

**New South Wales
Health Promotion Demonstration
Research Grants Scheme**

**A POPULATION-BASED LIFESTYLE
INTERVENTION TO PROMOTE
HEALTHY WEIGHT AND PHYSICAL
ACTIVITY IN PEOPLE WITH
CARDIAC DISEASE**



THE PANACHE TRIAL

NSW MINISTRY OF HEALTH

73 Miller Street
NORTH SYDNEY NSW 2060
Tel. (02) 9391 9000
Fax. (02) 9391 9101
TTY. (02) 9391 9900
www.health.nsw.gov.au

Produced by:

Centre for Epidemiology and Evidence
Population and Public Health Division
NSW Ministry of Health

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Research advisory group

Janice Sangster,^{1,2} Susan Furber,^{1,3} Adrian Bauman,⁴ Philayrath Phongsavan,⁴ Margaret Allman-Farinelli,⁴ Andy Mark,⁵ Marian Haas,⁶ Jody Church⁶ and Julie Redfern.⁷

Project advisory group

Janice Sangster,^{1,2} Susan Furber,^{1,3} Andy Mark,⁵ Jody Church,⁶ Jo Leonard,⁸ Jacquie Maidment,⁸ Glenn Paull,⁹ Beth Connelly,⁹ Wendy Mullooly,¹⁰ Robyn O'Brien¹¹ and Bev Lloyd.¹²

Support in data management, statistical analysis and editorial advice

Ken Russell (Charles Sturt University, Wagga Wagga), Annabel Bowcher (AnDi Communications Wagga Wagga), Tania Starr¹ and Belinda Fabrianesi.¹

Organisations

1. Health Promotion Service, Illawarra Shoalhaven Local Health District (former South Eastern Sydney and Illawarra Area Health Service)
2. Health Promotion Service, Murrumbidgee Local Health District (former Greater Southern Area Health Service)
3. School of Public Health and Community Medicine, University of New South Wales
4. Sydney School of Public Health, University of Sydney
5. Heart Foundation, NSW Division
6. Centre for Health Economics Research and Evaluation, University of Technology, Sydney
7. George Institute for Global Health, Sydney
8. Wagga Wagga Base Hospital Cardiac Rehabilitation
9. St George Hospital Cardiac Rehabilitation
10. Sutherland Hospital Cardiac Rehabilitation
11. Goulburn Base Hospital Cardiac Rehabilitation
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List of abbreviations

AR-DRG	Australian refined diagnosis related groups
AQoL	Assessment of Quality of Life
AUC	Area under the curve
BMI	Body Mass Index
CI	Confidence interval
CR	Cardiac rehabilitation
HW	Healthy weight
ICER	Incremental cost-effectiveness ratio
ICC	Intraclass correlation coefficient
IQR	Interquartile range
MBS	Medicare Benefits Schedule
n	number
p	probability due to chance
PA	Physical activity
PANACHE	Physical Activity, Nutrition and Cardiac Health
QALY	Quality adjusted life year
RCT	Randomised controlled trial
SD	Standard deviation

Executive summary

Issue addressed

Cardiovascular disease is the leading cause of death and the most expensive disease group treated in Australia. Only one-third of clinically eligible patients attend cardiac rehabilitation (CR). Non-attendees are socio-economically disadvantaged, have higher cardiovascular risk and live further from health services. Many CR attendees do not achieve their weight or physical activity targets. Innovative models of secondary prevention for cardiac disease are needed to address these gaps. The aims of this project were to determine: (1) the effectiveness of a telephone-delivered pedometer-based intervention on weight and physical activity for urban and rural people referred to CR; (2) whether the findings on physical activity previously reported are replicated in the control group of this trial; and (3) the costs and cost-effectiveness of the interventions.

Methods

Rural and urban patients (n=313) referred to CR were randomised to a healthy weight (HW) intervention (four telephone coaching sessions on weight and physical activity) or a physical activity (PA) comparison group (two telephone coaching sessions on physical activity). Self-reported weight and physical activity were assessed at baseline, short-term (6–8 weeks) and medium-term (6–8 months). The physical activity outcomes of the PA group were also compared to a reference randomised controlled trial (RCT) that had previously showed the same intervention was effective for cardiac patients in one semi-rural setting. A cost-utility analysis assessed the incremental cost-effectiveness of the HW intervention over the PA intervention.

Results

The HW group decreased their weight ($p=0.005$), and HW participants with a BMI ≥ 25 kg/m² had a mean weight loss of 1.6 kg, a significantly greater weight loss than the PA group ($p=0.01$), over the medium-term. Both groups increased their physical activity short-term and the PA group maintained this increase medium-term. Increases in physical activity in the PA group were comparable to those of the reference study. The cost-utility analysis showed the HW intervention “dominated” the PA intervention (i.e. was less costly and more effective than the PA intervention and was more cost-effective for patients who did not attend CR and rural participants).

Conclusion

The low-contact, low-cost, telephone-based interventions tested are an effective and feasible means of delivering lifestyle interventions for underserved rural communities, for CR non-attendeess, or as an adjunct to existing CR programs.

Publications, presentations and thesis arising from this project

Publications

Sangster J, Furber S, Allman-Farinelli M, Haas M, Phongsavan P, Mark A, Bauman A. A population-based lifestyle intervention to promote healthy weight and physical activity in people with cardiac disease: The PANACHE (Physical Activity, Nutrition And Cardiac Health) study protocol. *BMC Cardiovasc Disord* 2010; 10: 17.

Sangster J, Furber S, Phongsavan P, Allman-Farinelli M, Redfern J, Bauman A. Where you live matters: Challenges and opportunities to address the urban-rural divide through innovative secondary cardiac rehabilitation programs. *Aust J Rural Health* 2013; 21: 170-7.

Sangster J, Church J, Haas M, Furber S, Bauman A. A comparison of the cost-effectiveness of two pedometer-based telephone coaching programs for people with cardiac disease. *Heart Lung Circ* 2015; 24: 471-9.

Sangster J, Furber S, Allman-Farinelli M, Phongsavan P, Redfern J, Haas M, Church J, Mark A, Bauman A. Effectiveness of a pedometer-based telephone coaching program on weight and physical activity for people referred to a cardiac rehabilitation program: randomised controlled trial. *J Cardiopulm Rehabil Prev* 2015; 35(2): 124-9.

Sangster J, Furber S, Phongsavan P, Redfern J, Mark A, Bauman A. The effects of a pedometer-based telephone coaching intervention on physical activity among people with cardiac disease in urban, rural and semi-rural settings: a replication study. *Heart Lung Circ* 2016; Aug 16. pii: S1443-9506(16)31537-2.

Conference presentations

Sangster J, Furber S, Allman-Farinelli M, Phongsavan P, Redfern J, Haas M, Church J, Mark A, Bauman A. Telephone coaching to promote healthy weight and physical activity for urban and

rural people with cardiac disease – a randomised controlled trial. 61st Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand, August 2013.

Sangster J, Furber S, Allman-Farinelli M, Phongsavan P, Redfern J, Haas M, Church J, Mark A, Bauman A. Efficacy and cost-effectiveness of a population-based lifestyle intervention to promote healthy weight and physical activity in urban and rural people with cardiac disease – a randomised controlled trial. 30st National Conference of the Dietitians Association of Australia, Canberra, May 2013. *Oral presentation.*

Sangster J, Furber S, Allman-Farinelli M, Phongsavan P, Mark A, Bauman A. Telephone coaching to promote healthy weight and physical activity in rural and urban people with cardiac disease. International Congress of Dietitians Conference, Sydney, September 2012. *Workshop.*

Sangster J, Furber S, Allman-Farinelli M, Phongsavan P, Mark A, Bauman A. Translation Research with PANACHE – The Physical Activity, Nutrition and Cardiac Health Study. Prevention Research Collaboration Translation Research Forum, University of Sydney, October 2011. *Invited paper.*

Sangster J, Furber S, Allman-Farinelli M, Phongsavan P, Mark A, Bauman A. Research with PANACHE – The Physical Activity, Nutrition and Cardiac Health Project. The Collaboration for the Advancement of Research in Dietetics (CARD) Conference, University of Sydney, November 2010. *Invited paper.*

Thesis for degree of Doctor of Philosophy

Sangster J. *A population-based lifestyle intervention to promote healthy weight and physical activity in people with cardiac disease.* A thesis submitted in fulfillment of the requirement for the degree of Doctor of Philosophy. UNSW, April 2013. Available at:
<http://unsworks.unsw.edu.au/fapi/datastream/unsworks:11504/SOURCE01>

SECTION 1

Introduction

Cardiovascular disease imposes a heavy burden of death, disability and excess health costs on the Australian community,¹ much of which is preventable through maintaining a healthy weight and engaging in regular physical activity.² It is widely recommended that cardiac patients participate in secondary prevention programs such as exercise-based CR.^{3,4} These programs have been shown to reduce mortality⁵ and recurrent cardiac events,⁶ improve cardiac risk factors⁷ and enhance quality of life.⁸ However attendance at CR is poor with only 15–30% of those eligible attending CR in Australia^{9,10} and worldwide.¹¹ The greatest burden of disease comes from those presenting with repeat events, thus secondary prevention is a key priority.⁴ That the majority of people with cardiac disease are left with unmet health needs and with a higher risk of cardiac-related disability and death is a major public health issue.

Those not attending CR are likely to have more risk factors (e.g. physical inactivity, smoking),¹² be more socio-economically disadvantaged¹³ and live further from health services.¹⁴ For patients that do attend CR a substantial treatment gap exists between the recommended targets and actual patient outcomes,¹⁵ indicating an urgent need to develop more effective approaches to lifestyle management for people with coronary disease. In addition, the clinical profile of the CR population is becoming more challenging with a 10-year study of patients entering CR reporting that patients were becoming older, more overweight, less fit and more likely to present with features of metabolic syndrome such as impaired glucose tolerance and high blood pressure.¹⁶

To improve the utilisation and outcomes of CR programs the Australian Cardiovascular Health and Rehabilitation Association has recommended that studies of effectiveness of different service models be conducted.³ Interventions that are based on a sound behavioural change framework¹⁷ and that are mediated by telephone have been shown to be effective for facilitating physical activity and dietary behaviour change for people with chronic conditions¹⁸ and coronary heart disease.¹⁹ However there is limited research on the effectiveness of such programs for cardiac patients that do not attend conventional outpatient CR, and for rural residents with cardiac disease.

In order to advance the translation of research into practice, evidence that interventions can be replicated in a range of settings is needed, as well as information on intervention implementation

costs and cost-effectiveness. However, replication studies of health interventions²⁰ or economic evaluations of CR are seldom conducted.²¹

The current research addresses a significant gap in public health knowledge and practice, and also in health services planning and implementation, by providing evidence of the effectiveness and cost-effectiveness of a potentially low cost, low contact, high reach intervention promoting healthy weight and physical activity among people with cardiac disease in rural and urban areas in Australia. This research builds on evidence from a recent study^{22,23} that showed that a telephone coaching intervention using pedometers could increase physical activity in people with cardiac disease irrespective of whether they attended CR programs or not. The control group of the current research replicates the physical activity intervention trialled by Butler et al²² and Furber et al,²³ thus assessing its effectiveness and acceptability when implemented in diverse settings such as urban and rural locations.

The current research provides important information for the development of health services policy, by showing whether the low contact interventions tested in this research are effective and can be delivered cost-effectively. These interventions have the potential to improve access to CR services, particularly for disadvantaged and rural people. If found to be effective, pedometer-based telephone coaching programs could be a feasible addition to existing CR services to address the needs of the large population of patients currently not attending CR programs. Telephone coaching programs could also be delivered to cardiac patients who attend CR programs as a “maintenance” program.

SECTION 2

Research aims

1. Determine the effectiveness of a telephone-delivered pedometer-based lifestyle intervention on weight and physical activity in people referred to CR in urban and rural settings.
2. Determine if the findings on physical activity previously reported²³ are replicated in the physical activity comparison group (control group) of this trial.
3. Determine the costs and cost-effectiveness of the interventions in urban and rural settings, compared to the outcomes achieved.

