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Complete List of Authors:	Barrett, Stephen; Bendigo Health - Bendigo Hospital Campus, Health Promotion; La Trobe University - Bendigo Campus, Rural Health School Begg, Stephen; La Trobe University - Bendigo Campus, Rural Health School O'Halloran, Paul; La Trobe University, Kingsley, M; La Trobe University School of Rural Health,
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Cost-effectiveness of telephone coaching for physically inactive non-admitted hospital patients: economic evaluation alongside the Healthy 4U randomised controlled trial

Stephen Barrett [1]

Stephen Begg [2]

Paul O'Halloran [3]

Michael Kingsley [4*]

[1] Bendigo Health, Bendigo, Victoria, Australia, 3552. Email: sbarrett@bendigohealth.org.au

[2] La Trobe University, La Trobe Rural Health School, PO Box 199, Bendigo, Victoria, Australia, 3552. Email: s.begg@latrobe.edu.au

[3] La Trobe University, School of Psychology and Public Health. Bundoora, Victoria, Australia, 3068. Email: p.ohalloran@latrobe.edu.au

[4] La Trobe University, La Trobe Rural Health School, PO Box 199, Bendigo, Victoria, Australia, 3552. Email: M.Kingsley@latrobe.edu.au

*Corresponding Author:

A/Prof Michael Kingsley

Discipline of Exercise Physiology,

La Trobe Rural Health School,

La Trobe University,

Victoria,

AUSTRALIA

Phone: +61 3 5444 7589

Email: M.Kingsley@latrobe.edu.au

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Abstract

Objective: To assess whether telephone coaching is a cost-effectiveness method for increasing physical activity and health-related quality of life for insufficiently active adults presenting to a non-admitted clinic in a public hospital.

Design: Within-trial cost-effectiveness analysis.

Setting: Participants were recruited from a non-admitted secondary care clinic in a public hospital in regional Australia.

Participants: Adults (aged 18-69) deemed insufficiently physically active via self-report.

Interventions: Participants were randomised to either an intervention group that received an education session and eight sessions of telephone coaching over a 12- week period, or to a control group that received the education session only. The intervention used in the telephone coaching intervention was integrated motivational interviewing and cognitive behaviour therapy (MI-CBT).

Outcome measures: The primary health outcome was change in moderate-to-vigorous physical activity (MVPA), objectively measured via accelerometry. The secondary outcome was the quality-adjusted life-year (QALY) determined by the SF-12 Questionnaire. Outcome data was measured at baseline, post-intervention (3-months) and follow-up (6-months). Incremental cost-effectiveness ratios (ICERs) were calculated for each outcome. Non-parametric bootstrapping techniques and sensitivity analyses were performed to account for uncertainty.

Results: The mean intervention cost was $279 ± $13 per person. At six-months follow-up, relative to control, the intervention group undertook 18 more minutes of daily MVPA at an ICER of $15/minute for each additional minute of MVPA. With regard to QALYs, the intervention

yielded an ICER of $36,857 per QALY gained. Sensitivity analyses indicated that results were robust to varied assumptions.

Conclusion: Integrating telephone coaching into non-admitted hospital care is a relatively low-cost strategy for increasing MVPA and QALYs in insufficiently physically active non-admitted hospital patients. Additional research could explore the potential economic impact of the intervention from a broader healthcare perspective.

Trial Registration

ANZCTR: ACTRN12616001331426. Registered 23 September 2016

Keywords

Health promotion; Hospital; Secondary Care; Physical activity; Cost-benefit analysis

Article Summary

Strengths and limitations of this study

- This study is the first to investigate the cost-effectiveness of telephone delivered MI-CBT for insufficiently physically active secondary care hospital patients.
- Economic evaluations enable hospitals to estimate the costs of delivering preventive health interventions, which are important for addressing the burden of chronic disease.
- Changes in physical activity were measured using accelerometers, strengthening the confidence in the findings.
- Results are limited by a short time horizon and a narrow costing perspective.
- Further research is needed to explore the potential long-term economic impact of the intervention from a broader healthcare perspective.

INTRODUCTION

Insufficient physical activity (PA) is an established risk factor for the development of a number of chronic diseases, including cardiovascular disease, type 2 diabetes and obesity[1]. Despite the well-established benefits of PA[2], more than half of the population does not attain sufficient levels of PA to derive such benefits[3]. The estimated cost of insufficient PA in Australia is AU$805 million per annum[4]. Addressing the prevelance of insufficient physical activity is a major public health priority, and necessitates that multiple sectors of the healthcare industry are actively engaged in physical activity promotion[5].

Hospitals are important settings in which to offer health promotion interventions. Patients attending outpatient hospital clinics are more likely than the general population to have one or more chronic disease[6 7]. Additionally, patients in situations of ill-health are more open to behaviour change contemplation[8]. Substantial efforts have been made to promote increased engagement in PA using individual and population-based approaches[9]. This has resulted in an increased use of behaviour change interventions to influence participation in PA[10].

Studies suggest that telephone coaching interventions improve clinical outcomes, self-efficacy, and health status[11 12]. To make the benefits of telephone coaching more broadly available in hospital settings, alternative models have been implemented and found to be effective[13]. The addition of telephone coaching to standard care resulted in significant improvements in objectively measured physical activity and health related outcomes[13], however, the cost to improve these outcomes has not been reported.

Few studies have employed any form of economic analyses on telephone coaching, and little is known about the relative cost-effectiveness of adding telephone coaching to routine care in non-admitted hospital settings. The purpose of this study was to evaluate the cost-effectiveness of the Healthy4U program for increasing measured PA and the number of quality adjusted life years (QALYs) experienced over a 6-month period from a hospital perspective.

METHODS

Study design

The Healthy4U study was a single-blind randomised controlled trial reported in line with the CHEERS reporting guidelines[14] (Additional file 1). The trial design, participants, sample size, intervention, outcomes and ethics approvals have been described in detail elsewhere[13]. Briefly, study participants (n = 72) were insufficiently physically active adults recruited from ambulatory outpatient clinics at a major tertiary hospital in a regional town in Victoria, Australia. The primary aim was to promote change in objectively measured physical activity during the trial.

Intervention

All enrolled participants attended a 30-minute group education session. The education session was a facilitated learning session focused on self-management and lifestyle modification, and was carried out using a self-determination theory framework[15].

The intervention group completed a telephone-based, integrated motivational interviewing and cognitive behaviour therapy (MI-CBT) intervention, delivered in eight 30-minute sessions over 12 weeks. The intervention was delivered by an experienced allied health clinician trained in MI-CBT. All participants enrolled into the control arm attended the education session. Apart from contact regarding follow-up outcome measures, participants in the control group received no further contact initiated by the research team.

Measurement of effects

Outcome measures were recorded at baseline, after 3 months of intervention (post-intervention) and at 6 months (follow-up) by assessors blinded to the study group assignment. The primary outcome measure was a change in moderate-to-vigorous physical activity (MVPA), objectively measured by accelerometry (wGT3X-BT; Actigraph, USA). To be included in the analysis, a minimum wear time of ≥10 h/day for 5 of the 7-day period was required, including at least 1 weekend day[16]. Weekly PA totals were summed from the daily totals for persons with 7 valid days of monitoring, or estimated as 7 times the average daily total for persons with 5 to 6 valid days of monitoring. Using the summed weekly totals, participants were classified as either meeting or not meeting the recommended PA guidelines[17].

A secondary outcome was a change in health-related quality of life (HrQoL) and QALYs, which was derived from the Medical Outcomes Study Short Form 12 Health Survey (SF-12) and the standard Brazier algorithm[18 19]. The SF-12 scores were converted to utility scores on a scale of 0 to 1, with a higher score indicating a more favourable health state[19]. These utility estimates were converted to QALYs by calculating the 'area under the curve' utility estimates for

the different follow-up time intervals for each participant, weighted by the length of follow-up at that time interval.

Measurement of costs

The cost analysis was designed and conducted from a hospital perspective, which allows health care organizations to gauge the approximate cost of offering this program[20]. A bottom-up micro-costing approach was used to calculate the intervention costs[21]. This approach involves the detailed collection of information regarding the quantities of resources consumed while implementing and executing the interventions, as well as their respective unit prices[21]. Only those costs involved in implementing the intervention (e.g., training of individuals carrying out and undertaking the intervention) were included. Protocol-driven costs, namely the costs of gathering data as part of the clinical trial were considered to be sunk costs and were therefore excluded from the cost-effectiveness analysis[20].

The program costs included group facilitator time, intervention time, and supplies. The group facilitator's time that was spent preparing for and facilitating group meetings. The intervention assistant's time was calculated as the time spent undertaking reminder phone calls to participants. The intervention costs were calculated as the time spent in 1:1 consultation with the participants. Both group facilitation and intervention costs were calculated using the annual salary of an experienced allied health clinician as they would most likely to be used in delivering MI-CBT were the intervention to be implemented on a large scale (AU$82,924). Intervention assistant costs were based upon the annual salary of an Allied Health Assistant (AU$45,338). Finally, the costs of supplies, including the program manuals were included in the program cost.

The group facilitator's time per group meeting was estimated at 2.5 hours, which included 0.5 hours for the group meeting itself, 1.0 hour to set up before and clean up after the group meeting, and 1.0 hour to prepare for the group meeting (i.e., reviewing meeting notes and presentation material). The group facilitator's cost per meeting per participant was calculated by dividing the facilitator's cost per meeting by the number of participants that attended each meeting. Due to the short time frame in which costs and effects occurred discounting was not necessary[22]. All program costs were calculated in 2017 Australian dollars (AU$).

Statistical analysis

Analyses of trial data have been reported elsewhere[13]. In brief, mixed-model ANOVAs were used to assess the effects of the intervention on each of the outcome variables. The mean ± SD for the overall cost and for the change in each outcome at 6-months was calculated. For each outcome, the incremental cost-effectiveness ratio (ICER) was calculated by dividing the difference in costs by the difference in effects between the intervention and control groups where the difference in effects between the two groups was calculated using a change from baseline approach to control for different baseline utilities. Uncertainty in the ICER estimates was accounted for by generating 1000 bootstrap replicates of the dataset, a widely used method in health economic evaluations. To account for uncertainty, 95% confidence intervals were calculated for each ICER using nonparametric bootstrapping based on the 2.5th and 97.5th percentiles of 1000 bootstrap replications. Probabilistic sensitivity analysis was completed by calculating the cost-effectiveness acceptability curve (CEAC) derived from the bootstrap replicates. CEAC indicates the probability that the intervention was cost effectiveness at different values of willingness to pay for the additional improvement in the outcome[23].

An additional 4 sensitivity analyses were used to examine how the results changed under different input assumptions. In the first 2 analyses, personnel wages and training costs were varied by 20% in either direction before recalculating the ICERs. The third sensitivity analysis using the summed weekly MVPA totals to estimate the ICER for each additional minute of MVPA per week. The fourth sensitivity analysis considered a different outcome measure for PA, using the summed weekly MVPA totals to estimate the ICER for changing one individual from insufficiently physically active to sufficiently physical activity (≥ 150 minutes MVPA per week)[17].

Patient and public involvement

The study was approved by the Research Ethics Committees of Bendigo Health Care group (approved September 16, 2016; reference number LNR/16/BHCG/42) and La Trobe University College of Science Health and Engineering Human Ethics Sub-Committee (approved October 3, 2016) and is registered on ANZCTR.org.au (registration number ACTRN12616001331426). Participants gave written informed consent for participation in the study for the original randomised trial. There are no plans to disseminate the results of the current study to study participants. For further information on patient involvement see reference [13].

RESULTS

Resource use and costs

A total of 72 participants completed their baseline and 3-month assessment, and 68 participants completed the 6-month assessment. The group consisted of 54 females and 18 males, with an average age of 53 ± 8. The program resources and cost per participant are described in Table

1. Attendance at the education session was mandatory, with full attendance recorded for both groups. The mean group program time was 34 ± 6 minutes, and the mean total participant time spent in the intervention was 242 ± 14 minutes. The mean cost per participant was $279 ± $10 for intervention versus $21 ± $3 for control. The main component costs of MI-CBT were intervention delivery and training.

Table 1. Utilisation and cost of program delivery for intervention and control groups

Item	Provider	Units	Time (h)	Cost/h	Total AU$ cost per participant
Intervention group					
Group Sessions	Allied Health professional	1	2.5	41.90	17.45
Phone call reminders	Intervention assistant	8	0.25	22.80	45.6
Intervention sessions	Allied Health professional	8	0.5	41.90	167.6
Program manual					3.5
Staff training					44.6
Total cost/participant					**279**
Control group					
Group Sessions	Allied Health professional	1	2.5	41.90	17.45
Program manual					3.5
Total cost/participant					**21**

Health outcomes

Table 2 presents the mean costs and the mean change in each outcome at follow-up for each group, and the corresponding ICERs. The ICER for MVPA was $15 per each additional minute of MVPA per day. The difference in QALYs between intervention and control groups was 0.007 QALYs over the course of the follow-up period. The ICER for the intervention group in comparison with the control group was $36,857 per QALY gained. Figures 1 and 2 illustrate the cost-effectiveness acceptability curves for each outcome. For physical activity, given a

willingness to pay of $15 per additional minute of MVPA, the probability that the intervention was cost effective was 67%. At a willingness to pay of $37,000 per QALY gained, the probability that the intervention is cost effective was 52%. If the decision maker was willing to pay $40,000 per QALY, the probability of cost-effectiveness was 70%.

