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Preventing chronic disease in patients with low health literacy using eHealth and teamwork in primary health care (HeLP-GP): A cluster randomised controlled trial.

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ABSTRACT

Objectives

To evaluate a multifaceted intervention on diet, physical activity and health literacy of overweight and obese patients attending primary care.

Design

A pragmatic two arm cluster randomised controlled trial.

Setting

Urban general practices in lower socio-economic areas in Sydney and Adelaide.

Participants

We aimed to recruit 800 patients in each arm. Baseline assessment was completed by 215 patients (120 intervention and 95 control).

Intervention

A practice nurse led preventive health check, a mobile application and telephone coaching.

Primary and secondary outcome measures

Primary outcomes were measured at baseline, 6 and 12 months and included changes in diet, physical activity, patient health and eHealth literacy, weight, and blood pressure. Secondary outcomes included preventive advice and referral, blood lipids, quality of life and costs. Univariate and multivariate analysis of difference-in-difference estimates for each outcome were conducted.

Results

At 6 months, the intervention group, compared with the control group, demonstrated a greater increase in HLQ domain 8 score (Ability to find good health information; mean DiD 0.22; 95% CI 0.01-0.44). There were similar differences for domain 9 score (Understanding health information well enough to know what to do) among patients below the median at baseline. There were no differences at 12 months. There was a small improvement in diet scores at 6 months (DiD 0.78 (0.10-1.47; p=0.026) but not at 12 months. There were no differences in e-health literacy, physical activity scores, BMI, weight, waist circumference or blood pressure.

Conclusions

Recruitment and engagement were challenging in this population. While the intervention was associated with some improvements in health literacy and diet, substantial differences in other intended outcomes were not observed. More intensive interventions in the complex environment of general practice may produce a different result.

Trial Registration

This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12617001508369). http://www.ANZCTR.org.au/ACTRN12617001508369.aspx. Date registered 30 October 2017.

Trial Protocol

The protocol for this trial has been published (open access) https://bmjopen.bmj.com/content/8/6/e023239

Key words: Primary Care, Preventive Medicine, Health Services Administration and Management.

Article Summary

Strengths and limitations of this study

- The cluster randomised design allowed testing of the nurse led intervention among patients without contamination.
- Recruitment of practices and patients did not meet our planned sample size.
- We noted variable uptake of the intervention components among patients reflecting real world general practice
- The measures used to assess health literacy, diet and physical activity had some limitations.
- The study was conducted in only two urban areas of Australia and the findings should therefore not be generalised to other communities, especially rural areas.

INTRODUCTION

Obesity is a complex health issue and is influenced by biological, environmental, social, and psychological factors.[1] Overweight and obesity account for 8.4% of the burden of disease being a risk factor for 11 types of cancer, three cardiovascular conditions, chronic kidney disease, diabetes, dementia, gallbladder disease, fatty liver, gout, back pain and osteoarthritis.[2] In 2017/18, 67% of the Australian population were overweight (BMI 25-29 kg/m^2; 35.6%) or obese (BMI 30+ kg/m^2; 31.3%) with those who were more socially disadvantaged being more likely to be overweight or obese.[3] Within Australia, rates of overweight and obesity peak for men at age 55 to 64 years (83.6%) and for women at 65 to 74 years (73.3%).[4]

Current Australian guidelines recommend that people who are overweight and obese attending general practice undergo routine measurements (BMI and waist circumference) and are engaged in discussions about lifestyle risk factors and positive messaging to improve health and wellbeing.[5] Behavioural interventions in primary care have been demonstrated to achieve a 5-7% improvement in weight, blood pressure (BP) or lipids for patients, potentially preventing or delaying the onset of Type 2 diabetes and cardiovascular disease.[6] Patients generally accept their GPs' role in management of overweight and obesity[7], however lower socioeconomic groups tend to be less likely to take up weight management programs.[8 9]

Low functional health literacy (i.e., health-related reading and numeracy) is more common in socioeconomically disadvantaged populations and is associated with an increased likelihood of overweight and obesity.[10 11] It is also a potential barrier to the uptake and effectiveness of a range of preventive interventions that mediate change in lifestyle behaviours.[12 13] Patients with low health literacy are less likely to engage in health promoting behaviours[14-16] and attend or complete programs to which they have been referred.[17 18] Interventions with multiple components to improve health literacy for behavioural risk factors have been shown to be more effective at improving

nutritional health literacy in primary care than those with single components.[6] Other barriers to delivering weight loss management have also been identified, including low confidence levels of clinicians in obesity management [19], stigmatisation of patients[20] and lost opportunities by providers to initiate earlier, effective weight loss conversations.[21]

OBJECTIVES

The HeLP GP trial aimed to evaluate a multifaceted intervention provided to overweight and obese patients attending primary care. The primary hypothesis was that the intervention would lead to improved health literacy, eHealth literacy, physiological risk factors, lifestyle behaviours and quality of life.

METHODS

Trial Design

A pragmatic, two-arm, unblinded cluster randomised controlled trial. This design was chosen to provide protection against contamination within sites (general practices) as practice staff were providing the intervention. Primary and secondary outcomes were assessed at the patient level.

Participants and setting

The trial was conducted in general practices located in metropolitan and urban fringe areas of south-western and western Sydney in New South Wales and Adelaide in South Australia. Practice eligibility included:

- Geographical location in a Local Government Areas (LGAs) with a Socio-Economic Index for Area (SEIFA) Index of Relative Socio-economic Disadvantage (IRSD)[22] equal to or below the 8th decile.
- Using clinical software compatible with the trial data extraction and recruitment tool, *Doctors Control Panel* (DCP)[23], and an active internet connection.
- Participation by at least one practice nurse (PN) and one general practitioner (GP) from the practice.
- Participation of reception staff to distribute trial materials to eligible trial participants as they present for appointments.

Patient eligibility included:

- Aged 40-74 years.
- BMI≥28 recorded within the previous 12 months (The cut point for BMI was chosen to target people at higher risk and to capture people from Asian backgrounds who have a lower equivalent BMI).
- Blood pressure and total serum cholesterol recorded within the previous 12 months.
- Speaking English and/or Arabic, Vietnamese or Chinese (Languages representing common migrant groups in the catchment areas).
- Access to a smart phone or tablet device and internet connection.

Patients were excluded if they:

- Had a diagnosis of diabetes requiring insulin or a current prescription for insulin, a diagnosis of cardiovascular disease (angina, myocardial infarction, heart failure, heart valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident)
- Had experienced weight loss of >5% in the past 3 months, were taking medication for weight loss (orlistat or phentermine) or had undergone weight loss surgery.
- Had a diagnosis of serious mental illness (schizophrenia, psychosis, bipolar depression, and unipolar depression) or cognitive impairment.
- Had a physical impairment which would prohibit engaging in moderate level physical activity.

Practice Recruitment

Between March 2018 and October 2018, general practices within the specified geographical locations were approached by partner Primary Health Networks (PHNs), which are regional organisations providing quality improvement and education to general practices. Invitations to express interest were distributed through mail, email, newsletters, GP educational events, websites,

Facebook groups for health professionals, discussion groups and research networks. A face-to-face meeting was held between responding practices, a PHN representative and a member of the research team to discuss in detail and confirm eligibility.

Randomisation

Randomisation of practices was performed by an epidemiologist using the SAS[24] statistical package. Practices were characterised by size (fewer than 5 GPs, or 5 or more GPs) and by State into four strata, and intervention and control lists of random numbers (6-digit) were generated for each stratum. The resultant intervention and control strata lists were combined and sorted. Four batches were created. Allocation of intervention or control was then sequentially allocated from the lists based on the date of entry of the practice into the study by an independent researcher. Batching was undertaken to ensure similar numbers of control and intervention practices at any point in time. Practices were informed in writing as to what allocation they had received.

Recruitment of Patients

From October 2018 to September 2019, patients of participating practices were flagged at the point of presentation using DCP. The software was programmed with clinical inclusion/exclusion criteria to identify potential participants as they presented. Once flagged, patient information was automatically printed and attached to trial information and consent forms by the reception staff. It was not the responsibility of GPs to gain consent, but patients could discuss the trial with their GP or PN. As DCP was only able to determine eligibility based on the information within the practice's clinical software, eligibility was also checked by a member of the practice. Patients could return their consent forms by leaving them in a secure collection point at the practice or returning them in a reply-paid envelope to the study centre (UNSW Sydney).

The HeLP-GP Intervention

The intervention was a multi-component intervention which has been previously described and piloted [25 26]. It aimed to increase the knowledge of patients relating to diet and physical activity and their individual skills to address weight management behaviours. It comprised:

a) A PN-led health check designed to support Australian Guidelines for the management of overweight and obesity [5 27] and based on the 5A's (Assess, Advise, Agree, Assist and Arrange).[28 29] Review was conducted by the PN at 6 weeks and the GP at 12 weeks.

b) A lifestyle app (*mysnapp*) modified from *healthy.me,* a personally controlled health management platform designed to help patients and consumers to manage their health.[30] The components of *mysnapp* were informed by research into behaviour change through mobile and electronic platforms that suggest that goal setting and self-monitoring, and additional methods to interact with patients, particularly text messaging, can be more effective than advice alone.[31 32-34] *Mysnapp* allowed patients to set and revise physical activity and diet-based goals and to view graphs of their progress over the previous 6 weeks. A free text diary allowed patients to document individualised content. A range of video and written resources related to diet and physical activity, linked to the app, were available for the patient to view. Text messages reminded patients to attend the follow up with the PN and GP and once registered, each patient received one nutrition and one physical activity message each week for 6 weeks.[26]

c) Health coaching via the 'Get Healthy' Telephone coaching program (https://www.gethealthynsw.com.au/) provided free, confidential telephone-based health coaching to support patients to reach personalised lifestyle goals relating to healthy eating, increasing physical activity, alcohol reduction and achieving and maintaining a healthy weight. Coaching was available in multiple languages with the assistance of an interpreter service.

At the health check patients could choose to take up *mysnapp*, Get Healthy or both. Control practices provided 'usual care' (the clinical practice routinely offered to patients by the GP and PN of the practice).

Training and implementation of the intervention

Training was completed by all participating PNs. Training comprised three on-line modules covering physical assessment (weight, height, BP, waist circumference and BMI), delivery of relevant lifestyle advice and promotion of individual goal setting. The 'teach-back' method[35] (asking the patient to repeat in their own words what they have understood), was encouraged to ensure they had understood and were confident with the content of the health check. PNs assisted patients to download and set up *mysnapp* including setting goals during the health check and were encouraged to review the patient's use of the app and the progress of health coaching at the 6-week follow up. Written and video resources were developed for PNs and patients on the installation and use of the app. PNs referred patients to Get Healthy using a trial-specific online referral form.

Patients could claim Medicare benefits (usually without out-pocket payments) for GP visits as part of the intervention (Medicare is Australia's national universal health insurance scheme). Patients did not pay for the PN visits. The PN health checks were reimbursed directly to the practice by the study at a rate of AUD$40 per patient for the health check and AUD$20 per patient for follow-up.

Ethics and consent

This trial was approved by the University of New South Wales Human Research Ethics Committee (HC17474). The University of Adelaide Human Research Ethics committee ratified this approval.

Written consent was obtained from all participating practices to conduct the trial in the practice and access practice data; individual consent was obtained from all participating GPs and PNs. Patients

provided written consent to participate in the trial and additional written consent was obtained for the researchers to access individual health service usage data (Medicare Benefits Schedule (MBS)) and pharmaceutical use (Pharmaceutical Benefit Scheme (PBS)) according to protocols governing access to this data through Services Australia[36].

All practices received an AUD $1000 payment to cover the administrative costs of participation. To compensate them for their time, patients from both groups who completed the baseline and 6-month follow up received an AUD$30 shopping voucher and then an additional AUD$30 voucher if they completed the 12-month follow up.

Patient and Public involvement

Patients and members of the public were not involved in the design of this study. Consumer volunteers with the Adelaide Primary health Network did pilot the lifestyle app (mysnapp) and provide input to its final design.

Data collection and trial outcomes

Table 1 provides a summary of the data collected to assess trial outcomes, the collection method and the timepoints of collection. A proposed 18 month follow up of patients was abandoned due to the need to extend the period for patient recruitment and lower than expected numbers of patients being recruited to the trial. Surveys administered over the telephone were used to collect demographic and other patient data.

Primary outcomes

We used two domains of the Health Literacy Questionnaire (HLQ) (Domain 8: Ability to find good health information (5 items) and Domain 9: Understand health information well enough to know what to do (5 items)). [37] The individual domains of the HLQ were selected to identify specific health

literacy strengths and challenges or to test a hypothesis.[38 39] Domains 8 and 9 have a 5-point response option scale (cannot do or always difficult, usually difficult, sometimes difficult, usually easy, or always easy). The eHealth Literacy Scale (eHeals) was used to assess digital health literacy.[40]

Patient self-report was used to determine lifestyle behaviours including a diet score (portions of fruit plus portions of vegetables intake), the number of 30-minute sessions of physical activity (moderate/vigorous) per week and changes in diet and physical activity. Questions to assess these behaviours were adapted from previous research.[41 42]

DCP was used to extract patient data related to biomedical risk factors (BMI, systolic and diastolic blood pressure, and waist circumference) at two timepoints (coinciding with baseline and 12 month follow up interviews).

Secondary outcomes

Patient self-report was used to determine advice received and referral for diet, physical activity and weight loss. Patient questions also assessed quality of life (using the EQ-5D-5L standardised to UK reference population with no imputation of missing values).[43] Total cholesterol, low density lipoprotein (LDL), high density lipoprotein (HDL) and triglyceride (TG) values were extracted by the DCP at baseline and 12-month follow up.

Sample size calculation

The original sample size calculation of 800 in each arm was based on the primary hypothesis that the intervention would lead to improved health and eHealth literacy, diet, physical activity, weight, and blood pressure. This was based on assumption of hypothesised means and effect sizes is described in the trial protocol [26]. This was not reached despite an extended recruitment period. Post-hoc power calculations showed that with a sample of 100 in each arm we would be able to detect a mean

difference in diet score of 0.2 to 0.3 (serves per day) and a mean difference in the health literacy scale scores of 0.5 to 0.6. However, for all the other measures the differences that were able to be detected were larger than expected (mean PA score difference of 1.5, mean BMI difference of 5.5kg/m^2, mean BP change of 15mmHg, mean cholesterol difference of 0.8).

Table 1. Patient Level Outcomes

Outcome	Instrument/contributing data	Primary or secondary outcome	Data collection method	Timepoint for collection		
				BL	6 months	12 months
a) Literacy and e-health literacy						
Health literacy	HLQ (Domains 8 and 9)	Primary	Patient survey - Administered via Telephone interview	x	x	x
eHealth literacy	eHEALS	Primary	Patient survey - Administered via Telephone interview	x	x	x
b) Lifestyle risk factors (patient)						
Fruit and vegetable intake	Patient self-report – serves of fruit and vegetables per day	Primary	Patient survey - Administered via Telephone interview	x	x	x
Level of physical activity	Patient self-report (Moderate and vigorous physical activity per week)	Primary	Patient survey - Administered via Telephone interview	x	x	x
c) Biomedical risk factors (patient)						
Weight/height/waist circumference/BMI	Clinical record	Primary	DCP	x	-	x
Blood pressure	Clinical record	Primary	DCP	x	-	x
Lipids (total chol)	Clinical record	Secondary	DCP	x	-	x
Quality of life						
QOL	EQ-5D-5L	Secondary	Patient survey - Administered via Telephone interview	x	-	x
Advice and referral						
Recall of advice and goal setting for diet, physical activity, weight loss	Patient survey	Secondary	Patient survey - Administered via Telephone interview	x	x	-
Referral to behaviour change programs for diet, physical activity, or weight loss	Patient survey	Secondary	Patient survey - Administered via Telephone interview	x	x	-

Outcome	Instrument/contributing data	Primary or secondary outcome	Data collection method	Timepoint for collection		
				BL	6 months	12 months
Economic data						
Delivery cost of intervention	Study documentation/budget	Secondary	Study administrative records/Facilitator Diary	Calculated for trial costs (payments for health checks, practice staff education and practice facilitation; cost of the app and telephone coaching)		
Health service costs	Medicare Benefits Scheme data	Secondary	Output from Services Australia	Data collected 01/10/2017 to 30/06/2020		
Prescription medication	Pharmaceutical Benefits Schedule data	Secondary	Output from Services Australia	Data collected 01/10/2017 to 30/06/2020		

ANALYSIS

Statistical analyses were conducted on the intention to treat (ITT) population for both primary and secondary outcome analyses. The ITT population was defined as all those recruited at baseline regardless of what intervention they received and what follow-up data was available.

Summary participant baseline characteristics and primary outcomes at baseline were compared between control and intervention groups using either chi-squared test, t test or Mann-Whitney test. Means and standard deviations were reported for continuous outcomes and the number and percentage were reported for dichotomous outcomes at baseline, 6 month and 12-month follow up.

To measure the effect of the intervention on the outcomes of interest (primary or secondary), we used difference-in-differences (DID) estimate as some of the outcomes at baseline were significantly different [44]. We used generalised-estimating equation (GEE) with Gaussian family and identity link function to estimate DID accounting for the cluster (general practice) level correlation.[45] We put an interaction term for intervention group and a dummy variable for before/after the follow up measurement (6 month follow up or 12 month follow up) in the GEE model and the coefficient of the interaction term was considered as a DID estimate.[46] Separate models were used for estimating DID at 6 month follow up and 12 months follow up. The DID estimate were adjusted for the potential confounders which were substantially different between control and intervention groups at baseline. To adjust for possible ceiling effects, we did stratified analysis for the health literacy scores by above or below the median score at baseline. We set 5% as a level of statistical significance. We used the R4.0.3 programming language and environment for the statistical analysis.[47]

Economic evaluation

The extracted cost data informed a cost consequence analysis, undertaken from the Australian healthcare system perspective. We categorized costs as follows: 1) services provided or requested

by GPs (excluding consultations by specialists), 2) services provided or requested by GPs or specialists (excluding services related to surgical procedures), and 3) pharmaceutical costs. The number of times participants visited a GP was also analysed. Costs and number of GP visits were calculated for the 12 months preceding and the 12 months following the enrolment date for each participant, from which unadjusted difference-in-difference estimates were derived for each of the cost categories, as well as aggregate costs and GP visits. Bootstrapping (using 1000 resamples) was used to represent the uncertainty around the difference-in-difference estimates.

RESULTS

We used the Consort extension for cluster trials statement to guide reporting (Supplementary file 1) and summarise the flow of participants (Figure 1) through the HeLP-GP trial. [48]

1.Baseline

We recruited 215 participants to the study (120 to the intervention group and 95 to the control group) through 22 practices (clusters). Baseline characteristics of the intervention group were similar to the control group except that the proportion of males was higher (66.3% vs 50.0%). Participants in both groups were predominantly aged between 46-65 years, with over a third having been born overseas but only one in 6 spoke a language other than English. The median BMI was 33.3kgm^2. The intervention outcome measures at baseline were all similar to the control group except for health literacy which was lower (mean 4.0 vs 4.3 for domain 8, and 4.1 vs 4.3 for domain 9) (Table 2).

2. Intervention uptake

There was variable uptake of the intervention components by the 120 participants in the intervention group. Eighty-five attended the nurse health check and 73 also received either *mysnapp,* Get Healthy or both. Thirty-eight took up both *mysnapp* and Get-Healthy coaching. Of the 62 who adopted *mysnapp,* 60 participants set goals on 132 occasions to increase vegetables, 131 to increase fruit, 97 less take-away, 117 smaller portions, 73 less soft-drink, 129 to increase physical activity time. Of the 49 who adopted Get-Healthy telephone coaching, 31 set weight related goals.

Table 2: Baseline characteristics and outcomes by intervention and control

Variables	Responses	Control	Intervention	p-value	ICC[2]
n	215	95	120		
Age, mean (SD)		56.2 (9.6)	58.9 (8.8)	0.036	
Gender, n (%)	Female Male	32 (33.7) 63 (66.3)	60 (50.0) 60 (50.0)	0.024	
Place of Birth, n (%)	Australia Overseas	59 (62.1) 36 (37.9)	66 (55.0) 54 (45.0)	0.363	
Primary language at home, n (%)	English Other	88 (92.6) 7 (7.4)	96 (80.0) 24 (20.0)	0.015	
Hospital admissions in past 12 months, n (%)	Yes No	21 (22.1) 74 (77.9)	27 (22.5) 93 (77.5)	1.000	
State n (%)	NSW SA	35 (36.8) 60 (63.2)	99 (82.5) 21 (17.5)	<0.001	
HLQ8 Ability to find good health information	Mean (SD) Median (IQR)	4.3 (0.5) 4.0 (4.0, 4.8)	4.0 (0.8) 4.0 (4.0, 4.6)	**0.004** 0.062	0.0262
HLQ9 Understanding health information well enough to know what to do	Mean (SD) Median (IQR)	4.3 (0.5) 4.0 (4.0, 4.8)	4.1 (0.7) 4.0 (4.0, 4.6)	**0.022** 0.073	0.0230
eHealth literacy	Mean (SD) Median (IQR)	29.2 (6.3) 32.0 (26.0, 32.0)	27.4 (7.3) 29.0 (23.5, 32.0)	0.051 0.062	0.0026
Diet	Mean (SD) Median (IQR)	3.1 (1.6) 3.0 (2.0, 4.0)	3.2 (1.6) 3.0 (2.0, 4.0)	0.646 0.758	-0.0288
Physical activity	Mean (SD) Median (IQR)	2.9 (2.3) 2.0 (1.0, 4.0)	2.7 (2.5) 2.0 (1.0, 4.0)	0.553 0.352	0.0176
Body Mass Index (BMI)	Mean (SD) Median (IQR)	34.9 (6.9) 33.0 (30.3, 36.3)	34.7 (5.3) 33.3 (30.5, 37.2)	0.837 0.528	0.0122
Waist	Mean (SD) Median (IQR)	112.9 (15.2) 110.0 (104.0, 121.0)	109.4 (13.6) 108.5 (99.0, 115.5)	0.178 0.233	0.0263
Systolic blood pressure	Mean (SD) Median (IQR)	130.7 (14.1) 132.0 (121.0, 140.0)	130.6 (14.6) 131.0 (120.0, 139.0)	0.979 0.839	-0.0214
Diastolic blood pressure	Mean (SD) Median (IQR)	81.3 (9.1) 81.0 (75.5, 87.5)	79.2 (11.9) 80.0 (70.0, 86.0)	0.138 0.054	0.0098

[1]Missing values: Health literacy domain 8 (n=4); Health literacy domain 9 (n=3); eHealth (n=3); diet (n=1); BMI (n=1); Waist circumference (n=78); Systolic blood pressure (n=1); Diastolic blood pressure (n=1)
[2] ICC = Intra-cluster correlation coefficient

3. Change between baseline and 12 months

3.1 Primary outcomes

For health literacy, at 6 months, there was a greater increase in the intervention group for the HLQ8 Ability to find good health information score (DID 0.22; 95% CI 0.01-0.44; Table 3). This difference

was not sustained at 12 months. There was no difference in the HLQ9 Understanding health information or for eHealth literacy both at 6 and 12 months. For the group that was below the median at baseline, there was also an increase in the intervention group for the HLQ domain 8 and eHealth literacy score at 6 months, and in HLQ domain 9 score at both 6 and 12 months.