SECTION 3

The intervention

Healthy Weight intervention

The Healthy Weight (HW) participants received an eight week healthy weight telephone-coaching intervention based on social cognitive theory²⁴ and behaviour change coaching.²⁵ The intervention focused on increasing participants' self-efficacy (beliefs about the positive health consequences of taking action) and encouraged the use of planning and self-monitoring strategies for healthy eating and regular physical activity. The HW intervention was developed from the physical activity intervention used by Butler et al²² and Furber et al²³ and was enhanced to include self-monitoring and goal setting components relating to healthy weight and nutrition.

All the intervention components were delivered via mail or telephone. Participants were mailed written materials, a lifestyle calendar (to record nutrition and physical activity goals) and a pedometer. They took part in four behavioural coaching and goal setting sessions on weight, nutrition and physical activity via telephone plus two booster telephone calls after the intervention. The coaching and booster telephone calls were conducted by a health professional with post-graduate qualifications in nutrition and health promotion, and training in health coaching. The coaching calls were implemented using a written guide which was based on principles derived from successful behaviour change interventions. These included: assessment and feedback; advice (on diet and physical activity); assistance with goal setting; developing a personalised plan (for modifying diet and physical activity); and arranging follow-up support.^{22,23,26} Participants were taught how to self-monitor their food intake and physical activity using their lifestyle calendar and pedometer, and to use this information to set attainable nutrition and physical activity goals. Goal attainment was reviewed at subsequent telephone sessions and participants were assisted to develop strategies to overcome barriers encountered. The invitation letter and consent form are in Appendix 1. The HW intervention materials are in Appendix 2.

The advice on nutrition and physical activity was consistent with Australian national guidelines.^{2,27} Goals were individualised and if the participant's BMI was ≥ 25 kg/m² they were coached to follow the dietary guidelines,²⁷ to lose weight gradually,² and to undertake 60–90 minutes of physical activity on most days of the week.²⁸ If the participant's BMI was in the healthy weight range (18.5–24.9 kg/m²) they were provided with supportive coaching to follow the dietary guidelines²⁷ to

maintain their current weight² and to undertake at least 30 minutes of physical activity on most days of the week.²⁹ Individuals determined their physical activity goals according to their abilities and preferences, and were based on step counts or on time spent doing physical activity.

The HW intervention was piloted by conducting it with a convenience sample of nine participants recruited from a rural CR program. Pilot participants completed objective measures of weight and physical activity. Objective measures were food diaries, BMI measurements (i.e. weight and height) and accelerometer measures for physical activity. The data from the objective measurements were compared with the self-reported measurements. At the end of the intervention and data collection period pilot participants met individually with the researcher and were asked what they liked about the intervention and whether they had any difficulties with the resource materials, evaluation questions or data collection procedures. The findings were used to refine evaluation questions and procedures, modify the telephone coaching guide and improve the suitability of written support materials.

Physical Activity comparison group

The Physical Activity (PA) comparison group received the same six week physical activity intervention previously found to be efficacious for people with cardiac disease.^{22,23} This was also based on social cognitive theory.²⁴ Participants received a pedometer and step recording calendar via mail and participated in two telephone coaching and goal setting sessions specifically on physical activity, plus two booster telephone calls. They were coached to undertake at least 30 minutes of physical activity on most days of the week.²⁹ Participants were encouraged to build their physical activity levels gradually. The components of the PA intervention are listed in Appendix 3.

SECTION 4

Research methods

Study design

Three separate studies were conducted corresponding to the three aims of the project.

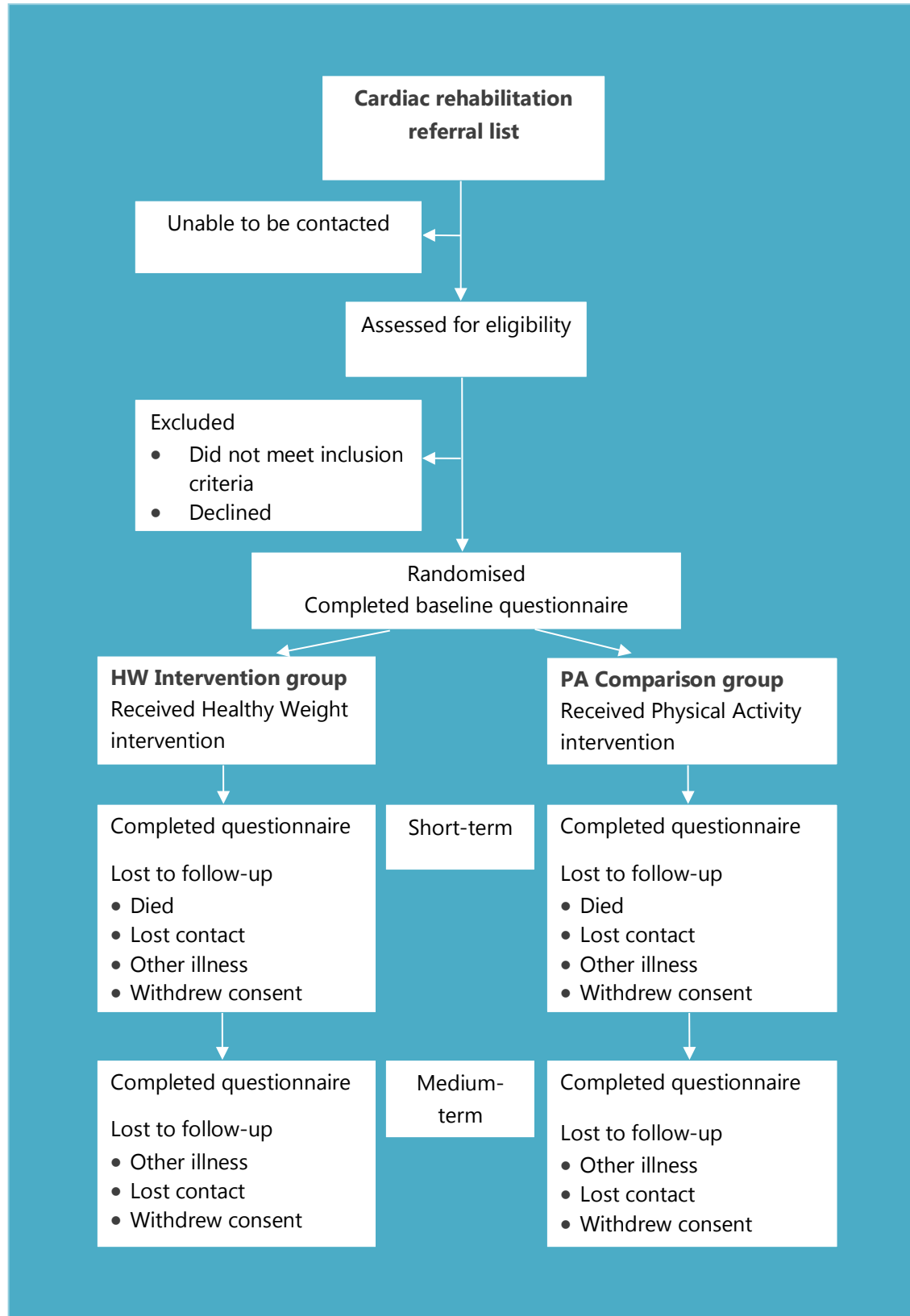
Study 1 Effectiveness study: to determine the effectiveness of a pedometer-based telephone coaching program on weight and physical activity for people referred to a CR program (PANACHE trial).

Study 2 Replication study: to determine if the findings on physical activity previously reported²³ are replicated in the control group of the PANACHE trial.

Study 3 Cost-effectiveness study: to determine the costs and cost-effectiveness of the interventions used in the PANACHE trial.

An RCT was conducted for Study 1 (see Figure 1). For Study 2, the findings on physical activity previously reported²³ were compared with those from the physical activity comparison (control) group of the PANACHE trial. For Study 3, a cost-utility analysis was conducted alongside the PANACHE trial (Study 1).

Figure 1: Outline of the PANACHE trial



Study participants

All patients referred to outpatient CR programs over 12 months at two urban public hospitals (metropolitan Sydney) and over 16 months at two rural public hospitals during 2010–11 were invited to participate. People could participate whether or not they attended a CR program, if they spoke English, and could undertake physical activity such as moderate walking. Participants received the invitation letter about 6–8 weeks after referral to CR by which time they would likely to be clinically stable in the recovery period.

Participants were randomised by the researcher into intervention and control groups when they agreed to be enrolled in the study. Participants were block randomised within site. Microsoft Excel was used to generate random numbers and the Statistical Analysis System (SAS) was used to randomise these numbers into sets of two letters (A and B, representing the intervention and control groups respectively) by blocks of four to ensure a balanced sample size across both study groups. The random numbers were generated and packaged by a person external to the study so the group allocation was concealed from the researcher until the participant had agreed to be in the study. Participants were not told whether they had been allocated to the intervention or control group and remained blinded to group allocation. Group allocation was not concealed from the researcher when delivering the intervention or assessing outcomes. The randomisation to intervention and control was balanced between rural and urban areas as the rural and urban areas received their own packet of random numbers.

Participants were not told which group they were allocated to. Participants for Study 2 were from the physical activity comparison group (control group) of the PANACHE trial and from the intervention arm (physical activity) in the study by Furber et al.²³

Ethics

This research was approved by the Human Research Ethics Committees from the University of Wollongong (HE08/234), the University of New South Wales and the former South Eastern Sydney and Illawarra Area Health Service (SSA/08/STG/184 STG and SSA/08/STG/185 TSH) and Greater Southern Area Health Service (08/GSAHS/81).

Data collection and measurement

STUDY 1: The primary study outcomes were self-reported weight and body mass index (BMI). Secondary outcomes were self-reported physical activity, sedentary time, health-related quality of life and nutrition habits. The Active Australia Questionnaire³⁰ was used to assess physical activity. It has demonstrated reliability and validity in Australian community³¹ and clinical populations.²² Sedentary time was assessed using the question on usual weekday sitting time from the International Physical Activity Questionnaire which has also demonstrated reliability and validity.³² The Assessment of Quality of Life (AQoL) questionnaire was used as an unweighted psychometric instrument to assess health-related quality of life.³³ Nutrition habits were assessed using questions modified from the NSW Population Health Survey.³⁴ For process evaluation, participants were asked about the usefulness of the pedometer, the lifestyle calendar (HW group), the step calendar (PA group), the HW/PA materials and the telephone counselling (HW group). All data were collected by telephone interview. Data for the PA group were collected at baseline, 6 weeks and 6 months. Data for the HW group were collected at baseline, 8 weeks and 8 months to allow for the longer intervention. For clarity, these follow-up periods are both referred to as 6 weeks (short-term) and 6 months (medium-term). The questionnaires used are shown in Appendix 4.

Validity of self-reported BMI and physical activity data was examined by comparing self-reported data with contemporaneously measured data obtained from a sub-group of HW participants.³⁵ At baseline, there was very good agreement between self-reported and measured BMI (n=18, Intraclass Correlation Coefficient (ICC)=0.98, $p < 0.001$; mean discrepancy -0.8 kg/m^2 , 95% CI=-1.2, -0.4), with similar results obtained at 6 months. There was fair to good agreement between baseline self-reported and measured total weekly minutes of moderate and vigorous physical activity (n=18, ICC=0.60, $p < 0.001$; median discrepancy 78.2 mins, 95% CI=43.0, 113.0).

STUDY 2: Physical activity data obtained for the physical activity comparison group (control group) of the PANACHE trial (as described for Study 1) were compared with the PA outcomes described in the study by Furber et al²³ (an RCT with those who did not attend CR).

STUDY 3: Cost-utility analysis was undertaken to determine the incremental cost-effectiveness of the HW intervention over the PA intervention. The incremental cost-effectiveness ratio (ICER)³⁶ is calculated using the following:

$$ICER = \frac{Cost_{New} - Cost_{Comparator}}{Effectiveness_{New} - Effectiveness_{Comparator}}$$

Data for Study 3 were obtained from participants at the same time as data for Study 1 and Study 2. See Appendix 4 for questions used.

Assessment of quality of life

For the cost-utility analysis effectiveness of the interventions was determined using estimates of quality of life that were derived using the AQoL 4D.³³ The AQoL 4D questions were completed by participants at baseline, 6 weeks and 6 months via a telephone-delivered questionnaire.