Table 2. Costs, changes in outcomes and incremental cost-effectiveness ratios at follow-up.

Outcome	Cost AU$/ Participant	Outcome	Incremental cost	Incremental outcome	ICER
MVPA					
Control	21	23			
Intervention	279	41	258	18	AU$15/min MVPA per day
QALYs					
Control	21	-0.005			
Intervention	279	0.002	258	0.007	AU$36, 857/QALY

ICER, Incremental cost-effectiveness ratio; MVPA, moderate to vigorous physical activity; QALYs: quality adjusted life years.

Figure 1 and 2 near here

In the sensitivity analyses, training and implementation costs were varied 20% in each direction, and the corresponding ICERs were recalculated (Table 3). The varied ICERs for MVPA was found to range from $11 to $17 per each additional minute of MVPA per day, while the ICER for QALYs ranged from $29,428 to AU$44,285 per QALY gained. The third sensitivity analysis

demonstrated an ICER of $2.86 per additional minute of MVPA per week. The final sensitivity analysis found that the intervention group was 33% more likely than control to meet recommended PA guidelines at follow-up, with an ICER of $781 per PA guideline attained.

Table 3. Sensitivity analyses for costs, changes in outcomes and incremental cost-effectiveness ratios at follow-up.

Outcome	Cost AU$/ Participant	Outcome	Incremental cost	Incremental outcome	ICER
MVPA + 20% variation in cost					
Control	25	23			
Intervention	335	41	310	18	AU$17/min MVPA per day
QALY + 20% variation in cost					
Control	25	-0.005			
Intervention	335	0.002	310	0.007	AU$44,285 QALY
MVPA - 20% variation in cost					
Control	17	23			
Intervention	223	41	206	18	AU$11/min MVPA per day
QALY - 20% variation in cost					
Control	17	-0.005			
Intervention	223	0.002	206	0.007	AU$29,428 QALY
MVPA min per week					
Control	21	170			
Intervention	279	260	258	90	AU$2.86/min MVPA per week
PA guidelines attained					
Control	21	20/36 (55%)			
Intervention	279	31/36 (86%)	258	33%	AU$781/ PA guideline achieved

ICER, Incremental cost-effectiveness ratio; MVPA, moderate to vigorous physical activity; PA, Physical activity; QALYs: quality adjusted life years

DISCUSSION

This study examined the clinical and economic implications of a behaviour change intervention for changes in PA and QALYs for insufficiently physically active adults presenting to an ambulatory care clinic in a regional public hospital setting. Over the follow-up period the MI-CBT intervention was significantly more effective than control in increasing PA and HrQoL. To the best of our knowledge, this is the first study to evaluate the cost-effectiveness and cost-utility of an integrated MI-CBT intervention for health-related behaviour change.

Telephone coaching can be cost effective for increasing physical activity with patients with or at risk of chronic disease[24]. However, little is known about the cost-effectiveness of adding preventive interventions to routine hospital care, where implementing an intervention requires an upfront investment of money. The total estimated cost of delivering the MI-CBT intervention was $279 per person, resulting in the average attainment of 41 ± 12 minutes of MVPA per day at follow-up. The per person cost was similar to the $245 per person found in recent primary care intervention for PA change[25], while both are considerably lower than costs of $1,756/person[26] and $1,562/person[27] reported in other lifestyle interventions aiming at changes in PA.

The cost-effective analysis for measured MVPA indicated a cost of $11 per each additional minute of MVPA per day. Over the 6-month follow-up period this can be translated to a total cost of $9 per day, or $63 per week to increase MVPA by 150 minutes. Sensitivity analysis indicated a one-time cost of $2.86 per each additional minute of MVPA per week, or $8.25 per week to increase MVPA to 150 minutes a week over the 6-month follow up. The cost of $8.25 per week to increase MVPA to 150 minutes is comparable to the $4.99[28], $8.13[29] and $10.19[30] per

week found in other interventions aimed at increasing physical activity. Increases in PA result in decreased healthcare use, even in the short term, which result in net savings to society over time[31]. Determining the cost-effectiveness of integrating telephone coaching into routine care from a hospital perspective is therefore depending on the willingness-to-pay for each additional minute of MVPA. The CEAC indicated a probability of 67% that $15 per additional minute of MVPA was cost effective.

The intervention group was 33% more likely than the control group to undertake sufficient PA at follow-up. Sensitivity analysis demonstrated an ICER of $781 for converting one insufficiently physically active adult to a sufficiently active state over the 6-month follow-up period. This value falls with the ranges of $175 to $1801[32], and $521 to $5790[33] estimated in systematic reviews investigating the cost-effectiveness of physical activity interventions. Undertaking sufficient PA is strongly associated with decreased risk of chronic disease, morbidity and mortality [1] as well as decreased healthcare expenditure over time[31].

At follow-up, an incremental change in QALYs of 0.007 was demonstrated between the intervention and control groups, resulting in an ICER of $36,857 per QALY gained. The ICER of $36,857 per QALY gained is considerably smaller than the $58,924 per QALY gained[26] and the $68,101 per QALY gained[27] found in similar intervention studies. Oskman et al. recently reported an ICER of $48,000 per QALY gained for a telephone-based health coaching intervention for chronic disease patients[34]. Direct comparison with the results from the aforementioned studies is challenging because different cost perspectives were considered in these analyses. Nonetheless, the ICER of $36,857 per QALY falls under the commonly used threshold of $50,000 per QALY gained proposed for medical treatments and procedures[35].

Sensitivity analysis demonstrated that costs for the Healthy4U study are only mildly sensitive to typical variation in the cost input values. A variation in hourly wage costs had the largest impact on the ICERs, however, the ICERs remained well below the threshold of $50,000 per QALY gained at all imputed values.

This study was unique in that we enrolled participants from an ambulatory care clinic in a public hospital, integrating preventative health into secondary care. It is important to note that this intervention was carried out in addition to standard care, not as a substitution, and as such an economic evaluation costed from a hospital perspective offers healthcare providers an estimate of the costs and effects of adding a preventative health intervention to clinical care. This study is one of the few economic evaluations of telephone coaching carried out in real-life settings using an RCT design. The addition of preventive health measures is likely to cost hospitals more, however, these preventive measures might be worthwhile due to the substantial health benefits that they confer, relative to their cost[31]. The greatest cost of the intervention was in the delivery, due to the fact that it was delivered individually by trained personnel. These costs could be reduced by decreasing the number of intervention sessions, with a recent meta-analysis indicating that 5 sessions of MI-CBT is significantly effective for physical activity change[36].

The use of objectively measured PA at all time points was a considerable strength of the study. Objective measures offer more precise estimates of activity intensity while removing many of the issues associated with participant recall and response bias[37]. Individuals have been demonstrated to overestimate their PA levels via self-report[38]. Overestimation of PA can result in inaccurate estimations of both effectiveness and the cost-effectiveness of interventions[38].

Using objectively measured changes in PA and the collection of full cost data for all participants strengthens our findings[37].

A noteworthy limitation of this study is the restricted perspective used for the economic evaluation. Using a single hospital perspective might have led to the exclusion of important costs and benefits from a societal perspective, including healthcare utilisation and changes in productivity[39]. Economic analyses from a societal perspective offer the most comprehensive evidence from which to base decisions[39]. However, due to the relatively short follow-up time of this study it was not feasible to undertake this method. Significant effects on overall healthcare utilisation or productivity loss were not expected over the timeframe of this study[40]. As the intervention was delivered using the telephone, the intervention required relatively small amounts of participant time. With this in mind, the participant opportunity costs were expected to be small and therefore not included in the analyses.

To the best of our knowledge this is the first study comparing the cost-effectiveness and cost-utility of an integrated MI-CBT intervention for health behaviour change amongst community-dwelling adults presenting to a secondary care clinic in a regional public hospital setting. Considering the large group of people who might benefit from such an intervention (i.e., approximately 50% of adults aged 18-69 years in Australia who are currently insufficiently physically active), the widespread adoption and implementation of MI-CBT to increase PA could have important economic implications. However, further research with a more comprehensive economic analysis is needed to investigate whether the long-term benefits of MI-CBT might justify this type of investment.

Conclusion

The Healthy4U program is a relatively low-cost strategy for increasing physical activity among insufficiently physically active adults presenting to a non-admitted hospital clinic. The intervention increased measured PA and quality of life at low costs, with positive effects maintained out to 6-months. By increasing physical activity and quality of life at low costs, integrating telephone coaching programs into secondary hospital care offers a potentially cost-effective investment to produce better public health outcomes. The results are however grounded on a short-term follow-up and a restricted economic perspective, and more evidence is needed to explore the potential long-term economic impact of the intervention from a broader healthcare perspective.

Footnotes

Author Contributions: SB[1], MK, SB[2] and PO'H conceived the project and assisted with the protocol design. SB[1] managed the trial including recruitment and data collection, coordinated the intervention program, performed statistical analysis, and drafted the manuscript. SB[1] and SB[2] interpreted the data and drafted the manuscript. All authors read, edited and approved the final manuscript as submitted.

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Ethics approval: The study was approved by the Research Ethics Committees of Bendigo Health Care group (approved September 16, 2016; reference number LNR/16/BHCG/42) and La Trobe University College of Science Health and Engineering Human Ethics Sub-Committee (approved October 3, 2016). Written informed consent was obtained from all participants before they join the study.

Data sharing statement: All data requests should be made to the corresponding author.

Patient consent for publication: Not required.

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Table Title

Table 1. Utilisation and cost of program delivery for intervention and control groups.

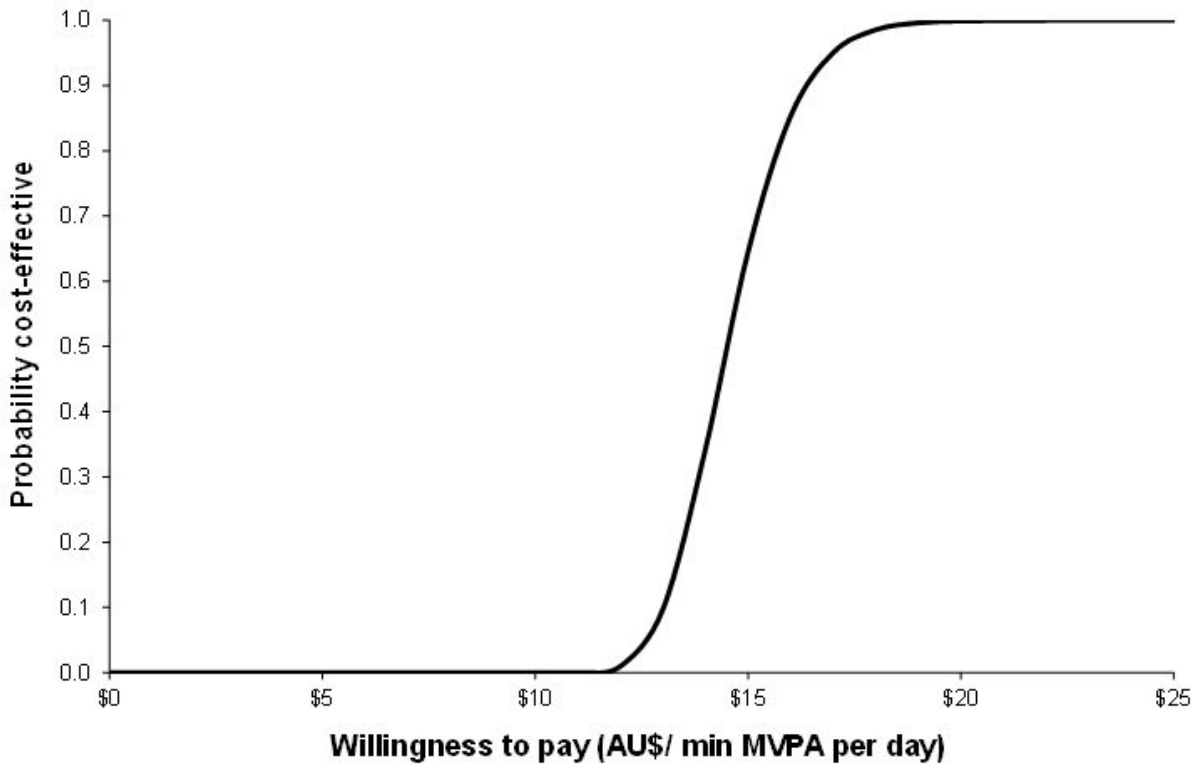
Table 2. Costs, changes in outcomes and incremental cost-effectiveness ratios at follow-up.