There was a greater increase in diet score in the intervention group at 6 months (DiD 0.98; 95% CI 0.50-1.47) due to an increase in fruit intake (DiD 0.50; 95% CI 0.20-0.80), however, this was not sustained at 12 months. There was no statistically significant effect of the intervention on physical activity score at 6 months (Table 4).

Table 3: Effect of intervention on health literacy score at 6 and 12 months of follow up- intent-to-treat (ITT) analysis

Outcome	Timepoint	Control		Intervention		Effect size[3]	Crude DID[1] (95% CI)[2]	Adj. DID[1] (95% CI)[2]
		n	Mean (SD)	n	Mean (SD)			
HLQ8 Ability to find good health information	Baseline	94	4.3 (0.5)	117	4.0 (0.8)		Ref	Ref
	6m follow up	79	4.3 (0.6)	68	4.2 (0.7)	0.31	0.22 (0.00, 0.44)	***0.22 (0.01, 0.44)***
	12m follow up	72	4.4 (0.5)	54	4.3 (0.6)	0.36	0.16 (-0.08, 0.39)	0.15 (-0.08, 0.39)
HLQ9 Understanding health information well enough to know what to do	Baseline	95	4.3 (0.5)	117	4.1 (0.7)		Ref	Ref
	6m follow up	79	4.4 (0.5)	68	4.3 (0.7)	0.16	0.11 (-0.09, 0.32)	0.13 (-0.07, 0.33)
	12m follow up	72	4.4 (0.5)	54	4.4 (0.5)	0.40	0.20 (-0.03, 0.43)	0.20 (-0.03, 0.44)
eHealth literacy	Baseline	93	29.2 (6.3)	119	27.4 (7.3)			
	6m follow up	78	28.3 (6.3)	68	28.0 (5.8)	0.25	1.60 (-0.40, 3.59)	1.60 (-0.39, 3.58)
	12m follow up	70	29.4 (5.9)	52	29.5 (6.1)	0.32	1.94 (-0.48, 4.36)	1.82 (-0.65, 4.29)
Below median value (baseline)								
Health literacy score domain 8	Baseline	53	3.9 (0.2)	73	3.6 (0.7)		Ref	Ref
	6m follow up	43	4.1 (0.5)	38	4.2 (0.6)	0.72	***0.34 (0.08, 0.60)***	***0.34 (0.09, 0.59)***
	12m follow up	43	4.3 (0.5)	32	4.2 (0.7)	0.33	0.19 (-0.06, 0.44)	0.19 (-0.06, 0.43)
Health literacy score domain 9	Baseline	49	3.9 (0.3)	71	3.7 (0.6)		Ref	Ref
	6m follow up	40	4.2 (0.5)	35	4.3 (0.7)	0.49	***0.27 (0.06, 0.48)***	***0.28 (0.08, 0.48)***

	12m follow up	40	4.3 (0.5)	29	4.5 (0.5)	0.8	***0.32 (0.12, 0.53)***	***0.33 (0.12, 0.54)***
eHealth literacy score	Baseline	41	23.8 (5.2)	69	22.5 (5.3)		Ref	Ref
	6m follow up	34	25.6 (7.1)	34	26.7 (4.8)	0.40	2.40 (-0.21, 5.02)	2.34 (-0.39, 5.06)
	12m follow up	27	26.5 (6.2)	25	29.5 (4.7)	0.42	***4.12 (1.48, 6.75)***	***3.77 (0.96, 6.59)***
Above median value (baseline)								
Health literacy score domain 8	Baseline	41	4.8 (0.3)	44	4.7 (0.3)		Ref	Ref
	6m follow up	35	4.4 (0.6)	28	4.2 (0.7)	0.15	-0.09 (-0.45, 0.27)	-0.44 (-2.27, 1.39)
	12m follow up	28	4.5 (0.5)	20	4.4 (0.6)	0	-0.04 (-0.41, 0.33)	-0.18 (-2.04, 1.67)
Health literacy score domain 9	Baseline	46	4.7 (0.3)	46	4.7 (0.3)		Ref	Ref
	6m follow up	39	4.6 (0.4)	31	4.3 (0.7)	0.53	-0.27 (-0.55, 0.01)	-0.25 (-0.54, 0.03)
	12m follow up	32	4.5 (0.4)	23	4.4 (0.6)	0.39	-0.17 (-0.41, 0.07)	0.17 (-0.41, 0.08)
eHealth literacy score	Baseline	52	33.5 (3.0)	50	34.1 (3.1)		Ref	Ref
	6m follow up	42	30.8 (4.3)	33	29.5 (6.5)	0.35	-1.90 (-4.50, 0.70)	-1.77 (-4.36, 0.82)
	12m follow up	42	31.1 (4.9)	26	30.0 (7.0)	0.28	-1.70 (-5.25, 1.85)	-1.68 (-5.18, 1.81)

[1]DID = Difference in Differences. [2] adjusted for age, gender, and state. [3] Cohen's d

Table 4: Effect of intervention on physical activity and diet score at 6 and 12 months of follow up- intent-to-treat (ITT) analysis

Outcome	Timepoint	Control		Intervention		Effect size[2]	Crude DID (95% CI)	Adj. DID (95% CI)[1]
		n	Mean (SD)	n	Mean (SD)			
Total physical activity score	Baseline	95	2.9 (2.3)	120	2.7 (2.5)		Ref	Ref
	6m follow up	79	3.6 (2.6)	68	3.0 (2.3)	0.16	-0.45 (-1.06, 0.15)	-0.56 (-1.19, 0.06)
	12m follow up	72	3.6 (2.5)	54	3.9 (2.2)	0.21	0.47 (-0.47, 1.42)	0.38 (-0.59, 1.35)
Diet score	Baseline	95	3.1 (1.6)	119	3.2 (1.6)		Ref	Ref
	6m follow up	79	3.1 (1.7)	68	4.1 (1.5)	0.56	***0.98 (0.48, 1.48***)	***0.98 (0.50, 1.47)***
	12m follow up	72	3.8 (1.5)	54	3.9 (1.9)	0	-0.04 (-0.51, 0.44)	0.05 (-0.41, 0.50)
Vegetable intake	Baseline	95	1.8 (1.2)	120	1.8 (1.2)		Ref	Ref
	6m follow up	79	1.9 (1.3)	68	2.3 (1.3)	0.31	***0.46 (0.02, 0.90)***	***0.46 (0.03, 0.89)***
	12m follow up	72	2.4 (1.2)	54	2.3 (1.4)	0.46	-0.14 (-0.53, 0.26)	-0.07 (-0.44, 0.31)
Fruit intake	Baseline	95	1.3 (0.9)	119	1.4 (1.0)		Ref	Ref
	6m follow up	79	1.2 (0.9)	68	1.8 (0.8)	0.59	***0.49 (0.20, 0.79)***	***0.50 (0.20, 0.80)***
	12m follow up	72	1.4 (0.9)	54	1.6 (0.9)	0.11	0.03 (-0.23, 0.30)	0.05 (-0.22, 0.32)

[1]DID = Difference in Differences. [2] Cohen's d

There was no statistically significant effect of the intervention on BMI or BP at 12 months (Table 5). The intervention group's mean BMI decreased but mean waist circumference at 12 months increased (DiD 7.08, 95% CI 2.26-11.90).

Table 5: Effect of intervention on anthropometry and blood pressure at 12 months of follow up- intent-to-treat (ITT) analysis

Outcome	Timepoint	Control		Intervention		Effect size	Crude DID (95% CI)	Adj. DID (95% CI)[1]
		n	Mean (SD)	n	Mean (SD)			
BMI	Baseline	94	34.9 (6.9)	120	34.7 (5.3)		Ref	Ref
	12m follow up	49	32.9 (5.7)	52	34.3 (6.0)	0.27	1.45 (-0.16, 3.06)	1.22 (-0.46, 2.90)
Waist circumference	Baseline	49	112.9 (15.2)	88	109.4 (13.6)		Ref	Ref
	12m follow up	20	107.0 (9.6)	49	112.4 (15.6)	0.62	8.24 (2.73, 13.74)	7.08 (2.26, 11.90)
Systolic blood pressure	Baseline	95	130.7 (14.1)	119	130.6 (14.6)		Ref	Ref
	12m follow up	64	133.0 (15.3)	50	130.8 (14.6)	0.17	-2.13 (-8.18, 3.92)	-1.48 (-7.34, 4.38)
Diastolic blood pressure	Baseline	95	81.3 (9.1)	119	79.2 (11.9)		Ref	Ref
	12m follow up	64	82.7 (8.6)	50	77.6 (9.1)	0.12	-2.84 (-5.94, 0.25)	-3.18 (-6.50, 0.14)

[1]Adjusted for age, gender, and state

3.2 Secondary outcomes

Unexpectedly, mean physical activity score increased in the control group and decreased in the intervention group at 6 months. High Density Lipoprotein (HDL) fell in both groups by 7% (control) and 8% (intervention). However, total cholesterol, LDL and triglycerides all fell in the intervention group. There were no statistically significant effects of the intervention on lipids (Total cholesterol, Low Density Lipoprotein (LDL), High Density Lipoprotein (HDL) or Triglyceride (TG) or quality of life (EQ-5D-5L) at 12 months. Quality of life increased in the control group but decreased in the intervention group. At 6 months, the control group self-reported a decrease in the frequency of receiving advice on physical activity whereas the level stayed the same in intervention group (DiD 16.3%, 95% CI 1.4%-31.1%). Similarly, the frequency of weight loss counselling or referral for physical

activity fell in the control group but both increased in the intervention group (weight loss counselling DiD 27.8%, 95% CI 8.8%-46.8%; physical activity referral DiD 13.3%, 95% CI 2.32%-24.2%). There were no statistically significant differences between the groups in frequency of receiving information on healthy eating or being referred for healthy eating or weight loss (Tables 6 and 7).

Table 6: Effect of intervention on the secondary outcomes (from DCP data)- intent-to-treat (ITT) analysis [who had two different measurements at baseline and 12 months

Outcome	Timepoint	Control		Intervention		Crude DID (95% CI)	Adj. DID (95% CI)[1]
		n	Mean (SD)	n	Mean (SD)		
HDL cholesterol	Baseline	90	1.4 (0.4)	109	1.3 (0.4)	Ref	Ref
	12m follow up	43	1.3 (0.3)	31	1.2 (0.4)	0.02 (-0.09, 0.14)	0.04 (-0.08, 0.16)
LDL cholesterol	Baseline	77	2.8 (0.9)	108	2.9 (0.8)	Ref	Ref
	12m follow up	25	2.9 (1.2)	28	2.7 (0.7)	-0.28 (-0.71, 0.15)	-0.26 (-0.67, 0.15)
Triglyceride	Baseline	92	1.7 (0.8)	114	1.7 (0.8)	Ref	Ref
	12m follow up	46	1.7 (0.8)	32	1.5 (0.8)	-0.20 (-0.50, 0.09)	-0.22 (-0.52, 0.09)
Total cholesterol	Baseline	93	4.9 (0.9)	115	4.9 (1.0)	Ref	Ref
	12m follow up	51	4.9 (1.2)	33	4.6 (0.8)	-0.32 (-0.65, 0.01)	-0.31 (-0.64, 0.01)

[1]Adjusted for age, gender, and state

Table 7: Effect of intervention on the secondary outcomes (from Survey data)- intent-to-treat (ITT) analysis

Outcome	Timepoint	Control		Intervention		Crude DID (95% CI)	Adj. DID (95% CI)[1]
		n	% (n)	n	% (n)		
Quality of life change (Mean (SD))	Baseline	95	7.0 (2.1)	120	7.4 (2.3)	Ref	Ref
	12m follow up	72	7.3 (2.7)	54	6.8 (1.8)	-0.85 (-1.49, -0.21)	-0.81 (-1.47, -0.16)
Info or advice healthy eating	Baseline	95	27.4 (26)	120	44.2 (53)	Ref	Ref
	6m follow up	79	17.7 (14)	68	39.7 (27)	5.01 (-18.73, 28.76)	3.30 (-21.10, 27.69)
Info or advice physical activity	Baseline	95	30.5 (29)	120	40.8 (49)	Ref	Ref
	6m follow up	79	11.4 (9)	68	39.7 (27)	***18.03 (3.19, 32.86)***	***16.27 (1.40, 31.14)***
Info or advice weight loss	Baseline	95	34.7 (33)	120	43.3 (52)	Ref	Ref
	6m follow up	79	13.9 (11)	68	51.5 (35)	***29.07 (10.41, 47.74)***	***27.83 (8.83, 46.84)***
Referral to healthy eating	Baseline	95	11.6 (11)	120	10.0 (12)	Ref	Ref
	6m follow up	79	10.1 (8)	68	22.1 (15)	13.46 (-3.25, 30.16)	14.46 (-2.35, 31.27)
Referral to physical activity	Baseline	95	8.4 (8)	120	3.3 (4)	Ref	Ref
	6m follow up	79	5.1 (4)	68	13.2 (9)	***13.24 (2.45, 24.04)***	***13.28 (2.32, 24.24)***
Referral to weight loss	Baseline	95	7.4 (7)	120	7.5 (9)	Ref	Ref
	6m follow up	79	7.6 (6)	68	10.3 (7)	2.49 (-7.68, 12.66)	2.50 (-7.75, 12.74)

Adjusted for age, gender, and state

3.3 Economic analysis

The intervention costs included fixed (development of the *mysnapp* app and the online training modules) and variable (practice facilitation visits, PN health check payments and telephone coaching sessions) costs. Across the 120 patients in the intervention group, the per patient fixed and variable costs were $787 and $558, respectively, generating a total intervention cost per patient of $1,345.

The baseline characteristics and outcome measurements of participants in the cohort providing consent to access their cost data (n=65; 33 in the intervention group and 32 in the control group) and full cohort (n=215) were similar (see supplementary tables S2(a) and S2 (b)). One participant was excluded due to having only six months of cost data available after the enrolment date, and one participant had extremely high pharmaceutical costs in the 12 months prior to enrolment.

Supplementary table S2(c) presents the mean crude cost DIDs between the 12 months prior and post recruitment to the trial. Excluding the outlier participant with high pharmaceutical costs, mean costs were higher in the intervention group in all cost categories, but there were no statistically significant differences between the intervention and control groups for the alternative costs categories (GP costs, GP and specialist costs and PBS costs) nor for the aggregated cost.

Discussion

In this trial of an intervention involving a PN health check, a mobile app and phone coaching in primary health care, we found positive effects on some primary outcomes (health literacy and diet at 6 months) but not on physical activity, weight or other outcomes. The primary hypothesis was that the intervention would lead to improved health literacy, health behaviours and positive changes in weight and other physiological measures. At baseline, levels of health literacy were higher than anticipated and were in fact comparable with overweight or obese patients in the general population who were part of the national health literacy survey.[49] It is therefore possible that the requirements for informed consent and engagement with the research study may have tended to discourage those with lower literacy, as has been found in some research.[50]

Health literacy improved in the intervention group at 6 months, although there was no further change by 12 months. Additionally, eHealth literacy improved only among those whose baseline health literacy was below the median. Although similar proportions of participants in both groups set goals for diet and physical activity, patients in the intervention group were more likely to report an improved diet score (due to a greater increase in fruit intake) compared to the control group. There was no difference in the physical activity score between the intervention and control groups. A lack of change in physical activity outcomes may reflect a need for group rather than individual approaches to physical activity promotion for people from migrant or low socioeconomic backgrounds.[51] The intervention was tailored to patients' needs and motivation but was not codesigned or specifically tailored to differences in individual cultural and religious beliefs and practices which may mediate changes in physical activity.[52] The intervention was not associated with differences in BMI, BP, lipids, or quality of life after adjustment for age, gender, and State. This may be because we did not recruit our required sample size or because the intervention lacked sufficient intensity and duration, as has been observed in other studies.[53] The lack of change in physical activity, especially at 12 months, may also have contributed, and changes in BP and lipids

may have been confounded by treatment with medications since most patients' BP and lipids were within recommended guideline levels at baseline.

Only two thirds of the patients in the intervention group received the full intervention (i.e., received the health check with *mysnapp* and/or Get Healthy coaching components). This was influenced by patient choice through discussion with their clinicians reflecting the real world setting of Australian general practice. This variable engagement with the different components of the intervention may have reduced its overall effectiveness. However, patients in the intervention group were more likely to recall being offered information or referral for physical activity or weight loss counselling than their counterparts in the control group.

In the cost analyses, low recruitment made the study insufficiently powered to draw meaningful conclusions. There was no evidence of difference in numbers of GP visits, MBS, or PBS costs between the groups over the period of the study. Despite some positive changes in health literacy and diet scores, there were no changes in weight, other physiological measures, or quality of life at 12 months. Trials of weight loss in primary care often show little or no change.[54] However previous studies involving the use of apps and behavioural counselling by health care providers have proven successful even in low socioeconomic groups where goals were individually tailored to the patient's level of health literacy and the intervention were of moderate to high intensity.[55] This suggests that the intervention in the current study may have been more effective if it was more tailored to the patient's individual health literacy needs.

There were several limitations to our study. Like other studies, this study failed to achieve its planned sample size due to major challenges recruiting practices and patients despite considerable effort and an extension to the time frame of the study. [56] There was also variable uptake of

intervention components by clinicians and their patients. The study was conducted in only two urban areas of Australia and the findings should therefore not be generalised to other communities, especially rural areas. Lastly the measures of health literacy, diet and physical activity had some limitations, and may have not been sensitive enough to capture all change due to the intervention.

Conclusion

This trial of a multi-faceted intervention designed to support better preventive care for overweight and obese patients from low socioeconomic areas in the real-world environment of Australian general practice showed some short-term improvement in health literacy and diet but did not show any change in weight or other physiological variables. While there was evidence that the intervention was implemented as planned, there was variable uptake of its components, and it may therefore have been of insufficient intensity to achieve sustained change in weight and other primary outcomes. However, any preventive intervention in primary care needs to be sustainable and tailored to its capacity.

Data sharing statement

Individual participant data that underlie the results reported in this article, will be available within 12 months of publication after deidentification (text, tables, figures, and appendices) to investigators whose proposed use of the data has been approved by our Ethics Committee.

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Competing Interest Statement

None declared

Author Statement

MFH was the chief investigator and led the development of and implementation of the study, interpreted the data and drafted the manuscript.

SMP developed the trial processes, coordinated the trial across sites, contributed to the development of the data collection tools, collected and analysed data and drafted the manuscript.

MB cleaned the data, designed the analysis plan, conducted the analysis, interpreted the data and contributed to the draft of the manuscript.

NS led the development and implementation of the study in SA, was instrumental in designing the DCP module for the trial, interpreted the data and contributed to the manuscript.

EDW contributed to the design of the study, developed the training modules, contributed to the interpretation of the data and the manuscript.

NZ contributed to the trial design, trial implementation and interpretation of the data for the manuscript.

JK contributed to the trial design, designed the economic analysis and interpreted this data for the manuscript.

AK cleaned the DCP data, designed the analysis plan, conducted the analysis, developed the data tables and contributed to the draft of the manuscript.

DN contributed to the trial design, trial implementation and interpretation of the data for the manuscript, particularly the health literacy content.

JR conducted the economic analysis and interpreted the data for inclusion in the manuscript.

STL contributed to the trial design, trial implementation and interpretation of the data for the manuscript.

CM liaised with SA practices to collect patient and practice data, collated the data, and contributed to the interpretation of the data for the manuscript.

OF was instrumental in designing the DCP module for the trial and troubleshooting data collection using DCP, interpreted the outcome data and contributed to the manuscript.

AT liaised with NSW practices to collect patient and practice data, collated and cleaned the data and contributed to the management and interpretation of the data.

RO contributed to the trial design, particularly the tools to collect patient data and interpretation of data particularly the health literacy outcome data. He contributed to the draft manuscript.

AL designed and developed the mysnapp app and the data collected via the application and interpretation and plan for analysing this data

All authors approved the final version for publication and agree to be accountable for the integrity of the content, and responsible for any issues that arise from publication of the trial data.

