BMJ Open

Preventing chronic disease in patients with low health literacy using eHealth and teamwork in primary health care: Protocol for a cluster Randomised controlled trial.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-023239
Article Type:	Protocol
Date Submitted by the Author:	28-Mar-2018
Complete List of Authors:	Parker, Sharon; University of New South Wales, Centre for Primary Health Care and Equity Stocks, Nigel; University of Adelaide, General Practice Nutbeam, Don; The University of Sydney, Public Health Thomas, Louise ; University of New South Wales, Centre for Primary Health Care and Equity Denney-Wilson, Elizabeth; University of Sydney - Mallett Street Campus, Sydney Nursing School Zwar, N; University of Wollongong , Med9icine Karnon, Jon; The University of Adelaide Lloyd, Jane; University of New South Wales, Centre for Primary Health Care and Equity Noakes, Manny; CSIRO Health and Biosecurity Liaw, Siaw-Teng; UNSW Australia, School of Public Health and Community Medicine Lau, Annie; Macquarie University, Australian Institute of Health Innovation, Faculty of Medicine and Health Sciences Osborne, Richard; Deakin University, Public Health Innovation, Population Health Strategic Research Centre Harris, Mark; University of New South Wales, School of Public Health and Community Medicin
Keywords:	Overweight, Obesity, PRIMARY CARE, PREVENTIVE MEDICINE, health literacy, m-health

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Authors

Parker S[1], Stocks N[2], Nutbeam D[3], Thomas L[1], Denney-Wilson E[4], Zwar N[5], Karnon J[6], Lloyd J[1], Noakes M[7], Liaw ST[8], Lau A[9], Osborne R[10], Harris MF*[1].

[1] Centre for Primary Health Care and Equity, University of New South Wales

[2] Discipline of General Practice, University of Adelaide

[3] Sydney School of Public Health University of Sydney

[4] Sydney Nursing School University of Sydney.

[5] School of Medicine, University of Wollongong

[6] School of Public Health, University of Adelaide

[7] Nutrition and Health Program, CSIRO Health and Biosecurity.

[8] School of Public Health and Community Medicine, University of New South Wales.

[9] Centre for Health Informatics, Australian Institute of Health Innovation, Macquarie University

[10] School of Health and Social Development, Centre for Population Health Research, Faculty of Health, Deakin University

* Corresponding author

Word count: Abstract: 224; Body: 5082 (including tables)

Roles and Contact email for Authors

Sharon Parker	Project manager	sharon.parker@unsw.edu.au
Nigel Stocks	Chief investigator	nigel.stocks@adelaide.edu.au
Don Nutbeam	Chief investigator	don.nutbeam@sydney.edu.au
Louise Thomas	Research officer	louise.thomas@unsw.edu.au
Elizabeth Denney-Wilson	Chief investigator	elizabeth.denney-wilson@sydney.edu.au
Nicholas Zwar	Chief investigator	nzwar@uow.edu.au
Jonathan Karnon	Chief investigator	jonathan.karnon@adelaide.edu.au
Jane Lloyd	Associate investigator	j.lloyd@unsw.edu.au
Manny Noakes	Chief investigator	manny.noakes@csiro.au
Siaw-Teng Liaw	Chief investigator	siaw@unsw.edu.au
Annie Lau	Chief investigator	annie.lau@mq.edu.au
Richard Osborne	Associate investigator	richard.osborne@deakin.edu.au
Mark Fort Harris	Lead Investigator	m.f.harris@unsw.edu.au

Abstract

Background

Adults with lower levels of health literacy are less likely to engage in health promoting behaviours. Our trial evaluates the impacts and outcomes of a mobile health enhanced preventive intervention in primary care for people who are overweight or obese.

Methods/Design

A two-arm pragmatic practice-level cluster randomised trial will be conducted in 40 practices in low socioeconomic areas in Sydney and Adelaide, Australia. Forty patients aged 40-70 years with a BMI ≥ 28 will be enrolled per practice. The HeLP-GP intervention includes a practice-level quality improvement intervention (medical record audit and feedback, staff training and practice facilitation visits) to support practices to implement the clinical intervention for patients. The clinical intervention involves a health check visit with a practice nurse based on the 5As framework (assess, advise, agree, assist and arrange), the use of a purpose-built patient-facing app, *my snapp*, and referral for telephone coaching. The primary outcomes are change in health literacy, lifestyle behaviours, weight, waist circumference and blood pressure. The study will also evaluate changes in quality of life and health service use to determine the cost effectiveness of the intervention and examine the experiences of practices in implementing the program.

Discussion

Our trial will provide evidence to inform the role of primary health care in preventive care for overweight and obese adults and addressing the barriers of low health literacy.

Strengths and Limitations of this study

- This is a large cluster randomised controlled trial of an intervention that is designed to be implemented as part of routine general practice in Australia.
- The primary and secondary outcomes measured will inform policy and practice regarding the role of information technology in preventive care in primary health care and its relevance to adult patients in general practice.
- While the cluster design prevents contamination between intervention and control groups, it means that both providers and patients will not be blinded to the intervention.
- The study will be conducted in urban practices in two Australian states. This may limit its generalisability to rural settings and other countries.

Trial Registration

This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12617001508369).

Date registered 30 October 2017.

Keywords

Overweight, obesity, primary care, preventive medicine, health literacy, m-health

Introduction

Rationale

Reducing the burden of chronic disease is an important public health priority in Australia (1). Overweight and obesity account for 7% of the burden of disease (2) as 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) Currently around 63% of the Australian population are overweight or obese (BMI 25 kg/m2 or more) and the prevalence is increasing (3). The burden of overweight is unequally distributed with a 13% higher prevalence of overweight in the lowest compared with the highest socioeconomic group in females (4). There is an urgent need to find effective strategies at both the population and individual level to prevent and manage this condition.

Low functional health literacy (i.e., health related reading and numeracy) is present in approximately 59% of the population and is more common in socioeconomically disadvantaged populations (5). It is a potential barrier to the uptake and effectiveness of a range of preventive interventions (6). Aspects of health literacy have also been associated with poorer uptake of screening programs and immunisation (7, 8). Conversely higher health literacy has been associated with greater improvements in response to physical activity interventions in disadvantaged populations(9). Patients with low health literacy are less likely to engage in health promoting behaviours (10-12), receive and understand preventive advice, and attend or complete programs that they are referred to (13, 14). A systematic review of interventions in primary care to improve health literacy for chronic disease behavioural risk factors found that interventions with multiple components were more effective at improving nutritional health literacy (15).

Primary care is well positioned to contribute to the prevention and management of overweight and obesity. Over 86% of the population of Australia visit a general practitioner at least once a year (16). Almost a third of patients presenting in general practice are obese and two thirds are overweight or obese, which are rates similar to the prevalence in the general community (17). Behavioural interventions in primary care have been demonstrated to achieve a 5-7% improvement in weight, blood pressure or lipids for patients, potentially preventing or delaying the onset of Type 2 diabetes and cardiovascular disease (18-20). However these interventions tend to have lower uptake by low socioeconomic groups (21, 22) and, overall, most weight loss interventions in primary care achieve only small reductions in weight (23).

Preliminary work leading up to this study

Over the past decade we have sought to develop more effective interventions to prevent disease in primary care which target disadvantaged populations who are more likely to have low health literacy. In previous research we have found that ethnicity and language interact with health literacy to influence uptake of preventive interventions especially those for weight loss (24). This accords with the findings of others that health literacy differentials are greater among older people, for those born overseas, those who do not speak English at home and those with low educational attainment (25). In these groups patient-provider communication tends to be less effective, leading providers to incorrectly assume that patients with low health literacy are poorly motivated and they are therefore less likely to offer lifestyle interventions (26, 27). Organisational and practitioner barriers also contribute to low frequency and effectiveness of assessment, advice, goal setting, and referral of patients with low health literacy (6, 28). These barriers include time available for consultations and competing demands on primary care staff.

We have also identified a need to tailor prevention and management of excess weight to a patients' level of health literacy (29). Our review of primary health care level interventions targeting health

literacy around weight loss found limited information as to the effect of weight loss interventions on health literacy primarily because this is an outcome not frequently reported (30). We have evaluated a structured, nurse delivered health check intervention based on 5As that includes a brief assessment of health literacy, tailoring advice and the use of "teach-back"; goal setting that involves specific, time-bound goals that are set collaboratively and involve feedback; assisted navigation to referral services and pro-active follow up visits (30-33). This has proven feasible to implement (34), however, consistent with other studies, the impact on risk behaviours and weight have been small (23). This may be due to the limited capacity within primary care to provide interventions based on evidence that are of sufficient intensity and length.

We have concluded that there is a need to supplement weight management consultations in primary care with specific components that continue to operate outside the consultation such as coaching programs and other support services. There is some evidence of barriers to uptake of these components such as cost and accessibility (27, 35), although the evidence for health coaching suggests it is an accessible, affordable and effective method to change health behaviours (36, 37). Moreover an evaluation of a government funded telephone coaching service in NSW suggested that it could be effective in reaching disadvantaged population groups (38). Another promising approach is the use of e-health to supplement both clinical care and referral programs in supporting behaviour change. Previous research has demonstrated the effectiveness of mobile health (m-health) text messages as part of a lifestyle program to prevent unhealthy weight gain in young adults (39). This adds to the emerging evidence of the efficacy of using mobile apps and SMS text messaging in supporting change in health behaviours (40). However, the optimal form and role of this technology for patients with low health or e-health literacy is still unclear.

This paper describes the protocol for the development and evaluation of an intervention which combines face to face consultation in general practice with these digital health approaches based on

previous research which has demonstrated both feasibility of implementation and highlighted the potential for health gains.

Intervention Development

The various components of the HeLP-GP intervention have been developed and piloted over the past five years.

The brief primary care intervention which is designed to support practices to improve the quality of preventive care for the SNAP (smoking, nutrition, alcohol and physical activity) risk behaviours and weight management is based on behavioural theory and is structured on the 5As framework which encompasses assessment, advice, agreeing on goals, assisting with motivational counselling and referral options and arranging follow up (13, 41). Progress along the pathway from assessment to follow up is associated with increased patient motivation and behaviour change (42). This has been trialled in general practice and found to be feasible and acceptable and to lead to improvement in the quality of preventive care (30, 43, 44). This intervention was adapted for use by practice nurses and modified for patients with low health literacy to include brief screening for low health literacy, tailored communication and referral navigation to local lifestyle programs and piloted (45). It was subsequently evaluated in a trial which demonstrated its feasibility and acceptability to providers and patients (30).

The app used in this study is supported by *Healthy.me*, a personally controlled health management platform designed to help patients and consumers manage their health (46). This has been shown to improve uptake of preventive services (47, 48) and strong consumer acceptance has been demonstrated in Australia across different healthcare settings including primary care (49). This platform was modified to create the mobile application used in this study (*my snapp*). This was

informed by research that interventions based on theory and those involving goal-setting and self-monitoring as well as providing additional methods to interact with patients, particularly text messages, were more effective (50-53). Other research suggests that patients with low health literacy prefer apps or text messages to other sources of online information (54).

Aims and research questions

The aim of this study is to evaluate the implementation and effectiveness of a preventive intervention in primary care structured around the 5As framework supported by a patient-facing mobile app, consultations with the practice nurse and/or referral to a telephone coaching service. The intervention aims to develop the knowledge and skills of overweight or obese patients with low health literacy. The trial will assess the impact of the intervention on preventive care received, patients' health and e-health literacy, physical and behavioural risk factors, quality of life and costs.

Methods

Trial Design

The trial is a pragmatic, two-arm, practice-level cluster randomised controlled trial evaluating impacts and outcomes of a m-health enhanced preventive intervention in primary care.

Setting

Australian general practice. The study will be conducted in two regions of Sydney (South West Sydney and Central and Eastern Sydney) and Adelaide, in collaboration with the local Primary Health Networks (PHNs).

Randomisation

Randomisation of practices into intervention or control groups (providing usual care) will be performed using an internet-based randomisation service (RANDOMIZE.NET). Practice randomisation was chosen because of the risk of contamination if individual patients were randomised within practices. Randomisation will be performed in two waves. Practices will be stratified according to the size of the practice (less than 5 GPs and 5 or more GPs) and location (NSW/SA) prior to randomisation. GPs and Practice Nurses (PNs) will be delivering the intervention and are not blinded to the intervention.

Eligibility and Exclusion Criteria

General Practices

Eligibility for practices is based on meeting the following inclusion criteria. Practices should:

- Be situated in Local Government Areas (LGAs) with a low Socio-economic (SEIFA[1]) score equal to and below the 6th decile (usually associated with lower health literacy (5)
- Use clinical software compatible with the data extraction and recruitment tool *Doctors Control Panel* (DCP). This includes *Medical Director, MediNet, PracSoft and Best Practice* and associated compatible billing software (*Pracsoft and Best Practice Management*).
- Agree to the installation of DCP for the purposes of clinical audit and to identify eligible patients for the study
- Have access to an active internet connection
- Have at least one practice nurse who is prepared to conduct the HeLP- GP intervention with eligible and consenting patients and complete data management relating to these patients

[1] Australian Bureau of Statistics Socioeconomic Indexes for Areas (SEIFA) http://www.abs.gov.au/websitedbs/censushome.nsf/home/seifahelpansuis?opendocument&navpos=260&#01

- Agree to provide GP follow up health checks to participating patients at 12 weeks and 12-month time points
- Can make their staff available to distribute study materials to potential study participants when they register with reception prior to seeing a GP

Practice patients

Eligible patients are those who are:

- Aged 40-74 years
- Overweight or obese (BMI≥28 recorded in last 12 months)[2]
- With BP recorded in the clinical software within the previous 12 months
- Speaking English and/or Arabic [3]
- With access to a smart phone or tablet device

Exclusion criteria:

- Experiencing recent weight loss (>5% in past 3 months)
- A diagnosis of Diabetes requiring insulin or a current prescription for insulin
- A diagnosis of Cardiovascular disease (includes angina, myocardial infarction, heart failure, heart valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident))
- Taking medication for weight loss (Orlistat or Phenteremine)
- Cognitive impairment
- Physical impairment which prohibits engaging in moderate level physical activity

[2] 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.