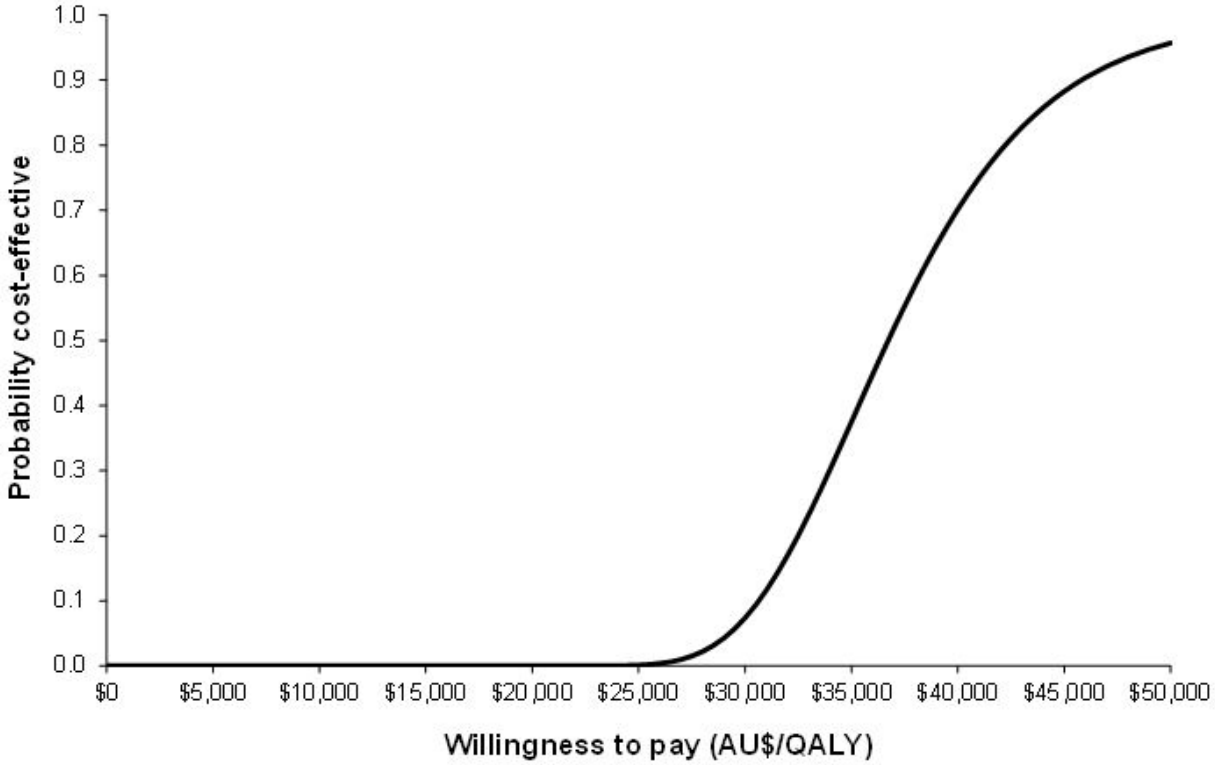
Table 3. Sensitivity analyses for costs, changes in outcomes and incremental cost-effectiveness ratios at follow-up.

Figure Title

Figure 1. Cost-effectiveness acceptability curve showing the probability of the interventions being cost-effective in comparison to control for moderate to vigorous physical activity (MVPA)

Figure 2. Cost-effectiveness acceptability curve showing the probability of the interventions being cost-effective in comparison to control for quality adjusted life years (QALYs)





Reporting checklist for economic evaluation of health interventions.

Based on the CHEERS guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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	Reporting Item	Page Number
Title		
#1	Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis”, and describe the interventions compared.	1

Abstract			
	#2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions	2-3
Introduction			
Background and objectives	#3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions	4-5
Methods			
Target population and subgroups	#4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	5
Setting and location	#5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	5
Study perspective	#6	Describe the perspective of the study and relate this to the costs being evaluated.	7
Comparators	#7	Describe the interventions or strategies being compared and state why they were chosen.	5-6
Time horizon	#8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	6

Discount rate	#9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate	8
Choice of health outcomes	#10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed	6
Meaurement of effectiveness	#11a	Single study-based estimates: Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data	n/a
Measurement of effectiveness	#11b	Synthesis-based estimates: Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data	n/a
Measurement and valuation of preference based outcomes	#12	If applicable, describe the population and methods used to elicit preferences for outcomes.	n/a
**Estimating resources and costs **	#13a	Single study-based economic evaluation: Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource	n/a

		item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs	
Methods			
Estimating resources and costs	#13b	Model-based economic evaluation: Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	n/a
Currency, price date, and conversion	#14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	7-8
Choice of model	#15	Describe and give reasons for the specific type of decision analytical model used. Providing a figure to show model structure is strongly recommended.	n/a
Assumptions	#16	Describe all structural or other assumptions underpinning the decision-analytical model.	n/a
Analytical methods	#17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle	n/a

		corrections) to a model; and methods for handling population heterogeneity and uncertainty.	
Results			
Study parameters	#18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	9-13
Incremental costs and outcomes	#19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	9-13
Characterising uncertainty	#20a	Single study-based economic evaluation: Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).	11-13
Characterising uncertainty	#20b	Model-based economic evaluation: Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	n/a
Characterising heterogeneity	#21	If applicable, report differences in costs, outcomes, or cost effectiveness that can be explained by variations	n/a

		between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	
Discussion			
Study findings, limitations, generalisability, and current knowledge	#22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	14-17
Other			
Source of funding	#23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support	19
Conflict of interest	#24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations	19

Design and rationale of the Healthy 4U trial of a telephone based intervention of a blend of motivational interviewing and cognitive behaviour treatment for physical activity behaviour change and maintenance: a randomised controlled trial protocol.

BACKGROUND

Non communicable diseases (NCDs) are the leading cause of illness, disability and death in Australia, accounting for 90% of all deaths in 2011 [1]. NCDs have an intricate association with modifiable risk factors such as physical inactivity, poor nutrition, and smoking [2]. Seventy per cent of all cardiovascular disease mortality in Australia has been attributed to the combined effects of physical inactivity as well as hypertension and abnormal lipid profiles [3].

People who live in areas of socioeconomic disadvantage are more likely to take part in unhealthy behaviour, or a combination of unhealthy behaviours, which can lead to both chronic disease manifestation, and to poorer chronic disease outcomes [4]. The prevalence of decreased physical activity levels, as well as overweight and obesity is higher in both rural areas and low socio-economic areas than in the metropolitan areas [4]. Bendigo Health (BH) Specialist Outpatient Clinic (SOPC) serves a wide geographical area, encompassing many local government areas that have scored highly on the 'Socio-Economic Indexes for Areas' [5]. This indicates that the regions serviced by Bendigo Health includes many areas of socio-economic disadvantage: Bendigo 983.1; Loddon 934.1; Campaspe 964.1; Mount Alexander 983.3; Strathbogie 970.2; Macedon Ranges 1055.1 [5]. The health profile of the Bendigo region highlights the potential need for greater access to health services and programs aimed at improving the health of residents. Only 40.4% of adults in the Greater Bendigo region meet the physical activity guidelines, 91.4% do not eat the recommended daily serves of vegetables, and almost half (47.6%) do not eat adequate amounts of fruit [6]. More than half of the population in the Greater Bendigo are either overweight or obese [6]. Due to the high risk of chronic disease development in low socio-economic areas, coordinated and targeted screening of these populations has been recommended for early risk factor identification and subsequent management [7].

Population approaches to NCD management are based around the modification of the associated risk factors- uptake of regular physical activity, smoking cessation and dietary modifications [8]. Regular physical activity promotes a myriad of health benefits that contribute to the prevention and management of many NCDs [8,9]. The Department of Health advises adults to perform at least 30 minutes of at least moderate intensity physical activity on five or more days per week, in at least 10 minute bouts, for optimum health benefits [10]. The benefits associated with regular physical activity are also shown to occur regardless of the Body Mass Index (BMI) of the participant [11]. Health improvements appear most marked when an individual changes from sedentary behaviour to engaging in physical activity of moderate intensity [11]. Despite its known efficacy, only 43% of adult Australians do enough physical activity to be deemed sufficiently active [12].

Interventions aimed at engagement in physical activity have demonstrated success with physical activity uptake, however, over the long term, less success has been demonstrated with physical activity maintenance [13]. More than 50% of individuals who initiate physical activity uptake do not maintain behaviour change in physical activity [13]. The factors that predict physical activity uptake have been shown to be different from those that predict physical activity maintenance [13]. As physical activity has been identified as a leading indicator of preventative health, recommendations have been made for the development and provision of efficacious programs to encourage uptake and maintenance of physical activity behaviour [13].

Self-efficacy refers to an individual's belief in his or her own capacity to plan and undertake particular behaviors necessary to produce specific performance attainments [14]. Self-efficacy is representative of an individual's confidence in the ability to exert control over one's own motivation, behavior choices, and social environment [14]. The Self-Efficacy Theory [14] highlights specific determinants of self-efficacy that are associated with behavior change: mastery building via achievable goal setting; verbal persuasion; ability to cope in high-risk, stressful situations; and behavior modeling [14]. There are a number of self-efficacy

determinants specific to the maintenance of physical activity: self-efficacy to be physically active in various environments, self-efficacy to effectively schedule physical activity, self-efficacy to be physically active in spite of stressful life event [14]. Realistic achievable goal setting and outcome expectations related to PA are also hypothesised to increase adherence to long-term PA [15]. Self-efficacy has inherent associations with short-term goal setting and motivation [14]. Increases in self-efficacy were associated with subsequent motivation to join a physical activity programs among older adults [16]. Through the establishment of realistic physical activity goals, calling attention to potentially problematic situations and planning on how to overcome them, and through achieving short-term goals of PA maintenance, individual's self-efficacy for maintenance of physical activity may be fortified [13].

Motivational interviewing (MI) has been demonstrated to be effective in promoting and establishing health related behaviour change [17-20]. MI interventions have been shown to be efficacious in increasing physical activity [18-20]. MI focuses on individual goal setting and self-appraisal facilitated through regular contact from trained professionals [21]. The structured approach of MI, built upon self-management and self-learning has been found to result in positive changes in risk factor management [21]. MI has demonstrated an increased likelihood for long-term health promoting behavior adherence [22].

MI was designed as a model to elicit and build motivation for initial change [21]. Strategies for behaviour change maintenance through the use of MI are less frequently discussed. Following the use of MI to foster initial change, it has been recommended to integrate action-orientated treatments such as cognitive-behavioural therapy (CBT) in an effort to build behaviour change maintenance skills [21].

Cognitive Behaviour Treatment (CBT) is an individual focused approach to the treatment of many types of emotional and behavioural problems [23]. CBT are 'action-orientated' treatments, according to the problem being addressed [23]. CBT remains a collaborative and individualised program assisting individuals in identifying behavior's they wish to change, and

formulating actions related to these goals [24]. CBT aims to allow individuals to challenge their beliefs around behaviour, and then utilise strategies to change and/or modify their behaviour [23-4].

A combination of MI and CBT may be more effective in terms of behavior change than a single treatment undertaken on its own [25-27]. Systematic reviews indicate that most effective components in improving physical activity were built upon self-regulatory behaviors, grounded in MI/CBT frameworks, such as goal setting, feedback provision, self-monitoring, and the utilisiation of social support [28]. Preceding any behaviour change is the formation of an intention to change [21]. MI is a useful tool for evoking intention, while CBT may be effective for translating behaviour change intention into action [23-4].

Many studies have their focus on initial behaviour change, and not on the maintenance of change [17]. There has been little research around a combination of MI and CBT on behaviour change and maintenance in regards to physical activity.

The H4U project aims to examine if a blend of MI and CBT increases physical activity in patients attending a non-admitted elective clinic in a public hospital who do not participate in enough physical activity to be deemed sufficiently physically active. Secondary aims relate to the effect of the MI/CBT intervention on self-efficacy, quality of life, type 2 diabetes risk, and anthropometric measures.

Literature Search

To gain greater insight into best practice program development and delivery, a review of the literature specific to the delivery of a blend of MI and CBT in this area, a non-admitted hospital setting was undertaken.

Search strategy

A literature search was conducted to identify evidence on programs conducted through non-admitted pathways in hospitals aimed at the modification of lifestyle related risk factors.

The search aimed to establish an evidence base around the effectiveness of MI and CBT interventions, specifically with the aim of prevention and/or management of health risk behaviour through non-admitted hospital pathways.

Initial searches were limited to: systematic review and meta-analyses. This search format was chosen on economic and logistic grounds, aimed at highlighting findings from major international research collaborations. This collaborate nature ensures that the review is inclusive of international perspectives.

Reviews were chosen primarily where the effectiveness of program was measured through a lifestyle related outcome measure, for example, an increase in physical activity, the prevention of weight gain, and improvement in nutritional status.

The search was extended to primary research articles (not included within the reviews) in an attempt to identify the broad spectrum of screening interventions,

The search included the following:

- Literature search of electronic databases: including CINAHL, EMBASE, PUBMED, and MEDLINE. Search terms used were within the major constructs of the project (hospital, lifestyle screening, lifestyle modification, motivational interviewing, cognitive behaviour treatment, lifestyle risk factors, primary prevention, secondary prevention, rural and remote) combined with the AND/OR operator
- Search of EBM reviews databases (Cochrane, Projects Register, DARE,). Terms used: lifestyle modification, pre-surgery, hospital, prevention, motivational interviewing, cognitive behaviour treatment
- Reference lists of selected papers were also examined to identity other publications that may be relevant.