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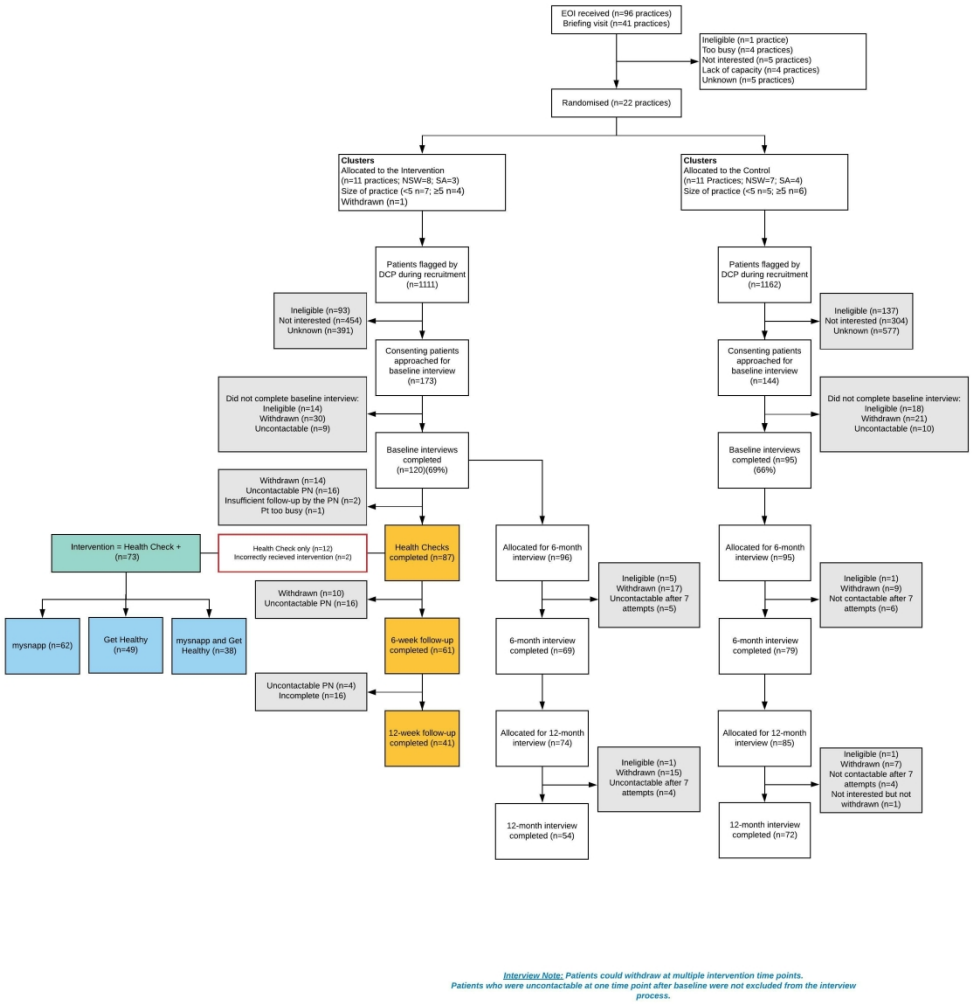

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Supplementary 1. CONSORT checklist when reporting a cluster randomised trial: HeLP GP Trial.

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	Abstract
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	Page 3
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	Page 3
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	Page 3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		Page 8
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	Page 3/4
	4b	Settings and locations where the data were collected		Page 3/4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	Page 6/7
Outcomes	6a	Completely defined pre-specified primary and	Whether outcome measures pertain to the cluster level, the	Table 1

		secondary outcome measures, including how and when they were assessed	individual participant level or both	
	6b	Any changes to trial outcomes after the trial commenced, with reasons		NA
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	Page 9
	7b	When applicable, explanation of any interim analyses and stopping guidelines		NA
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		Page 5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	Page 5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	Page 5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	See 10a – 10c
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	Page 5

	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	Page 5
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	Page 8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		NA
	11b	If relevant, description of the similarity of interventions		NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	Page 13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		Page 13
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up		Page 4/5

	14b	Why the trial ended or was stopped		NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Table 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Page 14
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	ICC included in Table 2 Effect size included in Tables 3, 4 and 5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		Absolute differences provided
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		**NA**
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		NA
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		Page 23/24
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	Page 24
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and		Conclusions

		considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	Title page
Protocol	24	Where the full trial protocol can be accessed, if available	Title page
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 25

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Supplementary Tables: Economic analysis

Table S2(a): Baseline characteristics by intervention and control for full cohort and cohort for cost analysis

Variables	Responses	Full cohort		Cohort for cost analysis	
		Control	Intervention	Control	Intervention
n	215	95	120	32	33
Age, mean (SD)		56.2 (9.6)	58.9 (8.8)	61.0 (9.8)	60.5 (8.1)
Gender, n(%)	Female Male	32 (33.7) 63 (66.3)	60 (50.0) 60 (50.0)	10 (31.3) 22 (68.7)	17 (51.5) 16 (48.5)
Place of Birth, n(%)	Australia Overseas	59 (62.1) 36 (37.9)	66 (55.0) 54 (45.0)	17 (53.1) 15 (46.9)	20 (60.6) 13 (39.4)
Primary language at home, n(%)	English Other	88 (92.6) 7 (7.4)	96 (80.0) 24 (20.0)	31 (96.9) 1 (3.1)	25 (75.8) 8 (24.2)
Hospital admissions in past 12 months, n(%)	Yes No	21 (22.1) 74 (77.9)	27 (22.5) 93 (77.5)	8 (25.0) 24 (75.0)	7 (21.2) 26 (78.8)
State	NSW SA	35 (36.8) 60 (63.2)	99 (82.5) 21 (17.5)	6 (18.8) 26 (81.2)	28 (84.9) 5 (15.1)

Table S2(b): Outcome measurement at baseline by control and intervention for full cohort and cohort for cost analysis

Variables	Measure[1]	Full cohort		Cohort for cost analysis	
		Control	Intervention	Control	Intervention
n	215	95	120	32	32
Health literacy domain 8	Mean (SD) Median (IQR)	4.3 (0.5) 4.0 (4.0, 4.8)	4.0 (0.8) 4.0 (4.0, 4.6)	4.4 (0.5) 4.0 (4.0, 4.8)	4.4 (0.5) 4.0 (4.0, 4.8)
Health literacy domain 9	Mean (SD) Median (IQR)	4.3 (0.5) 4.0 (4.0, 4.8)	4.1 (0.7) 4.0 (4.0, 4.6)	4.3 (0.5) 4.1 (4.0, 4.8)	4.4 (0.5) 4.0 (4.0, 5.0)
eHealth	Mean (SD) Median (IQR)	29.2 (6.3) 32.0 (26.0, 32.0)	27.4 (7.3) 29.0 (23.5, 32.0)	29.2 (6.6) 32.0 (26.0, 32.0)	28.6 (6.0) 30.5 (25.5, 32.0)
Diet	Mean (SD) Median (IQR)	3.1 (1.6) 3.0 (2.0, 4.0)	3.2 (1.6) 3.0 (2.0, 4.0)	3.4 (1.5) 3.0 (2.0, 4.0)	3.4 (1.5) 3.0 (2.0, 5.0)
Physical activity	Mean (SD) Median (IQR)	2.9 (2.3) 2.0 (1.0, 4.0)	2.7 (2.5) 2.0 (1.0, 4.0)	3.6 (2.3) 4.0 (2.0, 4.0)	3.0 (2.6) 2.0 (1.0, 4.0)
BMI	Mean (SD) Median (IQR)	34.9 (6.9) 33.0 (30.3, 36.3)	34.7 (5.3) 33.3 (30.5, 37.2)	31.9 (3.1) 30.9 (29.9, 33.8)	33.8 (4.8) 33.3 (30.5, 35.4)
Waist	Mean (SD) Median (IQR)	112.9 (15.2) 110.0 (104.0, 121.0)	109.4 (13.6) 108.5 (99.0, 115.5)	107.4 (10.1) 107.0 (98.0, 116.0)	115.6 (14.6) 110.0 (100.0, 117.0)
Systolic blood pressure	Mean (SD) Median (IQR)	130.7 (14.1) 132.0 (121.0, 140.0)	130.6 (14.6) 131.0 (120.0, 139.0)	127.6 (13.0) 127.0 (120.5, 137.5)	131.3 (13.7) 131.5 (120.0, 140.0)
Diastolic blood pressure	Mean (SD) Median (IQR)	81.3 (9.1) 81.0 (75.5, 87.5)	79.2 (11.9) 80.0 (70.0, 86.0)	79.4 (8.3) 79.5 (74.0, 85.0)	79.5 (15.7) 79.0 (70.0, 89.5)

Table S2(c): Costs 12 months before and 12 months after enrolment date by control and intervention (excluding outlier)

Outcome	Timepoint	Control			Intervention			Crude DID (95% CI)
		n	Mean (SD)	Mean Diff (95% CI)	n	Mean (SD)	Mean Diff (95% CI)	
GP costs	12m before enrolment	32	$1,109 ($485)	Ref	32	$912 ($564)	Ref	Ref
	12m after enrolment	32	$1,088 ($683)	-$21 (-$248, $207)	32	$931 ($579)	$20 (-$215, $254)	-$40 (-$353, $273)
GP & specialist costs	12m before enrolment	32	$1,268 ($571)	Ref	32	$1,158 ($677)	Ref	Ref
	12m after enrolment	32	$1,345 ($1,013)	$77 (-$247, $400)	32	$1,275 ($837)	$116 (-$220, $453)	-$40 (-$491, $412)
PBS Costs	12m before enrolment	32	$315 ($403)	Ref	32	$289 ($366)	Ref	Ref
	12m after enrolment	32	$328 ($458)	$12 (-$52, $77)	32	$320 ($479)	$32 (-$62, $125)	-$19 (-$131, $93)
GP & PBS costs	12m before enrolment	32	$1,424 ($672)	Ref	32	$1,201 ($754)	Ref	Ref
	12m after enrolment	32	$1,416 ($923)	-$8 (-$259, $243)	32	$1,252 ($824)	$51 (-$217, $319)	-$59 (-$412, $293)
GP, specialist & PBS costs	12m before enrolment	32	$1,583 ($751)	Ref	32	$1,447 ($801)	Ref	Ref
	12m after enrolment	32	$1,672 ($1,203)	$89 (-$257, $435)	32	$1,595 ($1,037)	$148 (-$205, $502)	-$59 (-$535, $417)
Number of GP visits	12m before enrolment	32	10.9 (0.9)	Ref	32	11.0 (1.1)	Ref	Ref
	12m after enrolment	32	11.3 (1.0)	0.3 (-1.2, 1.9)	32	10.7 (1.0)	-0.3 (-2.5, 2.0)	0.7 (-2.1, 3.4)

BMJ Open

Preventing chronic disease in patients with low health literacy using eHealth and teamwork in primary health care (HeLP-GP): A cluster randomised controlled trial.

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Preventing chronic disease in patients with low health literacy using eHealth and teamwork in primary health care (HeLP-GP): A cluster randomised controlled trial.

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ABSTRACT

Objectives

To evaluate a multifaceted intervention on diet, physical activity and health literacy of overweight and obese patients attending primary care.

Design

A pragmatic two arm cluster randomised controlled trial.

Setting

Urban general practices in lower socio-economic areas in Sydney and Adelaide.

Participants

We aimed to recruit 800 patients in each arm. Baseline assessment was completed by 215 patients (120 intervention and 95 control).

Intervention

A practice nurse led preventive health check, a mobile application and telephone coaching.

Primary and secondary outcome measures

Primary outcomes were measured at baseline, 6 and 12 months and included patient health and eHealth literacy, weight, waist circumference and blood pressure. Secondary outcomes included changes in diet and physical activity, preventive advice and referral, blood lipids, quality of life and costs. Univariate and multivariate analysis of difference-in-difference estimates for each outcome were conducted.

Results

At 6 months, the intervention group, compared with the control group, demonstrated a greater increase in HLQ domain 8 score (Ability to find good health information; mean DiD 0.22; 95% CI 0.01-0.44). There were similar differences for domain 9 score (Understanding health information well enough to know what to do) among patients below the median at baseline. Differences were reduced and non-statistically significant at 12 months. There was a small improvement in diet scores at 6 months (DiD 0.78 (0.10-1.47; p=0.026) but not at 12 months. There were no differences in e-health literacy, physical activity scores, BMI, weight, waist circumference or blood pressure.

Conclusions

Targeted recruitment and engagement were challenging in this population. While the intervention was associated with some improvements in health literacy and diet, substantial differences in other outcomes were not observed. More intensive interventions and using codesign strategies to engage the practices earlier may produce a different result. Codesign may also be valuable when targeting lower socioeconomic populations.

Trial Registration

This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12617001508369). http://www.ANZCTR.org.au/ACTRN12617001508369.aspx. Date registered 30 October 2017.

Trial Protocol

The protocol for this trial has been published (open access) https://bmjopen.bmj.com/content/8/6/e023239

Key words: Primary Care, Preventive Medicine, Health Services Administration and Management.

Article Summary

Strengths and limitations of this study

- The cluster randomised design allowed testing of the nurse led intervention among patients without contamination.
- Recruitment of practices and patients did not meet our planned sample size.
- We noted variable uptake of the intervention components among patients reflecting real world general practice
- The measures used to assess health literacy, diet and physical activity had some limitations.
- The study was conducted in only two urban areas of Australia and the findings may not therefore be generalised to other communities, such as rural areas.

INTRODUCTION

Obesity is a complex health issue and is influenced by biological, environmental, social, and psychological factors.[1] Overweight and obesity account for 8.4% of the burden of disease being a risk factor for 11 types of cancer, three cardiovascular conditions, chronic kidney disease, diabetes, dementia, gallbladder disease, fatty liver, gout, back pain and osteoarthritis.[2] In 2017/18, 67% of the Australian population were overweight (BMI 25-29 kg/m^2; 35.6%) or obese (BMI 30+ kg/m^2; 31.3%) with those who were more socially disadvantaged being more likely to be overweight or obese.[3] Within Australia, rates of overweight and obesity peak for men at age 55 to 64 years (83.6%) and for women at 65 to 74 years (73.3%).[4]

Current Australian guidelines recommend that people who are overweight and obese attending general practice undergo routine measurements (BMI and waist circumference) and are engaged in discussions about lifestyle risk factors and positive messaging to improve health and wellbeing.[5] Behavioural interventions in primary care have been demonstrated to achieve a 5-7% improvement in weight, blood pressure (BP) or lipids for patients, potentially preventing or delaying the onset of Type 2 diabetes and cardiovascular disease.[6] A recent systematic review and meta-analysis supports weight loss programs delivered by primary care practitioners as they provide effective weight loss and reduction in waist circumference.[7] Multicomponent intensive behavioural interventions (delivered by various clinicians and provided through group, individual, technology or print based methods), has been recommended for patients with a BMI of 30 or higher[8]. Health coaching provided by a trained professional has become a popular tool to address weight through behaviour change strategies[9] and high intensity behavioural counselling (12 or more sessions per year) delivered in person, by phone or electronically) is accepted to produce clinically meaningful weight loss[10].

The Track Study[11] which combined tailored weight related behaviour change goals for patients as a basis for self-monitoring with 18 coaching calls over 12 months found intervention patients

significantly more likely to lose ≥ 5% of their baseline weight at 6 months and 12 months. A recent retrospective analysis of 25,000 people receiving blended care behaviour change interventions (a combination of digital care and coaching)[12] supports the use of these interventions for weight loss but highlights the need for more understanding as to which elements would be best delivered by health coaches and which can be delegated to a digital device.

Patients generally accept their GPs' role in management of overweight and obesity[13], however lower socioeconomic groups tend to be less likely to take up weight management programs.[14 15] Low functional health literacy (i.e., health-related reading and numeracy) is more common in socioeconomically disadvantaged populations and is associated with an increased likelihood of overweight and obesity.[16 17] It is also a potential barrier to the uptake and effectiveness of a range of preventive interventions that mediate change in lifestyle behaviours.[18 19] Patients with low health literacy are less likely to engage in health promoting behaviours[20-22] and attend or complete programs to which they have been referred.[23 24] Interventions with multiple components to improve health literacy for behavioural risk factors have been shown to be more effective at improving nutritional health literacy in primary care than those with single components.[6] Other barriers to delivering weight loss management have also been identified, including low confidence levels of clinicians in obesity management [25], stigmatisation of patients[26] and lost opportunities by providers to initiate earlier, effective weight loss conversations.[27]

OBJECTIVES

The HeLP GP trial aimed to evaluate a multifaceted intervention provided to overweight and obese patients attending primary care. The primary hypothesis was that the intervention would lead to improved health literacy, eHealth literacy, physiological risk factors, lifestyle behaviours and quality of life.

METHODS

Trial Design

A pragmatic, two-arm, unblinded cluster randomised controlled trial. This design was chosen to provide protection against contamination within sites (general practices) as practice staff were providing the intervention. Primary and secondary outcomes were assessed at the patient level.

Participants and setting

The trial was conducted in general practices located in metropolitan and urban fringe areas of south-western and western Sydney in New South Wales and Adelaide in South Australia. Practice eligibility included:

- Geographical location in a Local Government Areas (LGAs) with a Socio-Economic Index for Area (SEIFA) Index of Relative Socio-economic Disadvantage (IRSD)[28] equal to or below the 8th decile.
- Using clinical software compatible with the trial data extraction and recruitment tool, *Doctors Control Panel* (DCP)[29], and an active internet connection.
- Participation by at least one practice nurse (PN) and one general practitioner (GP) from the practice.
- Participation of reception staff to distribute trial materials to eligible trial participants as they present for appointments.

Patient eligibility included:

- Aged 40-74 years.
- BMI≥28 recorded within the previous 12 months (The cut point for BMI was chosen to target people at higher risk and to capture people from Asian backgrounds who have a lower equivalent BMI).
- Blood pressure and total serum cholesterol recorded within the previous 12 months.
- Speaking English and/or Arabic, Vietnamese or Chinese (Languages representing common migrant groups in the catchment areas).
- Access to a smart phone or tablet device and internet connection.

Patients were excluded if they:

- Had a diagnosis of diabetes requiring insulin or a current prescription for insulin, a diagnosis of cardiovascular disease (angina, myocardial infarction, heart failure, heart valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident)
- Had experienced weight loss of >5% in the past 3 months, were taking medication for weight loss (orlistat or phentermine) or had undergone weight loss surgery.
- Cognitive impairment (including serious mental illness).
- Had a physical impairment which would prohibit engaging in moderate level physical activity.

Practice Recruitment

Between March 2018 and October 2018, general practices within the specified geographical locations were approached by partner Primary Health Networks (PHNs), which are regional organisations providing quality improvement and education to general practices. Invitations to express interest were distributed through mail, email, newsletters, GP educational events, websites, Facebook groups for health professionals, discussion groups and research networks. A face-to-face

meeting was held between responding practices, a PHN representative and a member of the research team to discuss in detail and confirm eligibility.

Randomisation

Randomisation of practices was performed by an epidemiologist (MB) who was not involved in the data collection or intervention using the SAS[30] statistical package. Practices were characterised by size (fewer than 5 GPs, or 5 or more GPs) and by State into four strata, and intervention and control lists of random numbers (6-digit) were generated for each stratum. The resultant intervention and control strata lists were combined and sorted. Four batches were created. Allocation of intervention or control was then sequentially allocated from the lists based on the date of entry of the practice into the study by an independent researcher. Batching was undertaken to ensure similar numbers of control and intervention practices at any point in time. Practices were informed in writing as to what allocation they had received.

Recruitment of Patients

From October 2018 to September 2019, patients of participating practices were flagged at the point of presentation using DCP. The software was programmed with clinical inclusion/exclusion criteria to identify potential participants as they presented. Once flagged, patient information was automatically printed and attached to trial information and consent forms by the reception staff. It was not the responsibility of GPs to gain consent, but patients could discuss the trial with their GP or PN. As DCP was only able to determine eligibility based on the information within the practice's clinical software, eligibility was also checked by a member of the practice. Patients could return their consent forms by leaving them in a secure collection point at the practice or returning them in a reply-paid envelope to the study centre (UNSW Sydney).

The HeLP-GP Intervention

The intervention was a multi-component intervention which has been previously described and piloted [31 32]. It aimed to increase the knowledge of patients relating to diet and physical activity and their individual skills to address weight management behaviours. It comprised:

a) A PN-led health check designed to support Australian Guidelines for the management of overweight and obesity [5 33] and based on the 5A's (Assess, Advise, Agree, Assist and Arrange).[34 35] Review was conducted by the PN at 6 weeks and the GP at 12 weeks.

b) A lifestyle app (*mysnapp*) modified from *healthy.me,* a personally controlled health management platform designed to help patients and consumers to manage their health.[36] The components of *mysnapp* were informed by research into behaviour change through mobile and electronic platforms that suggest that goal setting and self-monitoring, and additional methods to interact with patients, particularly text messaging, can be more effective than advice alone.[37 38-40] *Mysnapp* allowed patients to set and revise physical activity and diet-based goals and to view graphs of their progress over the previous 6 weeks. A free text diary allowed patients to document individualised content. A range of video and written resources related to diet and physical activity, linked to the app, were available for the patient to view. Text messages reminded patients to attend the follow up with the PN and GP and once registered, each patient received one nutrition and one physical activity message each week for 6 weeks.[32]

c) Health coaching via the 'Get Healthy' Telephone coaching program (https://www.gethealthynsw.com.au/) provided free, confidential telephone-based health coaching to support patients to reach personalised lifestyle goals relating to healthy eating, increasing physical activity, alcohol reduction and achieving and maintaining a healthy weight. Coaching was available in multiple languages with the assistance of an interpreter service.

At the health check patients could choose to take up *mysnapp*, Get Healthy or both. Control practices provided 'usual care' (the clinical practice routinely offered to patients by the GP and PN of the practice).

Training and implementation of the intervention

Training was completed by all participating PNs. Training comprised three on-line modules covering physical assessment (weight, height, BP, waist circumference and BMI), delivery of relevant lifestyle advice and promotion of individual goal setting. The 'teach-back' method[41] (asking the patient to repeat in their own words what they have understood), was encouraged to ensure they had understood and were confident with the content of the health check. PNs assisted patients to download and set up *mysnapp* including setting goals during the health check and were encouraged to review the patient's use of the app and the progress of health coaching at the 6-week follow up. Written and video resources were developed for PNs and patients on the installation and use of the app. PNs referred patients to Get Healthy using a trial-specific online referral form.