The AQoL 4D scores were converted to utility scores. To do this, the AQoL 4D utility scores were scaled such that the worst health state is -0.04 (indicating a state worse than death), death is 0.00 and the best health state is 1. An algorithm was used to convert the AQoL 4D scores into utility values representing preference scores. The difference between baseline and follow-up utility scores was calculated, allowing measurement of the difference in the mean change in quality adjusted life years (QALYs). For patients who did not complete the trial, the last observation was carried forward. These utility estimates were converted to QALYs by calculating the 'area under the curve' (AUC) utility estimates for the short and medium-term time intervals, weighted by the length of follow up. The change in the AUC from baseline utility was then calculated, which controlled for baseline differences in quality of life between the HW and PA groups.³⁷ For each patient, the change from baseline was estimated and averaged over the trial follow-up. The average change in the AUC for each intervention was used to estimate the incremental effectiveness for the purpose of calculating the ICERs.

Resource use

Resources used were those associated with delivering the HW and PA interventions and with participants' use of cardiac-related health care resources. The time required to deliver the HW and PA interventions was estimated from records. Expenditure records were used to quantify the equipment and consumable resources required to run the interventions. Participants' utilisation of cardiac-specific health care resources was assessed at 6 weeks and 6 months via a telephone questionnaire. Participants were asked to report inpatient or outpatient cardiac-related health services used. Participants were also asked about expenditure on exercise-related products or services, and how many days they had taken off work for their cardiac problem (if still in the workforce).

Cost valuation

Costs associated with the resources used were derived using a “bottom up” costing approach and measured in Australian dollars for 2011/2012. Bottom up costing refers to measuring costs at a service level. It involves identifying activity, estimating the resource use associated with this activity, and then assigning a value to those resources to obtain unit costs. For example, in the PANACHE study the health resources captured in the study were assigned the appropriate cost in order to estimate the overall average health costs per person. The same approach was used to cost the intervention, where each resource use was identified, the number of resources used were measured, assigned a unit cost, and the average intervention cost per participant calculated. Health service utilisation data were assigned a cost weight based on current Australian refined diagnosis-related groups (AR-DRG) or Medicare Benefits Schedule (MBS) data.³⁸ The AR-DRG cost weights were sourced from the Costs of Care Standards 2009/2010.³⁹ Costs were inflated to 2011/2012 dollars using an inflation rate of 2.9%. Actual co-payment data was not used. The MBS schedule fee was used which assumes the portion between the benefit (75% of the fee) and the fee would estimate the co-payment. So the cost estimates contain a portion that we estimated to be patient co-payments. The total cost attributed to each patient was the aggregated cost of the intervention, emergency visits, hospital admissions, general practitioner visits, specialist visits, day procedures and any patient expenditure on exercise-related products or services. Fixed costs (such as office rental) were not included as the interventions used existing health facilities and it was assumed that similar costs would be incurred in both programs. Due to the high retention of the participants (88% of HW and 92% of PA participants), techniques for censoring the cost data were not employed.

Sample size

The sample size was calculated to detect a reduction of 1.3 kg in weight and 0.5 kg/m² BMI between the HW and PA groups (based on the COACH study effects on weight loss⁴⁰ with a power of 90% [alpha 0.01]). A final sample size of 143 was required in each group, which was increased by 10% to allow for attrition.

Statistical analyses

STUDY 1: Baseline variables between the HW and PA groups and between those who completed the study and those who withdrew or were lost to follow-up were compared using independent t tests (for continuous variables) and chi-square tests (for categorical variables).

Data were analysed using intention-to-treat procedures. Complete case analysis was also performed for the primary outcomes. For all analyses change scores from baseline to 6 weeks and baseline to 6 months were calculated for each variable. These change scores had an approximately normal distribution and were analysed using a univariate general linear model to assess whether there was any effect of treatment (HW and PA), location (urban and rural) and whether participants attended a CR program or not. For each analysis, examination of the residuals showed that the data met the assumptions of the general linear model. Analyses were performed with PASW 18.0 (SPSS Inc., Chicago, IL). Cohen's *d* effect sizes were calculated for statistically significant between-group changes in the primary outcome. An effect size of 0.20 to 0.49 is considered small, 0.50 to 0.79 is considered moderate, and 0.8 or above is considered to be a large effect size.⁴¹ Statistical significance was set at $p < 0.05$.

STUDY 2: Data for the replication study were analysed using the same analysis method as the reference study.²³ Paired analysis with complete cases were performed using PASW 18.0 (SPSS Inc., Chicago, IL). Paired t-tests and Wilcoxon rank tests were used to detect changes in continuous variables within groups. Frequency of physical activity behaviours, mean and standard deviation for normally distributed variables or median and inter-quartile range for non-normal distributions were calculated. For categorical variables, Pearson's Chi-square test was used to detect any differences between groups. Cohen's *d* effect sizes were calculated for within-group differences in physical activity variables. Data are presented by location (urban, rural and combined urban/rural) and are compared to the reference effectiveness study that used the same intervention in a semi-urban setting.²³

STUDY 3: Statistical analyses were conducted to compare the difference in mean costs between the HW and PA groups, as well as the change in quality of life over the trial period. Analyses were performed with Stata 11.0 (StataCorp LP, College Station, TX). A negative binomial distribution was applied to analyse the cost data due to the large number of zero costs and the resulting skewness of the cost data. As the health care utilisation data were not normally distributed, a non-parametric Wilcoxon-Mann Whitney test was used.

To generate ICERs, the incremental total mean cost of the HW group relative to the PA group was divided by the average incremental gain in QALYs for the HW group relative to the PA group, over the study period. The cost-utility was explored further by generating ICERs for patient sub-groups (urban, rural, attended CR, did not attend CR). Bootstrapping was used to obtain a confidence interval around the ICERs using 1,000 samples of cost and effect pairs drawn from each of the intervention arms. This allows comparison of the arithmetic means without making assumptions about the cost distribution. The net benefit was calculated from the bootstrapped results, assuming a willingness to pay threshold of \$60,000 per QALY.⁴²

SECTION 5

Results

Study 1: The physical activity, nutrition and cardiac health (PANACHE) trial

A total of 313 people (313/1036 or 30% of those contacted) consented to participate in the trial, were randomly allocated to the HW or PA group, and completed the baseline questionnaire. Overall, participants had a mean age of 64.2 years and a mean BMI of 28.5 kg/m². The majority of participants were: born in Australia (80.0%); male (72.9%); married or with a partner (70.0%); educated to high school level or less (66.4%); retired (54.0%); and did not attend CR (51.7%). Almost half (44.8%) lived in a rural area. Retention was high, with 90.1% of participants completing the study. There were no significant differences in baseline characteristics between the treatment groups (see Table 1).

Table 1. Baseline characteristics by Healthy Weight intervention group and Physical Activity comparison group

Characteristic	Healthy Weight n=156	Physical Activity n=157	p value
Body mass index, kg/m², mean (SD)	28.8 (5.1)	28.2 (4.8)	0.31
Body mass index ≥ 25 kg/m², n %	115 (74.7)	114 (74.0)	0.83
Age, years, mean (SD)	65.1 (9.0)	63.3 (12.3)	0.14
Gender, n (% male)	116 (74.4)	112 (71.3)	0.13
Born in Australia, n (%)	126 (80.8)	121 (77.1)	0.42
Marital status, n (% married/living with partner)	102 (65.4)	117 (74.5)	0.08
Education, n (% secondary education or less)	96 (63.2)	107 (69.5)	0.24
Employment, n (% retired)	84 (53.8)	85 (54.1)	0.99
Receive a pension or benefit, n (%)	97 (62.2)	92 (58.6)	0.51
Have private health insurance, n (%)	73 (46.8)	75 (47.8)	0.85
Household income, n (% up to \$40,000)	73 (57.9)	51 (47.2)	0.13
Rate health as fair or poor, n (%)	51 (32.7)	54 (34.4)	0.87
SEIFA index^a, n (% 5th quintile, most disadvantaged)	9 (5.8)	10 (6.4)	0.12
Location, n (% referred from rural service)	70 (44.9)	70 (44.6)	0.96
Cardiac rehabilitation^b, n (% not attending)	75 (54.0)	73 (49.3)	0.48
Diagnosis, n (%)			
Myocardial infarct or acute coronary syndrome	44 (28.2)	45 (28.6)	0.99
Coronary artery bypass graft surgery	23 (14.7)	25 (15.9)	
Percutaneous coronary intervention	51 (32.7)	52 (33.1)	
Other	38 (24.4)	35 (22.3)	
Sufficiently active, n (% ≥150 minutes physical activity /week AND ≥ 5 sessions)	70 (49.6)	71 (50.4)	0.97
Usual sitting time, minutes per day, median (IQR)	360.0 (240.0, 480.0)	300.0 (180.0, 480.0)	0.20
Fruit, serves per day, median (IQR)	1.5 (1.0, 2.0)	2.0 (1.0, 3.0)	0.09
Vegetables, serves per day, median (IQR)	3.0 (2.0, 4.0)	3.0 (2.0, 4.0)	0.97
Crisps or salty snacks, times per week, median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.35
Sweetened, carbonated drinks, cups per week, median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.49
Take away, meals per week, median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.97
Cakes, pastries, creamy biscuits or chocolate, times per week, median (IQR)	1.0 (0.0, 3.0)	1.0 (0.0, 2.0)	0.57
Alcohol, standard drinks per week, median (IQR)	1.0 (0.0, 7.0)	1.5 (0.0, 7.0)	0.61

Standard deviation (SD), Interquartile range (IQR).

^aSocio-economic Index for Areas (SEIFA) indicates relative advantage or disadvantage of all the residents in an area (Australian Bureau of Statistics, 2006).

^bData obtained from short-term questionnaire.

Primary outcomes

Table 2 shows the HW group lost significantly more weight than the PA group in the short-term (effect size=0.28) and medium-term (effect size=0.32). The short-term intention-to-treat analysis shows the HW group lost 1.1 kg compared to the PA comparison group which lost 0.2 kg, and this difference was significant between the groups. These changes in weight remained significant in the medium-term.

Table 2. Mean short-term and medium-term changes in Body Mass Index (BMI) and weight by Healthy Weight intervention group and Physical Activity comparison group

Outcome	Healthy Weight Mean (95% CI)	Physical Activity Mean (95% CI)	P value ^a
Intention-to-treat analysis			
	n=156	n=157	
Short-term^b			
BMI, kg/m ²	-0.4 (-0.5, -0.2)*	-0.1 (-0.3, 0.1)	0.01
Weight, kg	-1.1 (-1.6, -0.6)*	-0.2 (-0.7, 0.2)	0.01
Medium-term^c			
BMI, kg/m ²	-0.4 (-0.6, -0.2)*	0.0 (-0.2, 0.2)	0.005
Weight, kg	-1.2 (-1.8, -0.6)*	0.1 (-0.5, 0.6)	0.005
Complete case analysis			
Short-term			
	n=140	n=148	
BMI, kg/m ²	-0.4 (-0.6, -0.2)*	-0.1 (-0.3, 0.1)	0.01
Weight, kg	-1.3 (-1.8, -0.7)*	-0.3 (-0.8, 0.2)	0.01
Medium-term			
	n=137	n=145	
BMI, kg/m ² I	-0.5 (-0.7, -0.2)*	0.0 (-0.2, 0.2)	0.003
Weight, kg	-1.4 (-2.0, -0.7)*	0.1 (-0.6, 0.7)	0.003

^aBetween groups comparison (univariate general linear model).

^bShort-term minus baseline.

^cMedium-term minus baseline.

*Significant change from baseline, $p < 0.05$ (within group).

Overall the HW group decreased their weight ($p=0.005$), and HW participants with a BMI ≥ 25 kg/m² had a mean weight loss of 1.6 kg, a significantly greater weight loss than the PA group ($p=0.01$), over the medium-term. Table 3 shows that, when stratified by baseline BMI, the HW participants who were coached to lose weight lost significantly more weight than participants in the PA group with a BMI ≥ 25 kg/m² (effect size=0.29 at 6 weeks, 95% CI: 0.11, 0.47 and effect size=0.32 at 6 months, 95% CI: 0.09, 0.54).