The National Public Health Partnership's Schema for Evaluating Evidence on Public Health Interventions developed key criteria for the critical appraisal of both reviews and individual studies [29].

The critical appraisal criteria have been developed to provide a framework for the qualitative assessment of reviews and individual studies included in this review. The use of the critical appraisal tool is aimed at assessing the relevance and methodological rigor of the studies. It also offers guidelines as to appraisal of a papers external validity, and transferability.

Searches of literature in hospital settings around lifestyle modification are primary based upon secondary prevention strategies, while literature on pre-surgical lifestyle modification falls into the category of 'prehabilitation', which covers ranges of procedures including but not exclusive to orthopaedic and oncology amongst others. This project is not limited to patients of one medical specialty, as such no exact replicable project was found. However, some generalizations may be inferred from highlighted research, namely those with the aim of health risk modification.

Secondary prevention is highly active in the field of cardiovascular disease, targeting the highest risk patients with proven treatments [30]. In spite of targeted recruitment, adherence to physical activity recommendations has been found to be as low as 30% for patients with acute coronary symptoms [30]. Roughly 33% of patients have been reported to be still smoking following an acute coronary event [31].

In systematic reviews of preoperative exercise therapy on outcomes postoperatively, the results are favourable in terms of outcome metrics [31]. Pre-surgical interventions in research settings have predominantly measured both medical metrics such as pain, length of stay, reduced complications, as well as potential economic benefits derived from any improvements [32]. Patient lifestyle risk factors, physical activity and nutrition for example are typically not measured post-surgery [32].

The majority of research around health risk behavior modification is based in primary care, and/or admitted hospital patients requiring secondary prevention [15-18]. While the literature

indicates that programs aimed at the modification of health risk behaviours such as physical inactivity, poor nutrition and smoking have shown reasonable effectiveness, these programs have not been delivered in a quasi-primary prevention setting such the elective non-emergency clinic within a public hospital that this project proposes.

MI has been shown to be an effective intervention for health related behavior change, including increasing physical activity [18-20]. Longer term research has shown effectiveness for MI for physical activity change and maintenance- the measurement of physical activity was self-reported, with the authors noting that use of accelerometers may have provided more rigor to the analysis of behaviour change [22]. The majority of studies included in a meta-analysis of the effect of MI on physical activity used self-reporting methods as the primary measure of physical activity- further research utilizing objective measures was recommended as part of the meta-analysis [33].

In terms of blending MI and CBT the research has indicated that a combination of MI and CBT may be more effective than single treatment by itself for influencing health related behaviour change [25-7]. This research has not however been conducted around physical activity change. While health benefits are derived from increased levels of physical activity, most notably changing from sedentary to active, the most important factor related to the benefits of physical activity is the maintenance in physical activity [13]. In order to maintain behaviour change, especially around physical activity, a mixture of theories and skill requirements may be required from both the individual and facilitator perspective [13]. Blending MI and CBT may offer a framework to build skills for physical activity maintenance [13].

Summary

There are considerable, potential benefits at the population level health related behavior change, such as increasing physical activity. Despite this, identifying and implementing the most effective intervention for behaviour change and maintenance remains difficult and challenging to both researchers and to policy makers.

Currently there is a gap in the knowledge around the implementation of a blend of MI and CBT to increase physical activity amongst elective non-admitted hospital patients. This paper details the project protocol for a randomised controlled trial that aims to evaluate the effectiveness of a blend of MI and CBT to increase physical activity amongst elective non-admitted hospital patients presenting to an elective clinic in a public hospital in the regional town of Bendigo in Victoria.

The hypothesis is that by the end of the six-month program, the participants receiving the blended MI and CBT intervention will show improvements in physical activity levels compared to baseline measures. In terms of secondary endpoints, it hypothesised that the intervention group will show improvements in self-efficacy, quality of life, type 2 diabetes risk and anthropometric measures relative to baseline measures.

METHODS AND ANALYSIS

Design

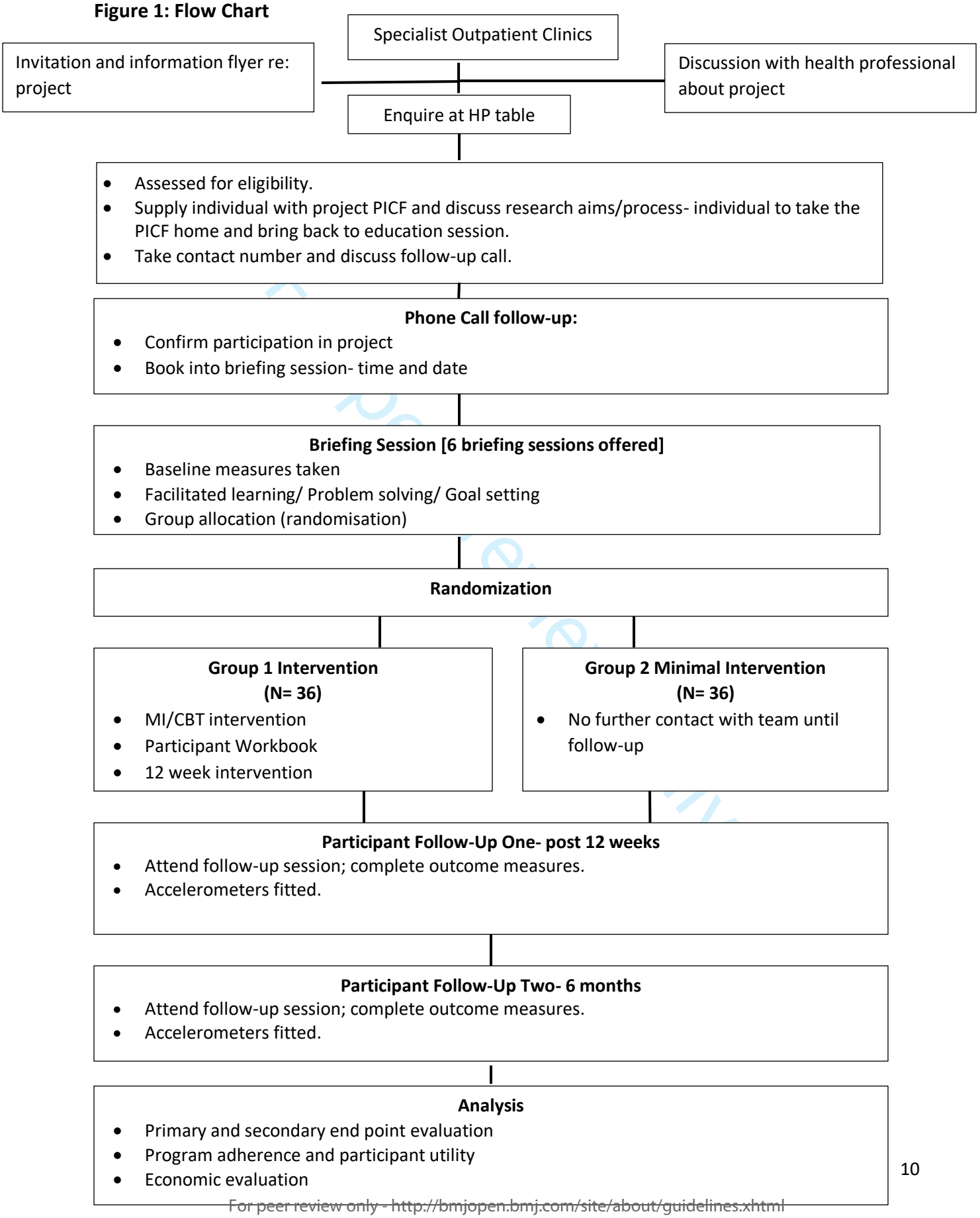
The H4U project is a randomised controlled trial with assessment of outcomes at three points- baseline, post 12 weeks and 6 months (Figure 1). The H4U project aims to examine if a telephone based intervention of a blend of MI and CBT increases physical activity in patients attending a non-admitted elective clinic in a public hospital who do not participate in enough physical activity to be deemed 'sufficiently active'. Secondary aims relate to the effect of the blend of MI and CBT intervention on self-efficacy, quality of life, type 2 diabetes risk, and anthropometric measures.

The project will be conducted at BH, a regional tertiary public hospital that's serves a wide geographical region, with a socioeconomically diverse population. A total of seventy-two patients who present to BH Specialist Outpatients Clinic as an elective admission will be recruited and included in the project (figure 1).

Randomisation

Randomisation will be completed via a computerised randomisation program that will only be accessible to project staff with access via specific username and password via a web interface. The random allocation sequence will be uniform 1:1 (intervention: minimal intervention) allocation ratio. Project members taking follow-up outcome measures will be blinded to the group allocations.

Figure 1: Flow Chart



Participants

The project target population is patients presenting to the BH Specialist Outpatients Clinic over a four-month recruiting period. These patients are elective non-emergency presentations for a consultant with a medical specialist.

The inclusion criteria are: fluent in conversational English, insufficiently physically active (not participating thirty minutes or more of moderate physical activity on at least five days a week-150 mins/week) [10].

The exclusion criteria are: under 18 years and over 69 years; poor comprehension of English language (determined by project team); too physically active (participating in more than thirty minutes of moderate physical activity on at least five days a week); diagnosis of diabetes; deaf/hearing impaired; disabling neurological disorder; severe mental illness such as psychosis, learning disability, dementia and cognitive impairment; registered blind; housebound or resident in nursing home; unable to move about independently or not ambulatory; pregnancy; advanced cancer; categorised as a Category 1 in the BH surgical waitlist classification: patient's categorised as a Category 1 should expect to receive their surgical procedure within thirty days. This categorisation may be confirmed during either initial conversation or during follow-up phone conversation.

Interested participants will be required to complete a Physical Activity Readiness Questionnaire (PAR-Q) (appendix 3) [34]. The PAR-Q offers a safe preliminary screening of candidates for exercise testing and prescription [34]. If a participant answers 'yes' to one or more questions then they will be required to speak to their doctor regarding the intervention, and the amount of physical activity that they should perform. The use of the PAR-Q as a screening tool is part of duty of care to the participants. The PAR-Q must be completed before any participant attends a briefing session.

Recruitment

All participants will be recruited from the BH Specialist Outpatients Clinic following the same pathway (figure 1):

- During the recruitment timeframe invitational fliers will be distributed within the SOPC inviting patients to participate in the project (appendix 1). The information will briefly detail to the patients what the project will entail and the exclusion criteria. Potential participants will be encouraged to come speak to the project team who will be located in a dedicated area within the SOPC during specific clinic times.

- Health clinicians working in the SOPC (who are not involved in the research) project may highlight to patients that the study is being undertaken in the clinic. Facilitated via this conversation, the clinician may give the patient a copy of the research invitation. Potentially interested individuals may also consent to having their information passed onto the research project team, who will follow up with a telephone call. This pathway is an important step in the project design- clinicians who have a relationship with the individual may be in a good position to highlight the project, and its potential significance to the individual. This referral pathway is has the potential to be more sustainable in the long term aim of integrating health promotion into existing practice, and it is also a far more effective use of time, as opposed to a member of the project team manning a recruitment table for long period of time.

- Upon speaking to a project team member the details of the project may be further explained to potentially interested participants. Potentially interested participants will be given the Patient Information Sheet and Consent (PICF)- the PICF form gives an in-depth synopsis of the project (appendix 2). A project team member will go through the project details and the PICF with any interested person. Potentially interested participants will also be given a copy of the PAR-Q which needs to be competed as part of inclusion criteria.

- To limit pressure and coercion on the individual, the PICF does not need to be signed and completed at that time. The participant may take the PICF home to read and discuss with others. Completed PICF's will be collected at the briefing sessions. Participants will be given a stamped addressed envelope which they can return the PICF to the project team should they wish.

- Participants who express an interest in participation but want to take time to consider their choice will be offered a follow-up phone call from the project team to further discuss the project. A project team member will take the participants phone number and discuss appropriate times to contact them.

- Follow-up calls to potential participants will follow the same structure:

    - A member of the project team will make all follow-up calls.

    - Potential participants will be contacted on the number that they supply to the project team.

    - Potential participants will be informed that they will be contacted no sooner than one week after talking to the project team member. This time will allow the individual time to consider their decision.

    - Should the project team member call and the individual does not answer, no message will be left. The project team member will make two attempts to contact on this occasion. If no contact is made no message will be left on this occasion. In this circumstance the project team member will try to contact the individual again, a minimum of four days later. Two calls will be attempted, with a voice message left should the second attempt be unsuccessful. The message left will be scripted for uniformity:

      "*Hello [potential participant], this is [project team member] from Bendigo Health calling you in regards to the Health 4U project that we discussed with you in the*

specialist outpatient clinic. This call is following up on our conversation about your potential interest in participating in the project. If you would like to discuss this further please contact the Healthy 4U team directly on 5454 9118. Thank you".

- After leaving a voice message one more attempt at contact will be made, a minimum of four days later. If this call is unsuccessful no message will be left at this time, and no further contact will be attempted.