Patients could claim Medicare benefits (usually without out-pocket payments) for GP visits as part of the intervention (Medicare is Australia's national universal health insurance scheme). Patients did not pay for the PN visits. The PN health checks were reimbursed directly to the practice by the study at a rate of AUD$40 per patient for the health check and AUD$20 per patient for follow-up.

Ethics and consent

This trial was approved by the University of New South Wales Human Research Ethics Committee (HC17474). The University of Adelaide Human Research Ethics committee ratified this approval.

Written consent was obtained from all participating practices to conduct the trial in the practice and access practice data; individual consent was obtained from all participating GPs and PNs. Patients

provided written consent to participate in the trial and additional written consent was obtained for the researchers to access individual health service usage data (Medicare Benefits Schedule (MBS)) and pharmaceutical use (Pharmaceutical Benefit Scheme (PBS)) according to protocols governing access to this data through Services Australia[42].

All practices received an AUD $1000 payment to cover the administrative costs of participation. To compensate them for their time, patients from both groups who completed the baseline and 6-month follow up received an AUD$30 shopping voucher and then an additional AUD$30 voucher if they completed the 12-month follow up.

Patient and Public involvement

Patients and members of the public were not involved in the design of this study. Consumer volunteers with the Adelaide Primary health Network did pilot the lifestyle app (mysnapp) and provide input to its final design.

Data collection and trial outcomes

The methods are described in the protocol paper[43]. Table 1 provides a summary of the data collected to assess trial outcomes, the collection method and the timepoints of collection. A proposed 18 month follow up of patients was abandoned due to the need to extend the period for patient recruitment and lower than expected numbers of patients being recruited to the trial. Surveys administered over the telephone were used to collect demographic and other patient data.

Primary outcomes

We used two domains of the Health Literacy Questionnaire (HLQ) (Domain 8: Ability to find good health information (5 items) and Domain 9: Understand health information well enough to know what to do (5 items)). [44] The individual domains of the HLQ were selected to identify specific health

literacy strengths and challenges or to test a hypothesis.[45 46] Domains 8 and 9 have a 5-point response option scale (cannot do or always difficult, usually difficult, sometimes difficult, usually easy, or always easy). The scores for these domains are averages for the domain (with a range between 1 to 5). The eHealth Literacy Scale (eHeals) was used to assess digital health literacy.[47] DCP was used to extract clinical patient data related to biomedical risk factors (BMI, systolic and diastolic blood pressure, and waist circumference). We used the measurements recorded by the GP at the nearest timepoint to follow up (baseline and 12 month follow up interviews).

Secondary outcomes

Patient self-report was used to determine lifestyle behaviours including a diet score (portions of fruit (between 0 and a maximum of 2 per day) plus portions of vegetables intake (between 0 and a maximum of 5 per day) with a range between 0 and 7 based on the sum of fruit and vegetable scores), the number of 30-minute sessions of physical activity (moderate/vigorous) per week and changes in diet and physical activity. Questions to assess these behaviours were adapted from previous research.[48 49] The scores for diet were between 1 and 7.

Patient self-report was used to determine advice received and referral for diet, physical activity and weight loss. Patient questions also assessed quality of life (using the EQ-5D-5L standardised to UK reference population with no imputation of missing values).[50 51] Total cholesterol, low density lipoprotein (LDL), high density lipoprotein (HDL) and triglyceride (TG) values were extracted by the DCP from the GP medical record at baseline and 12-month follow up.

Sample size calculation

The original sample size calculation of 400 in each arm was based on the primary hypothesis that the intervention would lead to improved health and eHealth literacy, diet, physical activity, weight, and blood pressure. This was based on assumption of hypothesised effect sizes is described in the trial

protocol.[43] Sample size estimates were based on a two-sided test of significance at α=0.05. β= 0.8 and 20% loss to follow up. For Health Literacy (HLQ) domains 8 and 9 the anticipated effect size was 0.4 (based on means 3.7 (SD 0.9) and 3.9 (SD 0.8) respectively). For body mass index and systolic blood pressure the effect sizes were 0.1 and 0.2 respectively (based on means of 30 (SD 6) and 131 (SD 15).

Table 1. Patient Level Outcomes

Outcome	Instrument/contributing data	Primary or secondary outcome	Data collection method	Timepoint for collection		
				BL	6 months	12 months
Literacy and e-health literacy						
Health literacy	HLQ (Domains 8 and 9)	Primary	Patient survey - Administered via Telephone interview	x	x	x
eHealth literacy	eHEALS	Primary	Patient survey - Administered via Telephone interview	x	x	x
Biomedical risk factors (patient)						
Weight/height/waist circumference/BMI	Clinical record	Primary	DCP	x	-	x
Blood pressure	Clinical record	Primary	DCP	x	-	x
Lipids (total chol)	Clinical record	Secondary	DCP	x	-	x
Lifestyle risk factors (patient)						
Fruit and vegetable intake	Patient self-report – serves of fruit and vegetables per day	Secondary	Patient survey - Administered via Telephone interview	x	x	x
Level of physical activity	Patient self-report (Moderate and vigorous physical activity per week)	Secondary	Patient survey - Administered via Telephone interview	x	x	x
Quality of life						
QOL	EQ-5D-5L	Secondary	Patient survey - Administered via Telephone interview	x	-	x
Advice and referral						
Recall of advice and goal setting for diet, physical activity, weight loss	Patient survey	Secondary	Patient survey - Administered via Telephone interview	x	x	-

Outcome	Instrument/contributing data	Primary or secondary outcome	Data collection method	Timepoint for collection		
				BL	6 months	12 months
Referral to behaviour change programs for diet, physical activity, or weight loss	Patient survey	Secondary	Patient survey - Administered via Telephone interview	x	x	-
Economic data						
Delivery cost of intervention	Study documentation/budget	Secondary	Study administrative records/Facilitator Diary	Calculated for trial costs (payments for health checks, practice staff education and practice facilitation; cost of the app and telephone coaching)		
Health service costs	Medicare Benefits Scheme data	Secondary	Output from Services Australia	Data collected 01/10/2017 to 30/06/2020		
Prescription medication	Pharmaceutical Benefits Schedule data	Secondary	Output from Services Australia	Data collected 01/10/2017 to 30/06/2020		

ANALYSIS

Statistical analyses were conducted on the intention to treat (ITT) population for both primary and secondary outcome analyses. The ITT population was defined as all those recruited at baseline regardless of what intervention they received and what follow-up data was available.

Summary participant baseline characteristics and primary outcomes at baseline were compared between control and intervention groups using either chi-squared test, t test or Mann-Whitney test. Means and standard deviations were reported for continuous outcomes and the number and percentage were reported for dichotomous outcomes at baseline, 6 month and 12-month follow up.

To measure the effect of the intervention on the outcomes of interest (primary or secondary), we used difference-in-differences (DID) estimate as some of the outcomes at baseline were significantly different [52]. We used generalised-estimating equation (GEE) with Gaussian family and identity link function to estimate DID accounting for the cluster (general practice) level correlation.[53] We put an interaction term for intervention group and a dummy variable for before/after the follow up measurement (6 month follow up or 12 month follow up) in the GEE model and the coefficient of the interaction term was considered as a DID estimate.[54] Separate models were used for estimating DID at 6 month follow up and 12 months follow up. The DID estimate were adjusted for the potential confounders which were substantially different between control and intervention groups at baseline. To adjust for possible ceiling effects, we did stratified analysis for the health literacy scores by above or below the median score at baseline. We set 5% as a level of statistical significance. We used the R4.0.3 programming language and environment for the statistical analysis.[55]

Economic evaluation

The extracted cost data informed a cost consequence analysis, undertaken from the Australian healthcare system perspective. We categorized costs as follows: 1) services provided or requested

by GPs (excluding consultations by specialists), 2) services provided or requested by GPs or specialists (excluding services related to surgical procedures), and 3) pharmaceutical costs. The number of times participants visited a GP was also analysed. Costs and number of GP visits were calculated for the 12 months preceding and the 12 months following the enrolment date for each participant, from which unadjusted difference-in-difference estimates were derived for each of the cost categories, as well as aggregate costs and GP visits. Bootstrapping (using 1000 resamples) was used to represent the uncertainty around the difference-in-difference estimates.

RESULTS

We used the Consort extension for cluster trials statement to guide reporting (Supplementary file 1) and summarise the flow of participants (Figure 1) through the HeLP-GP trial. [56]

1.Baseline

We recruited 215 participants to the study (120 to the intervention group and 95 to the control group) through 22 practices (clusters). Baseline characteristics of the intervention group were similar to the control group except that the proportion of males was higher (66.3% vs 50.0%). Participants in both groups were predominantly aged between 46-65 years, with over a third having been born overseas (mostly from Europe or Asia) but only a third of those born overseas had arrived in Australia in the past 10 years and one in 6 of all participants spoke a language other than English. 39.5% has school qualifications only and 59% were employed. The median BMI was 33.3kgm^2. The intervention outcome measures at baseline were all similar to the control group except for health literacy which was lower (mean 4.0 vs 4.3 for domain 8, and 4.1 vs 4.3 for domain 9) (Table 2).

2. Intervention uptake

There was variable uptake of the intervention components by the 120 participants in the intervention group. Eighty-five attended the nurse health check and 73 also received either *mysnapp,* Get Healthy or both. Thirty-eight took up both *mysnapp* and Get-Healthy coaching. Of the 62 who adopted *mysnapp,* 60 participants set goals on 132 occasions to increase vegetables, 131 to increase fruit, 97 less take-away, 117 smaller portions, 73 less soft-drink, 129 to increase physical activity time. Of the 49 who adopted Get-Healthy telephone coaching, 31 set weight related goals.

Table 2: Baseline characteristics and outcomes by intervention and control

Variables	Responses	Control	Intervention	ICC[2]
n	215	95	120	
Age, mean (SD)		56.2 (9.6)	58.9 (8.8)	
Gender, n (%)	Female Male	32 (33.7) 63 (66.3)	60 (50.0) 60 (50.0)	
Place of Birth, n (%)	Australia Overseas	59 (62.1) 36 (37.9)	66 (55.0) 54 (45.0)	
Place of Birth, n (%)	Australia Europe Asia Other	59 (62.8) 16 (17.0) 11 (11.7) 7 (7.4)	66 (55.0) 15 (12.5) 13 (10.8) 25 (20.8)	
Year of arrival in Australia	Before 2000 On or after 2000[4]	24 (68.6)[3] 11 (31.4)	40 (81.6) 9 (18.4)	
Primary language at home, n (%)	English Other	88 (92.6) 7 (7.4)	96 (80.0) 24 (20.0)	
Hospital admissions in past 12 months, n (%)	Yes No	21 (22.1) 74 (77.9)	27 (22.5) 93 (77.5)	
State n (%)	NSW SA	35 (36.8) 60 (63.2)	99 (82.5) 21 (17.5)	
Qualification, n (%)	School only Professional or technical University degree Other	38 (40.0) 30 (31.6) 18 (18.9) 9 (9.5)	47 (39.2) 40 (33.3) 26 (21.7) 7 (5.8)	
Current working status, n (%)	Working Retired Other	56(58.9) 20(21.1) 19(20.0)	71(59.7) 28(23.5) 20(16.8)	
HLQ8 Ability to find good health information	Mean (SD) Median (IQR)	4.3 (0.5) 4.0 (4.0, 4.8)	4.0 (0.8) 4.0 (4.0, 4.6)	0.0262
HLQ9 Understanding health information well enough to know what to do	Mean (SD) Median (IQR)	4.3 (0.5) 4.0 (4.0, 4.8)	4.1 (0.7) 4.0 (4.0, 4.6)	0.0230
eHealth literacy	Mean (SD) Median (IQR)	29.2 (6.3) 32.0 (26.0, 32.0)	27.4 (7.3) 29.0 (23.5, 32.0)	0.0026
Diet	Mean (SD) Median (IQR)	3.1 (1.6) 3.0 (2.0, 4.0)	3.2 (1.6) 3.0 (2.0, 4.0)	-0.0288
Physical activity	Mean (SD) Median (IQR)	2.9 (2.3) 2.0 (1.0, 4.0)	2.7 (2.5) 2.0 (1.0, 4.0)	0.0176
Body Mass Index (BMI)	Mean (SD) Median (IQR)	34.9 (6.9) 33.0 (30.3, 36.3)	34.7 (5.3) 33.3 (30.5, 37.2)	0.0122
Waist	Mean (SD) Median (IQR)	112.9 (15.2) 110.0 (104.0, 121.0)	109.4 (13.6) 108.5 (99.0, 115.5)	0.0263
Systolic blood pressure	Mean (SD) Median (IQR)	130.7 (14.1) 132.0 (121.0, 140.0)	130.6 (14.6)	-0.0214

			131.0 (120.0, 139.0)	
Diastolic blood pressure	Mean (SD) Median (IQR)	81.3 (9.1) 81.0 (75.5, 87.5)	79.2 (11.9) 80.0 (70.0, 86.0)	0.0098

[1]Missing values: Health literacy domain 8 (n=4); Health literacy domain 9 (n=3); eHealth (n=3); diet (n=1); BMI (n=1); Waist circumference (n=78); Systolic blood pressure (n=1); Diastolic blood pressure (n=1)
[2] ICC = Intra-cluster correlation coefficient
[3]Denominator for these percentages is the number of people who born outside Australia (n=84;); there were 3 missing values for those who born outside Australia (n=87)
[4]There were 17.1% (n=6) and 2.0% (n=1) people who recently (on or after 2009) moved to Australia in control and intervention groups respectively.

3. Change between baseline and 12 months

3.1 Primary outcomes

For health literacy, at 6 months, there was a greater increase in the intervention group for the HLQ8 Ability to find good health information score (DID 0.22; 95% CI 0.01-0.44; Table 3). This difference was not sustained at 12 months. There was no difference in the HLQ9 Understanding health information or for eHealth literacy both at 6 and 12 months. For the group that was below the median at baseline, there was also an increase in the intervention group for the HLQ domain 8 and eHealth literacy score at 6 months, and in HLQ domain 9 score at both 6 and 12 months.

Table 3: Effect of intervention on health literacy score at 6 and 12 months of follow up- intent-to-treat (ITT) analysis

Outcome	Timepoint	Control		Intervention		Effect size[3]	Crude DID[1] (95% CI)[2]	Adj. DID[1] (95% CI)[2]
		n	Mean (SD)	n	Mean (SD)			
HLQ8 (Ability to find good health information)	Baseline	94	4.3 (0.5)	117	4.0 (0.8)		Ref	Ref
	6m follow up	79	4.3 (0.6)	68	4.2 (0.7)	0.31	0.22 (0.00, 0.44)	***0.22 (0.01, 0.44)***
	12m follow up	72	4.4 (0.5)	54	4.3 (0.6)	0.36	0.16 (-0.08, 0.39)	0.15 (-0.08, 0.39)
HLQ9 (Understanding health information well enough to know what to do)	Baseline	95	4.3 (0.5)	117	4.1 (0.7)		Ref	Ref
	6m follow up	79	4.4 (0.5)	68	4.3 (0.7)	0.16	0.11 (-0.09, 0.32)	0.13 (-0.07, 0.33)
	12m follow up	72	4.4 (0.5)	54	4.4 (0.5)	0.40	0.20 (-0.03, 0.43)	0.20 (-0.03, 0.44)
eHealth literacy	Baseline	93	29.2 (6.3)	119	27.4 (7.3)			

	6m follow up	78	28.3 (6.3)	68	28.0 (5.8)	0.25	1.60 (-0.40, 3.59)	1.60 (-0.39, 3.58)
	12m follow up	70	29.4 (5.9)	52	29.5 (6.1)	0.32	1.94 (-0.48, 4.36)	1.82 (-0.65, 4.29)
Below median value (baseline)								
HLQ8 (Ability to find good health information)	Baseline	53	3.9 (0.2)	73	3.6 (0.7)		Ref	Ref
	6m follow up	43	4.1 (0.5)	38	4.2 (0.6)	0.72	***0.34 (0.08, 0.60)***	***0.34 (0.09, 0.59)***
	12m follow up	43	4.3 (0.5)	32	4.2 (0.7)	0.33	0.19 (-0.06, 0.44)	0.19 (-0.06, 0.43)
HLQ9 (Understanding health information well enough to know what to do)	Baseline	49	3.9 (0.3)	71	3.7 (0.6)		Ref	Ref
	6m follow up	40	4.2 (0.5)	35	4.3 (0.7)	0.49	***0.27 (0.06, 0.48)***	***0.28 (0.08, 0.48)***
	12m follow up	40	4.3 (0.5)	29	4.5 (0.5)	0.8	***0.32 (0.12, 0.53)***	***0.33 (0.12, 0.54)***
eHealth literacy score	Baseline	41	23.8 (5.2)	69	22.5 (5.3)		Ref	Ref
	6m follow up	34	25.6 (7.1)	34	26.7 (4.8)	0.40	2.40 (-0.21, 5.02)	2.34 (-0.39, 5.06)
	12m follow up	27	26.5 (6.2)	25	29.5 (4.7)	0.42	***4.12 (1.48, 6.75)***	***3.77 (0.96, 6.59)***
Above median value (baseline)								
HLQ8 (Ability to find good health information)	Baseline	41	4.8 (0.3)	44	4.7 (0.3)		Ref	Ref
	6m follow up	35	4.4 (0.6)	28	4.2 (0.7)	0.15	-0.09 (-0.45, 0.27)	-0.44 (-2.27, 1.39)
	12m follow up	28	4.5 (0.5)	20	4.4 (0.6)	0	-0.04 (-0.41, 0.33)	-0.18 (-2.04, 1.67)
HLQ9 (Understanding health information well enough to know what to do)	Baseline	46	4.7 (0.3)	46	4.7 (0.3)		Ref	Ref
	6m follow up	39	4.6 (0.4)	31	4.3 (0.7)	0.53	-0.27 (-0.55, 0.01)	-0.25 (-0.54, 0.03)
	12m follow up	32	4.5 (0.4)	23	4.4 (0.6)	0.39	-0.17 (-0.41, 0.07)	0.17 (-0.41, 0.08)
eHealth literacy score	Baseline	52	33.5 (3.0)	50	34.1 (3.1)		Ref	Ref
	6m follow up	42	30.8 (4.3)	33	29.5 (6.5)	0.35	-1.90 (-4.50, 0.70)	-1.77 (-4.36, 0.82)
	12m follow up	42	31.1 (4.9)	26	30.0 (7.0)	0.28	-1.70 (-5.25, 1.85)	-1.68 (-5.18, 1.81)

[1]DID = Difference in Differences. [2] adjusted for age, gender, and state. [3] Cohen's d

There was no statistically significant effect of the intervention on BMI or BP at 12 months (Table 4). The intervention group's mean BMI decreased but mean waist circumference at 12 months increased (DiD 7.08, 95% CI 2.26-11.90).

Table 4: Effect of intervention on anthropometry and blood pressure at 12 months of follow up- intent-to-treat (ITT) analysis

Outcome	Timepoint	Control		Intervention		Effect size	Crude DID (95% CI)	Adj. DID (95% CI)[1]
		n	Mean (SD)	n	Mean (SD)			
BMI, kg/m^2	Baseline	94	34.9 (6.9)	120	34.7 (5.3)		Ref	Ref
	12m follow up	49	32.9 (5.7)	52	34.3 (6.0)	0.27	1.45 (-0.16, 3.06)	1.22 (-0.46, 2.90)
Waist circumference, cm	Baseline	49	112.9 (15.2)	88	109.4 (13.6)		Ref	Ref
	12m follow up	20	107.0 (9.6)	49	112.4 (15.6)	0.62	8.24 (2.73, 13.74)	7.08 (2.26, 11.90)
Systolic blood pressure, mmHg	Baseline	95	130.7 (14.1)	119	130.6 (14.6)		Ref	Ref
	12m follow up	64	133.0 (15.3)	50	130.8 (14.6)	0.17	-2.13 (-8.18, 3.92)	-1.48 (-7.34, 4.38)
Diastolic blood pressure, mmHg	Baseline	95	81.3 (9.1)	119	79.2 (11.9)		Ref	Ref
	12m follow up	64	82.7 (8.6)	50	77.6 (9.1)	0.12	-2.84 (-5.94, 0.25)	-3.18 (-6.50, 0.14)

[1]Adjusted for age, gender, and state

3.2 Secondary outcomes

There was a greater increase in diet score in the intervention group at 6 months (DiD 0.98; 95% CI 0.50-1.47) due to an increase in fruit intake (DiD 0.50; 95% CI 0.20-0.80), however, this was not sustained at 12 months. There was no statistically significant effect of the intervention on physical activity score at 6 months (Table 5).

Table 5: Effect of intervention on physical activity and diet score at 6 and 12 months of follow up- intent-to-treat (ITT) analysis

Outcome	Timepoint	Control		Intervention		Effect size[2]	Crude DID (95% CI)	Adj. DID (95% CI)[1]
		n	Mean (SD)	n	Mean (SD)			
Total physical activity score	Baseline	95	2.9 (2.3)	120	2.7 (2.5)		Ref	Ref
	6m follow up	79	3.6 (2.6)	68	3.0 (2.3)	0.16	-0.45 (-1.06, 0.15)	-0.56 (-1.19, 0.06)
	12m follow up	72	3.6 (2.5)	54	3.9 (2.2)	0.21	0.47 (-0.47, 1.42)	0.38 (-0.59, 1.35)
Diet score	Baseline	95	3.1 (1.6)	119	3.2 (1.6)		Ref	Ref
	6m follow up	79	3.1 (1.7)	68	4.1 (1.5)	0.56	***0.98 (0.48, 1.48)***	***0.98 (0.50, 1.47)***
	12m follow up	72	3.8 (1.5)	54	3.9 (1.9)	0	-0.04 (-0.51, 0.44)	0.05 (-0.41, 0.50)

Vegetable intake	Baseline	95	1.8 (1.2)	120	1.8 (1.2)		Ref	Ref
	6m follow up	79	1.9 (1.3)	68	2.3 (1.3)	0.31	***0.46 (0.02, 0.90)***	***0.46 (0.03, 0.89)***
	12m follow up	72	2.4 (1.2)	54	2.3 (1.4)	0.46	-0.14 (-0.53, 0.26)	-0.07 (-0.44, 0.31)
Fruit intake	Baseline	95	1.3 (0.9)	119	1.4 (1.0)		Ref	Ref
	6m follow up	79	1.2 (0.9)	68	1.8 (0.8)	0.59	***0.49 (0.20, 0.79)***	***0.50 (0.20, 0.80)***
	12m follow up	72	1.4 (0.9)	54	1.6 (0.9)	0.11	0.03 (-0.23, 0.30)	0.05 (-0.22, 0.32)

[1]DID = Difference in Differences. [2] Cohen's d

High Density Lipoprotein (HDL) fell in both groups by 7% (control) and 8% (intervention). However, total cholesterol, LDL and triglycerides all fell in the intervention group (Table 6). There were no statistically significant effects of the intervention on lipids (Total cholesterol, Low Density Lipoprotein (LDL), High Density Lipoprotein (HDL) or Triglyceride (TG) or quality of life (EQ-5D-5L) at 12 months. Quality of life did not change in control or the intervention group (Table 6).