[3] Arabic was chosen as many recently arrived immigrants in the geographical areas are Arabic speaking

Recruitment

The recruitment process for practices and patients is outlined in Figure 1. The target practice recruitment is 24 practices from two regions in Sydney (South West Sydney and Central and Eastern Sydney) and 16 practices from Adelaide, South Australia.

The primary source of practice recruitment will be through participating Primary Health Networks (PHNs) in the target locations. PHNs will approach potentially eligible practices using mail, fax and practice visits to ascertain their interest. Practices will be provided with a study outline and asked to complete an Expression of Interest (EOI). A face to face practice visit will provide detailed information about practice tasks and confirm eligibility.

Recruitment of Practice Patients

Patients will be recruited at the point of presentation using the *Doctors' Control Panel* software (DCP) which has also been used in previous research [12]. This software will be programmed according to the inclusion and exclusion criteria to identify potential participants as they present to the practice. These patients will be flagged and information on patients BMI, lipids and blood pressure will be extracted from the medical record and printed. This information will be attached to information and consent forms by the practice receptionist and given to patients to read and discuss with the GP or practice nurse. The practice will be reimbursed for the time spent by the reception staff.

[Insert Figure 1 about here].

Ethics

The study has been approved by the University of New South Wales Human Research Ethics Committee (HC17474). The University of Adelaide Human Research Ethics committee has ratified this approval.

Practice and Provider consent

Written consent will be obtained from all participating practices including consent to conduct the study in the practice and access practice data, and individual consent from all participating GPs and PNs.

Patient Consent

Patients will be given information and consent forms in English or Arabic language and be able to ask further questions of the GP or PN. The patient will provide their written consent by filling in the consent form and either placing it in a collection box at reception, or by returning it in a 'reply paid' envelope to the research team. To increase comprehension and meaningful consent within our target population of patients with low health literacy, we have shortened and simplified the Participant Information Statement and Consent forms. Patient eligibility will be confirmed by the GP and at subsequent interview. They will be invited by mail at 6 months to separately consent to the use of routinely collected data on health service use (from Medicare (MBS) Australia's national health insurance program), pharmaceutical use (from the Pharmaceutical Benefits Scheme (PBS)) and hospitalisation data (from State admitted patient data collections).

Withdrawal

Practices or patients may withdraw from the study at any time. If patients commence weight loss medication or develop cognitive impairment or severe illness they will be withdrawn from the study. Withdrawals and reasons for withdrawal will be recorded.

Trial Registration

The HeLP trial is prospectively registered with the Australian Clinical Trials Registry (ANZCTR): ACTRN12617001508369 http://www.ANZCTR.org.au/ACTRN12617001508369.aspx

Description of the intervention

The HeLP GP intervention includes a practice level quality improvement (QI) intervention and a clinical intervention. A logic model for the intervention can be found in Appendix 1.

1. Practice intervention

This includes a de-identified medical record audit, training of practice staff (GPs and PNs) and a series of three practice facilitation visits.

a) Medical record audit

A de-identified medical record audit will be conducted by research staff using the DCP program pre-baseline in both intervention and control patients aged 40-74 years (who have not had a heart attack or stroke or do not have diabetes requiring insulin), on the recording of smoking status, alcohol consumption, BMI, waist circumference, blood pressure and total cholesterol. In intervention practices an identified medical audit of the records of consenting patients participating in the trial will be conducted at baseline and 12 months. This will include assessing the control of their risk factors and cardiovascular risk. Audit reports will be fed back to practitioners (GPs and PNs), who will reflect on the reports and be supported to make improvements in the practice facilitation visits (See below and Figure 2).

[Insert Figure 2 about here]

b) GP and Nurse training to deliver intervention

Three comprehensive online training modules will cover study processes, the health risks of obesity, benefits of weight loss, the role of GPs and nurses in weight management, the components of the HeLP-GP intervention, tailoring care to the needs of people with low health literacy, processes to be followed for the health check visits and the use of the App with patients. Online videos will reinforce the GPs' and PNs' use of the App and referral to telephone coaching. Links to these will be provided

to participating GPs and PNs. An on-line post training questionnaire and evaluation form will be completed by GP and PN participants and will provide information to evaluate the training and its impact.

c) Facilitation visits conducted by CIs and PHNs

Facilitation visits will be made up to three times over three months to each intervention practice during the beginning of intervention phase to support PNs and the practice. The aim of the practice facilitation is to support each intervention practice to implement the HeLP-GP intervention including making improvements in recording based on the initial de-identified clinical audit and prepare for the health check visits.

2. Clinical intervention

The clinical intervention has three components, each of which will be offered to all patients in the intervention group: a health check visit with the PN; a patient-facing app - *my snapp*; and referral to telephone coaching. Patients may receive any concomitant care indicated for their medical conditions.

a) Practice nurse health check and follow up.

Eligible patients will attend a health check visit with the PN within 4 weeks of recruitment. The content of the nurse consult is based on the 5As (Table 2). The content of the consultation is consistent with the Australian Guidelines for the management of overweight and obesity [28, 48, 49] and will include assessment of health literacy, brief advice, use of "teachback" to determine if the patient has understood the advice given, goal setting (using *my snapp* or recorded using a health check form) and offering referral to telephone coaching (Get Healthy). The nurse will be alerted to those patients who have low e-health literacy (from the baseline assessment) and will spend extra

time demonstrating and checking the use of *my snapp* (over one or two consultations). Patients will be reviewed by the PN at 6 weeks and by the GP at 12 weeks.

Table 1: Initial practice nurse health check (40 minutes)

Assess	Review baseline BMI, waist circumference, blood pressure and lipids. Briefly assess diet, physical activity, health literacy and e-health literacy.
Advise/ Agree	Provide brief advice on risk factors and health behaviours checking understanding using the Teach-back method. Register patient for the app. Download and log into the app using the patients phone. Work with patient to enter profile and set relevant lifestyle goals in the app.
Assist	Introduce and provide referral to the Get Healthy telephone coaching program to the patient, (outline purpose of the program and details about participation).
Arrange	Arrange follow up visit at 6 weeks and a further visit with the GP at 12 weeks

b) my snapp

The components of the App are described in Table 2 and Figure 3. The PN explains the App, supports the patient to register and download the App, enters information on risk factors (BMI, WC, BP) and the practice and helps the patient to set goals and navigate the App. There is also a patient website where participants can get further information and communicate any problems or issues with the App. The content of *my snapp* aligns with both the nurse health check and the telephone coaching (Table 2).

Table 2: *my snapp* content

Section	**Description**
My Starting Point	Nurse records initial measurements (height, weight, waist circumference, blood pressure) during health check visit
My Practice Contact	This records GP and PN's contact details.
My Goals	Nurse assists patient to set and revise diet and physical activity goals during health check visit and at 6-week follow-up.

My Measures	Patient records achievement of goals and views graphs of progress over time in weeks in which they achieved goals for diet and physical activity.
My Resources	Patient accesses fact sheets and videos about healthy eating and exercise. The fact sheets can be accessed in English or Arabic.
My Diary	Patient keeps notes on progress and any problems for discussion with the nurse or GP.
Text messages	Two text messages (one focused on diet and one on physical activity) are sent from the app each week. These are tailored to week and provide direct advice and a web link for further information.

[Insert Figure 3 about here]

c) Telephone Coaching

The telephone coaching program recommended to patients is "Get Healthy" which is supported by the relevant state government and provided free of charge. Get Healthy delivers 10 free coaching calls over 10 weeks which provide:

- Review of lifestyle goals (diet and physical activity) and ways to address barriers to achieving these goals
- Practical health information
- Support and resources to promote self-monitoring of diet, physical activity and weight
- Resources and tools to develop and maintain motivation for a healthier lifestyle
- Assistance to deal with set-backs and problem solve
- Social support to help participants to try new ideas and approaches to address lifestyle behaviours

The coaching is available in multiple languages with the assistance of the national interpreter service.

Assessing the implementation fidelity of the intervention

Implementation of the intervention will be assessed by the following measures:

- % of GPs and PNs who complete the online training modules
- % of intervention patients who receive baseline, and 6-week clinical review by a PN
- % of patients who receive a health check at 12-weeks by a GP
- Usage of the lifestyle App determined by app-analytics (% of patients with documented goals related to lifestyle change)
- % who received assisted referral to Get Healthy telephone coaching
- % of patients who take up and complete Get Healthy telephone coaching program

Evaluation

Outcomes

All primary outcomes are changes at the level of the individual patient between baseline and 12 months. These include change in:

- Two domains of health literacy from the Health Literacy Questionnaire (55) (Ability to find good health information and Understand health information well enough to know what to do) and e-health literacy (using the eHeals) (56);
- Lifestyle behaviours including portions of fruit and vegetables, soft drink, high fat and snack food consumed per day, use of a dietary plan and the level of physical activity adapted from existing instruments (57-59).
- Weight, height, BMI, waist circumference, blood pressure extracted from patient medical records.

Secondary outcomes include health related quality of life using the EQ-5D-5L(60) , total cholesterol extracted from the medical record and patient reported advice and referral given by the GP or

practice nurse(30) and health service use and costs from routinely collected data by Australia's health insurance agency and pharmaceutical benefits service (MBS and PBS).

Data collection (See Figure 4)

Practice: A practice assessment survey will be conducted by the research team at baseline to determine organization and staffing, use of health education materials and links to other services.

Providers: GPs and PNs involved in the study will complete a questionnaire at baseline and 12 months. This will ask about their existing preventive practices and referral pattern, approach to and confidence with health literacy and health education, previous training and education (43, 61).

Patient surveys: All patients will participate in a survey administered by research staff by telephone at baseline, 6 and 12 months to assess diet and physical activity behaviours, health literacy and e-health literacy. The interview will include questions about education received in general practice and referral for lifestyle or weight interventions at baseline and 6 months and quality of life at baseline and 12 months. Intervention group patients will be interviewed at 18 months about lifestyle behaviours.

Medical record audits: These will be conducted at baseline, 6 months, 12 months and 18 months.

Administrative health service data: All patients will be asked to consent to provision of health service and medication use from routinely collected data from Australia's national health insurance and pharmaceutical benefits authorities (MBS and PBS).

Qualitative interviews: A sample of up to 25 patients and 20 providers stratified by state and practice size will be interviewed between 3 and 6 months post intervention. The interviews will explore patient and provider perceptions of how preventive care is influenced by health literacy and provide feedback on the fidelity and barriers to the adoption of the intervention.

[Insert Figure 4 about here]

Data will be collected on all participants who discontinue or are excluded.

Control Practices

After the initial audit of recording of risk factors, which will be fed back to control practices to improve recording, they will recruit patients in the same way as intervention practices. They will provide usual care (the clinical practice routinely offered to patients by the GP and PN). Data from patients attending control practices will be collected from their medical records at baseline and 12 months and they will receive the same telephone questionnaire as patients in the intervention group which includes the frequency of advice and referral at baseline and 12 months. Control practices will be offered the intervention after 12 months.

Sample size calculation

We aim to recruit 40 practices (24 NSW; 16 SA); 20 practices intervention and 20 practices control. We are aiming to consent 40 patients per practice (1600 total) based on previous research [30]. We anticipate a loss of approximately 20-25% at follow up (12 months). We will seek mobile numbers and alternative contacts to improve follow up. Estimates for sample size based on intra-cluster correlation coefficients, prevalence, variance and effect sizes from our previous research are in table 3, based on a two-sided test of significance at α=0.05. β= 0.8 and 20% loss to follow up [40] (Table 3).

Table 3: ICC and sample size estimates for primary outcomes

Outcome	Intra-cluster Correlation Coefficient	Design effect (30-40 patients per practice)	Effect size or difference in proportions	Sample size per group
Mean Health Literacy Score	0.014	1.43	0.4	140
Mean Diet score	0.001	1.03	0.21	367
Mean PA score	0.018	1.56	0.28	312
Mean BMI	0.042	2.30	0.30	401
Mean Systolic BP	0.057	2.77	0.39	285

Data management

Data will be cleaned and coded and stored in a secure environment according to the data management protocol.

Adverse events

An independent adverse events committee will monitor and if necessary investigate any reports of possible adverse events or harms.

Analysis

We will examine differences in the change in the primary and secondary outcomes between intervention and control practices at six months for health literacy and patient behaviours and 12 months for all outcomes. Analyses will be conducted on an intention-to-treat basis and adjusted for baseline differences in any characteristics (e.g. age, gender) between groups. We will analyse outcome variables (health literacy, e-health literacy, diet and physical activity behaviours, BMI, waist circumference, BP, total cholesterol, quality of life and health service use) using multilevel linear and logistic regression techniques that adjust for clustering by practice with multiple imputation for missing values.

Economic evaluation

Information on resource use associated with the intervention will be collected by research staff, including the cost of setting up the intervention: practice staff education, practice support visits and materials and web support. Other relevant resource use includes GP and PN visits, referrals, hospital attendances and prescribing. We will request patient consent to access their medical records, MBS and PBS data, and public hospital data from the State Health Departments. The MBS, PBS and State data will capture most primary care and hospital costs. The cost of PN visits for health checks will be assigned an hourly rate based on PN salary levels plus on-costs. Questions on patient use of lifestyle services and programs, and non-Medicare funded allied health will also be included in the patient

questionnaire. Cost estimates will be generated for referrals to community-based programs. In the base case analysis, undertaken from a health service perspective, referrals to allied health professionals will only be costed if supported by a Medicare claim. The incremental costs of the intervention, will be presented alongside the consequences with respect to changes in quality of life (including the estimation of QALY gains informed by the EQ5D-5L) and differences in health literacy, behavioural outcomes, and clinical measures (BMI, blood pressure and Lipids). Deterministic and bootstrapped sensitivity analyses will be undertaken to identify key uncertain parameters and represent uncertainty around the mean estimates, respectively.