- If, on speaking to a potential participant the individual states that they are no longer interested in participating in the project the project officer will thank the individual for their time and consideration, and inform the individual that no further contact will be instigated by the project team.

- If, on speaking to a potential participant the individual states that they are still unsure about whether they are interested in participating in the project the project officer will ask if the individual would like to be contacted again to follow this up. Subsequent calls will follow the structure as above.

- For individuals who choose to participate in the project, a project team member will book them into one of the mandatory briefing sessions. A number of sessions will be held to accommodate participant schedules, including day and evening sessions. During this phone call the project team member will:

    - Remind participants to bring their PICF to the briefing session.

    - Discuss availability of briefing session times and dates, and book the participant into the most suitable session.

    - Check that the potential participant has completed a PAR-Q and that they bring it to the briefing session.

- At the briefing session participants will complete their outcome measures (appendix 4). Completion of the outcome measures should take approximately fifteen minutes. Members of the project team can assist during this time. The outcome measures will be taken prior to any briefing interventions. Participants will be informed that repeat measures are required after week 12 and at 6 months.

- At the end of the briefing session, the participants will be allocated into their respective groups- group 1 or group 2. This allocation will be completed through a computer-generated program. The particulars of each group will be outlined below in this document.

- All participants will be asked to attend two follow-up sessions, one after the 12-week intervention and the other at 6 months. A number of sessions will be held to accommodate participant schedules, including day and evening sessions. During attendance at the sessions repeat outcome measures will be taken and accelerometers will be fitted again.

- All participants will be offered a survey to complete as part of process evaluation (appendix 5). This survey will be distributed at the follow-up session and can also be completed online via survey money, and/or mail out copies.

- Participants who withdraw from the study who wish that their data is not included in the analysis will be required to complete a withdrawal of consent form.

This underlying methodology of offering health promotion within existing care is designed to align with the BH Strategic Plan of Healthy Communities [35]. One of the aims of the BH Strategic Plan is enabling patients to take better care of their health [35]. The development of effective community partnerships is another aim of the BH Strategic Plan [35]. This project aims to utilise the blend of MI/CBT to increase physical activity- part of the support around participation in physical activity may include highlighting to participants what programs are available in the community to suit their needs and referring into these programs. This

partnering with already existing community programs avoids the necessity for BH to develop and run specialist programs, ultimately avoiding service duplication, which is important in regional and rural areas [36].

As part of the project evaluation process, in situation where participants express interest in the project but choose not to proceed, and, offer an unprompted reason for this choice, the individual reasons will be recorded. This information may be used in project process evaluation.

As with the majority of physical activity interventions the research team note that there is an inherent degree of bias associated with recruiting participants to a study under the premise of increasing physical activity. The degree of bias may be equal across both the intervention and the minimal intervention groups.

Intervention

Briefing Session

All project participants enrolling in the project will have to attend a briefing session (Figure 1).

The briefing session will be a facilitated learning session based around self-management and lifestyle modification. Education sessions and problem solving will be developed and carried out using the Self Determination Theory (SDT) framework [37]. This theory is used to support, educate and motivate participants around positive lifestyle choices, as well as the empowerment of individuals over their health care [37]. SDT reflects that an individual's on-going functioning is a product of a continuous interaction between cognitive, behavioural, and contextual factors, and more than a matter of education by itself [37]. Classroom learning for example is shaped by factors within the academic environment, but particularly by the reinforcements experienced by individuals and by others [37]. To adhere to this framework, participants will be encouraged to participate actively in the briefing sessions through group and task orientated learning, and education will be delivered through case studies to stimulate vicarious learning [37]. Participants will be exposed to real life scenarios of health risk modification and given brief tasks to stimulate this thought process. SDT has been chosen as

the framework in which to deliver the briefing session as has been shown to complement MI and CBT integration [37].

The briefing sessions will be facilitated by a member of the project team who is registered healthcare practitioner through the Australian Health Practitioner Regulating Authority (AHPRA). The sessions will also include a guest speaker representing the community health programs.

At the end of the briefing sessions participants will be informed of which arm of the project they have been randomized to.

Group 1

Group 1 will receive the blend of MI and CBT. This model of patient-centred self-management support, delivered as an office-based program through telephone calls has demonstrated successful outcomes for similar populations [19,22,38-9].

The use of the MI/CBT model is based upon supporting participant self-management, in this case facilitated via the interviewer acting as a decision aid for participants around the decision of whether or not to change behaviour. One of the fundamental goals of the self-management support is assisting in highlighting the participant's awareness of the problem and to assist the participant to weigh up the pros and cons of making associated health changes (21).

A member of the project team will facilitate the MI/CBT intervention via the telephone. The individual who will deliver the telephone support is a registered healthcare practitioner through the Australian Health Practitioner Regulating Authority (APHRA). He has attended a 2-day workshop on MI and will receive additional coaching from Dr. Paul O'Halloran, who is a nationally endorsed Health Psychologist and Sport and Exercise Psychologist who has been registered and practicing as a Psychologist since 1998. Dr O'Halloran has undergone extensive training in MI, including training from the two people who developed the technique (Miller and Rollnick). Dr O'Halloran is an accredited Motivational Interviewing Network of Trainers (MINT) trainer.

Each participant will receive eight phone calls, each lasting 30 minutes. The most recent version of MI, MI-3 uses the eight call methodology which allows for participants to move along the stages of engagement, focusing, evoking and planning at a pace unique to each individual. Telephone support following a CBT approach, bedded in MI philosophy has shown to be effective in behaviour modification [38-9].

Each participant will receive 8 calls over the 12-week period. Participants will receive 6 calls in the first 8 weeks, and 2 calls in the final 4 weeks. In terms of incorporating the MI/CBT blend, MI will be utilised for sessions 1 to 5, as MI is identified as an effective tool for behaviour change initiation [21]. From session 5 to session 8 a blend of MI/CBT will be used, as CBT is an action orientated treatment [21, 23-4].

As part of the intervention group 1 participants may be given a workbook. The workbook will be used during the phone conversation for the participant to record their own goals and the action plans they decide upon in order to reach those goals. The action plans are smaller more achievable targets that are required to complete a larger goal. The use of a workbook will not be uniform however, in keeping with the MI philosophy of the facilitator not prescribing advice or actions [21].

As part of self-management support, participants, where the intervention is appropriate, will be referred into programs aimed at lifestyle risk modification, including community health programs. Following the MI/CBT theory, no mandatory referrals will be made to these programs, however the facilitator may highlight the existence of these programs should the situation warrant it. The facilitators will be aware of the programs that are available in the community and can make appropriate referral to the programs on behalf of the participants. This pathway may highlight to participants the range of programs that are available in the community. Utilizing existing programs in the community may be of benefit to the participants, while it also encourages service co-ordination and avoidance of service duplication.

Group 2

Group 2 is the minimal intervention arm of the project. All Group 2 participants will attend the briefing session so they will receive the same educational material around lifestyle risk factor modification as group 1 from that session.

Participants of Group 2 will be contacted to enquire about their attendance at the follow-up session, reminding them about the requirement for outcome measure completion. Apart from this contact participants of Group 2 will receive no further routine contact initiated by the project team.

The use of a second group allows for more rigour in evaluation of the effectiveness of the intervention.

Intervention Fidelity

To assist with improving the credibility of evidence resulting from behaviour change studies the reporting on treatment fidelity has been recommended [40]. Assessments in intervention fidelity are integral to intervention research but few published trials report these processes in detail [41]. This methodological shortcoming makes it very difficult to distinguish between the quality of MI interventions, and, consequently, to be able to establish whether MI provision has contributed to any intervention effects [41]. Treatment fidelity has been defined as the "methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions" [41]. To measure the fidelity of the treatment the Motivational Interviewing Treatment Integrity code will be used [42].

As mentioned above, the individual who will deliver the telephone support will receive additional coaching from Dr. Paul O'Halloran, who is a nationally endorsed Health Psychologist and Sport and Exercise Psychologist. Dr O'Halloran is an accredited Motivational Interviewing Network of Trainers (MINT) trainer.

The treatment fidelity will be evaluated and measured prior to the intervention and midway through the intervention time-frame. This will be carried out through the recording of sessions

between the facilitator and Dr O'Halloran and having the recordings assessed by an independent assessor who will rate the MI proficiency by using a validate tool the Motivational Interviewing Treatment Integrity scale [42].

Outcome measures

The primary endpoint is a change in physical activity levels, measured at 3 points- baseline, just after the 12-week intervention, and at 6 months (Table 1). Secondary endpoints include a change in self-efficacy, quality of life, type II diabetes risk, waist circumference, BMI, and smoking status (Table 1.)

Participants will complete all the outcome measures at the 3 points, at baseline, following the 12 weeks of intervention, and at 6 months.

Physical Activity

The primary endpoint is a change in physical activity levels. Physical activity will be measured objectively using an accelerometer (ActiGraph, Florida, United States) and a log diary to document the type of activity completed, and any occasions when the accelerometer was removed.

The Evidence-based Physical Activity Recommendations for Adults advises adults to perform at least 30 minutes of moderate intensity physical activity on five or more days per week [10]. While these 30-minute periods can be broken down, to derive optimal health benefits bouts of moderate intensity physical activity should last for least for 10 minutes [10].

The ActiGraph GT3X+ is a validated, tri-axial activity monitor that provides data on physical activity including activity counts, steps and activity intensity (METs) [43]. The research team will explain to the participant how to wear the accelerometer, requesting it to be worn from waking in the morning until going to bed at night. Participants will be asked to remove the ActiGraph when they are showering, bathing or swimming. After seven days of wearing the accelerometer, the accelerometers will be collected at the next possible visit to the hospital or

arrangement will be made for collection from participants at a location most convenient to them.

The output from the tri-axial accelerometer measures time spent in physical activity using standard cut-off points for sedentary, light, moderate, vigorous and very vigorous physical activity. As moderate-vigorous physical activity (MVPA) needs to last for bouts of 10 minutes or more to derive health benefits, 10 minutes intervals of MVPA will be will be recorded and extracted from the data collected.

The outcome will be minutes of physical activity at moderate intensity or greater per week.

Physical activity will also be recorded as the time spent walking each day, time spent in sedentary behaviour each day, number of days a week performing strength straining, and the number of steps per day.

Self-Efficacy

Self-Efficacy to be physically active will be measured via a physical activity self-efficacy survey. This survey has been built upon previous research, with modifications to suit the target group that this study proposes [44]. The survey measures confidence related to completing physical activity while faced with recognised barriers to physical activity completion.

Physical Activity Stages of Change

Physical Activity Stages of Change will be measured via the Physical Activity Stages of Change Questionnaire [45].

The Physical Activity Stages of Change Questionnaire is a simple tool based upon The Stages of Change (SOC) Model. The SOC model was originally developed by James Prochaska and Carlo DiClemente in the late 1970's and early 1980's with the model originally devised around smoking cessation though it has since been applied to a broad range of behaviour change situations [46]. The SOC model theorises that individuals move through a series of stages as they both adopt and maintain a new behaviour [46]. The stages within the model include

Precontemplation, Contemplation, Preparation, Action, Maintenance and Relapse. In terms of physical activity, Precontemplators are seen as inactive and not thinking of becoming active [47]. Contemplators are inactive but they are considering becoming active. Preparers intend to be physically active in the next month or have unsuccessfully taken action in the past year (not at the recommended levels). Individuals who are in the Action Stage are physically active at the recommended levels but have been active for less than six months. Individuals in the Maintenance Stage are physically active at the recommended levels and have been for six or more months [47]. Research indicates that it may take numerous attempts before individuals succeed in adopting and maintaining PA, therefore the movement across the SOC is considered to be a cyclical rather than linear process [48].

For this study, determining the stage of change aims to assess both the intention and the perception of physical activity behaviour. Determining the stage of change may assist in improving the effectiveness of intervention when the proposed intervention is targeted and tailored to suit the current state of readiness rather than generic physical activity messaging and promotion [48]. Readiness to change physical activity may increase even in the absence of actual PA behavioural change as assessed objectively [21]. The Physical Activity Stages of Change questionnaire may also offer a measure on this theory.

Medical Outcomes Study Short Form 12 Health Survey (SF-12)

To measure quality of life the Medical Outcomes Study Short Form 12 Health Survey (SF-12) will be used [49]. The SF-12 was derived from twelve questions of the SF-36, which make up the MCS (Mental Component Summary) and PCS (Physical Component Summary). The survey can be administered in two to three minutes, which saves both time and resources in large-scale population surveys. The SF-36 has been validated in an Australian population 3. The two scores range between 0 and 100, with increasing values equating to better health.

Using the SF-12 also allows for conversion to utility scores which can also facilitate the undertaking of an economic analysis.

AUSDRISK tool

The AUSDRISK was developed from the national Australian diabetes obesity and lifestyle study (AusDiab) [50]. It represents the most up to date information on the risk factors for the development of diabetes [50].

Smoking status will be self-reported, as part of the AUSDRISK tool.

Waist circumference will be measured to the nearest 0.5 cm using a plastic measuring tape.

BMI will be measured by project team members; weight will be recorded to the nearest 0.01kg using a digital scale; height will be recorded to the nearest 0.1 cm using a stadiometer with the participant barefoot. The BMI will be subsequently calculated.