At 6 months, the control group self-reported a decrease in the frequency of receiving advice on physical activity whereas the level stayed the same in intervention group (DiD 16.3%, 95% CI 1.4%-31.1%). Similarly, the frequency of weight loss counselling or referral for physical activity fell in the control group but both increased in the intervention group (weight loss counselling DiD 27.8%, 95% CI 8.8%-46.8%; physical activity referral DiD 13.3%, 95% CI 2.32%-24.2%). There were no statistically significant differences between the groups in frequency of receiving information on healthy eating or being referred for healthy eating or weight loss (Table 7).

Table 6: Effect of intervention on the secondary outcomes intent-to-treat (ITT) analysis [who had two different measurements at baseline and 12 months

Outcome	Timepoint	Control		Intervention		Crude DID (95% CI)	Adj. DID (95% CI)[1]
		n	Mean (SD)	n	Mean (SD)		
HDL cholesterol	Baseline	90	1.4 (0.4)	109	1.3 (0.4)	Ref	Ref
	12m follow up	43	1.3 (0.3)	31	1.2 (0.4)	0.02 (-0.09, 0.14)	0.04 (-0.08, 0.16)
LDL cholesterol	Baseline	77	2.8 (0.9)	108	2.9 (0.8)	Ref	Ref
	12m follow up	25	2.9 (1.2)	28	2.7 (0.7)	-0.28 (-0.71, 0.15)	-0.26 (-0.67, 0.15)
Triglyceride	Baseline	92	1.7 (0.8)	114	1.7 (0.8)	Ref	Ref
	12m follow up	46	1.7 (0.8)	32	1.5 (0.8)	-0.20 (-0.50, 0.09)	-0.22 (-0.52, 0.09)
Total cholesterol	Baseline	93	4.9 (0.9)	115	4.9 (1.0)	Ref	Ref
	12m follow up	51	4.9 (1.2)	33	4.6 (0.8)	-0.32 (-0.65, 0.01)	-0.31 (-0.64, 0.01)
Quality of life change (Mean (SD))	Baseline	95	0.9 (0.1)	120	0.9 (0.1)	Ref	Ref
	12m follow up	72	0.9 (0.2)	54	0.9 (0.1)	0.04 (0.00, 0.08)	0.04 (0.00, 0.08)

[1]Adjusted for age, gender, and state

Table 7: Effect of intervention on the secondary outcomes (from Survey data)- intent-to-treat (ITT) analysis

Outcome	Timepoint	Control		Intervention		Crude DID (95% CI)	Adj. DID (95% CI)[1]
		n	% (n)	n	% (n)		
Info or advice healthy eating	Baseline	95	27.4 (26)	120	44.2 (53)	Ref	Ref
	6m follow up	79	17.7 (14)	68	39.7 (27)	5.01 (-18.73, 28.76)	3.30 (-21.10, 27.69)
Info or advice physical activity	Baseline	95	30.5 (29)	120	40.8 (49)	Ref	Ref
	6m follow up	79	11.4 (9)	68	39.7 (27)	***18.03 (3.19, 32.86)***	***16.27 (1.40, 31.14)***
Info or advice weight loss	Baseline	95	34.7 (33)	120	43.3 (52)	Ref	Ref
	6m follow up	79	13.9 (11)	68	51.5 (35)	***29.07 (10.41, 47.74)***	***27.83 (8.83, 46.84)***
Referral to healthy eating	Baseline	95	11.6 (11)	120	10.0 (12)	Ref	Ref
	6m follow up	79	10.1 (8)	68	22.1 (15)	13.46 (-3.25, 30.16)	14.46 (-2.35, 31.27)
Referral to physical activity	Baseline	95	8.4 (8)	120	3.3 (4)	Ref	Ref
	6m follow up	79	5.1 (4)	68	13.2 (9)	***13.24 (2.45, 24.04)***	***13.28 (2.32, 24.24)***
Referral to weight loss	Baseline	95	7.4 (7)	120	7.5 (9)	Ref	Ref
	6m follow up	79	7.6 (6)	68	10.3 (7)	2.49 (-7.68, 12.66)	2.50 (-7.75, 12.74)

Adjusted for age, gender, and state

3.3 Economic analysis

The intervention costs included fixed (development of the mysnapp app and the online training modules) and variable (practice facilitation visits, PN health check payments and telephone coaching sessions) costs. Across the 120 patients in the intervention group, the per patient fixed and variable costs were $787 and $558, respectively, generating a total intervention cost per patient of $1,345.

The baseline characteristics and outcome measurements of participants in the cohort providing consent to access their cost data (n=65; 33 in the intervention group and 32 in the control group) and full cohort (n=215) were similar (see Supplementary tables S1). Two participants were excluded, one due to having only six months of cost data available after the enrolment date, and one due to extremely high pharmaceutical costs in the 12 months prior to enrolment for the treatment of age-related macular degeneration, a condition unrelated to the focus of the intervention.

Supplementary table S1 (c) presents the mean crude cost DIDs between the 12 months prior and post recruitment to the trial. Excluding the outlier participant with high pharmaceutical costs, mean costs were higher in the intervention group in all cost categories, but there were no statistically significant differences between the intervention and control groups for the alternative costs categories (GP costs, GP and specialist costs and PBS costs) nor for the aggregated cost. Including the participant with outlier PBS costs, mean costs are lower in the intervention group for comparisons including PBS cost data, but the confidence intervals remain very wide (Supplementary table S1 d).

There were no adverse events or harms were reported during the trial.

Discussion

In this trial of an intervention involving a PN health check, a mobile app and phone coaching in primary health care, we found positive effects on some outcomes (health literacy and diet at 6 months) but not on

physical activity, weight or other outcomes. The primary hypothesis was that the intervention would lead to improved health literacy, health behaviours and positive changes in weight and other physiological measures. Health literacy improved in the intervention group at 6 months, although there was no further change by 12 months. Additionally, eHealth literacy improved only among those whose baseline health literacy was below the median. Although similar proportions of participants in both groups set goals for diet and physical activity, patients in the intervention group were more likely to report an improved diet score (due to a greater increase in fruit intake) compared to the control group. There was no difference in the physical activity score between the intervention and control groups. A lack of change in physical activity outcomes may reflect a need for group rather than individual approaches to physical activity promotion for people from migrant or low socioeconomic backgrounds.[57] The intervention was tailored to patients' needs and motivation but was not codesigned or specifically tailored to differences in individual cultural and religious beliefs and practices which may mediate changes in physical activity.[58]

Although there were small changes in health literacy and diet, the intervention was not associated with differences in clinical endpoints such as BMI, BP, lipids, or in quality of life after adjustment for age, gender, and State. This may be because we did not recruit our required sample size or because the intervention lacked sufficient intensity and duration, as has been observed in other studies.[10] The lack of change in physical activity, especially at 12 months, may also have contributed, and changes in BP and lipids may have been confounded by treatment with medications since most patients' BP and lipids were within recommended guideline levels at baseline. Further research is thus required to optimise and evaluate the interventions.

Only two thirds of the patients in the intervention group received the full intervention (i.e., received the health check with *mysnapp* and/or Get Healthy coaching components). This was influenced by patient choice through discussion with their clinicians reflecting the real world setting of Australian general practice. This variable engagement with the different components of the intervention may

have reduced its overall effectiveness. However, patients in the intervention group were more likely to recall being offered information or referral for physical activity or weight loss counselling than their counterparts in the control group.

In the cost analyses, low recruitment made the study insufficiently powered to draw meaningful conclusions. There was no evidence of difference in numbers of GP visits, MBS, or PBS costs between the groups over the period of the study. Despite some positive changes in some behavioural endpoints (health literacy and diet), there were no changes in clinical endpoints such as weight or other physiological measures, or in quality of life at 12 months. Trials of weight loss in primary care often show little or no change.[59] However previous studies involving the use of apps and behavioural counselling by health care providers have proven successful even in low socioeconomic groups where goals were individually tailored to the patient's level of health literacy and the intervention were of moderate to high intensity.[11] This suggests that the intervention in the current study may have been more effective if it was more tailored to the patient's individual health literacy needs.

There were several limitations to our study. Like other studies, this study failed to achieve its planned sample size due to major challenges recruiting practices and patients despite considerable effort and an extension to the time frame of the study. [60] Post-hoc power calculations showed that with a sample of 100 in each arm we would be able to detect a mean difference in diet score of 0.2 to 0.3 (serves per day) and a mean difference in the health literacy scale scores of 0.5 to 0.6. Both these differences are less than in previous studies and may not be clinically meaningful.[43 61] For all the other measures the differences that were able to be detected were larger than expected from moderate intensity interventions (mean PA score difference of 1.5, mean BMI difference of 5.5kg/m^2, mean BP change of 15mmHg, mean cholesterol difference of 0.8)[62]. Our recruitment

challenges suggest the need for greater efforts to increase the perceived benefits (such as improved access to quality care) and decrease barriers (especially time) associated with participation.

There were five primary outcomes (including two HLQ domains, eHeals, weight and blood pressure). Furthermore the health literacy measures were assessed at both 6 and 12 months increasing the likelihood of a type 1 error (ie finding a significant difference). The study was conducted in only two urban areas of Australia and the findings may not therefore be generalised to other communities such as rural areas. Lastly the measures of health literacy, diet and physical activity had some limitations, and may have not been sensitive enough to capture all change due to the intervention.

Assessment of patient socioeconomic variables and health literacy indicate that the study fell short in recruiting its target population of people with low socioeconomic status and low health literacy. At baseline, levels of health literacy were higher than anticipated and were in fact comparable with overweight or obese patients in the general population who were part of the national health literacy survey.[63] Our figures for 'born overseas' are higher than the Australian average but 'language spoken at home' and 'employment status' are similar to the Australian average.[64] It is therefore possible that the requirements for written consent and engagement with the research study may have tended to discourage those with lower English language literacy, as has been found in some research.[65] Furthermore, uptake by the participants in our study in the various components of the intervention varied. Previous research has identified that socioeconomic factors have impacts on intervention/trial uptake, intervention adherence, and trial attrition.[66] Future research could consider using codesign principles to help better engage specific population groups, as well as general practitioners and practice nurses working with these groups, in the research design and development of the intervention.[67]

Conclusion

This trial of a multi-faceted intervention designed to support better preventive care for overweight and obese patients from low socioeconomic areas in the real-world environment of Australian general practice showed some short-term improvement in health literacy and diet but did not show any change in weight or other physiological variables. While there was evidence that the intervention was implemented as planned, there was variable uptake of its components, and it may therefore have been of insufficient intensity to achieve sustained change in weight and other primary outcomes. However, any preventive intervention in primary care needs to be sustainable and tailored to its capacity.

Data sharing statement

Individual participant data that underlie the results reported in this article, will be available within 12 months of publication after deidentification (text, tables, figures, and appendices) to investigators whose proposed use of the data has been approved by our Ethics Committee.

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Competing Interest Statement

None declared

Author Contributions

MH was the chief investigator and led the development of and implementation of the study, interpreted the data and drafted the manuscript.

SMP developed the trial processes, coordinated the trial across sites, contributed to the development of the data collection tools, collected and analysed data and drafted the manuscript.

MB cleaned the data, designed the analysis plan, conducted the analysis, interpreted the data and contributed to the draft of the manuscript.

NS led the development and implementation of the study in SA, was instrumental in designing the DCP module for the trial, interpreted the data and contributed to the manuscript.

EDW contributed to the design of the study, developed the training modules, contributed to the interpretation of the data and the manuscript.

NZ contributed to the trial design, trial implementation and interpretation of the data for the manuscript.

JK contributed to the trial design, designed the economic analysis and interpreted this data for the manuscript.

AK cleaned the DCP data, designed the analysis plan, conducted the analysis, developed the data tables and contributed to the draft of the manuscript.

DN contributed to the trial design, trial implementation and interpretation of the data for the manuscript, particularly the health literacy content.

JR conducted the economic analysis and interpreted the data for inclusion in the manuscript.

STL contributed to the trial design, trial implementation and interpretation of the data for the manuscript.

CM liaised with SA practices to collect patient and practice data, collated the data, and contributed to the interpretation of the data for the manuscript.

OF was instrumental in designing the DCP module for the trial and troubleshooting data collection using DCP, interpreted the outcome data and contributed to the manuscript.

AT liaised with NSW practices to collect patient and practice data, collated and cleaned the data and contributed to the management and interpretation of the data.

RO contributed to the trial design, particularly the tools to collect patient data and interpretation of data particularly the health literacy outcome data. He contributed to the draft manuscript.

AL designed and developed the mysnapp app and the data collected via the application and interpretation and plan for analysing this data

All authors approved the final version for publication and agree to be accountable for the integrity of the content, and responsible for any issues that arise from publication of the trial data.

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Ethics Approval

This trial was approved by the University of New South Wales Human Research Ethics Committee (HC17474). The University of Adelaide Human Research Ethics committee ratified this approval.

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Figure legend

Figure 1: Consort flow diagram

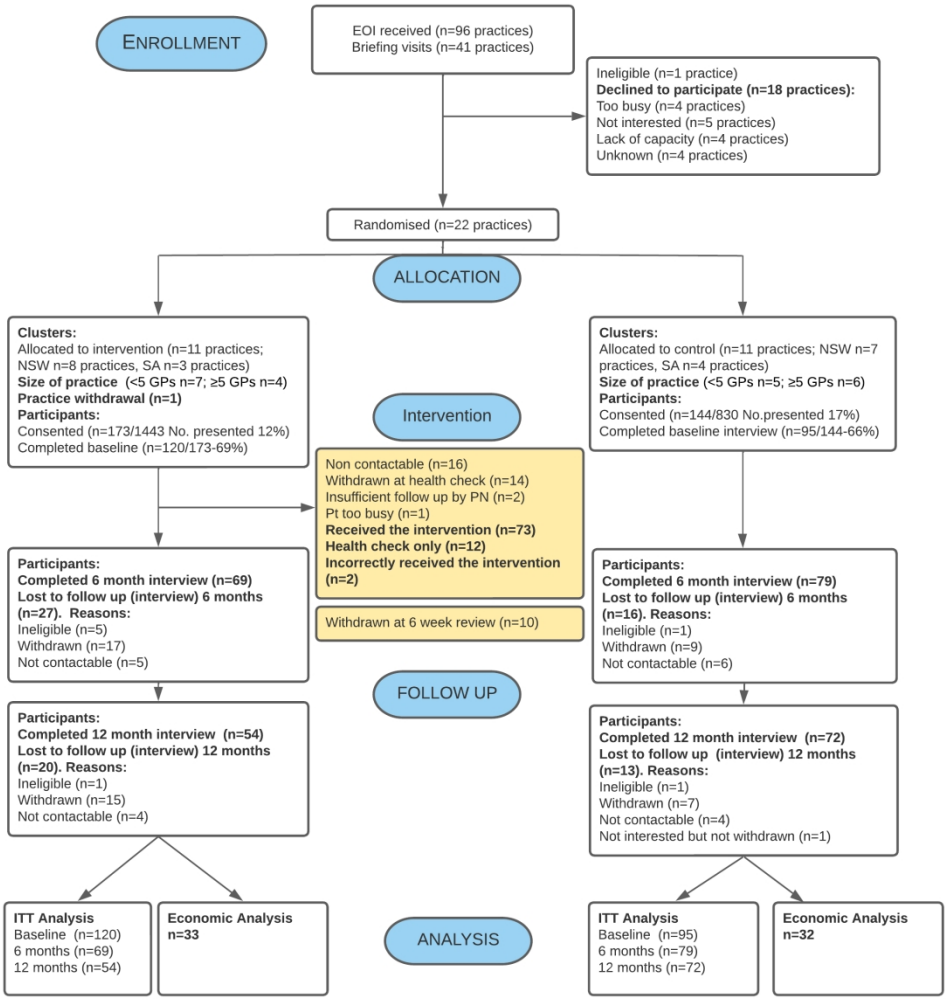

Figure 1 Consort Flow Diagram

Supplementary Tables S1

Table S1(a): Baseline characteristics by intervention and control for full cohort and cohort for cost analysis

Variables	Responses	Full cohort		Cohort for cost analysis	
		Control	Intervention	Control	Intervention
n	215	95	120	32	33
Age, mean (SD)		56.2 (9.6)	58.9 (8.8)	61.0 (9.8)	60.5 (8.1)
Gender, n(%)	Female Male	32 (33.7) 63 (66.3)	60 (50.0) 60 (50.0)	10 (31.3) 22 (68.7)	17 (51.5) 16 (48.5)
Place of Birth, n(%)	Australia Overseas	59 (62.1) 36 (37.9)	66 (55.0) 54 (45.0)	17 (53.1) 15 (46.9)	20 (60.6) 13 (39.4)
Primary language at home, n(%)	English Other	88 (92.6) 7 (7.4)	96 (80.0) 24 (20.0)	31 (96.9) 1 (3.1)	25 (75.8) 8 (24.2)
Hospital admissions in past 12 months, n(%)	Yes No	21 (22.1) 74 (77.9)	27 (22.5) 93 (77.5)	8 (25.0) 24 (75.0)	7 (21.2) 26 (78.8)
State	NSW SA	35 (36.8) 60 (63.2)	99 (82.5) 21 (17.5)	6 (18.8) 26 (81.2)	28 (84.9) 5 (15.1)

Table S1(b): Outcome measurement at baseline by control and intervention for full cohort and cohort for cost analysis

Variables	Measure[1]	Full cohort		Cohort for cost analysis	
		Control	Intervention	Control	Intervention
n	215	95	120	32	32
Health literacy domain 8	Mean (SD) Median (IQR)	4.3 (0.5) 4.0 (4.0, 4.8)	4.0 (0.8) 4.0 (4.0, 4.6)	4.4 (0.5) 4.0 (4.0, 4.8)	4.4 (0.5) 4.0 (4.0, 4.8)
Health literacy domain 9	Mean (SD) Median (IQR)	4.3 (0.5) 4.0 (4.0, 4.8)	4.1 (0.7) 4.0 (4.0, 4.6)	4.3 (0.5) 4.1 (4.0, 4.8)	4.4 (0.5) 4.0 (4.0, 5.0)
eHealth	Mean (SD) Median (IQR)	29.2 (6.3) 32.0 (26.0, 32.0)	27.4 (7.3) 29.0 (23.5, 32.0)	29.2 (6.6) 32.0 (26.0, 32.0)	29.6 (6.0) 30.5 (25.5, 32.0)
Diet	Mean (SD) Median (IQR)	3.1 (1.6) 3.0 (2.0, 4.0)	3.2 (1.6) 3.0 (2.0, 4.0)	3.4 (1.5) 3.0 (2.0, 4.0)	3.4 (1.5) 3.0 (2.0, 5.0)
Physical activity	Mean (SD) Median (IQR)	2.9 (2.3) 2.0 (1.0, 4.0)	2.7 (2.5) 2.0 (1.0, 4.0)	3.6 (2.3) 4.0 (2.0, 4.0)	3.0 (2.6) 2.0 (1.0, 4.0)
BMI	Mean (SD) Median (IQR)	34.9 (6.9) 33.0 (30.3, 36.3)	34.7 (5.3) 33.3 (30.5, 37.2)	31.9 (3.1) 30.9 (29.9, 33.8)	33.8 (4.8) 33.3 (30.5, 35.4)
Waist	Mean (SD) Median (IQR)	112.9 (15.2) 110.0 (104.0, 121.0)	109.4 (13.6) 108.5 (99.0, 115.5)	107.4 (10.1) 107.0 (98.0, 116.0)	114.6 (14.6) 114.0 (100.0, 117.0)
Systolic blood pressure	Mean (SD) Median (IQR)	130.7 (14.1) 132.0 (121.0, 140.0)	130.6 (14.6) 131.0 (120.0, 139.0)	127.6 (13.0) 127.0 (120.5, 137.5)	131.3 (13.7) 131.5 (120.0, 140.0)
Diastolic blood pressure	Mean (SD) Median (IQR)	81.3 (9.1) 81.0 (75.5, 87.5)	79.2 (11.9) 80.0 (70.0, 86.0)	79.4 (8.3) 79.5 (74.0, 85.0)	79.5 (15.7) 79.0 (70.0, 89.5)

Table S1(c): Costs 12 months before and 12 months after enrolment date by control and intervention (excluding outlier)