Qualitative analysis

The qualitative interviews will be transcribed and analysed thematically using the program NVivo (QSR NVivo 11). This will use an inductive approach based on the data as well as deductively based on health literacy and health information theory (13, 62).

Discussion

This trial evaluates a comprehensive intervention which is designed to support better preventive care for overweight and obese patients with low health literacy. It builds on previous work by the investigators and others to develop feasible interventions in primary care that address both patient and practice barriers to adoption, implementation and effectiveness. If successful, it will inform policy and practice including the role of primary care in addressing the challenge of overweight and obesity and the often-conflicting information that is available to practitioners and the public.

The complexity of the intervention and evaluation poses potential threats to internal and external validity. Recruiting and engaging a large number of practices to a trial such as this is becoming increasingly difficult. We have addressed this by working in partnership with Primary Health

Networks (district level organisations of general practice and allied health services) to identify, approach and brief practice principals and practitioners on the study. Practice costs will be reimbursed, and practitioners will be able to access continuing professional development points through the clinical audit and training. However, the main incentive is the value of the research itself and how it will inform policy and practice in the long run and this needs to be carefully discussed.

Problems with recruitment, retention or engagement of patients with the intervention and data collection have the potential to reduce statistical power and therefore the ability to detect the primary outcomes with adequate precision. In this setting, recruitment procedures need to avoid pressure from the research team and patient's own GP to ensure that eligible patients are approached and provided with sufficient information to make an informed decision about participation. We will work with practices to set up software and systems to make this possible. A significant part of the burden on participants will be from the telephone interviews by the research team. Although telephone interviews are preferred by most patients, they are onerous if they are too long. We have thus had to balance this burden against our desire to collect as much information as possible using robust instruments.

A further risk is that the clinical intervention will not be implemented in practice as we planned. Again, addressing this requires close work with the practices. The implementation measures and qualitative evaluation will provide some insight, but this may be too late to correct. We have thus built into the practice level intervention several measures to improve fidelity. These include feedback mechanisms in the online training, reflective feedback from practices on the audits and practice discussion during the facilitation visits. These will be tracked regularly during the implementation of the trial. A further risk is that some health and e-health literacy will both be required for adoption of the App by patients and is expected to improve as a result of the

intervention use. This will be addressed by the support provided to patients by practice nurses and general practitioners.

The fieldwork for the study is planned to be completed by December 2018 with follow-up completed by mid-2019. We anticipate circulation of the main findings from the study by 2020.

Acknowledgements

The authors would like to acknowledge the partnership of the Central and Eastern, South West Sydney and Adelaide Primary Health Networks and the other HeLP-GP investigators and research staff especially An Tran in Sydney and Carmel McNamara in SA. We also thank Paige Martin, Jason Dalmazzo, Abir Khurshied, Rattapon Kevin Deeraviset for their efforts in the development of *my snapp*; staff in the New South Wales and South Australian Ministry of Health and Get-Healthy (especially Ruth Chesser-Hawkins, Lyndall Thomas and Kate Reid) for their support in providing access to the telephone coaching program and collection of data associated with its use; and Anton Knieriemen, Colin Sheppard and Oliver Frank who developed a tailored version of the DCP program to facilitate patient recruitment and clinical audits. We would like to acknowledge the general practices involved in piloting for this for the project and the consumers linked to Adelaide PHN for piloting *my snapp*.

Funding

National Health and Medical Research Council (NHMRC) of Australia project grant 2017 (APP1125681). RO is funded in part through a NHMRC Senior Research Fellowship (APP1059122). The funder played no role in the design of this study.

Trial Sponsor

Centre for Primary Health Care and Equity, UNSW. Contact Professor Mark Harris +61 2 93858384 or m.f.harris@unsw.edu.au

Committees

The trial has a steering committee comprised on the project manager and investigators that oversees the project.

Contribution

MH, SP and LT drafted the paper and the protocol documents on which it was based. All authors reviewed the paper and made extensive comments and edits to it. The paper and protocol are based on the grant application submitted to and peer reviewed by the NHMRC in 2016.

Competing interests

The investigators have no competing interests to declare relevant to this study.

Data statement

Data and Meta-data will be stored in a repository at the University of New South Wales. De-identified data will be made available subject to ethics committee approval.

Dissemination

The findings of the study will be made available to participants and the public via the Centre for Primary Health Care web page 25and through conference presentations and research publications. There are no restricts on publication.

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Appendix 1: Trial Registration Data Set

1. Primary Registry and Trial Identifying Number: Australian New Zealand Clinical Trials Registry (ACTRN 12617001508369).
2. Date of Registration in Primary Registry: 26 October 2017 (Updated 20 March 2018)
3. Secondary Identifying Numbers: Australian National Health and Medical Research Council Project Number: APP1125681.
4. Source(s) of Monetary or Material Support: Australian National Health and Medical Research Council
5. Primary Sponsor: University of New South Wales, NSW 2052 Australia.
6. Secondary Sponsors: University of Adelaide, University of Sydney, University of Wollongong, CSIRO Health and Biosecurity, Macquarie University.
7. Contact for Public Queries: Ms Sharon Parker, Email: sharon.parker@unsw.edu.au; telephone: +61 (2) 9385 8396; and postal address: Centre for Primary Health Care and Equity, UNSW SYDNEY NSW 2052 AUSTRALIA..
8. Contact for Scientific Queries: Professor Mark Harris, email: m.f.harris@unsw.edu.au; telephone: +61 2 9385 8384; Postal address: Centre for Primary Health Care and Equity UNSW SYDNEY NSW 2052 AUSTRALIA.
9. Public Title: Health eLiteracy for Prevention in General Practice .
10. Scientific Title: Preventing chronic disease in patients with low health literacy using eHealth and teamwork in primary health care: Protocol for a cluster Randomised controlled trial. Acronym: HeLP-GP.
11. Countries of Recruitment: Australia
12. Health Condition(s) or Problem(s) Studied: Overweight and obesity.
13. Intervention(s): The HeLP-GP intervention includes a practice-level quality improvement intervention (medical record audit and feedback, staff training and practice facilitation visits) to support practices to implement the clinical intervention for patients. The clinical intervention involves a health check visit with a practice nurse based on the 5As framework (assess, advise, agree, assist and arrange), the use of a purpose-built patient-facing app, my snapp, and referral for telephone coaching. The aim of the intervention is to support patients to change diet and physical activity. Practices are randomly allocated to intervention and control groups. Patients recruited by control group practices will receive usual care (the clinical practice routinely offered to patients by the GP and PN).
14. Key Inclusion and Exclusion Criteria:

Practice Inclusion criteria: Situated in Local Government Areas (LGAs) with a SEIFA score equal to or below the 6th decile. Using Medical Director PracSoft or Best Practice software and allocate patients to individual GPs within this software. Agree to the use of Doctors Control Panel (DCP) linked with their software to identify eligible patients for the study; Have access to an active internet connection; Have at least one practice nurse who is prepared to conduct the HeLP intervention with eligible patients and complete data management relating to these patients

Patient Inclusion criteria: Aged 40-74 years; Overweight or obese (BMI≥28 recorded in last 12 months) ; BP recorded in the clinical software within the previous 12 months; Speaking English and/or Arabic; access to a smart phone or tablet device.

Patient Exclusion criteria: Experiencing recent weight loss (>5% in past 3 months); diagnosis of Diabetes requiring insulin or a current prescription for insulin; diagnosis of Cardiovascular disease (includes angina, myocardial infarction, heart failure, heart valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident)); Taking medication for weight loss (Orlistat or Phenteremine); Cognitive impairment; Physical impairment prohibiting the patient from undertaking moderate level physical activity.

15. Anticipated date of first enrolment: 1st May 2018.

16. Sample size: Planned: 1600

17. Sample size: Current: 0 patients

18. Recruitment Status: Pending: participants are not yet being recruited or enrolled at any site

19. Primary Outcome(s):

i) Health literacy. Measure Health Literacy Questionnaire: Timepoints: Baseline, 6 and 12 months

ii) e-health literacy. Measure eHeals. Timepoints: Baseline, 6, 12 and 18 months

v) Body Mass Index. Calculated from measured weight in Kg and height in cm. Timepoints: Baseline, 6 , 12 and 18 months.

vi) Waist circumference. Measured in cm. Timepoints: Baseline, 6 , 12 and 18 months.

vii) Blood pressure. Measured in mmHg using automated sphygmomanometer. Timepoints: Baseline, 6 , 12 and 18 months

20. Secondary outcomes

i) Daily fruit and vegetable consumption. Measure: questions adapted from NSW Population Health Survey and CSIRO Healthy diet score. Timepoints: Baseline and 6 months

ii) Physical activity level. Measure: Self-reported minutes of vigorous and moderate activity. Calculated as score. Timepoints: Baseline and 6 months.

iii) Health related quality of life. Measure: EQ-5D-5L. Baseline and 12 months.

ii) Total Cholesterol. Measure: Recorded total cholesterol from medical records. Up to 2 years prior to baseline and 12 months.

iii) Advice and Referral. Measure: Patient questionnaire on reported advice or referral given by GP for smoking, diet, physical activity or weight management in previous 6 months. Timepoints: Baseline, 6 months

iv) Cost. Measure: Practice nurse time plus Medical Benefits Schedule and Pharmaceutical Benefits Schedule data. Timepoints: 12 months.

21. Ethics Review

i) Status: Approved (HC17474)

ii) Date of approval: 27 July 2017

iii) Name and contact details of Ethics committee(s): University of New South Wales Human Research Ethics Committee. Phone P: +61 2 9385 6222, + 61 2 9385 7257 or + 61 2 9385 7007. Email: humanethics@unsw.edu.au

22. Completion date: Unknown

23. Summary Results: Not yet available

24. IPD sharing statement: Plan to share IPD: No

Figure 1. Practice and patient recruitment

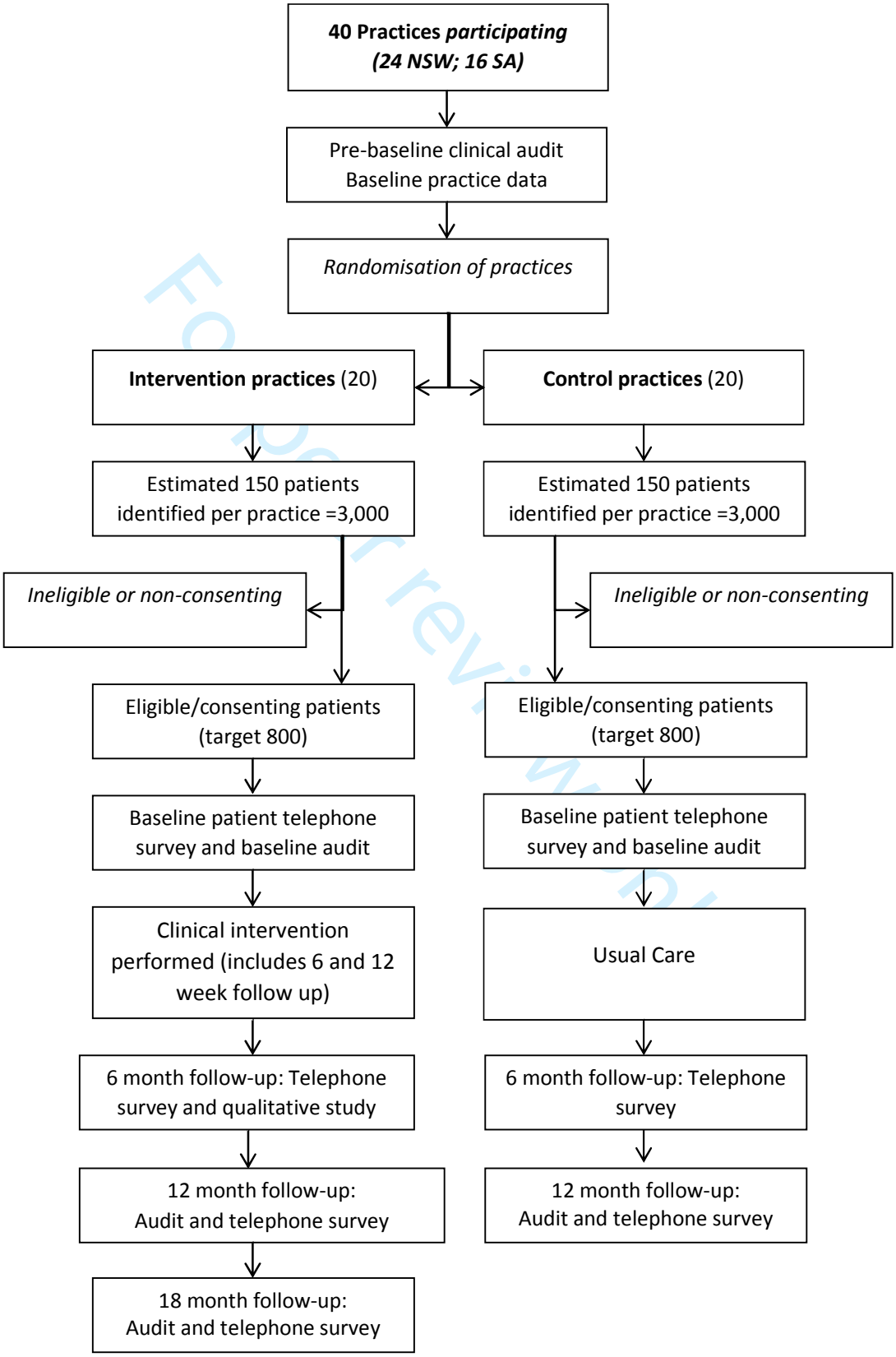


Figure 2: Clinical audit reports

Baseline deidentified audit report for patients aged 40-74 years

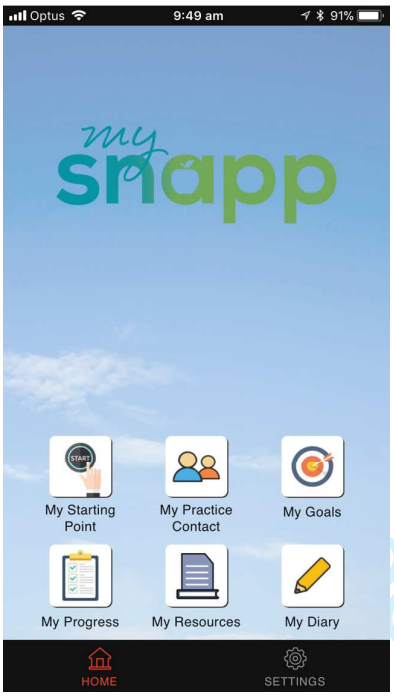
	Proportion of patients in your practice n (%)		Min Standards %
a) Smoking status Recorded *in past 2 years*			85
b) Alcohol intake Recorded in past 2 years			70
c) BMI *Recorded in past 12 months**			85
d) Waist Circumference *Recorded in 2 years*			70
e) Blood Pressure *Recorded in past 12 months**	*On antihypertensive medication*	*Not on antihypertensive Medication*	90
g) Fasting Blood Lipids *Recorded in past 12 months**	*On Lipid medication*	*Not on Lipid Medication*	
Total cholesterol			85
LDL-C			85
HDL-C			85
TG			85

* Recommended frequency because sample includes patients with type 2 diabetes and patients on medication.