Table 3. Mean short-term and medium-term changes in Body Mass Index (BMI) and weight in the Healthy Weight intervention group and Physical Activity comparison group, stratified by baseline BMI

	Healthy Weight Mean (95% CI)	Physical Activity Mean (95% CI)	<i>p</i> value ^a
BMI ≥ 25 kg/m² (weight loss)	n=115 ^b	n=114 ^b	
Change in BMI, kg/m ²			
6 weeks	-0.4 (-0.6, -0.2)*	-0.1 (-0.3, 0.1)	0.02
6 months	-0.6 (-0.8, -0.3)*	-0.1 (-0.4, 0.1)	0.01
Change in weight, kg			
6 weeks	-1.3 (-1.9, -0.8)*	-0.4 (-0.9, 0.2)	0.02
6 months	-1.6 (-2.3, -1.0)*	-0.4 (-1.1, 0.3)	0.01
BMI < 25 kg/m² (weight maintenance)	n=40 ^b	n=41 ^b	
Change in BMI, kg/m ²			
6 weeks	-0.1 (-0.4, 0.1)	0.0 (-0.3, 0.4)	0.36
6 months	0.1 (-0.3, 0.5)	0.4 (0.0, 0.9)	0.23
Change in weight, kg			
6 weeks	-0.4 (-1.3, 0.5)	0.2 (-0.8, 1.1)	0.38
6 months	0.3 (-0.9, 1.5)	1.3 (0.0, 2.6)	0.24

^aBetween groups comparison (univariate general linear model).

^bIntention to treat analysis HW n=155, PA n=155. Unable to calculate baseline BMI for n=1 HW and n=2 PA participants.

*Significant change from baseline, *p*<0.05.

Secondary outcomes

There were no significant differences between the treatment groups for the physical activity, health-related quality of life and dietary outcomes (Table 4). Both the HW and PA groups significantly increased their weekly physical activity minutes at 6 weeks, but only the PA group maintained a significant increase at 6 months. Both groups reduced their sitting time at 6 weeks and 6 months and had lower quality of life scores (indicating improved quality of life) at 6 weeks and 6 months. At 6 months there were no significant interactions between rural or urban location, and attendance at CR for the physical activity, health-related quality of life or dietary outcomes.

Table 4. Mean short-term and medium-term changes in physical activity, sedentary time and dietary outcomes by Healthy Weight intervention group and Physical Activity comparison group

	Healthy Weight Mean (95% CI) n=156	Physical Activity Mean (95% CI) n=157	p value^a
Physical activity , mins per week			
6 weeks	55.4 (14.5, 96.3)*	90.6 (49.9, 131.4)*	0.23
6 months	37.3 (-3.7, 78.3)	79.6 (38.7, 120.5)*	0.15
Sitting time , mins per day			
6 weeks	-45.2 (-74.1, -16.2)*	-32.1 (-60.9, -3.2)*	0.53
6 months	-62.3 (-90.5, -34.2)*	-31.0 (-59.0, -12.9)*	0.12
Health-related quality of life^b			
6 weeks	-1.3 (-1.8, -0.9)*	-0.9 (-1.3, -0.4)*	0.13
6 months	-1.3 (-1.8, -0.8)*	-0.8 (-1.3, -0.3)*	0.12
Fruit , serves per day			
6 weeks	0.3 (0.1, 0.4)*	0.2 (0.0, 0.4)	0.20
6 months	0.2 (0.1, 0.4)*	0.2 (0.0, 0.4)	0.79
Vegetables , serves per day			
6 weeks	0.2 (-0.2, 0.6)	0.3 (-0.1, 0.7)	0.69
6 months	0.2 (-0.2, 0.5)	0.1 (-0.3, 0.4)	0.70
Crisps or salty snacks , times per week			
6 weeks	0.0 (-0.2, 0.1)	-0.1 (-0.3, 0.1)	0.69
6 months	0.0 (-0.2, 0.2)	-0.1 (-0.3, 0.1)	0.45
Sweetened, carbonated drinks , cups per week			
6 weeks	-0.8 (-1.5, -0.1)*	-0.6 (-1.3, 0.1)	0.70
6 months	-0.7 (-1.4, 0.0)	-0.1 (-0.8, 0.6)	0.25
Take away , meals per week			
6 weeks	-0.1 (-0.2, 0.0)	0.0 (-0.1, 0.1)	0.28
6 months	-0.1 (-0.2, 0.1)	-0.0 (-0.2, 0.1)	0.72
Cakes, pastries, creamy biscuits or chocolate , times per week			
6 weeks	-0.3 (-0.7, 0.1)	0.0 (-0.4, 0.4)	0.31
6 months	-0.6 (-0.9, -0.2)*	-0.1 (-0.5, 0.3)	0.14
Alcohol , std drinks per week			
6 weeks	1.1 (0.1, 2.1)*	-0.2 (-1.2, 0.8)	-0.07
6 months	1.1 (0.0, 2.1)	1.2 (0.9, 2.3)*	0.85

^aBetween groups comparison.

^bAssessment of Quality of Life questionnaire.³³ Zero represents 'good health'. A reduction in score represents improved quality of life.

*Significant change from baseline, $p < 0.05$.

Process evaluation

Table 5 shows that the majority of participants found the PA and HW intervention activities useful or very useful. For the HW participants, 92.9% (130/140) rated the pedometer as useful or very useful and 78.6% (110/140) rated the lifestyle calendar as useful or very useful. For the PA participants, 91.9% (136/148) rated the pedometer as useful or very useful and 84.5% (125/148) reported the step calendar as useful or very useful. The mean length of the first telephone coaching session was 27 minutes for the HW group and 21 minutes for the PA group, with subsequent coaching sessions averaging 13 minutes for both groups. Booster calls were shorter, taking a mean time of 12 minutes for the HW group and 10 minutes for the PA group.

Table 5. Participants' opinions of the intervention activities

Question	Very useful or useful n (%)	Not useful n (%)	Not sure n (%)
Physical Activity comparison group			
Was the pedometer useful? (n=148)	136 (91.9%)	11 (7.4)	1 (0.7)
Was the step calendar useful? (n=148)	125 (84.5)	20 (13.5)	3 (2.0)
Were the physical activity brochures useful in helping you become more physically active? (n=121)	100 (82.6)	20 (16.5)	1 (0.8)
Healthy Weight intervention group			
Was the pedometer useful? (n=139)	130 (93.5)	8 (5.8)	1 (0.7)
Was the healthy lifestyle calendar useful? (n=138)	110 (79.7)	21 (15.2)	7 (5.1)
Were the healthy lifestyle brochures useful in helping you improve your nutrition? (n=130)	108 (83.1)	20 (15.4)	2 (1.5)
Were the healthy lifestyle brochures useful in helping you become more physically active? (n=130)	105 (80.8)	22 (16.9)	3 (2.3)
Healthy Weight intervention group			
	Yes n (%)	No n (%)	Not sure n (%)
Were the telephone calls useful in helping you improve your nutrition? (n=133)	120 (90.2)	9 (6.8)	4 (3.0)
Were the telephone calls useful in helping you become more physically active? (n=133)	112 (84.2)	16 (12.0)	5 (3.8)

Study 2: Replication study

Table 6 shows the baseline characteristics of the replication study participants alongside those of participants in the semi-rural reference study. There were significant differences in participants' diagnoses ($p=0.034$) and in the proportion of participants who: were sufficiently active at baseline

($p < 0.001$ for ≥ 150 mins total activity per week and $p = 0.018$ for ≥ 150 mins total activity and ≥ 5 sessions per week); did not attend a CR program ($p < 0.001$); were born in Australia ($p < 0.001$); had tertiary level education ($p < 0.001$); and were retired, employed or unemployed ($p = 0.006$).

Table 6. Baseline socio-demographic and clinical characteristics of participants of the two studies, across three locations

Characteristic	Replication Study		Reference Study	P value (χ^2)
	Urban	Rural	Semi-rural	
n	87	70	104	-
Age, mean years (SD)	63.1 (14.4)	63.6 (9.2)	66.7 (10.6)	
Gender, n (%)				0.937
Male	63 (72.4)	49 (70.0)	75 (71.2)	
Female	24 (27.6)	21 (30.0)	29 (27.9)	
Body mass index kg/m², mean (SD)	27.0 (4.0)	29.6 (5.3)	27.3 (5.2)	-
Sufficiently active, n (%)				
≥150 mins total physical activity per week	56 (64.4)	25 (35.7)	60 (57.7)	<0.001*
≥ 150 mins total physical activity and ≥ 5 sessions per week	47 (54.0)	24 (34.5)	55 (52.9)	0.018*
Did not attend a CR program, n (%)	36 (43.9)	37 (56.1)	104 (100)	<0.001*
Born in Australia, n (%)	56 (64.4)	65 (92.9)	83 (79.8)	<0.001*
Education, n (%)				0.001*
Secondary level or less	49 (56.3)	58 (82.9)	70 (67.3)	
Tertiary level	37 (42.5)	10 (4.3)	34 (32.7)	
Employment status, n (%)				0.006*
Retired	48 (55.2)	37 (52.9)	70 (67.3)	
Employed	35 (40.2)	20 (28.6)	22 (21.2)	
Unemployed/unable to work/volunteer/other	4 (4.6)	13 (18.5)	12 (11.5)	
Diagnosis, n (%)				0.034*
Myocardial infarction	11 (12.6)	14 (20.0)	30 (28.9)	
Acute Coronary syndrome	19 (21.8)	1 (1.4)	20 (19.2)	
Coronary artery bypass grafts	18 (20.7)	7 (10.0)	15 (14.4)	
Percutaneous coronary intervention	23 (26.4)	29 (41.4)	23 (22.1)	
Other	16 (18.4)	19 (27.1)	16 (15.4)	
Health rating, n (%)				0.062
Excellent	30 (34.5)	20 (28.6)	40 (38.5)	
Good	33 (37.9)	20 (28.6)	41 (39.4)	
Fair or poor	24 (27.6)	30 (42.9)	23 (22.1)	
Marital status, n (%)				0.341
Married/living with partner	65 (74.7)	52 (74.3)	77 (74.0)	
Widowed/separated/divorced	11 (12.7)	13 (18.6)	21 (20.2)	
Never married	11 (12.6)	5 (7.1)	6 (5.8)	

*Significant at p<0.05.

Improvements in total weekly physical activity time and walking minutes were significant from baseline to short-term in the replication (urban and rural) and reference (semi-rural) studies (Table 7). Significant improvements were seen in the total weekly physical activity minutes for the urban ($p < 0.001$, Cohen's d effect size = 0.57, 95% CI: -57.7, 58.1), rural ($p = 0.01$, Cohen's d effect size = 0.51, 95% CI: -47.3, 62.9) and semi-rural groups ($p < 0.001$, Cohen's d effect size = 0.31, 95% CI: -37.0, 42.3) after adjusting for baseline differences. At medium-term, improvements in physical activity remained significant across the three locations except for weekly walking minutes in the rural group (Table 7). Medium-term improvements were significant for total weekly physical activity minutes for the urban ($p = 0.03$, Cohen's d effect size = 0.35, 95% CI: -57.9, 60.7), rural ($p = 0.005$, Cohen's d effect size = 0.56, 95% CI: -47.9, 75.1) and semi-rural groups ($p < 0.001$, Cohen's d effect size = 0.35, 95% CI: -42.0, 45.0) after adjusting for baseline differences.

Table 7. Changes in physical activity from baseline to short-term and baseline to medium-term for the replication and reference studies across three locations

	Urban		Replication Study				Reference Study ^b	
	Change	<i>p</i> value	Change	<i>p</i> value	Change	<i>p</i> value	Change	<i>p</i> value
Short-term	n=82 ^a		n=65 ^a		n=147 ^a		n=97 ^a	
Total weekly physical activity								
Mean mins (SD)	97.0 (242.2)	<0.001**	96.7 (273.6)	0.01**	96.9 (255.6)	<0.001**	94.7 (213.9)	<0.001**
Walking per week								
Mean mins (SD)	58.0 (175.0)	0.004**	59.4 (209.8)	0.03*	58.6 (190.5)	<0.001**	80.1 (176.1)	<0.001**
Medium-term	n=81 ^a		n=64 ^a		n=145 ^a		n=95 ^a	
Total weekly physical activity								
Mean mins (SD)	76.4 (308.5)	0.03*	96.3 (262.2)	0.005**	85.2 (288.2)	0.001**	86.4 (225.3)	<0.001**
Walking per week								
Mean mins (SD)	57.1 (190.7)	0.01*	33.5 (182.2)	0.15	46.7 (186.7)	0.003**	62.5 (172.3)	0.001**

^aComplete cases.