Outcome	Timepoint	Control			Intervention			Crude DID (95% CI)
		n	Mean (SD)	Mean Diff (95% CI)	n	Mean (SD)	Mean Diff (95% CI)	
GP costs	12m before enrolment	32	$1,109 ($485)	Ref	32	$912 ($564)	Ref	Ref
	12m after enrolment	32	$1,088 ($683)	-$21 (-$248, $207)	32	$931 ($579)	$20 (-$215, $254)	-$40 (-$353, $273)
GP & specialist costs	12m before enrolment	32	$1,268 ($571)	Ref	32	$1,158 ($677)	Ref	Ref
	12m after enrolment	32	$1,345 ($1,013)	$77 (-$247, $400)	32	$1,275 ($837)	$116 (-$220, $453)	-$40 (-$491, $412)
PBS Costs	12m before enrolment	32	$315 ($403)	Ref	32	$289 ($366)	Ref	Ref
	12m after enrolment	32	$328 ($458)	$12 (-$52, $77)	32	$320 ($479)	$32 (-$62, $125)	-$19 (-$131, $93)
GP & PBS costs	12m before enrolment	32	$1,424 ($672)	Ref	32	$1,201 ($754)	Ref	Ref
	12m after enrolment	32	$1,416 ($923)	-$8 (-$259, $243)	32	$1,252 ($824)	$51 (-$217, $319)	-$59 (-$412, $293)
GP, specialist & PBS costs	12m before enrolment	32	$1,583 ($751)	Ref	32	$1,447 ($801)	Ref	Ref
	12m after enrolment	32	$1,672 ($1,203)	$89 (-$257, $435)	32	$1,595 ($1,037)	$148 (-$205, $502)	-$59 (-$535, $417)
Number of GP visits	12m before enrolment	32	10.9 (0.9)	Ref	32	11.0 (1.1)	Ref	Ref
	12m after enrolment	32	11.3 (1.0)	0.3 (-1.2, 1.9)	32	10.7 (1.0)	-0.3 (-2.5, 2.0)	0.7 (-2.1, 3.4)

Table S1 (d): Costs and number of GP visits 12 months before and 12 months after enrolment date by control and intervention

Outcome	Timepoint	Control			Intervention			Crude DID (95% CI)
		n	Mean (SD)	Mean Diff (95% CI)	n	Mean (SD)	Mean Diff (95% CI)	
GP costs	12m before enrolment	32	$1,109 ($485)	Ref	33	$897 ($561)	Ref	Ref
	12m after enrolment	32	$1,088 ($683)	-$21 (-$248, $207)	33	$924 ($571)	$26 (-$181, $234)	-$47 (-$367, $273)
GP & specialist costs	12m before enrolment	32	$1,268 ($571)	Ref	33	$1,149 ($669)	Ref	Ref
	12m after enrolment	32	$1,345 ($1,013)	$77 (-$247, $400)	33	$1,257 ($830)	$108 (-$192, $407)	-$31 (-$491, $429)
PBS Costs	12m before enrolment	32	$315 ($403)	Ref	33	$445 ($969)	Ref	Ref
	12m after enrolment	32	$328 ($458)	$12 (-$52, $77)	33	$348 ($497)	$97 (-$362, $167)	$110 (-$158, $378)
GP & PBS costs	12m before enrolment	32	$1,424 ($672)	Ref	33	$1,343 ($1,103)	Ref	Ref
	12m after enrolment	32	$1,416 ($923)	-$8 (-$259, $243)	33	$1,271 ($819)	$71 (-$403, $261)	$63 (-$364, $490)
GP, specialist & PBS costs	12m before enrolment	32	$1,583 ($751)	Ref	33	$1,595 ($1,157)	Ref	Ref
	12m after enrolment	32	$1,672 ($1,203)	$89 (-$257, $435)	33	$1,605 ($1,022)	$10 (-$397, $417)	$79 (-$472, $630)
Number of GP visits	12m before enrolment	32	10.9 (0.9)	Ref	33	10.9 (1.0)	Ref	Ref
	12m after enrolment	32	11.3 (1.0)	0.3 (-1.2, 1.9)	33	10.6 (0.9)	-0.3 (-2.5, 2.0)	0.6 (-2.0, 3.2)

Supplementary 1. CONSORT checklist when reporting a cluster randomised trial: HeLP GP Trial.

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	Abstract
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	Page 3
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	Page 3
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	Page 3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		Page 8
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	Page 3/4
	4b	Settings and locations where the data were collected		Page 3/4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	Page 6/7
Outcomes	6a	Completely defined pre-specified primary and	Whether outcome measures pertain to the cluster level, the	Table 1

		secondary outcome measures, including how and when they were assessed	individual participant level or both	
	6b	Any changes to trial outcomes after the trial commenced, with reasons		NA
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	Page 9
	7b	When applicable, explanation of any interim analyses and stopping guidelines		NA
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		Page 5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	Page 5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	Page 5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	See 10a – 10c
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	Page 5

	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	Page 5
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	Page 8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		NA
	11b	If relevant, description of the similarity of interventions		NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	Page 13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		Page 13
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up		Page 4/5

	14b	Why the trial ended or was stopped		NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Table 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Page 14
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	ICC included in Table 2 Effect size included in Tables 3, 4 and 5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		Absolute differences provided
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		**NA**
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		NA
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		Page 23/24
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	Page 24
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and		Conclusions

		considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	Title page
Protocol	24	Where the full trial protocol can be accessed, if available	Title page
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 25

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Preventing chronic disease in overweight and obese patients with low health literacy using eHealth and teamwork in primary health care (HeLP-GP): A cluster randomised controlled trial.

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Preventing chronic disease in overweight and obese patients with low health literacy using eHealth and teamwork in primary health care (HeLP-GP): A cluster randomised controlled trial.

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Word Count: 4319

ABSTRACT

Objectives

To evaluate a multifaceted intervention on diet, physical activity and health literacy of overweight and obese patients attending primary care.

Design

A pragmatic two arm cluster randomised controlled trial.

Setting

Urban general practices in lower socio-economic areas in Sydney and Adelaide.

Participants

We aimed to recruit 800 patients in each arm. Baseline assessment was completed by 215 patients (120 intervention and 95 control).

Intervention

A practice nurse led preventive health check, a mobile application and telephone coaching.

Primary and secondary outcome measures

Primary outcomes were measured at baseline, 6 and 12 months and included patient health and eHealth literacy, weight, waist circumference and blood pressure. Secondary outcomes included changes in diet and physical activity, preventive advice and referral, blood lipids, quality of life and costs. Univariate and multivariate analysis of difference-in-difference estimates for each outcome were conducted.

Results

At 6 months, the intervention group, compared with the control group, demonstrated a greater increase in HLQ domain 8 score (Ability to find good health information; mean DiD 0.22; 95% CI 0.01-0.44). There were similar differences for domain 9 score (Understanding health information well enough to know what to do) among patients below the median at baseline. Differences were reduced and non-statistically significant at 12 months. There was a small improvement in diet scores at 6 months (DiD 0.78 (0.10-1.47; p=0.026) but not at 12 months. There were no differences in e-health literacy, physical activity scores, BMI, weight, waist circumference or blood pressure.

Conclusions

Targeted recruitment and engagement were challenging in this population. While the intervention was associated with some improvements in health literacy and diet, substantial differences in other outcomes were not observed. More intensive interventions and using codesign strategies to engage the practices earlier may produce a different result. Codesign may also be valuable when targeting lower socioeconomic populations.

Trial Registration

This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12617001508369). http://www.ANZCTR.org.au/ACTRN12617001508369.aspx. Date registered 26 October 2017.

Trial Protocol

The protocol for this trial has been published (open access) https://bmjopen.bmj.com/content/8/6/e023239

Key words: Primary Care, Preventive Medicine, Health Services Administration and Management.

Article Summary

Strengths and limitations of this study

- The cluster randomised design allowed testing of the nurse led intervention among patients without contamination.
- Recruitment of practices and patients did not meet our planned sample size.
- We noted variable uptake of the intervention components among patients reflecting real world general practice
- The measures used to assess health literacy, diet and physical activity had some limitations.
- The study was conducted in only two urban areas of Australia and the findings may not therefore be generalised to other communities, such as rural areas.

INTRODUCTION

Obesity is a complex health issue and is influenced by biological, environmental, social, and psychological factors.[1] Overweight and obesity account for 8.4% of the burden of disease being a risk factor for 11 types of cancer, three cardiovascular conditions, chronic kidney disease, diabetes, dementia, gallbladder disease, fatty liver, gout, back pain and osteoarthritis.[2] In 2017/18, 67% of the Australian population were overweight (BMI 25-29 kg/m^2; 35.6%) or obese (BMI 30+ kg/m^2; 31.3%) with those who were more socially disadvantaged being more likely to be overweight or obese.[3] Within Australia, rates of overweight and obesity peak for men at age 55 to 64 years (83.6%) and for women at 65 to 74 years (73.3%).[4]

Current Australian guidelines recommend that people who are overweight and obese attending general practice undergo routine measurements (BMI and waist circumference) and are engaged in discussions about lifestyle risk factors and positive messaging to improve health and wellbeing.[5] Behavioural interventions in primary care have been demonstrated to achieve a 5-7% improvement in weight, blood pressure (BP) or lipids for patients, potentially preventing or delaying the onset of Type 2 diabetes and cardiovascular disease.[6] A recent systematic review and meta-analysis supports weight loss programs delivered by primary care practitioners as they provide effective weight loss and reduction in waist circumference.[7] Multicomponent intensive behavioural interventions (delivered by various clinicians and provided through group, individual, technology or print based methods), has been recommended for patients with a BMI of 30 or higher[8]. Health coaching provided by a trained professional has become a popular tool to address weight through behaviour change strategies[9] and high intensity behavioural counselling (12 or more sessions per year) delivered in person, by phone or electronically) is accepted to produce clinically meaningful weight loss[10].

The Track Study[11] which combined tailored weight related behaviour change goals for patients as a basis for self-monitoring with 18 coaching calls over 12 months found intervention patients

significantly more likely to lose ≥ 5% of their baseline weight at 6 months and 12 months. A recent retrospective analysis of 25,000 people receiving blended care behaviour change interventions (a combination of digital care and coaching)[12] supports the use of these interventions for weight loss but highlights the need for more understanding as to which elements would be best delivered by health coaches and which can be delegated to a digital device.

Patients generally accept their GPs' role in management of overweight and obesity[13], however lower socioeconomic groups tend to be less likely to take up weight management programs.[14 15] Low functional health literacy (i.e., health-related reading and numeracy) is more common in socioeconomically disadvantaged populations and is associated with an increased likelihood of overweight and obesity.[16 17] It is also a potential barrier to the uptake and effectiveness of a range of preventive interventions that mediate change in lifestyle behaviours.[18 19] Patients with low health literacy are less likely to engage in health promoting behaviours[20-22] and attend or complete programs to which they have been referred.[23 24] Interventions with multiple components to improve health literacy for behavioural risk factors have been shown to be more effective at improving nutritional health literacy in primary care than those with single components.[6] Other barriers to delivering weight loss management have also been identified, including low confidence levels of clinicians in obesity management [25], stigmatisation of patients[26] and lost opportunities by providers to initiate earlier, effective weight loss conversations.[27]

OBJECTIVES

The HeLP GP trial aimed to evaluate a multifaceted intervention provided to overweight and obese patients attending primary care. The primary hypothesis was that the intervention would lead to improved health literacy, eHealth literacy, physiological risk factors, lifestyle behaviours and quality of life.

METHODS

Trial Design

A pragmatic, two-arm, unblinded cluster randomised controlled trial. This design was chosen to provide protection against contamination within sites (general practices) as practice staff were providing the intervention. Primary and secondary outcomes were assessed at the patient level.

Participants and setting

The trial was conducted in general practices located in metropolitan and urban fringe areas of south-western and western Sydney in New South Wales and Adelaide in South Australia. Practice eligibility included:

- Geographical location in a Local Government Areas (LGAs) with a Socio-Economic Index for Area (SEIFA) Index of Relative Socio-economic Disadvantage (IRSD)[28] equal to or below the 8th decile.
- Using clinical software compatible with the trial data extraction and recruitment tool, *Doctors Control Panel* (DCP)[29], and an active internet connection.
- Participation by at least one practice nurse (PN) and one general practitioner (GP) from the practice.
- Participation of reception staff to distribute trial materials to eligible trial participants as they present for appointments.

Patient eligibility included:

- Aged 40-74 years.
- BMI≥28 recorded within the previous 12 months (The cut point for BMI was chosen to target people at higher risk and to capture people from Asian backgrounds who have a lower equivalent BMI).
- Blood pressure and total serum cholesterol recorded within the previous 12 months.
- Speaking English and/or Arabic, Vietnamese or Chinese (Languages representing common migrant groups in the catchment areas – there were very few patients who spoke other languages but not English.
- Access to a smart phone or tablet device and internet connection.

Patients were excluded if they:

- Had a diagnosis of diabetes requiring insulin or a current prescription for insulin, a diagnosis of cardiovascular disease (angina, myocardial infarction, heart failure, heart valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident)
- Had experienced weight loss of >5% in the past 3 months, were taking medication for weight loss (orlistat or phentermine) or had undergone weight loss surgery.
- Cognitive impairment (including serious mental illness).
- Had a physical impairment which would prohibit engaging in moderate level physical activity.

Practice Recruitment

Between March 2018 and October 2018, general practices within the specified geographical locations were approached by partner Primary Health Networks (PHNs), which are regional organisations providing quality improvement and education to general practices. Invitations to express interest were distributed through mail, email, newsletters, GP educational events, websites,

Facebook groups for health professionals, discussion groups and research networks. A face-to-face meeting was held between responding practices, a PHN representative and a member of the research team to discuss in detail and confirm eligibility.

Randomisation

Randomisation of practices was performed by an epidemiologist (MB) who was not involved in the data collection or intervention using the SAS[30] statistical package. Practices were characterised by size (fewer than 5 GPs, or 5 or more GPs) and by State into four strata, and intervention and control lists of random numbers (6-digit) were generated for each stratum. The resultant intervention and control strata lists were combined and sorted. Four batches were created. Allocation of intervention or control was then sequentially allocated from the lists based on the date of entry of the practice into the study by an independent researcher. Batching was undertaken to ensure similar numbers of control and intervention practices at any point in time. Practices were informed in writing as to what allocation they had received.

Recruitment of Patients

From October 2018 to September 2019, patients of participating practices were flagged at the point of presentation using DCP. The software was programmed with clinical inclusion/exclusion criteria to identify potential participants as they presented. Once flagged, patient information was automatically printed and attached to trial information and consent forms by the reception staff. It was not the responsibility of GPs to gain consent, but patients could discuss the trial with their GP or PN. As DCP was only able to determine eligibility based on the information within the practice's clinical software, eligibility was also checked by a member of the practice. Patients could return their consent forms by leaving them in a secure collection point at the practice or returning them in a reply-paid envelope to the study centre (UNSW Sydney).

The HeLP-GP Intervention

The intervention was a multi-component intervention which has been previously described and piloted [31 32]. It aimed to increase the knowledge of patients relating to diet and physical activity and their individual skills to address weight management behaviours. It comprised:

a) A PN-led health check designed to support Australian Guidelines for the management of overweight and obesity [5 33] and based on the 5A's (Assess, Advise, Agree, Assist and Arrange).[34 35] Review was conducted by the PN at 6 weeks and the GP at 12 weeks.

b) A lifestyle app (*mysnapp*) modified from *healthy.me,* a personally controlled health management platform designed to help patients and consumers to manage their health.[36] The components of *mysnapp* were informed by research into behaviour change through mobile and electronic platforms that suggest that goal setting and self-monitoring, and additional methods to interact with patients, particularly text messaging, can be more effective than advice alone.[37 38-40] *Mysnapp* allowed patients to set and revise physical activity and diet-based goals and to view graphs of their progress over the previous 6 weeks. A free text diary allowed patients to document individualised content. A range of video and written resources related to diet and physical activity, linked to the app, were available for the patient to view. Text messages reminded patients to attend the follow up with the PN and GP and once registered, each patient received one nutrition and one physical activity message each week for 6 weeks.[32]

c) Health coaching via the 'Get Healthy' Telephone coaching program (https://www.gethealthynsw.com.au/) provided free, confidential telephone-based health coaching to support patients to reach personalised lifestyle goals relating to healthy eating, increasing physical activity, alcohol reduction and achieving and maintaining a healthy weight. Coaching was available in multiple languages with the assistance of an interpreter service.

At the health check patients could choose to take up *mysnapp*, Get Healthy or both. Control practices provided 'usual care' (the clinical practice routinely offered to patients by the GP and PN of the practice).

Training and implementation of the intervention

Training was completed by all participating PNs. Training comprised three on-line modules covering physical assessment (weight, height, BP, waist circumference and BMI), delivery of relevant lifestyle advice and promotion of individual goal setting. The 'teach-back' method[41] (asking the patient to repeat in their own words what they have understood), was encouraged to ensure they had understood and were confident with the content of the health check. PNs assisted patients to download and set up *mysnapp* including setting goals during the health check and were encouraged to review the patient's use of the app and the progress of health coaching at the 6-week follow up. Written and video resources were developed for PNs and patients on the installation and use of the app. PNs referred patients to Get Healthy using a trial-specific online referral form.

Patients could claim Medicare benefits (usually without out-pocket payments) for GP visits as part of the intervention (Medicare is Australia's national universal health insurance scheme). Patients did not pay for the PN visits. The PN health checks were reimbursed directly to the practice by the study at a rate of AUD$40 per patient for the health check and AUD$20 per patient for follow-up.

Ethics and consent

This trial was approved by the University of New South Wales Human Research Ethics Committee (HC17474). The University of Adelaide Human Research Ethics committee ratified this approval.

Written consent was obtained from all participating practices to conduct the trial in the practice and access practice data; individual consent was obtained from all participating GPs and PNs. Patients

provided written consent to participate in the trial and additional written consent was obtained for the researchers to access individual health service usage data (Medicare Benefits Schedule (MBS)) and pharmaceutical use (Pharmaceutical Benefit Scheme (PBS)) according to protocols governing access to this data through Services Australia[42].

All practices received an AUD $1000 payment to cover the administrative costs of participation. To compensate them for their time, patients from both groups who completed the baseline and 6-month follow up received an AUD$30 shopping voucher and then an additional AUD$30 voucher if they completed the 12-month follow up.

Patient and Public involvement

Patients and members of the public were not involved in the design of this study. Consumer volunteers with the Adelaide Primary health Network did pilot the lifestyle app (mysnapp) and provide input to its final design.

Data collection and trial outcomes

The methods are described in the protocol paper[43]. Table 1 provides a summary of the data collected to assess trial outcomes, the collection method and the timepoints of collection. A proposed 18 month follow up of patients was abandoned due to the need to extend the period for patient recruitment and lower than expected numbers of patients being recruited to the trial. Surveys administered over the telephone were used to collect demographic and other patient data.

Primary outcomes

We used two domains of the Health Literacy Questionnaire (HLQ) (Domain 8: Ability to find good health information (5 items) and Domain 9: Understand health information well enough to know what to do (5 items)). [44] The individual domains of the HLQ were selected to identify specific health

literacy strengths and challenges or to test a hypothesis.[45 46] Domains 8 and 9 have a 5-point response option scale (cannot do or always difficult, usually difficult, sometimes difficult, usually easy, or always easy). The scores for these domains are averages for the domain (with a range between 1 to 5). The eHealth Literacy Scale (eHeals) was used to assess digital health literacy.[47] DCP was used to extract clinical patient data related to biomedical risk factors (BMI, systolic and diastolic blood pressure, and waist circumference). We used the measurements recorded by the GP at the nearest timepoint to follow up (baseline and 12 month follow up interviews).

Secondary outcomes

Patient self-report was used to determine lifestyle behaviours including a diet score (portions of fruit (between 0 and a maximum of 2 per day) plus portions of vegetables intake (between 0 and a maximum of 5 per day) with a range between 0 and 7 based on the sum of fruit and vegetable scores), the number of 30-minute sessions of physical activity (moderate/vigorous) per week and changes in diet and physical activity. Questions to assess these behaviours were adapted from previous research.[48 49] The scores for diet were between 1 and 7.

Patient self-report was used to determine advice received and referral for diet, physical activity and weight loss. Patient questions also assessed quality of life (using the EQ-5D-5L standardised to UK reference population with no imputation of missing values).[50 51] Total cholesterol, low density lipoprotein (LDL), high density lipoprotein (HDL) and triglyceride (TG) values were extracted by the DCP from the GP medical record at baseline and 12-month follow up.

Sample size calculation

The original sample size calculation of 400 in each arm was based on the primary hypothesis that the intervention would lead to improved health and eHealth literacy, diet, physical activity, weight, and blood pressure. This was based on assumption of hypothesised effect sizes is described in the trial

protocol.[43] Sample size estimates were based on a two-sided test of significance at α=0.05. 1-β= 0.8 and 20% loss to follow up. For Health Literacy (HLQ) the anticipated mean difference was 0.4 for both domains 8 and 9 (based on domain 8 mean 3.7 (standard deviation (SD)= 0.9) and domain 9 mean 3.9 (SD 0.8)). For body mass index and systolic blood pressure the effect sizes were 0.2 respectively (based on means of 30 (SD 6) and 131 (SD 15) respectively).