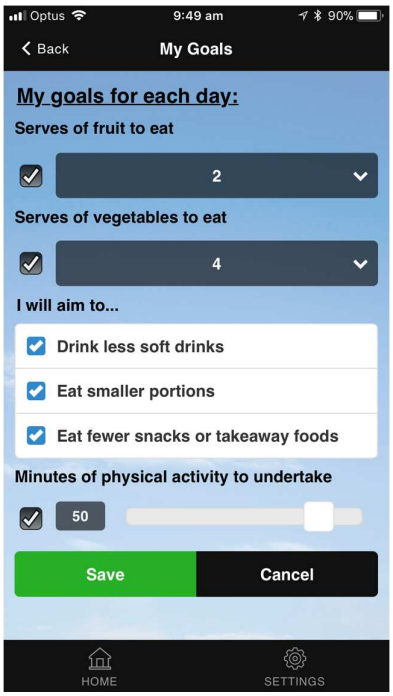
Identified audit report for patients enrolled in study

Patient Name	Gender	Age	Smoking Status	BMI	Systolic BP		Total cholesterol		Absolute risk
			Current, Ex- or Never		*On Medic*	*Not on Meds*	*On Meds*	*Not on Meds*	
Target			***Non or Ex***	***BMI≤ 25***	***Systolic BP <140 mmHg***		***Total Cholesterol <4mMol/L***		***<15%***
Total meeting standards									

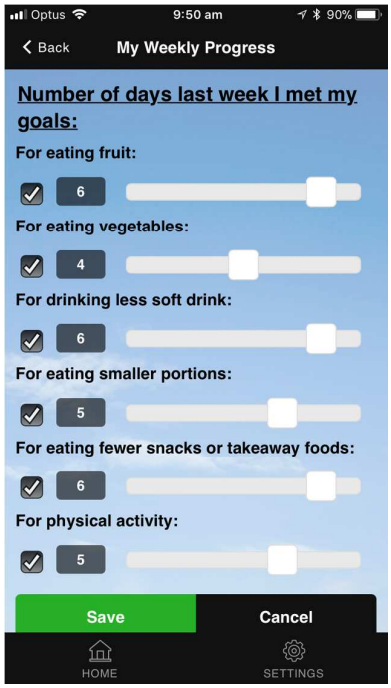
Figure 3: *My Snapp* screens



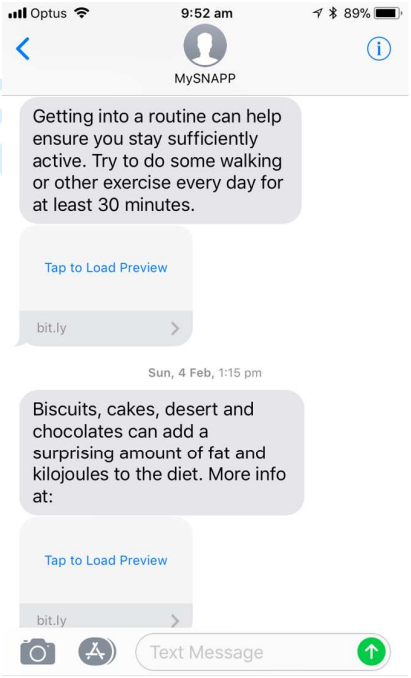
Landing Page



Goal Setting



Weekly self-monitoring



Text message

Figure 4: Outcomes and Data collection

Outcome	Source	Baseline	6 months	12 months	18 months (interv only)
Primary					
Health literacy e-health literacy	Patient questionnaire				
Diet and physical activity	Patient questionnaire				
BMI, waist circumference, BP	Record audit				
Secondary					
Total cholesterol	Record audit				
Quality of life (EQ-5D-5L)	Patient questionnaire				
Health service and medication use	Patient questionnaire MBS and PBS	6 m prior 12 m prior		6 m prior 12 m prior	

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

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

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

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	29
Protocol version	#3	Date and version identifier	29
Funding	#4	Sources and types of financial, material, and other support	24
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1 and 2
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	29

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	24
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	24
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-9
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	10
Objectives	#7	Specific objectives or hypotheses	9
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	9
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	9
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10,11
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	14-17

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	13
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	18
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	15
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	18-19
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	18-19
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	20-21
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	12
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	10

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	10
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	19-20
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	20
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	21
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	21
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	21

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	21
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	12
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	13
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	26
Data access	#29	Statement of who will have access to the final trial dataset,	26

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	26
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

BMJ Open

Preventing chronic disease in patients with low health literacy using eHealth and teamwork in primary health care: Protocol for a cluster Randomised controlled trial.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-023239.R1
Article Type:	Protocol
Date Submitted by the Author:	11-Apr-2018
Complete List of Authors:	Parker, Sharon; University of New South Wales, Centre for Primary Health Care and Equity Stocks, Nigel; University of Adelaide, General Practice Nutbeam, Don; The University of Sydney, Public Health Thomas, Louise ; University of New South Wales, Centre for Primary Health Care and Equity Denney-Wilson, Elizabeth; University of Sydney - Mallett Street Campus, Sydney Nursing School Zwar, N; University of Wollongong , Med9icine Karnon, Jon; The University of Adelaide Lloyd, Jane; University of New South Wales, Centre for Primary Health Care and Equity Noakes, Manny; CSIRO Health and Biosecurity Liaw, Siaw-Teng; UNSW Australia, School of Public Health and Community Medicine Lau, Annie; Macquarie University, Australian Institute of Health Innovation, Faculty of Medicine and Health Sciences Osborne, Richard; Deakin University, Public Health Innovation, Population Health Strategic Research Centre Harris, Mark; University of New South Wales, School of Public Health and Community Medicin
Primary Subject Heading:	Public health
Secondary Subject Heading:	General practice / Family practice, Health informatics, Nutrition and metabolism, Health services research
Keywords:	Overweight, Obesity, PRIMARY CARE, PREVENTIVE MEDICINE, health literacy, m-health

Title: Preventing chronic disease in patients with low health literacy using eHealth and teamwork in primary health care: Protocol for a cluster Randomised controlled trial

Authors

Parker S[1], Stocks N[2], Nutbeam D[3], Thomas L[1], Denney-Wilson E[4], Zwar N[5], Karnon J[6], Lloyd J[1], Noakes M[7], Liaw ST[8], Lau A[9], Osborne R[10], Harris MF*[1].

[1] Centre for Primary Health Care and Equity, University of New South Wales

[2] Discipline of General Practice, University of Adelaide

[3] Sydney School of Public Health University of Sydney

[4] Sydney Nursing School University of Sydney.

[5] School of Medicine, University of Wollongong

[6] School of Public Health, University of Adelaide

[7] Nutrition and Health Program, CSIRO Health and Biosecurity.

[8] School of Public Health and Community Medicine, University of New South Wales.

[9] Centre for Health Informatics, Australian Institute of Health Innovation, Macquarie University

[10] School of Health and Social Development, Centre for Population Health Research, Faculty of Health, Deakin University

* Corresponding author

Word count: Abstract: 224; Body: 5082 (including tables)

Roles and Contact email for Authors

Sharon Parker	Project manager	sharon.parker@unsw.edu.au
Nigel Stocks	Chief investigator	nigel.stocks@adelaide.edu.au
Don Nutbeam	Chief investigator	don.nutbeam@sydney.edu.au
Louise Thomas	Research officer	louise.thomas@unsw.edu.au
Elizabeth Denney-Wilson	Chief investigator	elizabeth.denney-wilson@sydney.edu.au
Nicholas Zwar	Chief investigator	nzwar@uow.edu.au
Jonathan Karnon	Chief investigator	jonathan.karnon@adelaide.edu.au
Jane Lloyd	Associate investigator	j.lloyd@unsw.edu.au
Manny Noakes	Chief investigator	manny.noakes@csiro.au
Siaw-Teng Liaw	Chief investigator	siaw@unsw.edu.au
Annie Lau	Chief investigator	annie.lau@mq.edu.au
Richard Osborne	Associate investigator	richard.osborne@deakin.edu.au
Mark Fort Harris	Lead Investigator	m.f.harris@unsw.edu.au

Abstract

Background

Adults with lower levels of health literacy are less likely to engage in health promoting behaviours. Our trial evaluates the impacts and outcomes of a mobile health enhanced preventive intervention in primary care for people who are overweight or obese.

Methods/Design

A two-arm pragmatic practice-level cluster randomised trial will be conducted in 40 practices in low socioeconomic areas in Sydney and Adelaide, Australia. Forty patients aged 40-70 years with a BMI ≥ 28 will be enrolled per practice. The HeLP-GP intervention includes a practice-level quality improvement intervention (medical record audit and feedback, staff training and practice facilitation visits) to support practices to implement the clinical intervention for patients. The clinical intervention involves a health check visit with a practice nurse based on the 5As framework (assess, advise, agree, assist and arrange), the use of a purpose-built patient-facing app, *my snapp*, and referral for telephone coaching. The primary outcomes are change in health literacy, lifestyle behaviours, weight, waist circumference and blood pressure. The study will also evaluate changes in quality of life and health service use to determine the cost effectiveness of the intervention and examine the experiences of practices in implementing the program.

Discussion

Our trial will provide evidence to inform the role of primary health care in preventive care for overweight and obese adults and addressing the barriers of low health literacy.

Strengths and Limitations of this study

- This is a large cluster randomised controlled trial of an intervention that is designed to be implemented as part of routine general practice in Australia.
- The primary and secondary outcomes measured will inform policy and practice regarding the role of information technology in preventive care in primary health care and its relevance to adult patients in general practice.
- While the cluster design prevents contamination between intervention and control groups, it means that both providers and patients will not be blinded to the intervention.
- The study will be conducted in urban practices in two Australian states. This may limit its generalisability to rural settings and other countries.

Trial Registration

This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12617001508369).

Date registered 30 October 2017.

Keywords

Overweight, obesity, primary care, preventive medicine, health literacy, m-health

Introduction

Rationale

Reducing the burden of chronic disease is an important public health priority in Australia (1). Overweight and obesity account for 7% of the burden of disease (2) as 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) Currently around 63% of the Australian population are overweight or obese (BMI 25 kg/m2 or more) and the prevalence is increasing (3). The burden of overweight is unequally distributed with a 13% higher prevalence of overweight in the lowest compared with the highest socioeconomic group in females (4). There is an urgent need to find effective strategies at both the population and individual level to prevent and manage this condition.

Low functional health literacy (i.e., health related reading and numeracy) is present in approximately 59% of the population and is more common in socioeconomically disadvantaged populations (5). It is a potential barrier to the uptake and effectiveness of a range of preventive interventions (6). Aspects of health literacy have also been associated with poorer uptake of screening programs and immunisation (7, 8). Conversely higher health literacy has been associated with greater improvements in response to physical activity interventions in disadvantaged populations(9). Patients with low health literacy are less likely to engage in health promoting behaviours (10-12), receive and understand preventive advice, and attend or complete programs that they are referred to (13, 14). A systematic review of interventions in primary care to improve health literacy for chronic disease behavioural risk factors found that interventions with multiple components were more effective at improving nutritional health literacy (15).

Primary care is well positioned to contribute to the prevention and management of overweight and obesity. Over 86% of the population of Australia visit a general practitioner at least once a year (16). Almost a third of patients presenting in general practice are obese and two thirds are overweight or obese, which are rates similar to the prevalence in the general community (17). Behavioural interventions in primary care have been demonstrated to achieve a 5-7% improvement in weight, blood pressure or lipids for patients, potentially preventing or delaying the onset of Type 2 diabetes and cardiovascular disease (18-20). However these interventions tend to have lower uptake by low socioeconomic groups (21, 22) and, overall, most weight loss interventions in primary care achieve only small reductions in weight (23).

Preliminary work leading up to this study

Over the past decade we have sought to develop more effective interventions to prevent disease in primary care which target disadvantaged populations who are more likely to have low health literacy. In previous research we have found that ethnicity and language interact with health literacy to influence uptake of preventive interventions especially those for weight loss (24). This accords with the findings of others that health literacy differentials are greater among older people, for those born overseas, those who do not speak English at home and those with low educational attainment (25). In these groups patient-provider communication tends to be less effective, leading providers to incorrectly assume that patients with low health literacy are poorly motivated and they are therefore less likely to offer lifestyle interventions (26, 27). Organisational and practitioner barriers also contribute to low frequency and effectiveness of assessment, advice, goal setting, and referral of patients with low health literacy (6, 28). These barriers include time available for consultations and competing demands on primary care staff.

We have also identified a need to tailor prevention and management of excess weight to a patients' level of health literacy (29). Our review of primary health care level interventions targeting health

literacy around weight loss found limited information as to the effect of weight loss interventions on health literacy primarily because this is an outcome not frequently reported (30). We have evaluated a structured, nurse delivered health check intervention based on 5As that includes a brief assessment of health literacy, tailoring advice and the use of "teach-back"; goal setting that involves specific, time-bound goals that are set collaboratively and involve feedback; assisted navigation to referral services and pro-active follow up visits (30-33). This has proven feasible to implement (34), however, consistent with other studies, the impact on risk behaviours and weight have been small (23). This may be due to the limited capacity within primary care to provide interventions based on evidence that are of sufficient intensity and length.