^bFurber et al.²³

*Significant at *p*<0.05.

**Significant at *p*<0.01.

Table 8 shows that across the replication and reference groups a similar proportion of participants moved from an insufficient level of physical activity at baseline, to sufficient physical activity (≥ 150 mins total activity and ≥ 5 sessions per week), or increased their weekly physical activity by 60 minutes or more, over the short-term and medium-term.

Table 8. Proportion of participants moving from insufficient to sufficient physical activity or increasing total physical activity by at least 60 minutes from baseline to short-term and from baseline to medium-term for the replication and reference studies across three locations (urban, rural and semi-rural)

	Replication Study			Reference Study ^a
	Urban	Rural	Combined	Semi-rural
Short-term	n (%)	n (%)	n (%)	n (%)
Insufficient physical activity at baseline to sufficient physical activity ^b	19 (23.2)	20 (30.1)	39 (26.5)	23 (23.7)
Total weekly physical activity increase from baseline ≥ 60 minutes	49 (59.8)	37 (56.9)	86 (58.5)	55 (56.7)
Medium-term				
Insufficient physical activity at baseline to sufficient physical activity ^b	18 (22.2)	15 (23.4)	33 (22.8)	21 (22.1)
Total weekly physical activity increase from baseline ≥ 60 minutes	38 (46.9)	30 (46.9)	68 (46.9)	55 (57.9)

^aFurber et al.²³

^bSufficient physical activity ≥ 150 mins total activity and ≥ 5 sessions per week.

Study 3: Cost-effectiveness study

The estimated cost of delivering the interventions was \$201.48 per HW participant and \$138.00 for each PA participant. The average cost (health care utilisation plus patient costs) was \$1,260 per HW participant and \$2,048 per PA participant (Table 9).

Table 9. Mean direct costs per patient in the Healthy Weight and Physical Activity groups

Resource category	Healthy Weight group	Physical Activity group	P value
Intervention costs	\$201.48	\$138.00	
Health care costs			
Emergency department visits			
short-term ^a	\$34.95	\$69.45	0.05
medium-term ^b	\$67.21	\$56.10	0.48
Hospital, number nights			
short-term	\$183.07	\$835.06	0.04*
medium-term	\$436.47	\$490.38	0.45
General practitioner visits			
short-term	\$39.65	\$53.73	0.49
medium-term	\$110.41	\$102.09	0.45
Specialist visits			
short-term	\$42.23	\$45.77	0.54
medium-term	\$46.61	\$67.57	0.03*
Day procedures			
short-term	\$17.23	\$28.62	0.79
medium-term	\$25.59	\$49.37	0.41
Patient costs			
Exercise-related services			
short-term	\$26.44	\$38.96	0.23
medium-term	\$15.21	\$60.85	0.003**
Exercise-related equipment			
short-term	\$6.87	\$4.07	0.09
medium-term	\$6.99	\$8.05	0.54
Average total direct costs	\$1,260	\$2,048	

*Difference is statistically significant at $p < 0.05$.

**Difference is statistically significant at $p < 0.01$.

^aData collection period from baseline to short-term.

^bData collection period from short-term to medium-term.

The incremental cost-effectiveness ratio indicated that the HW intervention was less costly and more effective than the PA intervention. Subgroup analysis demonstrates that the HW intervention was cost saving and more effective than the PA intervention for rural participants and for participants that did not attend CR (Table 10).

Table 10. Incremental cost (Healthy Weight minus Physical Activity) per quality adjusted life year (QALY)

Group	n	Average cost per patient	Incremental cost ^a	Average QALYs ^b	Average change in QALYs ^b	Incremental QALYs gained	Adjusted incremental QALYs gained ^c	ICER
Entire sample analysis								
HW	156	\$1,260		0.366	0.034			
PA	157	\$2,048	(\$788)	0.373	0.018	0.016	0.007	HW less costly, more effective ^d
Subgroup analysis								
Urban								
HW	86	\$977		0.372	0.025			
PA	87	\$2,307	(\$1,330)	0.389	0.020	0.005	(0.004)	HW less costly, less effective
Rural								
HW	70	\$1,608		0.360	0.044			
PA	70	\$1,727	(\$119)	0.355	0.015	0.029*	0.022	HW less costly, more effective ^d
Attended cardiac rehabilitation								
HW	64	\$1,379		0.373	0.030			
PA	75	\$2,395	(\$1,016)	0.384	0.029	0.001	(0.003)	HW less costly, less effective
Did not attend cardiac rehabilitation								
HW	75	\$1,384		0.379	0.048			
PA	73	\$1,918	(\$534)	0.376	0.008	0.040**	0.023	HW less costly, more effective ^d

Healthy Weight intervention (HW), Physical Activity comparison group (PA), Incremental cost effectiveness ratio (ICER).

*Difference is statistically significant at $p < 0.05$.

**Difference is statistically significant at $p \leq 0.01$.

^aCost in brackets (\$xxx) indicates PA intervention more costly than the HW intervention.

^bQALYs calculated using 'area under the curve' method.

^cAdjusted for baseline differences.

^dThe HW intervention is less costly and more effective and therefore 'dominates' the PA intervention in terms of cost-effectiveness. Using a willingness to pay threshold of \$60,000 per QALY, 96% of the bootstrapped ICERs would indicate that the HW is cost-effective compared to the PA intervention.

SECTION 6

Discussion

Study 1: The physical activity, nutrition and cardiac health (PANACHE) trial

Telephone-based interventions have the potential to support lifestyle change for people with cardiac disease, particularly for hard-to-reach groups. The present study shows that the HW intervention achieved improvements in weight among people with cardiac disease, irrespective of whether they attended a CR program. Nearly 20% of the HW group lost 4 kg or more (approximately 5% body weight), which is considered sufficient to achieve clinically relevant health benefits.⁴³ Although a mean loss of 1.6 kg for those with a BMI ≥ 25 kg/m² is modest, it is comparable to changes seen in other, more intensive, telephone-based interventions. Vale et al⁴⁰ reported a mean weight loss of 1.3 kg at 6 months for cardiac patients (four telephone sessions targeting multiple risk factors plus computer generated feedback report for each session) compared to usual care, while Jeffery et al⁴⁴ reported an intervention effect of 0.9 kg weight loss at 6 months for overweight members of a managed-care organisation (10 telephone sessions plus mailed lessons). Redfern et al⁴⁵ demonstrated a larger reduction in BMI: 2.3 kg/m² compared to usual care, for cardiac patients that did not attend CR (face-to-face session plus four telephone calls). Because Australians continue to gain weight until their mid 70s⁴⁶ modest weight loss or preventing further weight gain in middle age is important.⁴⁷ In the present study 76% of the HW participants maintained or lost weight compared to 56% in the PA group.

For physical activity, at 6 weeks, the HW and PA groups showed a mean increase of 55.4 minutes per week and 90.6 minutes per week, respectively, but only the PA group maintained a statistically significant increase at 6 months. Both groups were given pedometers and that both the HW and PA groups increased their physical activity may be because over 90% of participants in each group found the pedometers to be useful motivational and self-management tools. The HW participants who were overweight or obese (75%) were encouraged to do 60–90 minutes of activity on most days of the week, while HW participants with a healthy weight and PA participants were encouraged to do only 30 minutes of physical activity on most days. That the HW group did not maintain a significant increase in physical activity at 6 months suggests that overweight cardiac patients find it difficult to undertake the higher levels of activity recommended for weight loss,²⁸ and may be discouraged from continuing to undertake physical activity. The finding that the PA group increased their physical activity by 80 minutes at 6 months

is important and consistent with other studies that found, using the same PA intervention, a mean increase of 112.2 minutes per week (for cardiac patients who attended a CR program)²² and 86.4 minutes per week (for cardiac patients who did not attend a CR program).²³

No differences were observed between the groups for sitting time and health-related quality of life outcomes, as both groups significantly reduced their sitting time and increased their quality of life. There were no statistically significant between group differences in dietary outcomes, possibly because baseline dietary intakes were already reasonably consistent with dietary guidelines²⁷ with both groups overall consuming: the two recommended serves of fruit; three of the five recommended serves of vegetables; chips or take away less than once per week; cakes or sugar-sweetened drinks twice a week; and less than one alcoholic drink per day. It is possible that HW participants achieved their weight loss by limiting the intake of foods that were not directly accounted for by the brief dietary questions (such as fats and oils). Participants may also have lowered their energy intake by reducing portion sizes. To determine whether this is the case it would be necessary to assess participants' energy intake, requiring detailed nutritional assessments that were beyond the scope of this study.

There are several limitations to this study. The low-contact nature and rural residence of many participants necessitated using self-reported measures. In addition fewer women than men were referred to CR and thus women are underrepresented in the study. The study was limited to the comparison of two interventions over a relatively short period of 6–8 months. It should also be noted that it is possible that the referral practices of practitioners may differ over time and across areas, however assessment of any possible differences was outside the scope of our project.

Study 2: Replication study

The pedometer-based telephone coaching intervention investigated in this replication study resulted in significant short-term improvements in the total weekly physical activity minutes for urban and rural participants that were maintained at the medium-term, and that were comparable to those of the reference study. At the medium-term nearly half the participants in each setting had increased their physical activity time by at least 60 minutes per week. In addition, the mean increases in weekly physical activity time at the medium-term in the replication study (76.4 minutes for urban, 96.3 minutes for rural, 85.2 minutes for the combined urban/rural) and in the semi-rural reference study (86.4 minutes) are substantial enough to translate into meaningful improvements in cardio-respiratory fitness⁴⁸ and could potentially slow disease progression and increase survival.⁴⁹ Comparison of these results with other studies is difficult because of the variety of intervention components, target groups and physical activity

measures used in the research literature. However, the current study findings are similar to those reported by De Greef et al⁵⁰ who showed that a more intensive intervention (pedometer, face-to-face session and seven telephone follow-ups) increased physical activity time by 77 minutes per week at one year post intervention for people with type 2 diabetes. Reid et al⁵¹ also demonstrated physical activity increases of 86 and 67 minutes per week at 6 months and 12 months respectively for cardiac patients not participating in CR, using a motivational counselling intervention that included a face-to-face session and eight telephone contacts.

Effect sizes for the increase in weekly physical activity minutes ranged from 0.31 to 0.57, indicating small to moderate positive effects of the intervention⁴¹ that could be practically and clinically important.⁵² These effect sizes are consistent with the 0.35 effect size reported in a recent meta-analysis of physical activity interventions in people with heart disease.⁵³ However the results of the current study need to be interpreted with caution because of the wide confidence intervals for the Cohen's *d* values, due to the variability of the self-reported physical activity data and the relatively small sample size.

For practical purposes the reference and replication studies used different populations (only those who did not attend CR, and all those referred to CR, respectively). As attendance at CR is likely to be a confounder of the study outcomes, this limitation must be taken into consideration.

Study 3: Cost-effectiveness study

This study examined the incremental cost-effectiveness of the HW intervention over the PA intervention, for patients referred to CR. It shows that the additional cost of implementing the HW intervention (\$201 per HW participant versus \$138 per PA participant) was offset by reduced health care utilisation and patient costs (\$1,260 for the HW versus \$2,112 for the PA intervention) over the study period.

In Australia there is no pre-defined threshold of willingness to pay for a QALY, however an implicit threshold between \$50,000 and \$60,000 per QALY is commonly used to determine cost-effectiveness, based on funding decisions of the Pharmaceutical Benefits Advisory Committee.⁴² Using this threshold, the HW intervention would be considered cost-effective over the PA intervention. However these results should be interpreted with caution since the incremental QALYs gained between the HW and PA groups was small and because the costs were estimated on low rates of health service utilisation over a relatively short follow-up period.

The sub-group analyses demonstrated that the cost-effectiveness of the two interventions varied with the characteristics of participants. The HW intervention was more cost-effective for rural participants and for participants that did not attend CR, compared to the PA intervention. For HW participants that did not attend CR the incremental gain in QALYs (0.040) was statistically significant. The incremental gain in QALYs (0.029) for rural HW participants was also statistically significant.