Table 1. Patient Level Outcomes

Outcome	Instrument/contributing data	Primary or secondary outcome	Data collection method	Timepoint for collection		
				BL	6 months	12 months
Literacy and e-health literacy						
Health literacy	HLQ (Domains 8 and 9)	Primary	Patient survey - Administered via Telephone interview	x	x	x
eHealth literacy	eHEALS	Primary	Patient survey - Administered via Telephone interview	x	x	x
Biomedical risk factors (patient)						
Weight/height/waist circumference/BMI	Clinical record	Primary	DCP	x	-	x
Blood pressure	Clinical record	Primary	DCP	x	-	x
Lipids (total chol)	Clinical record	Secondary	DCP	x	-	x
Lifestyle risk factors (patient)						
Fruit and vegetable intake	Patient self-report – serves of fruit and vegetables per day	Secondary	Patient survey - Administered via Telephone interview	x	x	x
Level of physical activity	Patient self-report (Moderate and vigorous physical activity per week)	Secondary	Patient survey - Administered via Telephone interview	x	x	x
Quality of life						
QOL	EQ-5D-5L	Secondary	Patient survey - Administered via Telephone interview	x	-	x
Advice and referral						
Recall of advice and goal setting for diet, physical activity, weight loss	Patient survey	Secondary	Patient survey - Administered via Telephone interview	x	x	-

Outcome	Instrument/contributing data	Primary or secondary outcome	Data collection method	Timepoint for collection		
				BL	6 months	12 months
Referral to behaviour change programs for diet, physical activity, or weight loss	Patient survey	Secondary	Patient survey - Administered via Telephone interview	x	x	-
Economic data						
Delivery cost of intervention	Study documentation/budget	Secondary	Study administrative records/Facilitator Diary	Calculated for trial costs (payments for health checks, practice staff education and practice facilitation; cost of the app and telephone coaching)		
Health service costs	Medicare Benefits Scheme data	Secondary	Output from Services Australia	Data collected 01/10/2017 to 30/06/2020		
Prescription medication	Pharmaceutical Benefits Schedule data	Secondary	Output from Services Australia	Data collected 01/10/2017 to 30/06/2020		

ANALYSIS

Statistical analyses were conducted on the intention to treat (ITT) population for both primary and secondary outcome analyses. The ITT population was defined as all those recruited at baseline regardless of what intervention they received and what follow-up data was available.

Summary participant baseline characteristics and primary outcomes at baseline were compared between control and intervention groups using either chi-squared test, t test or Mann-Whitney test. Means and standard deviations were reported for continuous outcomes and the number and percentage were reported for dichotomous outcomes at baseline, 6 month and 12-month follow up.

To measure the effect of the intervention on the outcomes of interest (primary or secondary), we used difference-in-differences (DID) estimate as some of the outcomes at baseline were significantly different [52]. We used generalised-estimating equation (GEE) with Gaussian family and identity link function to estimate DID accounting for the cluster (general practice) level correlation.[53] We put an interaction term for intervention group and a dummy variable for before/after the follow up measurement (6 month follow up or 12 month follow up) in the GEE model and the coefficient of the interaction term was considered as a DID estimate.[54] Separate models were used for estimating DID at 6 month follow up and 12 months follow up. The DID estimate were adjusted for the potential confounders which were substantially different between control and intervention groups at baseline. To adjust for possible ceiling effects, we did stratified analysis for the health literacy scores by above or below the median score at baseline. We set 5% as a level of statistical significance. We used the R4.0.3 programming language and environment for the statistical analysis.[55]

Economic evaluation

The extracted cost data informed a cost consequence analysis, undertaken from the Australian healthcare system perspective. We categorized costs as follows: 1) services provided or requested

by GPs (excluding consultations by specialists), 2) services provided or requested by GPs or specialists (excluding services related to surgical procedures), and 3) pharmaceutical costs. The number of times participants visited a GP was also analysed. Costs and number of GP visits were calculated for the 12 months preceding and the 12 months following the enrolment date for each participant, from which unadjusted difference-in-difference estimates were derived for each of the cost categories, as well as aggregate costs and GP visits. Bootstrapping (using 1000 resamples) was used to represent the uncertainty around the difference-in-difference estimates.

RESULTS

We used the Consort extension for cluster trials statement to guide reporting (Supplementary file 1) and summarise the flow of participants (Figure 1) through the HeLP-GP trial. [56]

1.Baseline

We recruited 215 participants to the study (120 to the intervention group and 95 to the control group) through 22 practices (clusters). Baseline characteristics of the intervention group were similar to the control group except that the proportion of males was higher (66.3% vs 50.0%). Participants in both groups were predominantly aged between 46-65 years, with over a third having been born overseas (mostly from Europe or Asia) but only a third of those born overseas had arrived in Australia in the past 10 years and one in 6 of all participants spoke a language other than English. 39.5% has school qualifications only and 59% were employed. The median BMI was 33.3kgm^2. The intervention outcome measures at baseline were all similar to the control group except for health literacy which was lower (mean 4.0 vs 4.3 for domain 8, and 4.1 vs 4.3 for domain 9) (Table 2).

2. Intervention uptake

There was variable uptake of the intervention components by the 120 participants in the intervention group. Eighty-five attended the nurse health check and 73 also received either *mysnapp,* Get Healthy or both. Thirty-eight took up both *mysnapp* and Get-Healthy coaching. Of the 62 who adopted *mysnapp,* 60 participants set goals on 132 occasions to increase vegetables, 131 to increase fruit, 97 less take-away, 117 smaller portions, 73 less soft-drink, 129 to increase physical activity time. Of the 49 who adopted Get-Healthy telephone coaching, 31 set weight related goals.

Table 2: Baseline characteristics and outcomes by intervention and control

Variables	Responses	Control	Intervention	ICC[2]
n	215	95	120	
Age, mean (SD)		56.2 (9.6)	58.9 (8.8)	
Gender, n (%)	Female Male	32 (33.7) 63 (66.3)	60 (50.0) 60 (50.0)	
Place of Birth, n (%)	Australia Overseas	59 (62.1) 36 (37.9)	66 (55.0) 54 (45.0)	
Place of Birth, n (%)	Australia Europe Asia Other	59 (62.8) 16 (17.0) 11 (11.7) 7 (7.4)	66 (55.0) 15 (12.5) 13 (10.8) 25 (20.8)	
Year of arrival in Australia	Before 2000 On or after 2000[4]	24 (68.6)[3] 11 (31.4)	40 (81.6) 9 (18.4)	
Primary language at home, n (%)	English Other	88 (92.6) 7 (7.4)	96 (80.0) 24 (20.0)	
Hospital admissions in past 12 months, n (%)	Yes No	21 (22.1) 74 (77.9)	27 (22.5) 93 (77.5)	
State n (%)	NSW SA	35 (36.8) 60 (63.2)	99 (82.5) 21 (17.5)	
Qualification, n (%)	School only Professional or technical University degree Other	38 (40.0) 30 (31.6) 18 (18.9) 9 (9.5)	47 (39.2) 40 (33.3) 26 (21.7) 7 (5.8)	
Current working status, n (%)	Working Retired Other	56(58.9) 20(21.1) 19(20.0)	71(59.7) 28(23.5) 20(16.8)	
HLQ8 Ability to find good health information	Mean (SD) Median (IQR)	4.3 (0.5) 4.0 (4.0, 4.8)	4.0 (0.8) 4.0 (4.0, 4.6)	0.0262
HLQ9 Understanding health information well enough to know what to do	Mean (SD) Median (IQR)	4.3 (0.5) 4.0 (4.0, 4.8)	4.1 (0.7) 4.0 (4.0, 4.6)	0.0230
eHealth literacy	Mean (SD) Median (IQR)	29.2 (6.3) 32.0 (26.0, 32.0)	27.4 (7.3) 29.0 (23.5, 32.0)	0.0026
Diet	Mean (SD) Median (IQR)	3.1 (1.6) 3.0 (2.0, 4.0)	3.2 (1.6) 3.0 (2.0, 4.0)	-0.0288
Physical activity	Mean (SD) Median (IQR)	2.9 (2.3) 2.0 (1.0, 4.0)	2.7 (2.5) 2.0 (1.0, 4.0)	0.0176
Body Mass Index (BMI)	Mean (SD) Median (IQR)	34.9 (6.9) 33.0 (30.3, 36.3)	34.7 (5.3) 33.3 (30.5, 37.2)	0.0122
Waist	Mean (SD) Median (IQR)	112.9 (15.2) 110.0 (104.0, 121.0)	109.4 (13.6) 108.5 (99.0, 115.5)	0.0263
Systolic blood pressure	Mean (SD) Median (IQR)	130.7 (14.1) 132.0 (121.0, 140.0)	130.6 (14.6) 131.0 (120.0, 139.0)	-0.0214
Diastolic blood pressure	Mean (SD) Median (IQR)	81.3 (9.1) 81.0 (75.5, 87.5)	79.2 (11.9) 80.0 (70.0, 86.0)	0.0098

[1]Missing values: Health literacy domain 8 (n=4); Health literacy domain 9 (n=3); eHealth (n=3); diet (n=1); BMI (n=1); Waist circumference (n=78); Systolic blood pressure (n=1); Diastolic blood pressure (n=1)
[2] ICC = Intra-cluster correlation coefficient
[3]Denominator for these percentages is the number of people who born outside Australia (n=84;); there were 3 missing values for those who born outside Australia (n=87)
[4]There were 17.1% (n=6) and 2.0% (n=1) people who recently (on or after 2009) moved to Australia in control and intervention groups respectively.

3. Change between baseline and 12 months

3.1 Primary outcomes

For health literacy, at 6 months, there was a greater increase in the intervention group for the HLQ8 Ability to find good health information score (DID 0.22; 95% CI 0.01-0.44; Table 3). This difference was not sustained at 12 months. There was no difference in the HLQ9 Understanding health information or for eHealth literacy both at 6 and 12 months. For the group that was below the median at baseline, there was also an increase in the intervention group for the HLQ domain 8 and eHealth literacy score at 6 months, and in HLQ domain 9 score at both 6 and 12 months.

Table 3: Effect of intervention on health literacy score at 6 and 12 months of follow up- intent-to-treat (ITT) analysis

Outcome	Timepoint	Control		Intervention		Effect size[3]	Crude DID[1] (95% CI)[2]	Adj. DID[1] (95% CI)[2]
		n	Mean (SD)	n	Mean (SD)			
HLQ8 (Ability to find good health information)	Baseline	94	4.3 (0.5)	117	4.0 (0.8)		Ref	Ref
	6m follow up	79	4.3 (0.6)	68	4.2 (0.7)	0.31	0.22 (0.00, 0.44)	***0.22 (0.01, 0.44)***
	12m follow up	72	4.4 (0.5)	54	4.3 (0.6)	0.36	0.16 (-0.08, 0.39)	0.15 (-0.08, 0.39)
HLQ9 (Understanding health information well enough to know what to do)	Baseline	95	4.3 (0.5)	117	4.1 (0.7)		Ref	Ref
	6m follow up	79	4.4 (0.5)	68	4.3 (0.7)	0.16	0.11 (-0.09, 0.32)	0.13 (-0.07, 0.33)
	12m follow up	72	4.4 (0.5)	54	4.4 (0.5)	0.40	0.20 (-0.03, 0.43)	0.20 (-0.03, 0.44)
eHealth literacy	Baseline	93	29.2 (6.3)	119	27.4 (7.3)			
	6m follow up	78	28.3 (6.3)	68	28.0 (5.8)	0.25	1.60 (-0.40, 3.59)	1.60 (-0.39, 3.58)
	12m follow up	70	29.4 (5.9)	52	29.5 (6.1)	0.32	1.94 (-0.48, 4.36)	1.82 (-0.65, 4.29)

Below median value (baseline)								
HLQ8 (Ability to find good health information)	Baseline	53	3.9 (0.2)	73	3.6 (0.7)		Ref	Ref
	6m follow up	43	4.1 (0.5)	38	4.2 (0.6)	0.72	***0.34 (0.08, 0.60)***	***0.34 (0.09, 0.59)***
	12m follow up	43	4.3 (0.5)	32	4.2 (0.7)	0.33	0.19 (-0.06, 0.44)	0.19 (-0.06, 0.43)
HLQ9 (Understanding health information well enough to know what to do)	Baseline	49	3.9 (0.3)	71	3.7 (0.6)		Ref	Ref
	6m follow up	40	4.2 (0.5)	35	4.3 (0.7)	0.49	***0.27 (0.06, 0.48)***	***0.28 (0.08, 0.48)***
	12m follow up	40	4.3 (0.5)	29	4.5 (0.5)	0.8	***0.32 (0.12, 0.53)***	***0.33 (0.12, 0.54)***
eHealth literacy score	Baseline	41	23.8 (5.2)	69	22.5 (5.3)		Ref	Ref
	6m follow up	34	25.6 (7.1)	34	26.7 (4.8)	0.40	2.40 (-0.21, 5.02)	2.34 (-0.39, 5.06)
	12m follow up	27	26.5 (6.2)	25	29.5 (4.7)	0.42	***4.12 (1.48, 6.75)***	***3.77 (0.96, 6.59)***
Above median value (baseline)								
HLQ8 (Ability to find good health information)	Baseline	41	4.8 (0.3)	44	4.7 (0.3)		Ref	Ref
	6m follow up	35	4.4 (0.6)	28	4.2 (0.7)	0.15	-0.09 (-0.45, 0.27)	-0.44 (-2.27, 1.39)
	12m follow up	28	4.5 (0.5)	20	4.4 (0.6)	0	-0.04 (-0.41, 0.33)	-0.18 (-2.04, 1.67)
HLQ9 (Understanding health information well enough to know what to do)	Baseline	46	4.7 (0.3)	46	4.7 (0.3)		Ref	Ref
	6m follow up	39	4.6 (0.4)	31	4.3 (0.7)	0.53	-0.27 (-0.55, 0.01)	-0.25 (-0.54, 0.03)
	12m follow up	32	4.5 (0.4)	23	4.4 (0.6)	0.39	-0.17 (-0.41, 0.07)	0.17 (-0.41, 0.08)
eHealth literacy score	Baseline	52	33.5 (3.0)	50	34.1 (3.1)		Ref	Ref
	6m follow up	42	30.8 (4.3)	33	29.5 (6.5)	0.35	-1.90 (-4.50, 0.70)	-1.77 (-4.36, 0.82)
	12m follow up	42	31.1 (4.9)	26	30.0 (7.0)	0.28	-1.70 (-5.25, 1.85)	-1.68 (-5.18, 1.81)

[1]DID = Difference in Differences. [2] adjusted for age, gender, and state. [3] Cohen's d

There was no statistically significant effect of the intervention on BMI or BP at 12 months (Table 4). The intervention group's mean BMI decreased but mean waist circumference at 12 months increased (DiD 7.08, 95% CI 2.26-11.90).

Table 4: Effect of intervention on anthropometry and blood pressure at 12 months of follow up- intent-to-treat (ITT) analysis

Outcome	Timepoint	Control		Intervention		Effect size	Crude DID (95% CI)	Adj. DID (95% CI)[1]
		n	Mean (SD)	n	Mean (SD)			
BMI, kg/m^2	Baseline	94	34.9 (6.9)	120	34.7 (5.3)		Ref	Ref
	12m follow up	49	32.9 (5.7)	52	34.3 (6.0)	0.27	1.45 (-0.16, 3.06)	1.22 (-0.46, 2.90)
Waist circumference, cm	Baseline	49	112.9 (15.2)	88	109.4 (13.6)		Ref	Ref
	12m follow up	20	107.0 (9.6)	49	112.4 (15.6)	0.62	8.24 (2.73, 13.74)	7.08 (2.26, 11.90)
Systolic blood pressure, mmHg	Baseline	95	130.7 (14.1)	119	130.6 (14.6)		Ref	Ref
	12m follow up	64	133.0 (15.3)	50	130.8 (14.6)	0.17	-2.13 (-8.18, 3.92)	-1.48 (-7.34, 4.38)
Diastolic blood pressure, mmHg	Baseline	95	81.3 (9.1)	119	79.2 (11.9)		Ref	Ref
	12m follow up	64	82.7 (8.6)	50	77.6 (9.1)	0.12	-2.84 (-5.94, 0.25)	-3.18 (-6.50, 0.14)

[1]Adjusted for age, gender, and state

3.2 Secondary outcomes

There was a greater increase in diet score in the intervention group at 6 months (DiD 0.98; 95% CI 0.50-1.47) due to an increase in fruit intake (DiD 0.50; 95% CI 0.20-0.80), however, this was not sustained at 12 months. There was no statistically significant effect of the intervention on physical activity score at 6 months (Table 5).

Table 5: Effect of intervention on physical activity and diet score at 6 and 12 months of follow up- intent-to-treat (ITT) analysis

Outcome	Timepoint	Control		Intervention		Effect size[2]	Crude DID (95% CI)	Adj. DID (95% CI)[1]
		n	Mean (SD)	n	Mean (SD)			
Total physical activity score	Baseline	95	2.9 (2.3)	120	2.7 (2.5)		Ref	Ref
	6m follow up	79	3.6 (2.6)	68	3.0 (2.3)	0.16	-0.45 (-1.06, 0.15)	-0.56 (-1.19, 0.06)
	12m follow up	72	3.6 (2.5)	54	3.9 (2.2)	0.21	0.47 (-0.47, 1.42)	0.38 (-0.59, 1.35)
Diet score	Baseline	95	3.1 (1.6)	119	3.2 (1.6)		Ref	Ref
	6m follow up	79	3.1 (1.7)	68	4.1 (1.5)	0.56	***0.98 (0.48, 1.48)***	***0.98 (0.50, 1.47)***
	12m follow up	72	3.8 (1.5)	54	3.9 (1.9)	0	-0.04 (-0.51, 0.44)	0.05 (-0.41, 0.50)

Vegetable intake	Baseline	95	1.8 (1.2)	120	1.8 (1.2)		Ref	Ref
	6m follow up	79	1.9 (1.3)	68	2.3 (1.3)	0.31	***0.46 (0.02, 0.90)***	***0.46 (0.03, 0.89)***
	12m follow up	72	2.4 (1.2)	54	2.3 (1.4)	0.46	-0.14 (-0.53, 0.26)	-0.07 (-0.44, 0.31)
Fruit intake	Baseline	95	1.3 (0.9)	119	1.4 (1.0)		Ref	Ref
	6m follow up	79	1.2 (0.9)	68	1.8 (0.8)	0.59	***0.49 (0.20, 0.79)***	***0.50 (0.20, 0.80)***
	12m follow up	72	1.4 (0.9)	54	1.6 (0.9)	0.11	0.03 (-0.23, 0.30)	0.05 (-0.22, 0.32)

[1]DID = Difference in Differences. [2] Cohen's d

High Density Lipoprotein (HDL) fell in both groups by 7% (control) and 8% (intervention). However, total cholesterol, LDL and triglycerides all fell in the intervention group (Table 6). There were no statistically significant effects of the intervention on lipids (Total cholesterol, Low Density Lipoprotein (LDL), High Density Lipoprotein (HDL) or Triglyceride (TG) or quality of life (EQ-5D-5L) at 12 months. Quality of life did not change in control or the intervention group (Table 6).

At 6 months, the control group self-reported a decrease in the frequency of receiving advice on physical activity whereas the level stayed the same in intervention group (DiD 16.3%, 95% CI 1.4%-31.1%). Similarly, the frequency of weight loss counselling or referral for physical activity fell in the control group but both increased in the intervention group (weight loss counselling DiD 27.8%, 95% CI 8.8%-46.8%; physical activity referral DiD 13.3%, 95% CI 2.32%-24.2%). There were no statistically significant differences between the groups in frequency of receiving information on healthy eating or being referred for healthy eating or weight loss (Table 7).

Table 6: Effect of intervention on the secondary outcomes intent-to-treat (ITT) analysis [who had two different measurements at baseline and 12 months

Outcome	Timepoint	Control		Intervention		Crude DID (95% CI)	Adj. DID (95% CI)[1]
		n	Mean (SD)	n	Mean (SD)		
HDL cholesterol	Baseline	90	1.4 (0.4)	109	1.3 (0.4)	Ref	Ref
	12m follow up	43	1.3 (0.3)	31	1.2 (0.4)	0.02 (-0.09, 0.14)	0.04 (-0.08, 0.16)
LDL cholesterol	Baseline	77	2.8 (0.9)	108	2.9 (0.8)	Ref	Ref
	12m follow up	25	2.9 (1.2)	28	2.7 (0.7)	-0.28 (-0.71, 0.15)	-0.26 (-0.67, 0.15)
Triglyceride	Baseline	92	1.7 (0.8)	114	1.7 (0.8)	Ref	Ref
	12m follow up	46	1.7 (0.8)	32	1.5 (0.8)	-0.20 (-0.50, 0.09)	-0.22 (-0.52, 0.09)
Total cholesterol	Baseline	93	4.9 (0.9)	115	4.9 (1.0)	Ref	Ref
	12m follow up	51	4.9 (1.2)	33	4.6 (0.8)	-0.32 (-0.65, 0.01)	-0.31 (-0.64, 0.01)
Quality of life change (Mean (SD))	Baseline	95	0.88 (0.12)	120	0.87 (0.12)	Ref	Ref
	12m follow up	72	0.87 (0.16)	54	0.90 (0.11)	0.04 (0.00, 0.08)	0.04 (0.00, 0.08)

[1]Adjusted for age, gender, and state

Table 7: Effect of intervention on the secondary outcomes (from Survey data)- intent-to-treat (ITT) analysis

Outcome	Timepoint	Control		Intervention		Crude DID (95% CI)	Adj. DID (95% CI)[1]
		n	% (n)	n	% (n)		
Info or advice healthy eating	Baseline	95	27.4 (26)	120	44.2 (53)	Ref	Ref
	6m follow up	79	17.7 (14)	68	39.7 (27)	5.01 (-18.73, 28.76)	3.30 (-21.10, 27.69)
Info or advice physical activity	Baseline	95	30.5 (29)	120	40.8 (49)	Ref	Ref
	6m follow up	79	11.4 (9)	68	39.7 (27)	***18.03 (3.19, 32.86)***	***16.27 (1.40, 31.14)***
Info or advice weight loss	Baseline	95	34.7 (33)	120	43.3 (52)	Ref	Ref
	6m follow up	79	13.9 (11)	68	51.5 (35)	***29.07 (10.41, 47.74)***	***27.83 (8.83, 46.84)***
Referral to healthy eating	Baseline	95	11.6 (11)	120	10.0 (12)	Ref	Ref
	6m follow up	79	10.1 (8)	68	22.1 (15)	13.46 (-3.25, 30.16)	14.46 (-2.35, 31.27)
Referral to physical activity	Baseline	95	8.4 (8)	120	3.3 (4)	Ref	Ref
	6m follow up	79	5.1 (4)	68	13.2 (9)	***13.24 (2.45, 24.04)***	***13.28 (2.32, 24.24)***
Referral to weight loss	Baseline	95	7.4 (7)	120	7.5 (9)	Ref	Ref
	6m follow up	79	7.6 (6)	68	10.3 (7)	2.49 (-7.68, 12.66)	2.50 (-7.75, 12.74)

Adjusted for age, gender, and state

3.3 Economic analysis

The intervention costs included fixed (development of the mysnapp app and the online training modules) and variable (practice facilitation visits, PN health check payments and telephone coaching sessions) costs. Across the 120 patients in the intervention group, the per patient fixed and variable costs were $787 and $558, respectively, generating a total intervention cost per patient of $1,345.