We have concluded that there is a need to supplement weight management consultations in primary care with specific components that continue to operate outside the consultation such as coaching programs and other support services. There is some evidence of barriers to uptake of these components such as cost and accessibility (27, 35), although the evidence for health coaching suggests it is an accessible, affordable and effective method to change health behaviours (36, 37). Moreover an evaluation of a government funded telephone coaching service in NSW suggested that it could be effective in reaching disadvantaged population groups (38). Another promising approach is the use of e-health to supplement both clinical care and referral programs in supporting behaviour change. Previous research has demonstrated the effectiveness of mobile health (m-health) text messages as part of a lifestyle program to prevent unhealthy weight gain in young adults (39). This adds to the emerging evidence of the efficacy of using mobile apps and SMS text messaging in supporting change in health behaviours (40). However, the optimal form and role of this technology for patients with low health or e-health literacy is still unclear.

This paper describes the protocol for the development and evaluation of an intervention which combines face to face consultation in general practice with these digital health approaches based on

previous research which has demonstrated both feasibility of implementation and highlighted the potential for health gains.

Intervention Development

The various components of the HeLP-GP intervention have been developed and piloted over the past five years.

The brief primary care intervention which is designed to support practices to improve the quality of preventive care for the SNAP (smoking, nutrition, alcohol and physical activity) risk behaviours and weight management is based on behavioural theory and is structured on the 5As framework which encompasses assessment, advice, agreeing on goals, assisting with motivational counselling and referral options and arranging follow up (13, 41). Progress along the pathway from assessment to follow up is associated with increased patient motivation and behaviour change (42). This has been trialled in general practice and found to be feasible and acceptable and to lead to improvement in the quality of preventive care (30, 43, 44). This intervention was adapted for use by practice nurses and modified for patients with low health literacy to include brief screening for low health literacy, tailored communication and referral navigation to local lifestyle programs and piloted (45). It was subsequently evaluated in a trial which demonstrated its feasibility and acceptability to providers and patients (30).

The app used in this study is supported by *Healthy.me*, a personally controlled health management platform designed to help patients and consumers manage their health (46). This has been shown to improve uptake of preventive services (47, 48) and strong consumer acceptance has been demonstrated in Australia across different healthcare settings including primary care (49). This platform was modified to create the mobile application used in this study (*my snapp*). This was

informed by research that interventions based on theory and those involving goal-setting and self-monitoring as well as providing additional methods to interact with patients, particularly text messages, were more effective (50-53). Other research suggests that patients with low health literacy prefer apps or text messages to other sources of online information (54).

Aims and research questions

The aim of this study is to evaluate the implementation and effectiveness of a preventive intervention in primary care structured around the 5As framework supported by a patient-facing mobile app, consultations with the practice nurse and/or referral to a telephone coaching service. The intervention aims to develop the knowledge and skills of overweight or obese patients with low health literacy. The trial will assess the impact of the intervention on preventive care received, patients' health and e-health literacy, physical and behavioural risk factors, quality of life and costs.

Methods

Trial Design

The trial is a pragmatic, two-arm, practice-level cluster randomised controlled trial evaluating impacts and outcomes of a m-health enhanced preventive intervention in primary care.

Setting

Australian general practice. The study will be conducted in two regions of Sydney (South West Sydney and Central and Eastern Sydney) and Adelaide, in collaboration with the local Primary Health Networks (PHNs).

Randomisation

Randomisation of practices into intervention or control groups (providing usual care) will be performed using an internet-based randomisation service (RANDOMIZE.NET). Practice randomisation was chosen because of the risk of contamination if individual patients were randomised within practices. Randomisation will be performed in two waves. Practices will be stratified according to the size of the practice (less than 5 GPs and 5 or more GPs) and location (NSW/SA) prior to randomisation. GPs and Practice Nurses (PNs) will be delivering the intervention and are not blinded to the intervention.

Eligibility and Exclusion Criteria

General Practices

Eligibility for practices is based on meeting the following inclusion criteria. Practices should:

- Be situated in Local Government Areas (LGAs) with a low Socio-economic (SEIFA[1]) score equal to and below the 6th decile (usually associated with lower health literacy (5)
- Use clinical software compatible with the data extraction and recruitment tool *Doctors Control Panel* (DCP). This includes *Medical Director, MediNet, PracSoft and Best Practice* and associated compatible billing software (*Pracsoft and Best Practice Management*).
- Agree to the installation of DCP for the purposes of clinical audit and to identify eligible patients for the study
- Have access to an active internet connection
- Have at least one practice nurse who is prepared to conduct the HeLP- GP intervention with eligible and consenting patients and complete data management relating to these patients

[1] Australian Bureau of Statistics Socioeconomic Indexes for Areas (SEIFA) http://www.abs.gov.au/websitedbs/censushome.nsf/home/seifahelpansuis?opendocument&navpos=260&#01

- Agree to provide GP follow up health checks to participating patients at 12 weeks and 12-month time points
- Can make their staff available to distribute study materials to potential study participants when they register with reception prior to seeing a GP

Practice patients

Eligible patients are those who are:

- Aged 40-74 years
- Overweight or obese (BMI≥28 recorded in last 12 months)[2]
- With BP recorded in the clinical software within the previous 12 months
- Speaking English and/or Arabic [3]
- With access to a smart phone or tablet device

Exclusion criteria:

- Experiencing recent weight loss (>5% in past 3 months)
- A diagnosis of Diabetes requiring insulin or a current prescription for insulin
- A diagnosis of Cardiovascular disease (includes angina, myocardial infarction, heart failure, heart valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident))
- Taking medication for weight loss (Orlistat or Phenteremine)
- Cognitive impairment
- Physical impairment which prohibits engaging in moderate level physical activity

[2] 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.

[3] Arabic was chosen as many recently arrived immigrants in the geographical areas are Arabic speaking

Recruitment

The recruitment process for practices and patients is outlined in Figure 1. The target practice recruitment is 24 practices from two regions in Sydney (South West Sydney and Central and Eastern Sydney) and 16 practices from Adelaide, South Australia.

The primary source of practice recruitment will be through participating Primary Health Networks (PHNs) in the target locations. PHNs will approach potentially eligible practices using mail, fax and practice visits to ascertain their interest. Practices will be provided with a study outline and asked to complete an Expression of Interest (EOI). A face to face practice visit will provide detailed information about practice tasks and confirm eligibility.

Recruitment of Practice Patients

Patients will be recruited at the point of presentation using the *Doctors' Control Panel* software (DCP) which has also been used in previous research [12]. This software will be programmed according to the inclusion and exclusion criteria to identify potential participants as they present to the practice. These patients will be flagged and information on patients BMI, lipids and blood pressure will be extracted from the medical record and printed. This information will be attached to information and consent forms by the practice receptionist and given to patients to read and discuss with the GP or practice nurse. The practice will be reimbursed for the time spent by the reception staff.

[Insert Figure 1 about here].

Ethics

The study has been approved by the University of New South Wales Human Research Ethics Committee (HC17474). The University of Adelaide Human Research Ethics committee has ratified this approval.

Practice and Provider consent

Written consent will be obtained from all participating practices including consent to conduct the study in the practice and access practice data, and individual consent from all participating GPs and PNs.

Patient Consent

Patients will be given information and consent forms in English or Arabic language and be able to ask further questions of the GP or PN. The patient will provide their written consent by filling in the consent form and either placing it in a collection box at reception, or by returning it in a 'reply paid' envelope to the research team. To increase comprehension and meaningful consent within our target population of patients with low health literacy, we have shortened and simplified the Participant Information Statement and Consent forms. Patient eligibility will be confirmed by the GP and at subsequent interview. They will be invited by mail at 6 months to separately consent to the use of routinely collected data on health service use (from Medicare (MBS) Australia's national health insurance program), pharmaceutical use (from the Pharmaceutical Benefits Scheme (PBS)) and hospitalisation data (from State admitted patient data collections).

Withdrawal

Practices or patients may withdraw from the study at any time. If patients commence weight loss medication or develop cognitive impairment or severe illness they will be withdrawn from the study. Withdrawals and reasons for withdrawal will be recorded.

Patient and public involvement.

The development of the research question and outcome measures was informed by previous research conducted in general practice on preventive care, health literacy and obesity management. This included extensive qualitative study with patients about their experience of care in general

practice and the influence of their culture and health literacy (24, 34, 43, 55). Patients were not involved in the design of this study and will not be involved in the recruitment to and conduct of the study. We will conduct qualitative interviews with participants on their experience of the intervention. A summary report will be made available to participants via the study website.

Trial Registration

The HeLP trial is prospectively registered with the Australian Clinical Trials Registry (ANZCTR): ACTRN12617001508369 http://www.ANZCTR.org.au/ACTRN12617001508369.aspx

Description of the intervention

The HeLP GP intervention includes a practice level quality improvement (QI) intervention and a clinical intervention. A logic model for the intervention can be found in Appendix 1.

1. Practice intervention

This includes a de-identified medical record audit, training of practice staff (GPs and PNs) and a series of three practice facilitation visits.

a) Medical record audit

A de-identified medical record audit will be conducted by research staff using the DCP program pre-baseline in both intervention and control patients aged 40-74 years (who have not had a heart attack or stroke or do not have diabetes requiring insulin), on the recording of smoking status, alcohol consumption, BMI, waist circumference, blood pressure and total cholesterol. In intervention practices an identified medical audit of the records of consenting patients participating in the trial will be conducted at baseline and 12 months. This will include assessing the control of their risk factors and cardiovascular risk. Audit reports will be fed back to practitioners (GPs and PNs), who will reflect on the reports and be supported to make improvements in the practice facilitation visits (See below and Figure 2).

[Insert Figure 2 about here]

b) GP and Nurse training to deliver intervention

Three comprehensive online training modules will cover study processes, the health risks of obesity, benefits of weight loss, the role of GPs and nurses in weight management, the components of the HeLP-GP intervention, tailoring care to the needs of people with low health literacy, processes to be followed for the health check visits and the use of the App with patients. Online videos will reinforce the GPs' and PNs' use of the App and referral to telephone coaching. Links to these will be provided to participating GPs and PNs. An on-line post training questionnaire and evaluation form will be completed by GP and PN participants and will provide information to evaluate the training and its impact.

c) Facilitation visits conducted by CIs and PHNs

Facilitation visits will be made up to three times over three months to each intervention practice during the beginning of intervention phase to support PNs and the practice. The aim of the practice facilitation is to support each intervention practice to implement the HeLP-GP intervention including making improvements in recording based on the initial de-identified clinical audit and prepare for the health check visits.

2. Clinical intervention

The clinical intervention has three components, each of which will be offered to all patients in the intervention group: a health check visit with the PN; a patient-facing app - *my snapp*; and referral to telephone coaching. Patients may receive any concomitant care indicated for their medical conditions.

a) Practice nurse health check and follow up.

Eligible patients will attend a health check visit with the PN within 4 weeks of recruitment. The content of the nurse consult is based on the 5As (Table 1). The content of the consultation is consistent with the Australian Guidelines for the management of overweight and obesity [28, 48, 49] and will include assessment of health literacy, brief advice, use of "teachback" to determine if the patient has understood the advice given, goal setting (using *my snapp* or recorded using a health check form) and offering referral to telephone coaching (Get Healthy). The nurse will be alerted to those patients who have low e-health literacy (from the baseline assessment) and will spend extra time demonstrating and checking the use of *my snapp* (over one or two consultations). Patients will be reviewed by the PN at 6 weeks and by the GP at 12 weeks.

Table 1: Initial practice nurse health check (40 minutes)

Assess	Review baseline BMI, waist circumference, blood pressure and lipids. Briefly assess diet, physical activity, health literacy and e-health literacy.
Advise/ Agree	Provide brief advice on risk factors and health behaviours checking understanding using the Teach-back method. Register patient for the app. Download and log into the app using the patients phone. Work with patient to enter profile and set relevant lifestyle goals in the app.
Assist	Introduce and provide referral to the Get Healthy telephone coaching program to the patient, (outline purpose of the program and details about participation).
Arrange	Arrange follow up visit at 6 weeks and a further visit with the GP at 12 weeks

b) my snapp

The components of the App are described in Table 2 and Figure 3. The PN explains the App, supports the patient to register and download the App, enters information on risk factors (BMI, WC, BP) and the practice and helps the patient to set goals and navigate the App. There is also a patient website where participants can get further information and communicate any problems or issues with the

App. The content of *my snapp* aligns with both the nurse health check and the telephone coaching (Table 2).

Table 2: *my snapp* content

Section	Description
My Starting Point	Nurse records initial measurements (height, weight, waist circumference, blood pressure) during health check visit
My Practice Contact	This records GP and PN's contact details.
My Goals	Nurse assists patient to set and revise diet and physical activity goals during health check visit and at 6-week follow-up.
My Measures	Patient records achievement of goals and views graphs of progress over time in weeks in which they achieved goals for diet and physical activity.
My Resources	Patient accesses fact sheets and videos about healthy eating and exercise. The fact sheets can be accessed in English or Arabic.
My Diary	Patient keeps notes on progress and any problems for discussion with the nurse or GP.
Text messages	Two text messages (one focused on diet and one on physical activity) are sent from the app each week. These are tailored to week and provide direct advice and a web link for further information.

[Insert Figure 3 about here]

c) Telephone Coaching

The telephone coaching program recommended to patients is "Get Healthy" which is supported by the relevant state government and provided free of charge. Get Healthy delivers 10 free coaching calls over 10 weeks which provide:

- Review of lifestyle goals (diet and physical activity) and ways to address barriers to achieving these goals
- Practical health information
- Support and resources to promote self-monitoring of diet, physical activity and weight

- Resources and tools to develop and maintain motivation for a healthier lifestyle
- Assistance to deal with set-backs and problem solve
- Social support to help participants to try new ideas and approaches to address lifestyle behaviours

The coaching is available in multiple languages with the assistance of the national interpreter service.