Table 1. Primary and secondary outcome measures

Primary and secondary outcome measures
Primary • Physical Activity – ActiGraph [43]
Secondary • Self-Efficacy- Modified physical activity self-efficacy survey [44] • Physical Activity Stages of Change [45] • Quality of Life: SF-12 Survey [49] • Diabetes risk: AUDSRISK tool [50] • Waist Circumference- within AUSDRISK tool [50] • Smoking- within AUSDRISK tool [50] • Nutrition- within AUSDRISK tool [50] • BMI

Sample Size and Statistical Analysis

Data analysis will focus on testing the differences between the two groups across the 6-month follow-up period. The primary outcome variable will be average weekly minutes of moderate-intensity or more vigorous physical activity (MVPA). Previous trials investigating between group changes in MVPA indicate that in order to detect between-group differences of 30 minutes, with a standard deviation of 50 minutes, the standardized mean difference, or the effect size required is 0.60 [51-2] To detect an effect size of 0.60 or greater, with the alpha set at .05, and the power set at .80, a sample size of 30 participants per arm will be required. Protecting against a drop-out rate of 20% over the 6-month period, 36 participants will be recruited and randomized into each arm. The total study sample will therefore be 72.

To compare differences in our primary end point, physical activity, independent t-tests will be carried out on the follow–up data. Other continuous variables such as waist circumference, BMI will also be assessed via t-tests. Smoking status may be tested via Pearson's chi-squared test for categorical variables. Analysis of variance tests (ANOVA, linear regression) may be conducted where required. Between the groups the mean level of each risk factor may be compared both at the beginning and the end: these values may be expressed in relative risks. Mann–Whitney U tests will be used where data are not normally distributed.

The effects of the interventions will be compared to the minimal intervention group to give an estimation of the effect size associated with the interventions.

Statistical analysis will be carried by project team members, and facilitated through expert staff at La Trobe University.

Dissemination of results

Following the statistical analysis reports will be produced and disseminated to management of 'Healthy Communities and Continuing Care' in Bendigo Health.

Results and findings may be presented at external conferences.

Results and findings may be detailed and submitted for publication in peer-reviewed journals.

Procedure measures

The project team will log the number of individual contacts made in the BH SOPC initiated by interested participants. The project team will record patient feedback regarding interest and opinions on the project, which is hoped may give insight into future program development strategies.

A log will be maintained of how many project participants contact the project team during the intervention phase, the reason for contact, the method of contact and the outcome. During any non-structured contact no intervention is to be delivered at that time.

To examine the acceptability of the H4U study, participants allocated to the intervention group will also be administered an additional questionnaire, after the 6 months follow up. This questionnaire will include items addressing satisfaction with the components of the project, their perceived utility of the intervention. The questionnaire will also address whether participants attended a community health program, and the frequency of visits (appendix 5).

Economic analysis

Changes to both health outcomes and to economic costs from a larger adoption of the supporting self-management project may be estimated with cost-effectiveness analysis. Values will be collected for variables that describe the participant's use of the hospital services directly associated with this study. The cost of delivering the H4U service will be assessed by measuring and valuing the resources used [53].The intervention costs will be calculated, factoring in staff time involved in being trained, and in delivering the interventions. Also included will be any overhead costs and costs of sessions provided. For the group intervention the costs will be divided over the attendees.

Changes to health benefits will be assessed through the use of quality-adjusted life-years. The SF-12 Health Survey can be converted to short form 6-dimension (SF-6D) which allow for utility values to be calculated [49]. To calculate the quality-adjusted life years (QALY) gain over the entire follow-up period an ‘area under the curve’ methodology will be used [53]. As costs are

likely to be higher for one group compared to the other, and QALY gains may differ, an incremental cost-effectiveness ratio can be constructed to show the cost per extra QALY gained [53]. There will be uncertainty around cost and QALY estimates and this will be explored using cost-effectiveness planes generated from 1,000 bootstrapped resamples of the data for each of the three comparisons. Finally, we will generate cost-effectiveness acceptability curves, using the net-benefit approach and bootstrapping, to indicate the probability that any of the three approaches is the most cost-effective for different values placed on a QALY gain.

Within a project of this size significant differences in quality of life between the groups may not be seen, however, collecting data will provide an estimation of the baseline quality of life in this patient population.

Cost-effectiveness acceptability curves can be plotted and used to inform decisions around widespread adoption of this method.

CONCLUSION

The H4U study will evaluate an innovative means of increasing physical activity in patients attending a non-admitted elective clinic in a public hospital who are deemed insufficiently physically active. Only a small number of studies have tested the use of a blend of MI/CBT for behaviour change, with the evidence showing effectiveness of the blend over a single input [16, 22, 24-5]. None of these studies however have looked at a change in physical activity as a primary endpoint.

The long term follow-up of this study allows for the evaluation of the effectiveness of the intervention on both physical activity uptake and maintenance. Only a few studies exist testing behavioural interventions on physical activity uptake and long term maintenance [12,37]. These studies have tended to use self-reported methods for physical activity measurement- this study would be innovative in its use of accelerometers for objective measurement of physical activity.

A number of questions remain about the feasibility and effectiveness of a blend of MI/CBT, therefore a rigorously designed and carried out study is needed to evaluate both the effectiveness of the intervention, and the cost effectiveness of the intervention.

This project is targeting a group of patients, in a space where preventative health programs are not normally offered. This project would be innovative as its potentially sits on its own, in a quasi-primary care space, drawing parallels between both primary and secondary prevention, as well as some prehabilitation methodology.

In conclusion, H4U will test the effectiveness of a blend of MI/CBT for increasing physical activity in patients in a non-admitted hospital clinic who are insufficiently physically active. This project has potential as a cost-effective home office based intervention for physical activity uptake. The effectiveness of this must be shown in a rigorously conducted clinical trial.

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Cost-effectiveness of telephone coaching for physically inactive ambulatory care hospital patients: economic evaluation alongside the Healthy 4U randomised controlled trial

Stephen Barrett [1]

Stephen Begg [2]

Paul O'Halloran [3]

Michael Kingsley [4*]

[1] Bendigo Health, Bendigo, Victoria, Australia, 3552. Email: sbarrett@bendigohealth.org.au

[2] La Trobe University, La Trobe Rural Health School, PO Box 199, Bendigo, Victoria, Australia, 3552. Email: s.begg@latrobe.edu.au

[3] La Trobe University, School of Psychology and Public Health. Bundoora, Victoria, Australia, 3068. Email: p.ohalloran@latrobe.edu.au

[4] La Trobe University, La Trobe Rural Health School, PO Box 199, Bendigo, Victoria, Australia, 3552. Email: M.Kingsley@latrobe.edu.au

*Corresponding Author:

Professor Michael Kingsley

Discipline of Exercise Physiology,

La Trobe Rural Health School,

La Trobe University,

Victoria,

AUSTRALIA

Phone: +61 3 5444 7589

Email: M.Kingsley@latrobe.edu.au

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Abstract

Objective: To assess whether telephone coaching is a cost-effective method for increasing physical activity and health-related quality of life for insufficiently active adults presenting to an ambulatory care clinic in a public hospital.

Design: An economic evaluation was performed alongside a randomized controlled trial.

Setting: Participants were recruited from an ambulatory care clinic in a public hospital in regional Australia.

Participants: Seventy-two adults (aged 18-69) deemed insufficiently physically active via self-report.

Interventions: Participants were randomised to either an intervention group that received an education session and eight sessions of telephone coaching over a 12- week period, or to a control group that received the education session only. The intervention used in the telephone coaching intervention was integrated motivational interviewing and cognitive behaviour therapy (MI-CBT).

Outcome measures: The primary health outcome was change in moderate-to-vigorous physical activity (MVPA), objectively measured via accelerometry. The secondary outcome was the quality-adjusted life-year (QALY) determined by the SF-12 Questionnaire. Outcome data was measured at baseline, post-intervention (3-months) and follow-up (6-months). Incremental cost-effectiveness ratios (ICERs) were calculated for each outcome. Non-parametric bootstrapping techniques and sensitivity analyses were performed to account for uncertainty.

Results: The mean intervention cost was $279 ± $13 per person. At six-months follow-up, relative to control, the intervention group undertook 18 more minutes of daily MVPA at an ICER of $15/minute for each additional minute of MVPA. With regard to QALYs, the intervention

yielded an ICER of $36,857 per QALY gained. Sensitivity analyses indicated that results were robust to varied assumptions.

Conclusion: Telephone coaching was a low-cost strategy for increasing MVPA and QALYs in insufficiently physically active ambulatory care hospital patients. Additional research could explore the potential economic impact of the intervention from a broader healthcare perspective.

Trial Registration

ANZCTR: ACTRN12616001331426. Registered 23 September 2016

Keywords

Health promotion; Hospital; Secondary Care; Physical activity; Cost-benefit analysis

Article Summary

Strengths and limitations of this study

- This study is the first to investigate the cost-effectiveness of telephone delivered MI-CBT for insufficiently physically active secondary care hospital patients.
- Economic evaluations enable hospitals to estimate the costs of delivering preventive health interventions, which are important for addressing the burden of chronic disease.
- Changes in physical activity were measured using accelerometers, strengthening the confidence in the findings.
- Results are limited by a short time horizon and a narrow costing perspective.
- Further research is needed to explore the potential long-term economic impact of the intervention from a broader healthcare perspective.

INTRODUCTION

Insufficient physical activity (PA) is an established risk factor for the development of a number of chronic diseases, including cardiovascular disease, type 2 diabetes and obesity[1]. Despite the well-established benefits of PA[2], more than half of the population does not attain sufficient levels of PA to derive such benefits[3]. The estimated cost of insufficient PA in Australia is AU$805 million per annum[4]. Addressing the prevelance of insufficient physical activity is a major public health priority, and necessitates that multiple sectors of the healthcare industry are actively engaged in physical activity promotion[5].

Hospitals are important settings in which to offer health promotion interventions, for both admitted and ambulatory care. In the hospital setting, ambulatory care refers to non-admitted clinics that patients attend for specialist medical care. Patients attending ambulatory care hospital clinics are more likely than the general population to have one or more chronic disease[6, 7]. Hospital patients can be motivated to engage with lifestyle behaviour change as their health is already compromised[8, 9]. Attending a hospital has been identified as a major life event,[10] and a hospital visit has the potential to initiate health behaviour change[8]. Ambulatory care settings provide an ideal opportunity for behaviour change interventions[8, 10]. Substantial efforts have been made to promote increased engagement in PA using individual and population-based approaches[11]. This has resulted in an increased use of behaviour change interventions to influence participation in PA[12].

A number of studies suggest that telephone coaching results in improved clinical outcomes, self-efficacy and health status,[13, 14] as well as increases in physical activity[15, 16]. Additional work is required to embed telephone coaching within existing health services[13, 15].

To make the benefits of telephone coaching more broadly available for hospital outpatients, telephone coaching has been delivered in addition to standard ambulatory care[17]. The addition of telephone coaching to standard care resulted in significant improvements in objectively measured physical activity and health related outcomes,[17] however, the cost to improve these outcomes has not been reported.

Few studies have employed any form of economic analyses on telephone coaching, and little is known about the relative cost-effectiveness of adding telephone coaching to routine care in ambulatory care hospital settings. The purpose of this study was to evaluate the cost-effectiveness of the Healthy4U program for increasing measured PA and the number of quality adjusted life years (QALYs) experienced over a 6-month period from a hospital perspective.

METHODS

Study design

The Healthy4U study was a single-blind randomised controlled trial reported in line with the CHEERS reporting guidelines[18] (Online supplementary file 1). The trial design, participants, sample size, intervention, outcomes and ethics approvals have been described in detail elsewhere[17]. Briefly, between October 2016 and December 2017, seventy-two insufficiently physically active adults, aged 18-69 years, were recruited from ambulatory care clinics at a major hospital in a regional town in Victoria, Australia. The primary aim was to promote change in objectively measured physical activity during the trial.

Intervention

All enrolled participants attended a 30-minute group education session. The education session was a facilitated learning session focused on self-management and lifestyle modification, and was carried out using a self-determination theory framework[19].

The intervention group completed a telephone-based, integrated motivational interviewing and cognitive behaviour therapy (MI-CBT) intervention, delivered in eight 30-minute sessions over 12 weeks. The intervention was delivered by an experienced allied health clinician trained in MI-CBT. All participants enrolled into the control arm attended the education session. Apart from contact regarding follow-up outcome measures, participants in the control group received no further contact initiated by the research team.

Measurement of effects

Outcome measures were recorded at baseline, after 3 months of intervention (post-intervention) and at 6 months (follow-up) by assessors blinded to the study group assignment. The primary outcome measure was change in moderate-to-vigorous physical activity (MVPA), objectively measured by accelerometry (wGT3X-BT; Actigraph, USA). Daily MVPA was determined using the manufacturers software (Actilife; Actigraph, USA) and the Freedson Adult (1998) cut point (vector magnitude > 1961 cpm)[20]. To be included in the analysis, a minimum wear time of ≥10 h/day for 5 of the 7-day period was required, including at least 1 weekend day[21]. Weekly PA totals were summed from the daily totals for persons with 7 valid days of monitoring, or estimated as 7 times the average daily total for persons with 5 to 6 valid days of monitoring. Using the summed weekly totals, participants were classified as either meeting or not meeting the recommended PA guidelines[22].