The baseline characteristics and outcome measurements of participants in the cohort providing consent to access their cost data (n=65; 33 in the intervention group and 32 in the control group) and full cohort (n=215) were similar (see Supplementary tables S1). Two participants were excluded, one due to having only six months of cost data available after the enrolment date, and one due to extremely high pharmaceutical costs in the 12 months prior to enrolment for the treatment of age-related macular degeneration, a condition unrelated to the focus of the intervention.

Supplementary table S1 (c) presents the mean crude cost DIDs between the 12 months prior and post recruitment to the trial. Excluding the outlier participant with high pharmaceutical costs, mean costs were higher in the intervention group in all cost categories, but there were no statistically significant differences between the intervention and control groups for the alternative costs categories (GP costs, GP and specialist costs and PBS costs) nor for the aggregated cost. Including the participant with outlier PBS costs, mean costs are lower in the intervention group for comparisons including PBS cost data, but the confidence intervals remain very wide (Supplementary table S1 d).

There were no adverse events or harms were reported during the trial.

Discussion

In this trial of an intervention involving a PN health check, a mobile app and phone coaching in primary health care, we found positive effects on some outcomes (health literacy and diet at 6 months) but not on

physical activity, weight or other outcomes. The primary hypothesis was that the intervention would lead to improved health literacy, health behaviours and positive changes in weight and other physiological measures. There were some differences between intervention and control groups at baseline but minimal differences in the outcomes and unlikely to have had a major influence on the findings. Health literacy improved in the intervention group at 6 months, although there was no further change by 12 months. Additionally, eHealth literacy improved only among those whose baseline health literacy was below the median. Although similar proportions of participants in both groups set goals for diet and physical activity, patients in the intervention group were more likely to report an improved diet score (due to a greater increase in fruit intake) compared to the control group. There was no difference in the physical activity score between the intervention and control groups. A lack of change in physical activity outcomes may reflect a need for group rather than individual approaches to physical activity promotion for people from migrant or low socioeconomic backgrounds.[57] The intervention was tailored to patients' needs and motivation but was not codesigned or specifically tailored to differences in individual cultural and religious beliefs and practices which may mediate changes in physical activity.[58]

Although there were small changes in health literacy and diet, the intervention was not associated with differences in clinical endpoints such as BMI, BP, lipids, or in quality of life after adjustment for age, gender, and State. This may be because we did not recruit our required sample size or because the intervention lacked sufficient intensity and duration, as has been observed in other studies.[10] The lack of change in physical activity, especially at 12 months, may also have contributed, and changes in BP and lipids may have been confounded by treatment with medications since most patients' BP and lipids were within recommended guideline levels at baseline. Further research is thus required to evaluated digital interventions which allow tailoring to patients' differing health literacy and culture and actively supported in their use over a longer period.

Only two thirds of the patients in the intervention group received the full intervention (i.e., received the health check with *mysnapp* and/or Get Healthy coaching components). This was influenced by patient choice through discussion with their clinicians reflecting the real world setting of Australian general practice. This variable engagement with the different components of the intervention may have reduced its overall effectiveness. However, patients in the intervention group were more likely to recall being offered information or referral for physical activity or weight loss counselling than their counterparts in the control group.

In the cost analyses, low recruitment made the study insufficiently powered to draw meaningful conclusions. There was no evidence of difference in numbers of GP visits, MBS, or PBS costs between the groups over the period of the study. Despite some positive changes in some behavioural endpoints (health literacy and diet), there were no changes in clinical endpoints such as weight or other physiological measures, or in quality of life at 12 months. Trials of weight loss in primary care often show little or no change.[59] However previous studies involving the use of apps and behavioural counselling by health care providers have proven successful even in low socioeconomic groups where goals were individually tailored to the patient's level of health literacy and the intervention were of moderate to high intensity.[11] This suggests that the intervention in the current study may have been more effective if it was more tailored to the patient's individual health literacy needs.

There were several limitations to our study. Like other studies, this study failed to achieve its planned sample size due to major challenges recruiting practices and patients despite considerable effort and an extension to the time frame of the study. [60] Post-hoc power calculations, based on our results, showed that with a sample of 100 in each arm we would be able to detect a mean difference in diet score of 0.6 to 0.7 (serves per day) and a mean difference in the health literacy scale scores of 0.2 to 0.3. Both these differences are less than in previous studies and may not be clinically

meaningful.[43 61] For all the other measures the differences that were able to be detected were larger than expected from moderate intensity interventions (mean PA score difference of 1.5, mean BMI difference of 5.5kg/m^2, mean BP change of 15mmHg, mean cholesterol difference of 0.8)[62]. Our recruitment challenges suggest the need for greater efforts to increase the perceived benefits (such as improved access to quality care) and decrease barriers (especially time) associated with participation in studies such as this in the future.

There were five primary outcomes (including two HLQ domains, eHeals, weight and blood pressure). Furthermore, the health literacy measures were assessed at both 6 and 12 months increasing the likelihood of a type 1 error (ie finding a significant difference). The study was conducted in only two urban areas of Australia and the findings may not therefore be generalised to other communities such as rural areas. Lastly the measures of health literacy, diet and physical activity had some limitations, and may have not been sensitive enough to capture all change due to the intervention.

Assessment of patient socioeconomic variables and health literacy indicate that the study fell short in recruiting its target population of people with low socioeconomic status and low health literacy. At baseline, levels of health literacy were higher than anticipated and were in fact comparable with overweight or obese patients in the general population who were part of the national health literacy survey.[63] Our figures for 'born overseas' are higher than the Australian average but 'language spoken at home' and 'employment status' are similar to the Australian average.[64] It is therefore possible that the requirements for written consent and engagement with the research study may have tended to discourage those with lower English language literacy, as has been found in some research.[65] Furthermore, uptake by the participants in our study in the various components of the intervention varied. Previous research has identified that socioeconomic factors have impacts on intervention/trial uptake, intervention adherence, and trial attrition.[66] Future research could consider using codesign principles to help better engage specific population groups, as well as

general practitioners and practice nurses working with these groups, in the research design and development of the intervention.[67]

Conclusion

This trial of a multi-faceted intervention designed to support better preventive care for overweight and obese patients from low socioeconomic areas in the real-world environment of Australian general practice showed some short-term improvement in health literacy and diet but did not show any change in weight or other physiological variables. It was insufficiently powered for cost analysis. While there was evidence that the intervention was implemented as planned, there was variable uptake of its components, and it may therefore have been of insufficient intensity to achieve sustained change in weight and other primary outcomes. However, any preventive intervention in primary care needs to be sustainable and tailored to its capacity.

Data sharing statement

Individual participant data that underlie the results reported in this article, will be available within 12 months of publication after deidentification (text, tables, figures, and appendices) to investigators whose proposed use of the data has been approved by our Ethics Committee.

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Competing Interest Statement

None declared

Author Contributions

MH was the chief investigator and led the development of and implementation of the study, interpreted the data and drafted the manuscript.

SMP developed the trial processes, coordinated the trial across sites, contributed to the development of the data collection tools, collected and analysed data and drafted the manuscript.

MB cleaned the data, designed the analysis plan, conducted the analysis, interpreted the data and contributed to the draft of the manuscript.

NS led the development and implementation of the study in SA, was instrumental in designing the DCP module for the trial, interpreted the data and contributed to the manuscript.

EDW contributed to the design of the study, developed the training modules, contributed to the interpretation of the data and the manuscript.

NZ contributed to the trial design, trial implementation and interpretation of the data for the manuscript.

JK contributed to the trial design, designed the economic analysis and interpreted this data for the manuscript.

AK cleaned the DCP data, designed the analysis plan, conducted the analysis, developed the data tables and contributed to the draft of the manuscript.

DN contributed to the trial design, trial implementation and interpretation of the data for the manuscript, particularly the health literacy content.

JR conducted the economic analysis and interpreted the data for inclusion in the manuscript.

STL contributed to the trial design, trial implementation and interpretation of the data for the manuscript.

CM liaised with SA practices to collect patient and practice data, collated the data, and contributed to the interpretation of the data for the manuscript.

OF was instrumental in designing the DCP module for the trial and troubleshooting data collection using DCP, interpreted the outcome data and contributed to the manuscript.

AT liaised with NSW practices to collect patient and practice data, collated and cleaned the data and contributed to the management and interpretation of the data.

RO contributed to the trial design, particularly the tools to collect patient data and interpretation of data particularly the health literacy outcome data. He contributed to the draft manuscript.

AL designed and developed the mysnapp app and the data collected via the application and interpretation and plan for analysing this data

All authors approved the final version for publication and agree to be accountable for the integrity of the content, and responsible for any issues that arise from publication of the trial data.

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Ethics Approval

This trial was approved by the University of New South Wales Human Research Ethics Committee (HC17474). The University of Adelaide Human Research Ethics committee ratified this approval.

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Figure legend

Figure 1: Consort flow diagram

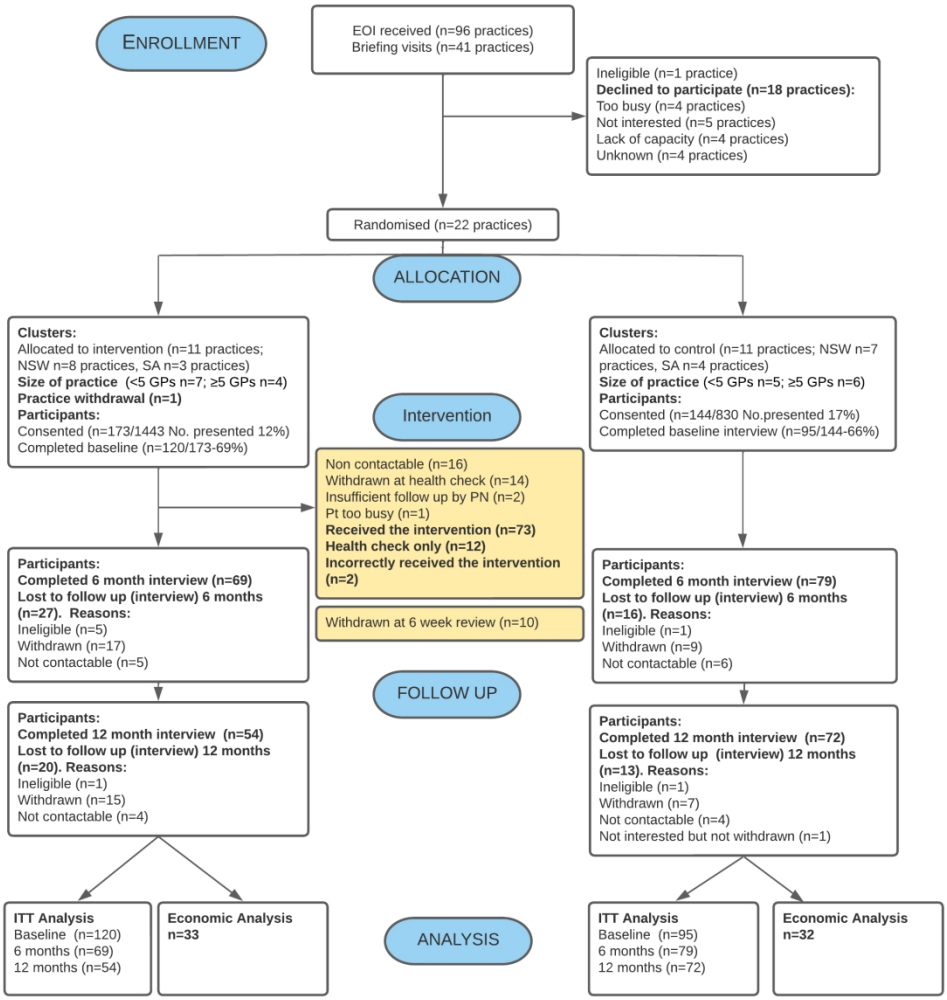

Figure 1 Consort Flow Diagram

Supplementary Tables S1

Table S1(a): Baseline characteristics by intervention and control for full cohort and cohort for cost analysis

Variables	Responses	Full cohort		Cohort for cost analysis	
		Control	Intervention	Control	Intervention
n	215	95	120	32	33
Age, mean (SD)		56.2 (9.6)	58.9 (8.8)	61.0 (9.8)	60.5 (8.1)
Gender, n(%)	Female Male	32 (33.7) 63 (66.3)	60 (50.0) 60 (50.0)	10 (31.3) 22 (68.7)	17 (51.5) 16 (48.5)
Place of Birth, n(%)	Australia Overseas	59 (62.1) 36 (37.9)	66 (55.0) 54 (45.0)	17 (53.1) 15 (46.9)	20 (60.6) 13 (39.4)
Primary language at home, n(%)	English Other	88 (92.6) 7 (7.4)	96 (80.0) 24 (20.0)	31 (96.9) 1 (3.1)	25 (75.8) 8 (24.2)
Hospital admissions in past 12 months, n(%)	Yes No	21 (22.1) 74 (77.9)	27 (22.5) 93 (77.5)	8 (25.0) 24 (75.0)	7 (21.2) 26 (78.8)
State	NSW SA	35 (36.8) 60 (63.2)	99 (82.5) 21 (17.5)	6 (18.8) 26 (81.2)	28 (84.9) 5 (15.1)

Table S1(b): Outcome measurement at baseline by control and intervention for full cohort and cohort for cost analysis

Variables	Measure[1]	Full cohort		Cohort for cost analysis	
		Control	Intervention	Control	Intervention
n	215	95	120	32	32
Health literacy domain 8	Mean (SD) Median (IQR)	4.3 (0.5) 4.0 (4.0, 4.8)	4.0 (0.8) 4.0 (4.0, 4.6)	4.4 (0.5) 4.0 (4.0, 4.8)	4.4 (0.5) 4.0 (4.0, 4.8)
Health literacy domain 9	Mean (SD) Median (IQR)	4.3 (0.5) 4.0 (4.0, 4.8)	4.1 (0.7) 4.0 (4.0, 4.6)	4.3 (0.5) 4.1 (4.0, 4.8)	4.4 (0.5) 4.0 (4.0, 5.0)
eHealth	Mean (SD) Median (IQR)	29.2 (6.3) 32.0 (26.0, 32.0)	27.4 (7.3) 29.0 (23.5, 32.0)	29.2 (6.6) 32.0 (26.0, 32.0)	29.6 (6.0) 30.5 (25.5, 32.0)
Diet	Mean (SD) Median (IQR)	3.1 (1.6) 3.0 (2.0, 4.0)	3.2 (1.6) 3.0 (2.0, 4.0)	3.4 (1.5) 3.0 (2.0, 4.0)	3.4 (1.5) 3.0 (2.0, 5.0)
Physical activity	Mean (SD) Median (IQR)	2.9 (2.3) 2.0 (1.0, 4.0)	2.7 (2.5) 2.0 (1.0, 4.0)	3.6 (2.3) 4.0 (2.0, 4.0)	3.0 (2.6) 2.0 (1.0, 4.0)
BMI	Mean (SD) Median (IQR)	34.9 (6.9) 33.0 (30.3, 36.3)	34.7 (5.3) 33.3 (30.5, 37.2)	31.9 (3.1) 30.9 (29.9, 33.8)	33.8 (4.8) 33.3 (30.5, 35.4)
Waist	Mean (SD) Median (IQR)	112.9 (15.2) 110.0 (104.0, 121.0)	109.4 (13.6) 108.5 (99.0, 115.5)	107.4 (10.1) 107.0 (98.0, 116.0)	114.6 (14.6) 114.0 (100.0, 117.0)
Systolic blood pressure	Mean (SD) Median (IQR)	130.7 (14.1) 132.0 (121.0, 140.0)	130.6 (14.6) 131.0 (120.0, 139.0)	127.6 (13.0) 127.0 (120.5, 137.5)	131.3 (13.7) 131.5 (120.0, 140.0)
Diastolic blood pressure	Mean (SD) Median (IQR)	81.3 (9.1) 81.0 (75.5, 87.5)	79.2 (11.9) 80.0 (70.0, 86.0)	79.4 (8.3) 79.5 (74.0, 85.0)	79.5 (15.7) 79.0 (70.0, 89.5)

Table S1(c): Costs 12 months before and 12 months after enrolment date by control and intervention (excluding outlier)

Outcome	Timepoint	Control			Intervention			Crude DID (95% CI)
		n	Mean (SD)	Mean Diff (95% CI)	n	Mean (SD)	Mean Diff (95% CI)	
GP costs	12m before enrolment	32	$1,109 ($485)	Ref	32	$912 ($564)	Ref	Ref
	12m after enrolment	32	$1,088 ($683)	-$21 (-$248, $207)	32	$931 ($579)	$20 (-$215, $254)	-$40 (-$353, $273)
GP & specialist costs	12m before enrolment	32	$1,268 ($571)	Ref	32	$1,158 ($677)	Ref	Ref
	12m after enrolment	32	$1,345 ($1,013)	$77 (-$247, $400)	32	$1,275 ($837)	$116 (-$220, $453)	-$40 (-$491, $412)
PBS Costs	12m before enrolment	32	$315 ($403)	Ref	32	$289 ($366)	Ref	Ref
	12m after enrolment	32	$328 ($458)	$12 (-$52, $77)	32	$320 ($479)	$32 (-$62, $125)	-$19 (-$131, $93)
GP & PBS costs	12m before enrolment	32	$1,424 ($672)	Ref	32	$1,201 ($754)	Ref	Ref
	12m after enrolment	32	$1,416 ($923)	-$8 (-$259, $243)	32	$1,252 ($824)	$51 (-$217, $319)	-$59 (-$412, $293)
GP, specialist & PBS costs	12m before enrolment	32	$1,583 ($751)	Ref	32	$1,447 ($801)	Ref	Ref
	12m after enrolment	32	$1,672 ($1,203)	$89 (-$257, $435)	32	$1,595 ($1,037)	$148 (-$205, $502)	-$59 (-$535, $417)
Number of GP visits	12m before enrolment	32	10.9 (0.9)	Ref	32	11.0 (1.1)	Ref	Ref
	12m after enrolment	32	11.3 (1.0)	0.3 (-1.2, 1.9)	32	10.7 (1.0)	-0.3 (-2.5, 2.0)	0.7 (-2.1, 3.4)

Table S1 (d): Costs and number of GP visits 12 months before and 12 months after enrolment date by control and intervention

Outcome	Timepoint	Control			Intervention			Crude DID (95% CI)
		n	Mean (SD)	Mean Diff (95% CI)	n	Mean (SD)	Mean Diff (95% CI)	
GP costs	12m before enrolment	32	$1,109 ($485)	Ref	33	$897 ($561)	Ref	Ref
	12m after enrolment	32	$1,088 ($683)	-$21 (-$248, $207)	33	$924 ($571)	$26 (-$181, $234)	-$47 (-$367, $273)
GP & specialist costs	12m before enrolment	32	$1,268 ($571)	Ref	33	$1,149 ($669)	Ref	Ref
	12m after enrolment	32	$1,345 ($1,013)	$77 (-$247, $400)	33	$1,257 ($830)	$108 (-$192, $407)	-$31 (-$491, $429)
PBS Costs	12m before enrolment	32	$315 ($403)	Ref	33	$445 ($969)	Ref	Ref
	12m after enrolment	32	$328 ($458)	$12 (-$52, $77)	33	$348 ($497)	$97 (-$362, $167)	$110 (-$158, $378)
GP & PBS costs	12m before enrolment	32	$1,424 ($672)	Ref	33	$1,343 ($1,103)	Ref	Ref
	12m after enrolment	32	$1,416 ($923)	-$8 (-$259, $243)	33	$1,271 ($819)	$71 (-$403, $261)	$63 (-$364, $490)
GP, specialist & PBS costs	12m before enrolment	32	$1,583 ($751)	Ref	33	$1,595 ($1,157)	Ref	Ref
	12m after enrolment	32	$1,672 ($1,203)	$89 (-$257, $435)	33	$1,605 ($1,022)	$10 (-$397, $417)	$79 (-$472, $630)
Number of GP visits	12m before enrolment	32	10.9 (0.9)	Ref	33	10.9 (1.0)	Ref	Ref
	12m after enrolment	32	11.3 (1.0)	0.3 (-1.2, 1.9)	33	10.6 (0.9)	-0.3 (-2.5, 2.0)	0.6 (-2.0, 3.2)

Supplementary 1. CONSORT checklist when reporting a cluster randomised trial: HeLP GP Trial.

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	Abstract
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	Page 3
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	Page 3
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	Page 3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		Page 8
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	Page 3/4
	4b	Settings and locations where the data were collected		Page 3/4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	Page 6/7
Outcomes	6a	Completely defined pre-specified primary and	Whether outcome measures pertain to the cluster level, the	Table 1

		secondary outcome measures, including how and when they were assessed	individual participant level or both	
	6b	Any changes to trial outcomes after the trial commenced, with reasons		NA
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	Page 9
	7b	When applicable, explanation of any interim analyses and stopping guidelines		NA
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		Page 5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	Page 5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	Page 5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	See 10a – 10c
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	Page 5

	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	Page 5
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	Page 8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		NA
	11b	If relevant, description of the similarity of interventions		NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	Page 13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		Page 13
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up		Page 4/5

	14b	Why the trial ended or was stopped		NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Table 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Page 14
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	ICC included in Table 2 Effect size included in Tables 3, 4 and 5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		Absolute differences provided
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		**NA**
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		NA
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		Page 23/24
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	Page 24
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and		Conclusions

		considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	Title page
Protocol	24	Where the full trial protocol can be accessed, if available	Title page
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 25

REFERENCES

1 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

2 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.