Assessing the implementation fidelity of the intervention

Implementation of the intervention will be assessed by the following measures:

- % of GPs and PNs who complete the online training modules
- % of intervention patients who receive baseline, and 6-week clinical review by a PN
- % of patients who receive a health check at 12-weeks by a GP
- Usage of the lifestyle App determined by app-analytics (% of patients with documented goals related to lifestyle change)
- % who received assisted referral to Get Healthy telephone coaching
- % of patients who take up and complete Get Healthy telephone coaching program

Evaluation

Outcomes

All primary outcomes are changes at the level of the individual patient between baseline and 12 months. These include change in:

- Two domains of health literacy from the Health Literacy Questionnaire (56) (Ability to find good health information and Understand health information well enough to know what to do) and e-health literacy (using the eHeals) (57);

- Lifestyle behaviours including portions of fruit and vegetables, soft drink, high fat and snack food consumed per day, use of a dietary plan and the level of physical activity adapted from existing instruments (58-60).
- Weight, height, BMI, waist circumference, blood pressure extracted from patient medical records.

Secondary outcomes include health related quality of life using the EQ-5D-5L(61) , total cholesterol extracted from the medical record and patient reported advice and referral given by the GP or practice nurse(30) and health service use and costs from routinely collected data by Australia's health insurance agency and pharmaceutical benefits service (MBS and PBS).

Data collection (See Figure 4)

Practice: A practice assessment survey will be conducted by the research team at baseline to determine organization and staffing, use of health education materials and links to other services.

Providers: GPs and PNs involved in the study will complete a questionnaire at baseline and 12 months. This will ask about their existing preventive practices and referral pattern, approach to and confidence with health literacy and health education, previous training and education (43, 62).

Patient surveys: All patients will participate in a survey administered by research staff by telephone at baseline, 6 and 12 months to assess diet and physical activity behaviours, health literacy and e-health literacy. The interview will include questions about education received in general practice and referral for lifestyle or weight interventions at baseline and 6 months and quality of life at baseline and 12 months. Intervention group patients will be interviewed at 18 months about lifestyle behaviours.

Medical record audits: These will be conducted at baseline, 6 months, 12 months and 18 months.

Administrative health service data: All patients will be asked to consent to provision of health service and medication use from routinely collected data from Australia's national health insurance and pharmaceutical benefits authorities (MBS and PBS).

Qualitative interviews: A sample of up to 25 patients and 20 providers stratified by state and practice size will be interviewed between 3 and 6 months post intervention. The interviews will explore patient and provider perceptions of how preventive care is influenced by health literacy and provide feedback on the fidelity and barriers to the adoption of the intervention.

[Insert Figure 4 about here]

Data will be collected on all participants who discontinue or are excluded.

Control Practices

After the initial audit of recording of risk factors, which will be fed back to control practices to improve recording, they will recruit patients in the same way as intervention practices. They will provide usual care (the clinical practice routinely offered to patients by the GP and PN). Data from patients attending control practices will be collected from their medical records at baseline and 12 months and they will receive the same telephone questionnaire as patients in the intervention group which includes the frequency of advice and referral at baseline and 12 months. Control practices will be offered the intervention after 12 months.

Sample size calculation

We aim to recruit 40 practices (24 NSW; 16 SA); 20 practices intervention and 20 practices control. We are aiming to consent 40 patients per practice (1600 total) based on previous research [30]. We anticipate a loss of approximately 20-25% at follow up (12 months). We will seek mobile numbers and alternative contacts to improve follow up. Estimates for sample size based on intra-cluster correlation coefficients, prevalence, variance and effect sizes from our previous research are in table 3, based on a two-sided test of significance at α=0.05. β= 0.8 and 20% loss to follow up [40] (Table 3).

Table 3: ICC and sample size estimates for primary outcomes

Outcome	Intra-cluster Correlation	Design effect (30-40 patients	Effect size or difference in	Sample size per group

	Coefficient	per practice)	proportions	
Mean Health Literacy Score	0.014	1.43	0.4	140
Mean Diet score	0.001	1.03	0.21	367
Mean PA score	0.018	1.56	0.28	312
Mean BMI	0.042	2.30	0.30	401
Mean Systolic BP	0.057	2.77	0.39	285

Data management

Data will be cleaned and coded and stored in a secure environment according to the data management protocol.

Adverse events

An independent adverse events committee will monitor and if necessary investigate any reports of possible adverse events or harms.

Analysis

We will examine differences in the change in the primary and secondary outcomes between intervention and control practices at six months for health literacy and patient behaviours and 12 months for all outcomes. Analyses will be conducted on an intention-to-treat basis and adjusted for baseline differences in any characteristics (e.g. age, gender) between groups. We will analyse outcome variables (health literacy, e-health literacy, diet and physical activity behaviours, BMI, waist circumference, BP, total cholesterol, quality of life and health service use) using multilevel linear and logistic regression techniques that adjust for clustering by practice with multiple imputation for missing values.

Economic evaluation

Information on resource use associated with the intervention will be collected by research staff, including the cost of setting up the intervention: practice staff education, practice support visits and materials and web support. Other relevant resource use includes GP and PN visits, referrals, hospital attendances and prescribing. We will request patient consent to access their medical records, MBS and PBS data, and public hospital data from the State Health Departments. The MBS, PBS and State data will capture most primary care and hospital costs. The cost of PN visits for health checks will be assigned an hourly rate based on PN salary levels plus on-costs. Questions on patient use of lifestyle services and programs, and non-Medicare funded allied health will also be included in the patient questionnaire. Cost estimates will be generated for referrals to community-based programs. In the base case analysis, undertaken from a health service perspective, referrals to allied health professionals will only be costed if supported by a Medicare claim. The incremental costs of the intervention, will be presented alongside the consequences with respect to changes in quality of life (including the estimation of QALY gains informed by the EQ5D-5L) and differences in health literacy, behavioural outcomes, and clinical measures (BMI, blood pressure and Lipids). Deterministic and bootstrapped sensitivity analyses will be undertaken to identify key uncertain parameters and represent uncertainty around the mean estimates, respectively.

Qualitative analysis

The qualitative interviews will be transcribed and analysed thematically using the program NVivo (QSR NVivo 11). This will use an inductive approach based on the data as well as deductively based on health literacy and health information theory (13, 63).

Discussion

This trial evaluates a comprehensive intervention which is designed to support better preventive care for overweight and obese patients with low health literacy. It builds on previous work by the investigators and others to develop feasible interventions in primary care that address both patient and practice barriers to adoption, implementation and effectiveness. If successful, it will inform policy and practice including the role of primary care in addressing the challenge of overweight and obesity and the often-conflicting information that is available to practitioners and the public.

The complexity of the intervention and evaluation poses potential threats to internal and external validity. Recruiting and engaging a large number of practices to a trial such as this is becoming increasingly difficult. We have addressed this by working in partnership with Primary Health Networks (district level organisations of general practice and allied health services) to identify, approach and brief practice principals and practitioners on the study. Practice costs will be reimbursed, and practitioners will be able to access continuing professional development points through the clinical audit and training. However, the main incentive is the value of the research itself and how it will inform policy and practice in the long run and this needs to be carefully discussed.

Problems with recruitment, retention or engagement of patients with the intervention and data collection have the potential to reduce statistical power and therefore the ability to detect the primary outcomes with adequate precision. In this setting, recruitment procedures need to avoid pressure from the research team and patient's own GP to ensure that eligible patients are approached and provided with sufficient information to make an informed decision about participation. We will work with practices to set up software and systems to make this possible. A significant part of the burden on participants will be from the telephone interviews by the research team. Although telephone interviews are preferred by most patients, they are onerous if they are

too long. We have thus had to balance this burden against our desire to collect as much information as possible using robust instruments.

A further risk is that the clinical intervention will not be implemented in practice as we planned. Again, addressing this requires close work with the practices. The implementation measures and qualitative evaluation will provide some insight, but this may be too late to correct. We have thus built into the practice level intervention several measures to improve fidelity. These include feedback mechanisms in the online training, reflective feedback from practices on the audits and practice discussion during the facilitation visits. These will be tracked regularly during the implementation of the trial. A further risk is that some health and e-health literacy will both be required for adoption of the App by patients and is expected to improve as a result of the intervention use. This will be addressed by the support provided to patients by practice nurses and general practitioners.

The fieldwork for the study is planned to be completed by December 2018 with follow-up completed by mid-2019. We anticipate circulation of the main findings from the study by 2020.

Figure Legends

Figure 1. Practice and patient recruitment

Figure 2: Clinical audit reports

Figure 3: My Snapp screens

Figure 4: Outcomes and Data collection

Acknowledgements

The authors would like to acknowledge the partnership of the Central and Eastern, South West Sydney and Adelaide Primary Health Networks and the other HeLP-GP investigators and research staff especially An Tran in Sydney and Carmel McNamara in SA. We also thank Paige Martin, Jason Dalmazzo, Abir Khurshied, Rattapon Kevin Deeraviset for their efforts in the development of *my snapp*; staff in the New South Wales and South Australian Ministry of Health and Get-Healthy (especially Ruth Chesser-Hawkins, Lyndall Thomas and Kate Reid) for their support in providing access to the telephone coaching program and collection of data associated with its use; and Anton Knieriemen, Colin Sheppard and Oliver Frank who developed a tailored version of the DCP program to facilitate patient recruitment and clinical audits. We would like to acknowledge the general practices involved in piloting for this for the project and the consumers linked to Adelaide PHN for piloting *my snapp*.

Funding

National Health and Medical Research Council (NHMRC) of Australia project grant 2017 (APP1125681). RO is funded in part through a NHMRC Senior Research Fellowship (APP1059122). The funder played no role in the design of this study.

Trial Sponsor

Centre for Primary Health Care and Equity, UNSW. Contact Professor Mark Harris +61 2 93858384 or m.f.harris@unsw.edu.au

Committees

The trial has a steering committee comprised on the project manager and investigators that oversees the project.

Contribution

SP co-drafted the paper and protocol documents on which it was based

NS contributed to and was CI on the peer reviewed funding proposal and commented on the paper and protocol documents on which it was based specially data collection and intervention in general practice

DN contributed to and was CI on the peer reviewed funding proposal and contributed to the overall design of the study and intervention and content of the paper and protocol documents on which it was based

LT co-drafted the paper and protocol documents on which it was based

ED-W contributed to and was CI on the peer reviewed funding proposal and contributed to the design of the study and content of the paper and protocol documents on which it was based especially in the education components of the intervention

NZ contributed to and was CI on the peer reviewed funding proposal and commented on the paper and protocol documents on which it was based especially in relation to the role of general practice

JK contributed to and was CI on the peer reviewed funding proposal especially the health economic component and commented on the paper and protocol documents on which it was based

JL contributed to and was AI on the peer reviewed funding proposal especially the health economic component and commented on the paper and protocol documents on which it was based

MN contributed to and was CI on the peer reviewed funding proposal especially the nutrition component and commented on the paper.

STL contributed to and was CI on the peer reviewed funding proposal especially the informatics component and commented on the paper and protocol documents on which it was based

AL contributed to and was CI on the peer reviewed funding proposal especially the m-health component and commented on the paper and protocol documents on which it was based

RO contributed to and was AI on the peer reviewed funding proposal especially the health literacy component and commented on the paper and protocol documents on which it was based

MFH developed and led the peer reviewed funding proposal including the design of the study and intervention and co-drafted the paper and protocol documents on which it was based.

The paper and protocol are based on the grant application submitted to and peer reviewed by the NHMRC in 2016.

Competing interests

The investigators have no competing interests to declare relevant to this study.

Data statement

Data and Meta-data will be stored in a repository at the University of New South Wales. De-identified data will be made available subject to ethics committee approval.

Dissemination

The findings of the study will be made available to participants and the public via the Centre for Primary Health Care web page 25and through conference presentations and research publications. There are no restricts on publication.

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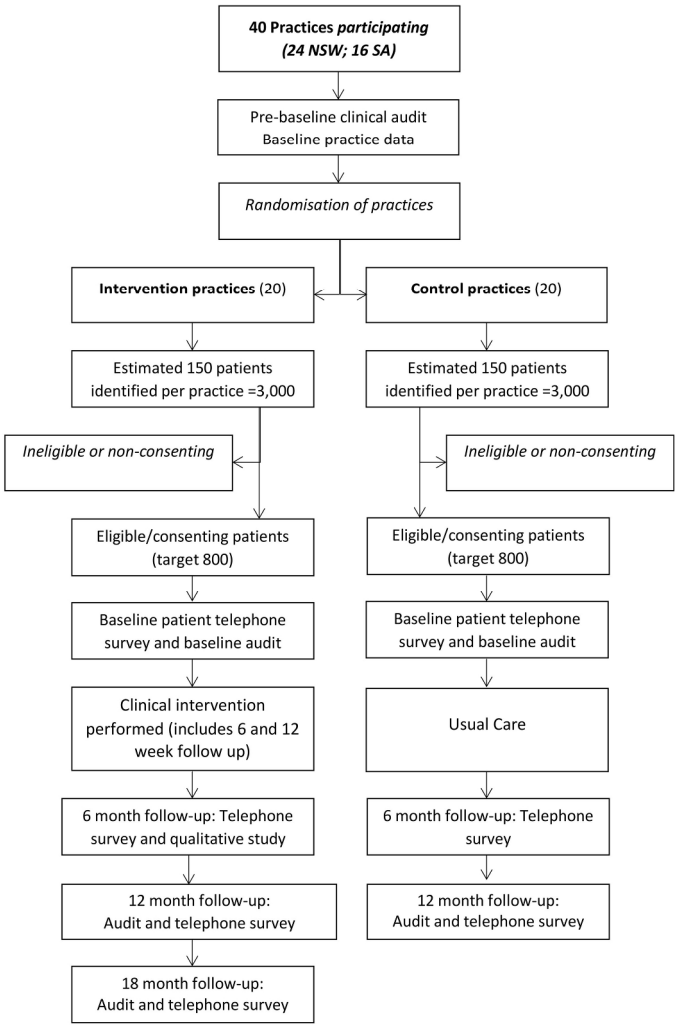

Figure 1

170x289mm (300 x 300 DPI)

Baseline deidentified audit report for patients aged 40-74 years

		Proportion of patients in your practice n (%)		Min Standards %
a) Smoking status Recorded *in past 2 years*				85
b) Alcohol intake Recorded in past 2 years				70
c) BMI *Recorded in past 12 months**				85
d) Waist Circumference *Recorded in 2 years*				70
e) Blood Pressure *Recorded in past 12 months**		*On antihypertensive medication*	*Not on antihypertensive Medication*	90
g) Fasting Blood Lipids *Recorded in past 12 months**		*On Lipid medication*	*Not on Lipid Medication*	
	Total cholesterol			85
	LDL-C			85
	HDL-C			85
	TG			85

* Recommended frequency because sample includes patients with type 2 diabetes and patients on medication.