SECTION 7

Conclusion and recommendations

Conclusion

The PANACHE trial demonstrated that a pedometer-based telephone coaching intervention achieved modest, but significant, improvements in weight among rural and urban people with cardiac disease, whether they attended a CR program or not. The PANACHE trial targeted a challenging community-based population, with nearly half the participants living in rural locations and approximately half not attending a CR program. This is important as relatively few studies have targeted cardiac patients that did not attend CR^{12,22,23,40} and none have targeted rural non-attenders.

The replication study adds to our knowledge of translation research by demonstrating that the PA intervention, previously found to be efficacious in a semi-rural location for those not attending CR,²³ achieved comparable increases in physical activity in more diverse urban and rural populations for all patients referred to CR. The replication study also demonstrates that the PA intervention can be implemented by different staff, in different settings and that it was well accepted and adhered to by participants with diverse backgrounds and health needs. In order to translate public health research into wide-scale practice Milat et al²⁰ recommended that if an intervention is shown to be both efficacious and replicable, dissemination studies can then be conducted to establish how to upscale interventions for widespread roll-out in communities and across organisations. This suggests that future research should focus on dissemination studies to evaluate how to effectively roll-out the PA intervention into large-scale practice in broader community and health settings. As demonstrated in our study, the HW intervention was effective in achieving modest weight loss in overweight and obese participants, however a replication study needs to be conducted to determine whether the intervention is effective in different settings (i.e. semi-rural) and when implemented by different staff, similar to the replication study conducted for the PA intervention.

The cost-effectiveness study adds to our current knowledge by providing evidence that brief telephone-based coaching programs can be implemented at relatively low cost, and that the HW intervention overall was less costly and more effective compared to the PA intervention.

Recommendations for future research

It is recommended that further research be conducted to:

- Determine levels of physical activity that are achievable and sustainable for overweight, older people with chronic illnesses such as cardiac disease in order to promote weight loss.
- Determine the effect of the HW and PA interventions at 12 months or longer.
- Determine the replicability of the HW intervention in different settings (i.e. semi-rural) and by different staff.
- Determine whether pedometer-based telephone coaching interventions can be extended to reach additional population groups (e.g. people living in very remote locations that are outside usual telephone networks; people who do not speak English).
- Determine the requirements for disseminating the PA intervention into wider practice. Such research could focus on the conditions required for developing partnerships, policy and organisational structures to integrate and sustain the pedometer-based telephone intervention as a routine healthcare option available to cardiac patients who do not attend a CR program and as an adjunct to regular CR programs.
- Conduct economic modelling studies to examine the longer-term economic outcomes of the HW and PA interventions for cardiac patients and to compare the costs and outcomes of these interventions to usual care.

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APPENDICIES

Appendix 1

General invitation letter

(Printed on relevant letterhead for each health area)

Dear

I would like to invite you to participate in the NSW Healthy Heart Project. This project is being conducted by a research team with members from South Eastern Sydney and Illawarra Area Health Service, Greater Southern Area Health Service, Sydney University and the Heart Foundation. The project is funded by NSW Health.

Your participation will help us to gather important information on the best ways to promote cardiovascular health when recovering from a heart condition.

The project will be delivered over the phone so you will not need to leave your home. There are no face to face meetings or major time commitments involved in participation. During the eight months of the project you will be asked to answer three questionnaires. The questionnaires will be read to you during telephone interviews that will last about half an hour.

Your participation is entirely voluntary and you are free to withdraw at any time during the study. All information collected will remain confidential. At no time will your personal details be divulged.

I will contact you in the next fortnight. If you are interested in being involved in the project I will send a consent form for you to sign. You will not be required to begin participation in the project until the project manager has your written consent. If you would like further information please contact the project manager Janice Sangster (02) 6938 6476.

Please consider participation in this project as an opportunity to make a difference to people recovering from the effects of heart disease.

I look forward to speaking with you soon.

Yours sincerely

Project Manager

Cardiac Rehabilitation Coordinators

Consent form for the Healthy Weight group

Consent form

Please read the following statements and sign below:

1. I agree to participate in the *NSW Healthy Heart Project* and understand the requirements of the project as stated in the Participant Information Sheet.
2. I understand that the project involves the following procedures:
 - a. Answering 3 questionnaires via telephone (at the beginning of the project, at eight weeks and at eight months).
 - b. Wearing a pedometer for a period of eight weeks
 - c. Participating in a series of brief telephone interviews with the researcher during the eight month project period
 - d. Recording my daily steps measured by the pedometer, daily physical activity, fortnightly weight and waist measurements, and goals for eight weeks
3. I understand that I am to cease participation in the project immediately and contact my doctor if any serious heart symptoms or problems arise. I have read the brochure on heart disease symptoms that was sent to me by the project manager.
4. I will contact Janice, the project manager, if I have to withdraw from the project due to health problems.
5. I have provided the name and telephone number of my general practitioner or specialist so that Janice can obtain written medical clearance for me to participate in the project.

My doctor's name..... **Doctor's telephone number**.....

6. Any questions that I have asked have been answered to my satisfaction.
7. I agree that research data gathered for the project may be published provided that I cannot be identified as a participant.
8. I agree to participate in this project and understand that I may withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

Name of participant..... **Date of Birth**.....

Signature of participant..... **Date**.....

9. I have explained the implications of participation in this project to this participant and I believe that he/she understands the implications of participation and has given consent based on the information I have provided.

Project Manager Janice Sangster

Signature.....**Date**.....

Please sign and return this form to Janice Sangster, project manager, in the envelope provided. You will be returned a copy of this form to keep. If you require further information, please telephone Janice Sangster, on (02) xxxx xxxx.

Appendix 2

Information sheet for the Healthy Weight group

NSW Healthy Heart Project

PARTICIPANT INFORMATION SHEET

Purpose of this study

The purpose of this study is to determine the best ways to improve the health of people with heart disease living in the community. People in the study will be randomly allocated to two groups which will receive different healthy lifestyle programs. This project has been funded by NSW Health Promotion Demonstration Research Grants Scheme 2008/09.

What do I have to do?

Your participation will be required for eight months. During this time you will be asked to answer three questionnaires over the phone. The questionnaires will be read to you and should take about 30 minutes to answer. The questions have been trialled with other cardiac patients and are generally easy to answer. You will be asked to answer a questionnaire at the beginning of the project, at eight weeks into the project and at the end of the project. Written consent will be obtained from you before you begin participation. I will need to contact your general practitioner or specialist so that I can obtain written medical clearance for you to participate in the project. Please write the name of your doctor and telephone number on the consent form.

After you have answered the first questionnaire you will be sent a package containing:

- A pedometer (a small electronic device that counts your steps)
- Instructions about how to use the pedometer
- A tape measure
- A healthy lifestyle calendar for recording your, weight, waist measurements, physical activity minutes and steps taken using the pedometer, and your goals.
- A brochure on heart disease symptoms
- A walking safely sheet
- Nutritional and physical activity information for weight loss or weight maintenance.

You will be required to wear the pedometer from when you get up in the morning until you go to bed at night for the first eight weeks of the project. You may keep your pedometer after the project has finished. I will explain how to use the healthy lifestyle calendar.

If you need to lose weight, you will be asked to accumulate 60 to 90 minutes of moderate intensity physical activity per day for most days of the week (e.g. walking) as well as follow recommended guidelines for losing weight. If you are concerned with your ability to accumulate this amount of physical activity, the project officer will discuss with you the best way to gradually build up your physical activity levels. The physical activity can be done in blocks of 10 minutes. There is evidence that people who accumulate 60 to 90 minutes of moderate intensity physical activity per day for most days of the week are more likely to lose weight than people who do less than 60 minutes and will reduce the likelihood of rehospitalisation. I will be seeking medical clearance from your doctor that you will be able to do this amount of physical activity.

If you do not need to lose weight, you will be asked to accumulate 30 minutes of moderate intensity physical activity (e.g. walking) per day for most days of the week as well as follow recommended guidelines for healthy eating. You can do the physical activity in blocks of 10 minutes.

As part of the project I will telephone you regularly to see how you are going with the pedometer and calendar. I would like to call you approximately every fortnight in the first eight weeks and then twice more until the end of the project in eight months. The purpose of these calls will be help you set some physical activity and nutrition goals and to provide you with support and advice in working toward these goals. The telephone calls will be made at a time convenient to you.

What's in it for me?

Participation in this exciting research project may be just what you need to help you to become more physically active and improve your nutrition and the health of your heart. You will have the opportunity to set some physical activity and nutrition goals and the regular follow up phone contact will help you to stay motivated and focused on your physical activity and nutrition plans. The physical activity that you decide to do can be done at a time and place that suits you. I will provide you with encouragement and advice about physical activity, but you will be free to decide when and where you exercise and how much you do.

What if I say yes and then change my mind?

Participation in this study is entirely voluntary and you are free to withdraw at any time without any penalty or loss of benefits to which you are otherwise entitled. All you need to do is let me know you have decided to withdraw.

All data collected will be confidential.

To ensure confidentiality of data and results, your name on the questionnaires will be changed to a code. All data will be securely kept in locked filing systems and electronic databases will be password protected. At no time will your personal details be divulged. Every effort will be made to maintain confidentiality of all information received by you.


This project has been approved by the University of Wollongong and South Eastern Sydney & Illawarra Area Health Service Human Research Ethics Committee. If you have any concerns of an ethical nature or complaints about the manner in which the project is conducted, you may contact the University of Wollongong Ethics Officer on (02) xxxx xxxx. The name of the principal site investigator is Ms Janice Sangster, Greater Southern Area Health Service, telephone (02) xxxx xxxx.

What happens now?

Please sign the consent form and return it to me in the envelope provided as soon as possible. When the consent form is received, I will call and arrange a time for you to answer the first questionnaire over the phone. A copy of the signed consent form will be returned to you to keep. If you have changed your mind and no longer wish to participate, just let me know when I call you.

If you have any concerns or questions, please contact the project manager Janice Sangster on (02) xxxx xxxx.

Lifestyle calendar



MY HEALTHY LIFESTYLE CALENDAR NAME: _____

Week	WEIGHT			WAIST MEASURE			NUTRITION	
	Weight	Fortnightly Goal	Fortnightly Goal Met Y/N?	Waist Measure	Fortnightly Goal	Fortnightly Goal Met Y/N?	Weekly Nutrition goals	Weekly Goals Met? Y/N
ONE								
TWO								
THREE								
FOUR								
FIVE								
SIX								
SEVEN								
EIGHT								

Long Term Goals


Weight _____ Waist Measure _____ Nutrition Goals: _____

MY HEALTHY LIFESTYLE CALENDAR

Week		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Weekly goal	Weekly Goal Met? Y/N
ONE	Physical activity minutes									
	Step count									
TWO	Physical activity minutes									
	Step count									
THREE	Physical activity minutes									
	Step count									
FOUR	Physical activity minutes									
	Step count									
FIVE	Physical activity minutes									
	Step count									
SIX	Physical activity minutes									
	Step count									
SEVEN	Physical activity minutes									
	Step count									
EIGHT	Physical activity minutes									
	Step count									

My Physical Activity Goals

Eight weeks _____ Long term goal _____



Pedometer Instruction Sheet
USING YOUR PEDOMETER



Step 1.

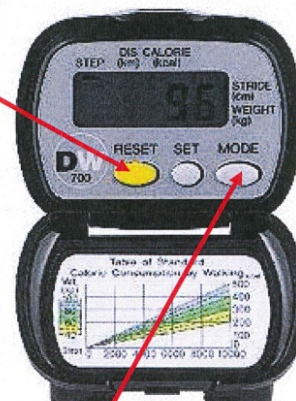
Press the **yellow reset button** to return the number of steps to zero.

Step 2.

Wear your pedometer **from when you get up in the morning until you go to bed at night** (except when showering or swimming).

Step 3.

Record the **number of steps** on your calendar when you take the pedometer off before you go to bed.



Note: If the pedometer does not display steps, press the **MODE** button until the step count is displayed (the small black bar will be under the word **STEP** at the top of the screen).

