. The study does help address the lack of information currently available, on healthy lifestyle interventions with preschoolers delivered in a community setting which directly involved the presence of a primary caregiver and targets socially disadvantage households.

Obesity is a major public health issue and while there is limited evidence available regarding effective ways to prevent obesity, particularly in early childhood, further research is recommended to enable researchers and policy makers to be more informed

[72] Follows 6400 individuals aged 15 or older annually for three-years with an aim of collecting information about the eating and PA habits and viewpoints of adult New Zealanders.

than the current evidence base allows. This is necessary to ensure that available resources including funding, time and expertise are maximised in the design, implementation and evaluation (using appropriate measures) of all future health promotion programmes.

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