Identified audit report for patients enrolled in study

Patient Name	Gender	Age	Smoking Status	BMI	Systolic BP		Total cholesterol		Absolute risk
			Current, Ex- or Never		*On Medic*	*Not on Meds*	*On Meds*	*Not on Meds*	
Target			*Non or Ex*	*BMI≤ 25*	*Systolic BP <140 mmHg*		*Total Cholesterol <4mMol/L*		*<15%*
Total meeting standards									

Figure 2

150x226mm (300 x 300 DPI)

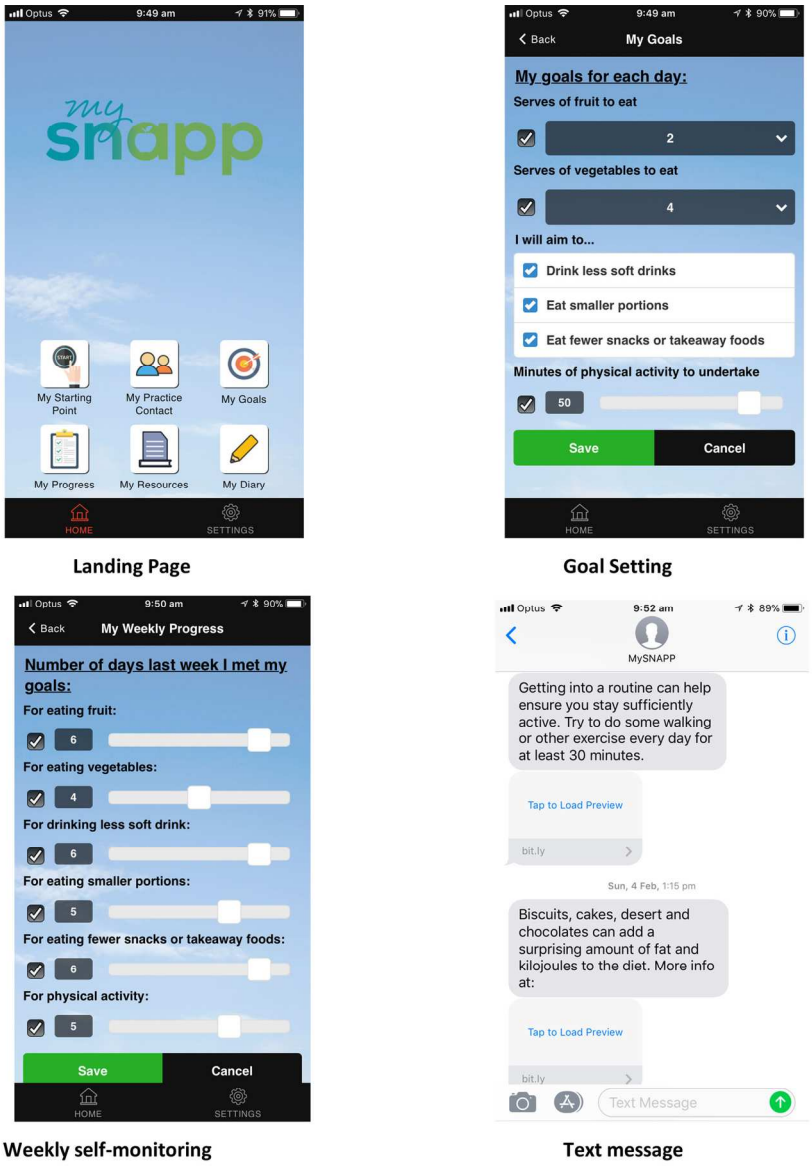

Figure 3

138x193mm (300 x 300 DPI)

Outcome	Source	Baseline	6 months	12 months	18 months (interv only)
Primary					
Health literacy e-health literacy	Patient questionnaire	■	■	■	
Diet and physical activity	Patient questionnaire	■	■	■	■
BMI, waist circumference, BP	Record audit	■		■	■
Secondary					
Total cholesterol	Record audit	■		■	
Quality of life (EQ-5D-5L)	Patient questionnaire	■		■	
Health service and medication use	Patient questionnaire MBS and PBS	■ 6 m prior 12 m prior		■ 6 m prior 12 m prior	

Figure 4

99x63mm (300 x 300 DPI)

Appendix 1: Trial Registration Data Set

1. Primary Registry and Trial Identifying Number: Australian New Zealand Clinical Trials Registry (ACTRN 12617001508369).

2. Date of Registration in Primary Registry: 26 October 2017 (Updated 20 March 2018)

3. Secondary Identifying Numbers: Australian National Health and Medical Research Council Project Number: APP1125681.

4. Source(s) of Monetary or Material Support: Australian National Health and Medical Research Council

5. Primary Sponsor: University of New South Wales, NSW 2052 Australia.

6. Secondary Sponsors: University of Adelaide, University of Sydney, University of Wollongong, CSIRO Health and Biosecurity, Macquarie University.

7. Contact for Public Queries: Ms Sharon Parker, Email: sharon.parker@unsw.edu.au; telephone: +61 (2) 9385 8396; and postal address: Centre for Primary Health Care and Equity, UNSW SYDNEY NSW 2052 AUSTRALIA..

8. Contact for Scientific Queries: Professor Mark Harris, email: m.f.harris@unsw.edu.au; telephone: +61 2 9385 8384; Postal address: Centre for Primary Health Care and Equity UNSW SYDNEY NSW 2052 AUSTRALIA.

9. Public Title: Health eLiteracy for Prevention in General Practice .

10. Scientific Title: Preventing chronic disease in patients with low health literacy using eHealth and teamwork in primary health care: Protocol for a cluster Randomised controlled trial. Acronym: HeLP-GP.

11. Countries of Recruitment: Australia

12. Health Condition(s) or Problem(s) Studied: Overweight and obesity.

13. Intervention(s): The HeLP-GP intervention includes a practice-level quality improvement intervention (medical record audit and feedback, staff training and practice facilitation visits) to support practices to implement the clinical intervention for patients. The clinical intervention involves a health check visit with a practice nurse based on the 5As framework (assess, advise, agree, assist and arrange), the use of a purpose-built patient-facing app, my snapp, and referral for telephone coaching. The aim of the intervention is to support patients to change diet and physical activity. Practices are randomly allocated to intervention and control groups. Patients recruited by control group practices will receive usual care (the clinical practice routinely offered to patients by the GP and PN).

14. Key Inclusion and Exclusion Criteria:

Practice Inclusion criteria: Situated in Local Government Areas (LGAs) with a SEIFA score equal to or below the 6th decile. Using Medical Director PracSoft or Best Practice software and allocate patients to individual GPs within this software. Agree to the use of Doctors Control Panel (DCP) linked with their software to identify eligible patients for the study; Have access to an active internet connection; Have at least one practice nurse who is prepared to conduct the HeLP intervention with eligible patients and complete data management relating to these patients

Patient Inclusion criteria: Aged 40-74 years; Overweight or obese (BMI≥28 recorded in last 12 months) ; BP recorded in the clinical software within the previous 12 months; Speaking English and/or Arabic; access to a smart phone or tablet device.

Patient Exclusion criteria: Experiencing recent weight loss (>5% in past 3 months); diagnosis of Diabetes requiring insulin or a current prescription for insulin; diagnosis of Cardiovascular disease (includes angina, myocardial infarction, heart failure, heart valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident)); Taking medication for weight loss (Orlistat or Phenteremine); Cognitive impairment; Physical impairment prohibiting the patient from undertaking moderate level physical activity.

15. Anticipated date of first enrolment: 1st May 2018.

16. Sample size: Planned: 1600

17. Sample size: Current: 0 patients

18. Recruitment Status: Pending: participants are not yet being recruited or enrolled at any site

19. Primary Outcome(s):

i) Health literacy. Measure Health Literacy Questionnaire: Timepoints: Baseline, 6 and 12 months

ii) e-health literacy. Measure eHeals. Timepoints: Baseline, 6, 12 and 18 months

v) Body Mass Index. Calculated from measured weight in Kg and height in cm. Timepoints: Baseline, 6 , 12 and 18 months.

vi) Waist circumference. Measured in cm. Timepoints: Baseline, 6 , 12 and 18 months.

vii) Blood pressure. Measured in mmHg using automated sphygmomanometer. Timepoints: Baseline, 6 , 12 and 18 months

20. Secondary outcomes

i) Daily fruit and vegetable consumption. Measure: questions adapted from NSW Population Health Survey and CSIRO Healthy diet score. Timepoints: Baseline and 6 months

ii) Physical activity level. Measure: Self-reported minutes of vigorous and moderate activity. Calculated as score. Timepoints: Baseline and 6 months.

iii) Health related quality of life. Measure: EQ-5D-5L. Baseline and 12 months.

ii) Total Cholesterol. Measure: Recorded total cholesterol from medical records. Up to 2 years prior to baseline and 12 months.

iii) Advice and Referral. Measure: Patient questionnaire on reported advice or referral given by GP for smoking, diet, physical activity or weight management in previous 6 months. Timepoints: Baseline, 6 months

iv) Cost. Measure: Practice nurse time plus Medical Benefits Schedule and Pharmaceutical Benefits Schedule data. Timepoints: 12 months.

21. Ethics Review

i) Status: Approved (HC17474)

ii) Date of approval: 27 July 2017

iii) Name and contact details of Ethics committee(s): University of New South Wales Human Research Ethics Committee. Phone P: +61 2 9385 6222, + 61 2 9385 7257 or + 61 2 9385 7007. Email: humanethics@unsw.edu.au

22. Completion date: Unknown

23. Summary Results: Not yet available

24. IPD sharing statement: Plan to share IPD: No

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

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

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

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	29
Protocol version	#3	Date and version identifier	29
Funding	#4	Sources and types of financial, material, and other support	24
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1 and 2
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	29

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	24
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	24
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-9
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	10
Objectives	#7	Specific objectives or hypotheses	9
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	9
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	9
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10,11
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	14-17

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	13
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	18
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	15
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	18-19
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	18-19
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	20-21
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	12
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	10

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	10
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	19-20
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	20
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	21
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	21
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	21

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	21
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	12
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	13
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	26
Data access	#29	Statement of who will have access to the final trial dataset,	26

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	26
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

BMJ Open

Preventing chronic disease in patients with low health literacy using eHealth and teamwork in primary health care: Protocol for a cluster Randomised controlled trial.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-023239.R2
Article Type:	Protocol
Date Submitted by the Author:	20-Apr-2018
Complete List of Authors:	Parker, Sharon; University of New South Wales, Centre for Primary Health Care and Equity Stocks, Nigel; University of Adelaide, General Practice Nutbeam, Don; The University of Sydney, Public Health Thomas, Louise ; University of New South Wales, Centre for Primary Health Care and Equity Denney-Wilson, Elizabeth; University of Sydney - Mallett Street Campus, Sydney Nursing School Zwar, N; University of Wollongong , Med9icine Karnon, Jon; The University of Adelaide Lloyd, Jane; University of New South Wales, Centre for Primary Health Care and Equity Noakes, Manny; CSIRO Health and Biosecurity Liaw, Siaw-Teng; UNSW Australia, School of Public Health and Community Medicine Lau, Annie; Macquarie University, Australian Institute of Health Innovation, Faculty of Medicine and Health Sciences Osborne, Richard; Deakin University, Public Health Innovation, Population Health Strategic Research Centre Harris, Mark; University of New South Wales, School of Public Health and Community Medicin
Primary Subject Heading:	Public health
Secondary Subject Heading:	General practice / Family practice, Health informatics, Nutrition and metabolism, Health services research
Keywords:	Overweight, Obesity, PRIMARY CARE, PREVENTIVE MEDICINE, health literacy, m-health

Title: Preventing chronic disease in patients with low health literacy using eHealth and teamwork in primary health care: Protocol for a cluster Randomised controlled trial

Authors

Parker S[1], Stocks N[2], Nutbeam D[3], Thomas L[1], Denney-Wilson E[4], Zwar N[5], Karnon J[6], Lloyd J[1], Noakes M[7], Liaw ST[8], Lau A[9], Osborne R[10], Harris MF*[1].

[1] Centre for Primary Health Care and Equity, University of New South Wales

[2] Discipline of General Practice, University of Adelaide

[3] Sydney School of Public Health University of Sydney

[4] Sydney Nursing School University of Sydney.

[5] School of Medicine, University of Wollongong

[6] School of Public Health, University of Adelaide

[7] Nutrition and Health Program, CSIRO Health and Biosecurity.

[8] School of Public Health and Community Medicine, University of New South Wales.