WEARING YOUR PEDOMETER

- a) Clip the pedometer onto **your belt or waist band** using the black plastic clip at the back of the pedometer.
- b) Position the pedometer as close to your **hip bone** as possible, over the midline of your thigh. Keep it parallel to the ground.
- c) If you have a large belly, wear the pedometer on the side of your hip, or clip it to your shirt pocket.

Be careful! The pedometer is **NOT** waterproof. Pedometers are fragile, try not to drop it or put excess pressure on it. It is important that you understand how to use the pedometer and the lifestyle calendar. For **HELP** please call Janice Sangster on 6938 6476

Appendix 3

Physical Activity Comparison Group

The Physical activity comparison group received a consent form and a participant information sheet similar to the ones in Appendices 1 and 2, however they did not include information on 'healthy weight'.


The six week intervention comprised:

- a pedometer (see Appendix 2)
- a step calendar (see below)
- two coaching telephone calls and two booster telephone calls.

Step calendar

MY STEP CALENDAR

NAME: _____



Part 1: Completing the one week step calendar

- Start wearing your pedometer the day after you receive it. Write the name of the day you start under the **blue** box for DAY 1. For example, if you receive your pedometer on Wednesday, start wearing it on Thursday and write Thursday in the box that says Day 1, Friday in the box that says Day 2 and so on, for the next week.
- Wear your pedometer from when you get up in the morning, until you go to bed at night (except when showering or swimming). When you take the pedometer off at night, record the number of steps in the **purple** STEP COUNT box that corresponds with the day. If you **forget to wear pedometer** for a day, that's okay, just leave that day blank and start again the next day.
- If you go for a walk or do any other physical activity for **at least 10 minutes continuously** record the activity in the **green** ACTIVITY box. **Keep doing what you would do in a normal week. Do not change your physical activity this week.**

ONE WEEK STEP CALENDAR FOR PART 1

WEEK ONE	Example DAY 1	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
	Thurs 2/7/05							
STEP COUNT	Write step number here							
ACTIVITY	Walk 20min Golf 2 hours							

Part 2: Using the six week step calendar: Please do not start filling out the six week step calendar over the page until I have called you.

- I will call you before you start the six week step calendar to help you set a physical activity goal for the first two weeks.
- We can also think about your long-term physical activity goals. These can be written in the space provided on the step calendar.

For help please call **Janice Sangster** at Wagga Wagga Community Health Centre on 6938 6476

SIX WEEK STEP CALENDAR FOR PART 2

WEEK	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	Weekly Goal	Weekly Goal Met? Y/N
ONE	Physical Activity Minutes Step Count								
TWO	Physical Activity Minutes Step Count								
THREE	Physical Activity Minutes Step Count								
FOUR	Physical Activity Minutes Step Count								
FIVE	Physical Activity Minutes Step Count								
SIX	Physical Activity Minutes Step Count								

Physical activity goals:

Six weeks: _____ Long-term: _____

Appendix 4

Questionnaires

Baseline questionnaire – Healthy Weight & Physical Activity group

Participant ID:

Group code:

Location:

Today's Date:

Good Morning/Afternoon _____, it's **[insert name of project officer]**. We have received your consent form for the NSW Healthy Heart Project and I am calling to make a time with you to answer the first questionnaire. This will take about 30 minutes, is now a good time for you to do this? (If not, make another appointment). Your participation in this questionnaire is entirely voluntary. You don't have to answer a question if you don't want to. All data is confidential, and your name will be changed to a code to protect your privacy.

Note: Fill out **Telephone Call Record** for each phone call made to participant.

The first questions I am going to ask you are about nutrition.

Q1. What type of bread do you usually have? [Include bread rolls or bread-type muffins]

1. Wholemeal or wholegrain
 2. White
 3. Other
 4. Don't eat bread
- X Don't know
R Refused

Q2. What type of milk do you usually have?

1. Regular milk (whole or full cream)
 2. Low- or reduced-fat milk
 3. Skim milk
 4. Evaporated or sweetened milk
 5. Other [SPECIFY] _____
 6. Don't have milk
- X Don't know
R Refused

Q3. How many serves of fruit do you usually eat each day? [one serve = one medium piece or 2 small pieces of fruit or one cup of diced pieces]

1. _____ serves per day
- X. Don't know
R. Refused

Q4. How many serves of vegetables do you usually eat each day? [one serve = 1/2 cup cooked or one cup of salad vegetables]

1. _____ serves per day
- X Don't know
R Refused

Q5. In the last week, how often did you eat potato crisps or other salty snacks (such as twisties or corn chips)?

1. _____ times per week

X Don't know

R Refused

Q6. In the last week, how many cups of sweetened soft drink, cordials or sports drink did you drink?

1. _____ cups per week

X Don't know

R Refused

Q7. In the last week, how often did you have meals or snacks such as burgers, pizza, chicken or chips from take-away shops?

1. _____ times per week

X Don't know

R Refused

Q8. In the last week, how often did you have cakes, pastries, creamy biscuits or chocolate?

1. _____ times per week

X Don't know [Don't read]

R Refused

Q9. In the last week, how many standard alcoholic drinks did you have?

1 middy light beer = 0.5 std drinks; 1 can or stubbie light beer = 0.8 std drinks; 1 middy regular beer = 1 std drink; 1 can or stubbie regular beer = 1.5 std drinks; 100mls wine = 1 std drink; 1 bottle wine = 7–8 std drinks; 1 nip spirits (30ml) = 1 std drink.

1. _____ number per week

X Don't know [Don't read]

R Refused

Q10. Are you currently following any special diet to help with your heart condition? (E.g. watching cholesterol or saturated fat intake)

1 Yes

2 No

3 Not Sure

Q11. Could I have your current weight please?

a. Weight: _____ kg OR _____ stone, lbs OR Don't know

The next questions are about any physical activities, (e.g. sport, recreation or leisure time physical activities) that you have participated in the past week.

Q12. In the past week, how many times have you walked continuously, for at least 10 minutes, for recreation, exercise or to get to or from places?

_____ **Number of times** _ if 0, go to Q14

Q13. What do you estimate was the total time that you spent walking in this way in the past week?

_____ **Total minutes**

Q14. In the past week, how many times did you do any vigorous gardening or heavy work around the yard, which made you breathe harder or puff and pant?

_____ **Number of times** _ if 0, go to Q16

Q15. What do you estimate was the total time that you spent doing vigorous gardening or heavy work around the yard in the past week?

_____ **Total minutes**

The next questions exclude household chores, gardening or yard work:

Q16. In the past week, how many times did you do any vigorous physical activity which made you breathe harder or puff and pant? (e.g. jogging, cycling, aerobics, competitive tennis)

_____ **Number of times** _ if 0, go to Q18

Q17. What do you estimate was the total time that you spent doing this vigorous physical activity in the past week?

_____ **Total minutes**

Q18. In the past week, how many times did you do any other more moderate physical activities that you have not already mentioned? (e.g. gentle swimming, social tennis, golf)

_____ **Number of times** _ if 0, go to Q20

Q19. What do you estimate was the total time that you spent doing these activities in the past week?

_____ **Total minutes**

The next question is about the time you spent sitting on weekdays during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television

Q20. In the last week, how much time did you usually spend sitting on a week day?

_____ **Total minutes**

X Don't know [Don't read]

R Refused

The next questions are about your confidence to eat a healthy diet and do regular physical activity

Q21. How confident are you that you can eat a healthy diet when you:

	Never	Rarely	Sometimes	Often	NA
a) are in a hurry?	1	2	3	4	5
b) feel stressed?	1	2	3	4	5
c) have a lot of demands at home?	1	2	3	4	5
d) feel depressed?	1	2	3	4	5

How confident are you that you can be physically active when you:

	Never	Rarely	Sometimes	Often	NA
e) are tired?	1	2	3	4	5
f) feel stressed?	1	2	3	4	5
g) have a lot of demands at home?	1	2	3	4	5
h) feel depressed?	1	2	3	4	5

The next set of questions is about the physical activity that you do which might be walking for exercise, cycling, swimming, playing tennis etc., and eating.

Q22. In the last week:

	Never	Rarely	Sometimes	Often
a) How often did you make plans about how often you were going to do physical activity (e.g. how many times a week or which days of the week)?	1	2	3	4

b) How often did you set a goal for how much physical activity you would like to do (e.g. how long, pace or intensity of your activity)?	1	2	3	4
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Q 23. In the last week:

	Never	Rarely	Sometimes	Often
a) How often did you plan what healthy foods to prepare and eat?	1	2	3	4

Q 24. In the past week:

	Never	Rarely	Sometimes	Often
a) How often did your family or friends help you prepare healthy foods?	1	2	3	4

b) How often did your family or friends eat healthy foods to make it easier for you to do so as well?	1	2	3	4
---	---	---	---	---

c) How often did your family or friends do physical activity with you?	1	2	3	4
--	---	---	---	---

d) How often did your family or friends make it easier for you to do regular physical activity?	1	2	3	4
---	---	---	---	---

Q25. Overall, how would you rate your health during the past four weeks?

1 Excellent 2 Very Good 3 Good 4 Fair 5 Poor

Q26. The following questions are about your health *during the last week*. For each question I will read out alternatives. Please tell me the one that **best describes you during the last week**.

a) Did you need any help looking after yourself in the last week? Would you say:

- i) You needed no help at all.
- ii) Occasionally you needed some help with personal care tasks.
- iii) You needed help with the more difficult personal care tasks.
- iv) You needed daily help with most or all personal care tasks.

b) When doing household tasks during the last week, did you need any help? (For example preparing food, gardening, using the video recorder, radio, telephone or washing the car.)

Would you say:

- i) You needed no help at all.
- ii) Occasionally you needed some help with household tasks.
- iii) You needed help with the more difficult household tasks.
- iv) You needed daily help with most or all household tasks.

c) Thinking about how easily can you get around your home or community in the last week. Would you say:

- i) You got around your home and community by yourself without any difficulty.
- ii) You found it difficult to get around your home and community by yourself.
- iii) You could not get around the community by yourself, but you got around your home with some difficulty.
- iv) You could not get around either the community or your home by yourself.

d) Were your personal relationships in the last week affected by your health? (For example your friends, partners or parents.) Would you say your relationships:

- i) Were very close and warm.
- ii) Were sometimes close and warm.
- iii) Were seldom close and warm.
- iv) You had no close and warm relationships.

e) During the last week were your relationships with other people affected by your health?

Would you say:

- i) That you had plenty of friends and were never lonely.
- ii) That although you have friends you were occasionally lonely.
- iii) That you have some friends but were often lonely for company.
- iv) That you felt socially isolated and lonely.

f) Thinking about your health and your relationship with your family in the last week. Would you say:

- i) Your role in the family was unaffected by your health.
- ii) There were some parts of your family role that you could not carry out.
- iii) There were many parts of your family role that you could not carry out.
- iv) You could not carry out any part of your family role.

g) Thinking about your vision in the last week, including when using glasses or contact lenses if needed.

Would you say:

- i) You saw normally.
- ii) You had some difficulty focussing on things, or you did not see them sharply. (For example small print, a newspaper, or seeing objects in the distance)
- iii) You had a lot of difficulty seeing things and your vision was blurred. (For example you saw just enough to get by with.)
- iv) You only saw general shapes, or you are blind. (For example you need a guide to move around.)

h) Thinking about your hearing in the last week, including using a hearing aid if needed. Would you say:

- i) You heard normally.
- ii) You had some difficulty hearing, or you did not hear clearly. (For example: You asked people to speak up or turn up the TV or radio volume.)
- iii) You had difficulty hearing things clearly. (For example: You often did not understand what was said. You usually did not take part in conversations because you could not hear what was said.)
- iv) You heard very little indeed. (For example: You could not fully understand loud voices speaking directly to you.)

i) When you communicated with others in the last week (For example: by talking, listening, writing or signing), would you say:

- i) You had no trouble speaking to others or understanding what they were saying.
- ii) You had some difficulty being understood by people who did not know you. You had no trouble understanding what others are saying to you.
- iii) You were only understood by people who knew you well. You had great trouble understanding what others are saying to you.
- iv) You could not adequately communicate with others.

j) Thinking about how you slept in the last week. Would you say:

- i) You slept without difficulty most of the time.
- ii) Your sleep was interrupted some of the time, but you were usually able to go back to sleep without difficulty.
- iii) Your sleep was interrupted most nights, but you were usually able to go back to sleep without difficulty.
- iv) You slept in short bursts only. You were awake most of the night.

k) Thinking about how you generally felt in the last week. Would you say:

- i) You did not feel anxious, worried or depressed.
- ii) You were slightly anxious, worried or depressed.
- iii) You felt moderately anxious, worried or depressed.
- iv) You were extremely anxious, worried or depressed.

l) How much pain or discomfort did you experience in the last week? Would you say:

- i) None at all.
- ii) You had moderate pain.
- iii) You suffered from severe pain.
- iv) You suffered unbearable pain.