A secondary outcome was a change in health-related quality of life (HrQoL) and QALYs, which was derived from the Medical Outcomes Study Short Form 12 Health Survey (SF-12) and the standard Brazier algorithm[23, 24]. The SF-12 scores were converted to utility scores on a scale of 0 to 1, with a higher score indicating a more favourable health state[24]. These utility estimates were converted to QALYs by calculating the 'area under the curve' utility estimates for the different follow-up time intervals for each participant, weighted by the length of follow-up at that time interval.

Measurement of costs

The cost analysis was designed and conducted from a hospital perspective, which allows health care organizations to gauge the approximate cost of offering this program[25]. A bottom-up micro-costing approach was used to calculate the intervention costs[26]. This approach involves the detailed collection of information regarding the quantities of resources consumed while implementing and executing the interventions, as well as their respective unit prices[26]. Only those costs involved in implementing the intervention (e.g., training of individuals carrying out and undertaking the intervention) were included. Protocol-driven costs, namely the costs of gathering data as part of the clinical trial were considered to be sunk costs and were therefore excluded from the cost-effectiveness analysis[25].

The program costs included group facilitator time, intervention time, and supplies. The group facilitator's time that was spent preparing for and facilitating group meetings. The intervention assistant's time was calculated as the time spent undertaking reminder phone calls to participants. The intervention costs were calculated as the time spent in one to one consultation with the participants. Both group facilitation and intervention costs were calculated using the

annual salary of an experienced allied health clinician as they would most likely to be used in delivering MI-CBT were the intervention to be implemented on a large scale (AU$82,924). Intervention assistant costs were based upon the annual salary of an Allied Health Assistant (AU$45,338). Finally, the costs of supplies, including the program manuals were included in the program cost.

The group facilitator's time per group meeting was estimated at 2.5 hours, which included 0.5 hours for the group meeting itself, 1.0 hour to set up before and clean up after the group meeting, and 1.0 hour to prepare for the group meeting (i.e., reviewing meeting notes and presentation material). The group facilitator's cost per meeting per participant was calculated by dividing the facilitator's cost per meeting by the number of participants that attended each meeting. Due to the short time frame in which costs and effects occurred discounting was not necessary[27]. All program costs were calculated in 2017 Australian dollars (AU$).

Statistical analysis

Analyses of trial data have been reported elsewhere[17]. In brief, mixed-model ANOVAs were used to assess the effects of the intervention on each of the outcome variables. The mean ± SD for the overall cost and for the change in each outcome at 6-months was calculated. For each outcome, the incremental cost-effectiveness ratio (ICER) was calculated by dividing the difference in costs by the difference in effects between the intervention and control groups where the difference in effects between the two groups was calculated using a change from baseline approach to control for different baseline utilities. Uncertainty in the ICER estimates was accounted for by generating 1000 bootstrap replicates of the dataset, a widely used method in health economic evaluations. Probabilistic sensitivity analysis was completed by calculating

the cost-effectiveness acceptability curve (CEAC) derived from the bootstrap replicates. CEAC indicates the probability that the intervention was cost effective at different values of willingness to pay for the additional improvement in the outcome[28].

An additional 4 sensitivity analyses were used to examine how the results changed under different input assumptions. In the first 2 analyses, personnel wages and training costs were varied by 20% in either direction before recalculating the ICERs. The third sensitivity analysis using the summed weekly MVPA totals to estimate the ICER for each additional minute of MVPA per week. The fourth sensitivity analysis considered a different outcome measure for PA, using the summed weekly MVPA totals to estimate the ICER for changing one individual from insufficiently physically active to sufficiently physical activity (≥ 150 minutes MVPA per week)[22].

Patient and public involvement

Patients were not involved in the research question, study design, or the conduction of the study.

RESULTS

Resource use and costs

Seventy two participants were randomised; the group consisting of 54 females and 18 males, with an average age of 53 ± 8 (Online supplementary file 2). A total of 72 participants completed their baseline and 3-month assessment, and 68 participants completed the 6-month

assessment. For participants with missing data at 6-month follow-up (n = 2 in both groups), the last-observation-carried forward approach was adopted. The program resources and cost per participant are described in Table 1. Attendance at the education session was mandatory, with full attendance recorded for both groups. The mean group program time was 34 ± 6 minutes, and the mean total participant time spent in the intervention was 242 ± 14 minutes. The mean cost per participant was $279 ± $10 for intervention versus $21 ± $3 for control. The main component costs of MI-CBT were intervention delivery and training.

Table 1. Utilisation and cost of program delivery for intervention and control groups

Item	Provider	Units	Time (h)	Cost/h AU$	Total AU$ cost per participant
Intervention group					
Group Sessions	Allied Health professional	1	2.5	41.90	17.45
Phone call reminders	Intervention assistant	8	0.25	22.80	45.6
Intervention sessions	Allied Health professional	8	0.5	41.90	167.6
Program manual					3.5
Staff training					44.6
Total cost/participant					**279**
Control group					
Group Sessions	Allied Health professional	1	2.5	41.90	17.45
Program manual					3.5
Total cost/participant					**21**

Health outcomes

Table 2 presents the mean costs and the mean change in each outcome at follow-up for each group, and the corresponding ICERs. The ICER for MVPA was $15 per each additional minute of MVPA per day. The difference in QALYs between intervention and control groups was 0.007 QALYs over the course of the follow-up period. The ICER for the intervention group in comparison with the control group was $36,857 per QALY gained. Figures 1 and 2 illustrate the cost-effectiveness acceptability curves (CEAC) for each outcome derived from non-parametric bootstrapping replicates. For physical activity, given a willingness to pay of $15 per additional minute of MVPA, the probability that the intervention was cost effective was 67% (Figure 1). At a willingness to pay of $37,000 per QALY gained, the probability that the intervention is cost effective was 52% (Figure 2). If the decision maker was willing to pay $40,000 per QALY, the probability of cost-effectiveness for the intervention was 70% (Figure 2).

Table 2. Costs, changes in outcomes and incremental cost-effectiveness ratios at follow-up.

Outcome	Cost AU$/ Participant	Outcome	Incremental cost AU$	Incremental outcome	ICER
MVPA					
Control	21	23			
Intervention	279	41	258	18	AU$15/min MVPA per day
QALYs					
Control	21	-0.005			
Intervention	279	0.002	258	0.007	AU$36, 857/QALY

ICER, Incremental cost-effectiveness ratio; MVPA, moderate to vigorous physical activity; QALYs: quality adjusted life years.

Figure 1 and 2 near here

In the sensitivity analyses, training and implementation costs were varied 20% in each direction, and the corresponding ICERs were recalculated (Table 3). The varied ICERs for MVPA was found to range from $11 to $17 per each additional minute of MVPA per day, while the ICER for QALYs ranged from $29,428 to AU$44,285 per QALY gained. The third sensitivity analysis demonstrated an ICER of $2.86 per additional minute of MVPA per week. The final sensitivity analysis found that the intervention group was 33% more likely than control to meet recommended PA guidelines at follow-up, with an ICER of $781 per PA guideline attained.

Table 3. Sensitivity analyses for costs, changes in outcomes and incremental cost-effectiveness ratios at follow-up.

Outcome	Cost AU$/ Participant	Outcome	Incremental cost AU$	Incremental outcome	ICER
MVPA + 20% variation in cost					
Control	25	23			
Intervention	335	41	310	18	AU$17/min MVPA per day
QALY + 20% variation in cost					
Control	25	-0.005			
Intervention	335	0.002	310	0.007	AU$44,285 QALY
MVPA - 20% variation in cost					
Control	17	23			
Intervention	223	41	206	18	AU$11/min MVPA per day
QALY - 20% variation in cost					
Control	17	-0.005			
Intervention	223	0.002	206	0.007	AU$29,428 QALY
MVPA min per week					
Control	21	170			
Intervention	279	260	258	90	AU$2.86/min MVPA per week
PA guidelines attained					
Control	21	20/36 (55%)			
Intervention	279	31/36 (86%)	258	33%	AU$781/ PA guideline achieved

ICER, Incremental cost-effectiveness ratio; MVPA, moderate to vigorous physical activity; PA, Physical activity; QALYs: quality adjusted life years

DISCUSSION

This study examined the clinical and economic implications of a behaviour change intervention for changes in PA and QALYs for insufficiently physically active adults presenting to an ambulatory care clinic in a regional public hospital setting. Over the follow-up period the MI-CBT intervention was significantly more effective than control in increasing PA and HrQoL. To the best of our knowledge, this is the first study to evaluate the cost-effectiveness and cost-utility of an integrated MI-CBT intervention for health-related behaviour change.

Telephone coaching can be cost effective for increasing physical activity with patients with or at risk of chronic disease[29, 30]. However, little is known about the cost-effectiveness of adding preventive interventions to routine hospital care, where implementing an intervention requires an upfront investment of money. The total estimated cost of delivering the MI-CBT intervention was $279 per person, resulting in the average attainment of 41 ± 12 minutes of MVPA per day at follow-up. The per person cost was similar to the $245 per person found in recent primary care intervention for PA change[31], while both are considerably lower than costs of $1,756/person[32] and $1,562/person[33] reported in other lifestyle interventions aiming at changes in PA.

The cost-effective analysis for measured MVPA indicated a cost of $15 per each additional minute of MVPA per day. Over the 6-month follow-up period this can be translated to a total cost of $9 per day, or $63 per week to increase MVPA by 150 minutes. Sensitivity analysis indicated a one-time cost of $2.86 per each additional minute of MVPA per week, or $8.25 per week to increase MVPA to 150 minutes a week over the 6-month follow up. The cost of $8.25 per week to increase MVPA to 150 minutes is comparable to the $4.99[34], $8.13[35] and $10.19[36] per

week found in other interventions aimed at increasing physical activity. Increases in PA result in decreased healthcare use, even in the short term, which result in net savings to society over time[37]. Determining the cost-effectiveness of integrating telephone coaching into routine care from a hospital perspective is dependent on the willingness-to-pay for each additional minute of MVPA. Interpreting the ICER of $15 per additional minute of MVPA found here is difficult as there is no standard value for how much policy-makers are willing to pay per additional minute of MVPA [34]. The CEAC indicated a probability of 67% that $15 per additional minute of MVPA was cost-effective (Figure 1).

The intervention group was 33% more likely than the control group to undertake sufficient PA at follow-up. Sensitivity analysis demonstrated an ICER of $781 for converting one insufficiently physically active adult to a sufficiently active state over the 6-month follow-up period. This value falls with the ranges of $175 to $1801,[38] and $521 to $5790[39] estimated in systematic reviews investigating the cost-effectiveness of physical activity interventions. Undertaking sufficient PA is strongly associated with decreased risk of chronic disease, morbidity and mortality,[1] as well as decreased healthcare expenditure over time[37].

In the cost-utility analysis an incremental change in QALYs of 0.007 was demonstrated between the intervention and control groups, resulting in an ICER of $36,857 per QALY gained. The ICER of $36,857 per QALY gained is considerably smaller than the $58,924 per QALY gained[32] and the $68,101 per QALY gained[33] found in similar intervention studies. Oskman et al. recently reported an ICER of $48,000 per QALY gained for a telephone-based health coaching intervention for chronic disease patients[40]. Direct comparison with the results from the aforementioned studies is challenging because different cost perspectives were considered

in these analyses. Nonetheless, the ICER of $36,857 per QALY falls under the commonly used threshold of $50,000 per QALY gained proposed for medical treatments and procedures[41]. Sensitivity analysis demonstrated that costs for the Healthy4U study are only mildly sensitive to typical variation in the cost input values. A variation in hourly wage costs had the largest impact on the ICERs, however, the ICERs remained well below the threshold of $50,000 per QALY gained at all imputed values. The CEAC provided a probability of 52% that the intervention was cost effective at a willingness to pay of $37,000 per QALY gained (Figure 2).

Behaviour change interventions are typically used to modify specific lifestyle factors known to predispose individuals to increased risk of chronic disease over the longer term[42]. The long-term impact of such interventions on overall quality of life is less established. While the follow-up period in this study was too short for the mediating effect of physical activity on broader health outcomes to become fully apparent,[42] the relatively small observed change in QALYs over 6 months was a combination of the -0.005 fall in the control group and the 0.002 increase in the intervention group. This finding supports the suggestion that an important impact of behavioural interventions on quality-of-life over the longer-term might be to attenuate expected declines in health related quality-of-life [43].

This study was unique in that we enrolled participants from an ambulatory care clinic in a public hospital, integrating preventative health into secondary care. It is important to note that this intervention was carried out in addition to standard care, not as a substitution, and as such an economic evaluation costed from a hospital perspective offers healthcare providers an estimate of the costs and effects of adding a preventative health intervention to clinical care. This study is one of the few economic evaluations of telephone coaching carried out in real-life settings using

an RCT design. The addition of preventive health measures is likely to cost hospitals more, however, these preventive measures might be worthwhile due to the substantial health benefits that they confer, relative to their cost[37]. Nevertheless, implementation remains a challenge for hospitals,[15] and it will be important to engage with key stakeholders, especially clinic leaders, to identify specific patients who can benefit from telephone coaching[44]. Health services with high implementation rates of telephone coaching have used multi-component strategies to engage staff, as they were the most important source of referrals[44]. Investigating hospital clinicians' practice and beliefs around preventive health can also facilitate the development of pathways to increase preventive health practice in the hospital setting[45].