Lastly, I would like to ask you a few questions about yourself. Please remember that all data is confidential. Only anonymous data will be used in the study

Q27. Date of Birth: ___/___/___

Q28. Age: _____

Q29. Country of Birth

a. Were you born in Australia? 1 Yes Go to Q30 2 No

b. What country were you born in? _____

c. When did you first arrive in Australia? 19 ___

d. What language do you usually speak at home? (If NOT English) _____

Q30. Are you of Aboriginal or Torres Strait Islander origin?

- 1 No 2 Yes, Aboriginal 3 Yes, Torres Strait Islander
- 4 Yes, both Aboriginal and Torres Strait Islander

Q31. Are you male or female? (only ask if not obvious)

- 1 Male 2 Female

Q32. Could I have your height please?

Height: _____m OR _____ft _____in OR Don't know

Q33. What is your current marital status?

- 1 Married 2 Living with partner 3 Widowed 4 Separated but not divorced
- 5 Divorced 6 Never Married

Short-term questionnaire – Healthy Weight group

Participant ID:

Group code:

Location:

Today's Date:

Good Morning/Afternoon _____, it's **[insert name of project officer]**. I am calling from the NSW Healthy Heart Project to make a time with you to answer the second questionnaire. This will take about 30 minutes, is now a good time for you to do this? (If not, make another appointment). Your participation in this questionnaire is entirely voluntary. You don't have to answer a question if you don't want to. All data is confidential, and your name will be changed to a code to protect your privacy. **Note:** Fill out **Telephone Call Record** for each phone call made to participant

Q1 – Q26 from Baseline Questionnaire are asked again here.

The next questions are about how you found the program.

Q27. Did you find the pedometer useful?

1 Very Useful 2 Useful 3 Not Useful 4 Not Sure

Q28. Did you find the healthy lifestyle calendar useful?

1 Very Useful 2 Useful 3 Not Useful 4 Not Sure

Q29. Did you receive the healthy lifestyle materials?

1 Yes 2 No 3 Not Sure *[don't read]*

a. If yes, did you find the healthy lifestyle material useful for improving your nutrition?

1 Very Useful 2 Useful 3 Not Useful 4 Not Sure

b. If yes, did you find the healthy lifestyle material useful in helping you become more physically active?

1 Very Useful 2 Useful 3 Not Useful 4 Not Sure

Q30. Do you remember receiving telephone calls on goal setting and advice on ways to be more physically active and to have a healthy diet from the project manager?

1 Yes 2 No (skip next 2 questions) 3 Not Sure *[don't read]* (skip next 2 questions)

Q31. Were the telephone calls useful in helping you improve your nutrition?

1 Very Useful 2 Useful 3 Not Useful 4 Not Sure

Q32. Were the telephone calls useful in helping you become more physically active?

1 Very Useful 2 Useful 3 Not Useful 4 Not Sure

The next questions are about your use of medical services in the last 2 months

Q33. Since being referred to cardiac rehabilitation have you had any admissions to a hospital emergency department for heart or cardiac problems? (e.g. accident, emergency, casualty)

1 Yes 2 No 3 Not Sure

If yes, how many emergency department visits have you made in the last 2 months for heart or cardiac problems? _____

Q34. Since being referred to cardiac rehabilitation have you stayed overnight in a hospital for heart or cardiac problems?

1 Yes 2 No 3 Not Sure

If yes, how many nights have you spent in a hospital in the last 2 months for heart or cardiac problems?

What problem were you hospitalised for? _____

Q35. Since being referred to cardiac rehabilitation have you had a day procedure?

- 1 Yes 2 No 3 Not Sure

What problem was this for? _____

Q36. Since being referred to cardiac rehabilitation have you seen a general practitioner at a surgery for heart or cardiac problems?

- 1 Yes 2 No 3 Can't Remember *[don't read]*

a. If yes, how many visits to a GP have you made in the last 2 months? _____

Q37. Since being referred to cardiac rehabilitation have you seen any medical specialists or health care professionals apart from your GP, or following referral from your GP for heart or cardiac problems?

- 1 Yes 2 No 3 Can't Remember *[don't read]*

a. If yes, what medical specialists or other health care professionals have you seen and how many times have you seen them in the last 2 months?

Q38. *Ask only if still in the paid workforce.* Since being referred for cardiac rehabilitation how many days have you taken off work due to heart or cardiac problems?

- 1 Nil

Number days off work in the past 2 months _____

Q39. Since being referred for cardiac rehabilitation, how many days have you been unable to do your usual activities (such as voluntary work, hobbies or sport) due to heart or cardiac problems?

- 1 Nil

Number days not able to do usual activities in the past 2 months _____

Q40. Have you recently attended a cardiac rehabilitation program?

- 1 Yes 2 No 3 Not Sure

a. If yes, what type of program did you attend?

b. If no, what are the reasons you did not attend?

The next questions are about your expenditure on exercise items.

Q41. In the past **month**, have you spent any money on exercise-related products or services (such as walking/running shoes, gym membership, exercise classes/equipment)?

- 1 Yes 2 No 3 Can't Remember *[don't read]*

a. If yes, how much have you spent on exercise-related products such as walking or running shoes, gym equipment clothing in the past **month**: \$ _____

b. If yes, how much have you spent on exercise-related services, such as gym membership or personal trainer in the past **month**: \$ _____

Thank you for your time today.

Interviewer: _____ Duration of interview: _____ mins

Notes: _____

Short-term questionnaire – Physical Activity group

Participant ID:

Group code:

Location:

Today's Date:

Good Morning/Afternoon _____, it's **[insert name of project officer]**. I am calling from the NSW Healthy Heart Project to make a time with you to answer the second questionnaire. This will take about 30 minutes, is now a good time for you to do this? (If not, make another appointment). Your participation in this questionnaire is entirely voluntary. You don't have to answer a question if you don't want to. All data is confidential, and your name will be changed to a code to protect your privacy.

Note: Fill out **Telephone Call Record** for each phone call made to participant

Q1 – Q26 from Baseline Questionnaire are asked again here.

The next questions are about how you found the program.

Q27. Did you find the pedometer useful?

1 Very Useful 2 Useful 3 Not Useful 4 Not Sure

Q28. Did you find the step calendar useful?

1 Very Useful 2 Useful 3 Not Useful 4 Not Sure

Q29. Did you receive the materials about physical activity?

1 Yes 2 No 3 Not Sure *[don't read]*

a. If yes, did you find the material useful in helping you become more physically active?

1 Very Useful 2 Useful 3 Not Useful 4 Not Sure

The next questions are about your use of medical services in the last 2 months

Q30. Since being referred to cardiac rehabilitation have you had any admissions to a hospital emergency department for heart or cardiac problems? (e.g. accident, emergency, casualty)

1 Yes 2 No 3 Not Sure

If yes, how many emergency department visits have you made in the last 2 months for heart or cardiac problems? _____

Q31. Since being referred to cardiac rehabilitation have you stayed overnight in a hospital for heart or cardiac problems?

1 Yes 2 No 3 Not Sure

If yes, how many nights have you spent in a hospital in the last 2 months for heart or cardiac problems? _____

What problem were you hospitalised for? _____

Q32. Since being referred to cardiac rehabilitation have you had a day procedure?

1 Yes 2 No 3 Not Sure

What problem was this for? _____

Q33. Since being referred to cardiac rehabilitation have you seen a general practitioner at a surgery for heart or cardiac problems?

1 Yes 2 No 3 Can't Remember *[don't read]*

a. If yes, how many visits to a GP have you made in the last 2 months? _____

Q34. Since being referred to cardiac rehabilitation have you seen any medical specialists or health care professionals apart from your GP, or following referral from your GP for heart or cardiac problems?

1 Yes 2 No 3 Can't Remember *[don't read]*

a. If yes, what medical specialists or other health care professionals have you seen and how many times have you seen them in the last 2 months?

Q35. *Ask only if still in the paid workforce.* Since being referred for cardiac rehabilitation how many days have you taken off work due to heart or cardiac problems?

1 Nil

Number days off work in the past 2 months _____

Q36. Since being referred for cardiac rehabilitation, how many days have you been unable to do your usual activities (such as voluntary work, hobbies or sport) due to heart or cardiac problems?

1 Nil

Number days not able to do usual activities in the past 2 months _____

Q37. Have you recently attended a cardiac rehabilitation program?

1 Yes 2 No 3 Not Sure

a. If yes, what type of program did you attend?

b. If no, what are the reasons you did not attend?

The next questions are about your expenditure on exercise items.

Q38. In the past **month**, have you spent any money on exercise-related products or services (such as walking/running shoes, gym membership, exercise classes/equipment)?

1 Yes 2 No 3 Can't Remember *[don't read]*

a. If yes, how much have you spent on exercise-related products such as walking or running shoes, gym equipment clothing in the past **month**: \$ _____

b. If yes, how much have you spent on exercise-related services, such as gym membership or personal trainer in the past **month**: \$ _____

Thank you for your time today.

Interviewer: _____ Duration of interview: _____ mins

Notes: _____

Medium-term questionnaire – Healthy Weight and Physical Activity group

Participant ID:

Group code:

Location:

Today's Date:

Good Morning/Afternoon _____, it's *[insert name of project officer]*. I am calling from the NSW Healthy Heart Project to make a time with you to answer the last questionnaire. This will take about 30 minutes, is now a good time for you to do this? (If not, make another appointment). Your participation in this questionnaire is entirely voluntary. You don't have to answer a question if you don't want to. All data is confidential, and your name will be changed to a code to protect your privacy. **Note:** Fill out **Telephone Call Record** for each phone call made to participant.

Q1 – Q26 from Baseline Questionnaire are asked again here.

The next questions are about your use of medical services in the last 6 months

Q27. Have you had any admissions to a hospital emergency department in the last 6 months for heart or cardiac problems? (e.g. accident, emergency, casualty)

1 Yes 2 No 3 Not Sure

a. If yes, how many emergency department visits have you made in the last 6 months for heart or cardiac problems? _____

Q28. Have you stayed overnight in a hospital in the last 6 months for heart or cardiac problems?

1 Yes 2 No 3 Not Sure

a. If yes, how many nights have you spent in a hospital in the last 6 months for heart or cardiac problems?

Q29. Have you had a day procedure in the last 6 months?

1 Yes 2 No 3 Not Sure

What problem was this for? _____

Q30. Have you seen a general practitioner at a surgery in the last 6 months for heart or cardiac problems?

1 Yes 2 No 3 Can't Remember [*don't read*]

a. If yes, how many visits to a GP have you made in the last 6 months? _____

Q31. Have you seen any medical specialists or health care professionals apart from your GP, or following referral from your GP in the last 6 months for heart or cardiac problems?

1 Yes 2 No 3 Can't Remember [*don't read*]

a. If yes, what medical specialists or other health care professionals have you seen and how many times have you seen them in the last 6 months?

Q32. *Ask only if still in the paid workforce.* In the past 6 months, how many days have you taken off work due to heart or cardiac problems?

1 Nil

Number days _____

Q33. In the past 6 months, how many days have you been unable to do your usual activities (such as voluntary work, hobbies or sport) due to heart or cardiac problems?

1 Nil

Number days not able to do usual activities in the past 6 months _____

The next questions are about your expenditure on exercise items.

Q34. In the past **month**, have you spent any money on exercise-related products or services (such as walking/running shoes, gym membership, exercise classes/equipment)?

1 Yes 2 No 3 Can't Remember [*don't read*]

a. If yes, how much have you spent on exercise-related products such as walking or running shoes, gym equipment clothing in the past **month**: \$ _____

b. If yes, how much have you spent on exercise-related services, such as gym membership or personal trainer in the past **month**: \$ _____

Thank you for your time today.

Interviewer: _____ Duration of interview: _____ min