The greatest cost of the intervention was in the delivery, due to the fact that it was delivered individually by trained personnel. These costs could be reduced by decreasing the number of intervention sessions, with a recent meta-analysis indicating that 5 sessions of MI-CBT is significantly effective for physical activity change[46]. Costs could potentially be reduced by incorporating digital technology into the intervention to decrease the time spent by trained professionals in 1:1 sessions. Innovations in digital technologies can assist individuals with health behaviour change,[47] which can potentially reduce health care expenditure[47, 48]. The long term cost-effectiveness of digital health technologies has not been established [47].

The use of objectively measured PA at all time points was a considerable strength of the study. Objective measures offer more precise estimates of activity intensity while removing many of the issues associated with participant recall and response bias[49]. Individuals have been demonstrated to overestimate their PA levels via self-report[38]. Overestimation of PA can result in inaccurate estimations of both effectiveness and the cost-effectiveness of interventions[50].

Using objectively measured changes in PA and the collection of full cost data for all participants strengthens our findings[49].

This study has a number of limitations. A noteworthy limitation of this study is the restricted perspective used for the economic evaluation. Using a single hospital perspective might have led to the exclusion of important costs and benefits from a societal perspective, including healthcare utilisation and changes in productivity[51]. Economic analyses from a societal perspective offer the most comprehensive evidence from which to base decisions[51]. However, due to the relatively short follow-up time of this study it was not feasible to undertake this method. Significant effects on overall healthcare utilisation or productivity loss were not expected over the timeframe of this study[52]. As the intervention was delivered using the telephone, the intervention required relatively small amounts of participant time. With this in mind, the participant opportunity costs were expected to be small and therefore not included in the analyses. Additionally, the study participants included 54 females and 18 males, which might limit the generalisability of the current findings to different populations.

To the best of our knowledge this is the first study comparing the cost-effectiveness and cost-utility of an integrated MI-CBT intervention for health behaviour change amongst community-dwelling adults presenting to a secondary care clinic in a regional public hospital setting. Considering the large group of people who might benefit from such an intervention (i.e., approximately 50% of adults aged 18-69 years in Australia who are currently insufficiently physically active), the widespread adoption and implementation of MI-CBT to increase PA could have important economic implications. However, further research with a more comprehensive economic analysis is needed to investigate whether the long-term benefits of MI-CBT might justify this type of investment.

Conclusion

The Healthy4U program is a relatively low-cost strategy for increasing physical activity among insufficiently physically active adults presenting to an ambulatory care hospital clinic. The intervention increased measured PA and quality of life at low costs, with positive effects maintained out to 6-months. By increasing physical activity and quality of life at low costs, integrating telephone coaching programs into secondary hospital care offers a potentially cost-effective investment to produce better public health outcomes. The results are however grounded on a short-term follow-up and a restricted economic perspective, and more evidence is needed to explore the potential long-term economic impact of the intervention from a broader healthcare perspective.

Footnotes

Author Contributions: SB[1], MK, SB[2] and PO'H conceived the project and assisted with the protocol design. SB[1] managed the trial including recruitment and data collection, coordinated the intervention program, performed statistical analysis, and drafted the manuscript. SB[1] and SB[2] interpreted the data and drafted the manuscript. All authors read, edited and approved the final manuscript as submitted.

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Competing interests: None declared.

Ethics approval: The study was approved by the Research Ethics Committees of Bendigo Health Care group (approved September 16, 2016; reference number LNR/16/BHCG/42) and La Trobe University College of Science Health and Engineering Human Ethics Sub-Committee (approved October 3, 2016). Written informed consent was obtained from all participants before they join the study.

Data sharing statement: Data are available upon reasonable request.

Patient consent for publication: Not required.

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Table Title

Table 1. Utilisation and cost of program delivery for intervention and control groups.

Table 2. Costs, changes in outcomes and incremental cost-effectiveness ratios at follow-up.

Table 3. Sensitivity analyses for costs, changes in outcomes and incremental cost-effectiveness ratios at follow-up.

Figure Title

Figure 1. Cost-effectiveness acceptability curve showing the probability of the interventions being cost-effective in comparison to control for moderate to vigorous physical activity (MVPA)

Figure 2. Cost-effectiveness acceptability curve showing the probability of the interventions being cost-effective in comparison to control for quality adjusted life years (QALYs)

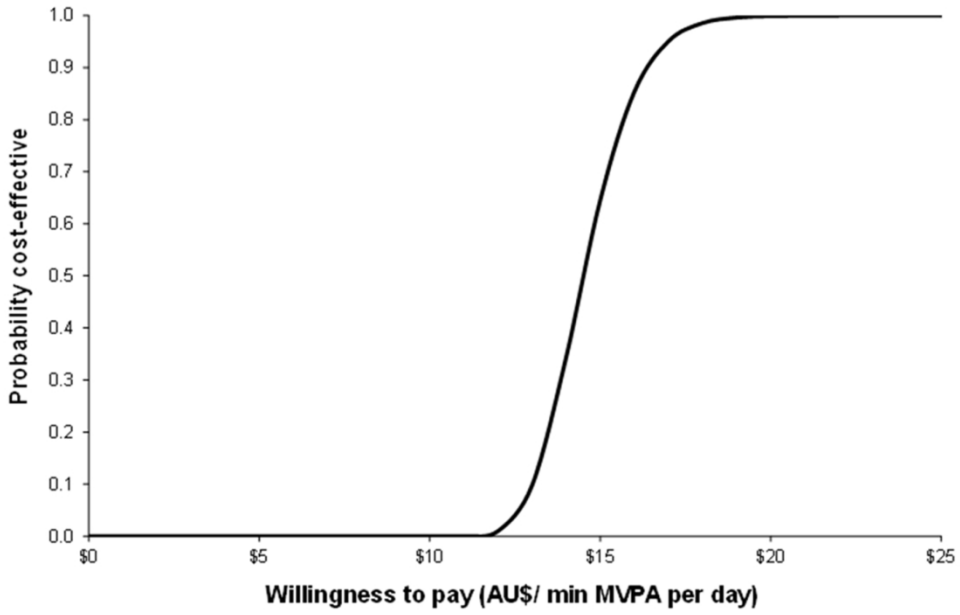

Figure 1 Cost-effectiveness acceptability curve showing the probability of the interventions being cost-effective in comparison to control for moderate to vigorous physical activity (MVPA)

162x105mm (300 x 300 DPI)

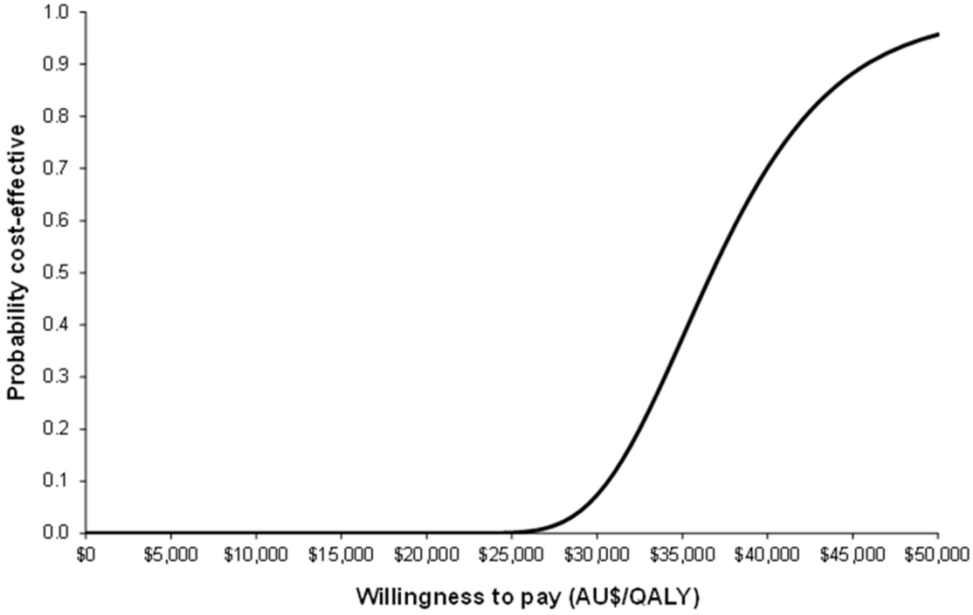

Figure 2 Cost-effectiveness acceptability curve showing the probability of the interventions being cost-effective in comparison to control for quality adjusted life years (QALYs)

157x103mm (300 x 300 DPI)

Table S1. Reporting checklist for economic evaluation of health interventions.

		Reporting Item	Page Number
Title			
	#1	Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis”, and describe the interventions compared.	1
Abstract			
	#2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions	2-3
Introduction			
Background and objectives	#3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions	4-5
Methods			
Target population and subgroups	#4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	5
Setting and location	#5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	5
Study perspective	#6	Describe the perspective of the study and relate this to the costs being evaluated.	7
Comparators	#7	Describe the interventions or strategies being compared and state why they were chosen.	5-6

Time horizon	#8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	5
Discount rate	#9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate	8
Choice of health outcomes	#10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed	6-7
Measurement of effectiveness	#11a	Single study-based estimates: Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data	n/a
Measurement of effectiveness	#11b	Synthesis-based estimates: Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data	n/a
Measurement and valuation of preference based outcomes	#12	If applicable, describe the population and methods used to elicit preferences for outcomes.	n/a
**Estimating resources and costs **	#13a	Single study-based economic evaluation: Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs	n/a
Methods			
Estimating resources and costs	#13b	Model-based economic evaluation: Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or	n/a

		secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	
Currency, price date, and conversion	#14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	7-8
Choice of model	#15	Describe and give reasons for the specific type of decision analytical model used. Providing a figure to show model structure is strongly recommended.	n/a
Assumptions	#16	Describe all structural or other assumptions underpinning the decision-analytical model.	n/a
Analytical methods	#17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	n/a
Results			
Study parameters	#18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	9-13
Incremental costs and outcomes	#19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	9-13
Characterising uncertainty	#20a	Single study-based economic evaluation: Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness	11-13

		parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).	
Characterising uncertainty	#20b	Model-based economic evaluation: Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	n/a
Characterising heterogeneity	#21	If applicable, report differences in costs, outcomes, or cost effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	n/a
Discussion			
Study findings, limitations, generalisability, and current knowledge	#22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	14-17
Other			
Source of funding	#23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support	20
Conflict of interest	#24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations	20

Table S2. Characteristics of participants at baseline.

Variable	Total	Intervention	Control	p-value
	72	36	36	
Age (years)	53 ± 8	53 ± 8	54 ± 7	0.70 [a]
Sex: female, n (%)	54 (75%)	28 (78%)	26 (72%)	0.58 [a]
Stature (cm)	166 ± 8	165 ± 9	168 ± 7	0.20 [a]
Weight (kg)	84.9 ± 9.4	84.5 ± 9.9	85.3 ± 8.9	0.72 [a]
BMI (kg/m^2)	30.8 ± 4.1	31.1 ± 4.0	30.5 ± 4.2	0.51 [a]
MVPA (min/day)	31.2 ± 10.1	28.9 ± 9.9	33.3 ± 10.3	0.03 [a]
PA Self-efficacy	31 ± 10	28 ± 8	33 ± 10	0.05 [a]
Smoker, n (%)	23 (32%)	12 (33%)	11 (31%)	0.80 [b]
Obesity, n (%)	38 (53%)	22 (61%)	16 (44%)	0.16 [b]
Hypertension, n (%)	14 (20%)	9 (25%)	5 (14%)	0.23 [b]
OA/RA, n (%)	27 (38%)	16 (44%)	11 (31%)	0.22 [b]
Depression/anxiety, n (%)	30 (42%)	16 (44%)	14 (40%)	0.63 [b]
Employment status, n (%)				0.43 [b]
Full time	22 (31%)	10 (28%)	12 (33%)	
Part time	30 (42%)	18 (50%)	12 (33%)	
Unemployed	7 (10%)	4 (11%)	3 (8%)	
Retired	12 (16%)	4 (11%)	8 (22%)	
Other	1 (1%)	0	1 (4%)	
Education, n (%)				0.47 [b]
Year 10/11	10 (14%)	4 (11%)	6 (17%)	
Year 12	22 (31%)	12 (33%)	10 (28%)	
Cert I-IV	18 (25%)	7 (20%)	11 (30%)	
Diploma	13 (18%)	9 (25%)	4 (11%)	
Bachelor or higher	9 (12%)	4 (11%)	5 (14%)	

Group data expressed as means ± standard deviations. Figures in parentheses are proportions. BMI: Body mass index; MVPA: Moderate-to-vigorous physical activity; OA: Osteoarthritis; RA: Rheumatoid arthritis. [a] t-test between intervention and control groups. [b] chi square test between intervention and control groups.