[9] Centre for Health Informatics, Australian Institute of Health Innovation, Macquarie University

[10] School of Health and Social Development, Centre for Population Health Research, Faculty of Health, Deakin University

* Corresponding author

Word count: Abstract: 224; Body: 5082 (including tables)

Roles and Contact email for Authors

Sharon Parker	Project manager	sharon.parker@unsw.edu.au
Nigel Stocks	Chief investigator	nigel.stocks@adelaide.edu.au
Don Nutbeam	Chief investigator	don.nutbeam@sydney.edu.au
Louise Thomas	Research officer	louise.thomas@unsw.edu.au
Elizabeth Denney-Wilson	Chief investigator	elizabeth.denney-wilson@sydney.edu.au
Nicholas Zwar	Chief investigator	nzwar@uow.edu.au
Jonathan Karnon	Chief investigator	jonathan.karnon@adelaide.edu.au
Jane Lloyd	Associate investigator	j.lloyd@unsw.edu.au
Manny Noakes	Chief investigator	manny.noakes@csiro.au
Siaw-Teng Liaw	Chief investigator	siaw@unsw.edu.au
Annie Lau	Chief investigator	annie.lau@mq.edu.au
Richard Osborne	Associate investigator	richard.osborne@deakin.edu.au
Mark Fort Harris	Lead Investigator	m.f.harris@unsw.edu.au

Abstract

Introduction

Adults with lower levels of health literacy are less likely to engage in health promoting behaviours. Our trial evaluates the impacts and outcomes of a mobile health enhanced preventive intervention in primary care for people who are overweight or obese.

Methods and analysis

A two-arm pragmatic practice-level cluster randomised trial will be conducted in 40 practices in low socioeconomic areas in Sydney and Adelaide, Australia. Forty patients aged 40-70 years with a BMI ≥ 28 will be enrolled per practice. The HeLP-GP intervention includes a practice-level quality improvement intervention (medical record audit and feedback, staff training and practice facilitation visits) to support practices to implement the clinical intervention for patients. The clinical intervention involves a health check visit with a practice nurse based on the 5As framework (assess, advise, agree, assist and arrange), the use of a purpose-built patient-facing app, *my snapp*, and referral for telephone coaching. The primary outcomes are change in health literacy, lifestyle behaviours, weight, waist circumference and blood pressure. The study will also evaluate changes in quality of life and health service use to determine the cost effectiveness of the intervention and examine the experiences of practices in implementing the program.

Ethics and dissemination

The study has been approved by the University of New South Wales (UNSW) Human Research Ethics Committee (HC17474) and ratified by the University of Adelaide Human Research Ethics committee. There are no restrictions on publication and findings of the study will be made available on a web, conference presentations and research publications. Deidentified data and meta-data will be stored in a repository at UNSW and made available subject to ethics committee approval.

Trial Registration

Registered with Australian Clinical Trials Registry (ACTRN12617001508369) on 30 Oct 2017

Strengths and Limitations of this study

- This is a large prospectively registered cluster randomised controlled trial
- Health economic evaluation will be based on linked health service data and costing of intervention.
- While the cluster design prevents contamination between intervention and control groups, it means that both providers and patients will not be blinded to the intervention.
- The study will be conducted in urban practices in two Australian states. This may limit its generalisability to rural settings and other countries.

Keywords

Overweight, obesity, primary care, preventive medicine, health literacy, m-health

Introduction

Rationale

Reducing the burden of chronic disease is an important public health priority in Australia (1). Overweight and obesity account for 7% of the burden of disease (2) as 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) Currently around 63% of the Australian population are overweight or obese (BMI 25 kg/m2 or more) and the prevalence is increasing (3). The burden of overweight is unequally distributed with a 13% higher prevalence of overweight in the lowest compared with the highest socioeconomic group in females (4). There is an urgent need to find effective strategies at both the population and individual level to prevent and manage this condition.

Low functional health literacy (i.e., health related reading and numeracy) is present in approximately 59% of the population and is more common in socioeconomically disadvantaged populations (5). It is a potential barrier to the uptake and effectiveness of a range of preventive interventions (6). Aspects of health literacy have also been associated with poorer uptake of screening programs and immunisation (7, 8). Conversely higher health literacy has been associated with greater improvements in response to physical activity interventions in disadvantaged populations(9). Patients with low health literacy are less likely to engage in health promoting behaviours (10-12), receive and understand preventive advice, and attend or complete programs that they are referred to (13, 14). A systematic review of interventions in primary care to improve health literacy for chronic disease behavioural risk factors found that interventions with multiple components were more effective at improving nutritional health literacy (15).

Primary care is well positioned to contribute to the prevention and management of overweight and obesity. Over 86% of the population of Australia visit a general practitioner at least once a year (16). Almost a third of patients presenting in general practice are obese and two thirds are overweight or obese, which are rates similar to the prevalence in the general community (17). Behavioural interventions in primary care have been demonstrated to achieve a 5-7% improvement in weight, blood pressure or lipids for patients, potentially preventing or delaying the onset of Type 2 diabetes and cardiovascular disease (18-20). However these interventions tend to have lower uptake by low socioeconomic groups (21, 22) and, overall, most weight loss interventions in primary care achieve only small reductions in weight (23).

Preliminary work leading up to this study

Over the past decade we have sought to develop more effective interventions to prevent disease in primary care which target disadvantaged populations who are more likely to have low health literacy. In previous research we have found that ethnicity and language interact with health literacy to influence uptake of preventive interventions especially those for weight loss (24). This accords with the findings of others that health literacy differentials are greater among older people, for those born overseas, those who do not speak English at home and those with low educational attainment (25). In these groups patient-provider communication tends to be less effective, leading providers to incorrectly assume that patients with low health literacy are poorly motivated and they are therefore less likely to offer lifestyle interventions (26, 27). Organisational and practitioner barriers also contribute to low frequency and effectiveness of assessment, advice, goal setting, and referral of patients with low health literacy (6, 28). These barriers include time available for consultations and competing demands on primary care staff.

We have also identified a need to tailor prevention and management of excess weight to a patients' level of health literacy (29). Our review of primary health care level interventions targeting health

literacy around weight loss found limited information as to the effect of weight loss interventions on health literacy primarily because this is an outcome not frequently reported (30). We have evaluated a structured, nurse delivered health check intervention based on 5As that includes a brief assessment of health literacy, tailoring advice and the use of "teach-back"; goal setting that involves specific, time-bound goals that are set collaboratively and involve feedback; assisted navigation to referral services and pro-active follow up visits (30-33). This has proven feasible to implement (34), however, consistent with other studies, the impact on risk behaviours and weight have been small (23). This may be due to the limited capacity within primary care to provide interventions based on evidence that are of sufficient intensity and length.

We have concluded that there is a need to supplement weight management consultations in primary care with specific components that continue to operate outside the consultation such as coaching programs and other support services. There is some evidence of barriers to uptake of these components such as cost and accessibility (27, 35), although the evidence for health coaching suggests it is an accessible, affordable and effective method to change health behaviours (36, 37). Moreover an evaluation of a government funded telephone coaching service in NSW suggested that it could be effective in reaching disadvantaged population groups (38). Another promising approach is the use of e-health to supplement both clinical care and referral programs in supporting behaviour change. Previous research has demonstrated the effectiveness of mobile health (m-health) text messages as part of a lifestyle program to prevent unhealthy weight gain in young adults (39). This adds to the emerging evidence of the efficacy of using mobile apps and SMS text messaging in supporting change in health behaviours (40). However, the optimal form and role of this technology for patients with low health or e-health literacy is still unclear.

This paper describes the protocol for the development and evaluation of an intervention which combines face to face consultation in general practice with these digital health approaches based on

previous research which has demonstrated both feasibility of implementation and highlighted the potential for health gains.

Intervention Development

The various components of the HeLP-GP intervention have been developed and piloted over the past five years.

The brief primary care intervention which is designed to support practices to improve the quality of preventive care for the SNAP (smoking, nutrition, alcohol and physical activity) risk behaviours and weight management is based on behavioural theory and is structured on the 5As framework which encompasses assessment, advice, agreeing on goals, assisting with motivational counselling and referral options and arranging follow up (13, 41). Progress along the pathway from assessment to follow up is associated with increased patient motivation and behaviour change (42). This has been trialled in general practice and found to be feasible and acceptable and to lead to improvement in the quality of preventive care (30, 43, 44). This intervention was adapted for use by practice nurses and modified for patients with low health literacy to include brief screening for low health literacy, tailored communication and referral navigation to local lifestyle programs and piloted (45). It was subsequently evaluated in a trial which demonstrated its feasibility and acceptability to providers and patients (30).

The app used in this study is supported by *Healthy.me*, a personally controlled health management platform designed to help patients and consumers manage their health (46). This has been shown to improve uptake of preventive services (47, 48) and strong consumer acceptance has been demonstrated in Australia across different healthcare settings including primary care (49). This platform was modified to create the mobile application used in this study (*my snapp*). This was

informed by research that interventions based on theory and those involving goal-setting and self-monitoring as well as providing additional methods to interact with patients, particularly text messages, were more effective (50-53). Other research suggests that patients with low health literacy prefer apps or text messages to other sources of online information (54).

Aims and research questions

The aim of this study is to evaluate the implementation and effectiveness of a preventive intervention in primary care structured around the 5As framework supported by a patient-facing mobile app, consultations with the practice nurse and/or referral to a telephone coaching service. The intervention aims to develop the knowledge and skills of overweight or obese patients with low health literacy. The trial will assess the impact of the intervention on preventive care received, patients' health and e-health literacy, physical and behavioural risk factors, quality of life and costs.

Description of the intervention

The HeLP GP intervention includes a practice level quality improvement (QI) intervention and a clinical intervention. A logic model for the intervention can be found in Appendix 1.

1. Practice intervention

This includes a de-identified medical record audit, training of practice staff (GPs and PNs) and a series of three practice facilitation visits.

a) Medical record audit

A de-identified medical record audit will be conducted by research staff using the DCP program pre-baseline in both intervention and control patients aged 40-74 years (who have not had a heart attack or stroke or do not have diabetes requiring insulin), on the recording of smoking status, alcohol consumption, BMI, waist circumference, blood pressure and total cholesterol. In intervention practices an identified medical audit of the records of consenting patients participating

in the trial will be conducted at baseline and 12 months. This will include assessing the control of their risk factors and cardiovascular risk. Audit reports will be fed back to practitioners (GPs and PNs), who will reflect on the reports and be supported to make improvements in the practice facilitation visits (See below and Figure 1).

[Insert Figure 1 about here]

b) GP and Nurse training to deliver intervention

Three comprehensive online training modules will cover study processes, the health risks of obesity, benefits of weight loss, the role of GPs and nurses in weight management, the components of the HeLP-GP intervention, tailoring care to the needs of people with low health literacy, processes to be followed for the health check visits and the use of the App with patients. Online videos will reinforce the GPs' and PNs' use of the App and referral to telephone coaching. Links to these will be provided to participating GPs and PNs. An on-line post training questionnaire and evaluation form will be completed by GP and PN participants and will provide information to evaluate the training and its impact.

c) Facilitation visits conducted by CIs and PHNs

Facilitation visits will be made up to three times over three months to each intervention practice during the beginning of intervention phase to support PNs and the practice. The aim of the practice facilitation is to support each intervention practice to implement the HeLP-GP intervention including making improvements in recording based on the initial de-identified clinical audit and prepare for the health check visits.

2. Clinical intervention

The clinical intervention has three components, each of which will be offered to all patients in the intervention group: a health check visit with the PN; a patient-facing app - *my snapp*; and referral to

telephone coaching. Patients may receive any concomitant care indicated for their medical conditions.

a) Practice nurse health check and follow up.

Eligible patients will attend a health check visit with the PN within 4 weeks of recruitment. The content of the nurse consult is based on the 5As (Table 1). The content of the consultation is consistent with the Australian Guidelines for the management of overweight and obesity [28, 48, 49] and will include assessment of health literacy, brief advice, use of "teachback" to determine if the patient has understood the advice given, goal setting (using *my snapp* or recorded using a health check form) and offering referral to telephone coaching (Get Healthy). The nurse will be alerted to those patients who have low e-health literacy (from the baseline assessment) and will spend extra time demonstrating and checking the use of *my snapp* (over one or two consultations). Patients will be reviewed by the PN at 6 weeks and by the GP at 12 weeks.

Table 1: Initial practice nurse health check (40 minutes)

Assess	Review baseline BMI, waist circumference, blood pressure and lipids. Briefly assess diet, physical activity, health literacy and e-health literacy.
Advise/ Agree	Provide brief advice on risk factors and health behaviours checking understanding using the Teach-back method. Register patient for the app. Download and log into the app using the patients phone. Work with patient to enter profile and set relevant lifestyle goals in the app.
Assist	Introduce and provide referral to the Get Healthy telephone coaching program to the patient, (outline purpose of the program and details about participation).
Arrange	Arrange follow up visit at 6 weeks and a further visit with the GP at 12 weeks

b) my snapp

The components of the App are described in Table 2 and Figure 2. The PN explains the App, supports the patient to register and download the App, enters information on risk factors (BMI, WC, BP) and the practice and helps the patient to set goals and navigate the App. There is also a patient website where participants can get further information and communicate any problems or issues with the App. The content of *my snapp* aligns with both the nurse health check and the telephone coaching (Table 2).

Table 2: *my snapp* content

Section	Description
My Starting Point	Nurse records initial measurements (height, weight, waist circumference, blood pressure) during health check visit
My Practice Contact	This records GP and PN's contact details.
My Goals	Nurse assists patient to set and revise diet and physical activity goals during health check visit and at 6-week follow-up.
My Measures	Patient records achievement of goals and views graphs of progress over time in weeks in which they achieved goals for diet and physical activity.
My Resources	Patient accesses fact sheets and videos about healthy eating and exercise. The fact sheets can be accessed in English or Arabic.
My Diary	Patient keeps notes on progress and any problems for discussion with the nurse or GP.
Text messages	Two text messages (one focused on diet and one on physical activity) are sent from the app each week. These are tailored to week and provide direct advice and a web link for further information.

[Insert Figure 2 about here]

c) Telephone Coaching

The telephone coaching program recommended to patients is "Get Healthy" which is supported by the relevant state government and provided free of charge. Get Healthy delivers 10 free coaching calls over 10 weeks which provide:

- Review of lifestyle goals (diet and physical activity) and ways to address barriers to achieving these goals
- Practical health information
- Support and resources to promote self-monitoring of diet, physical activity and weight
- Resources and tools to develop and maintain motivation for a healthier lifestyle
- Assistance to deal with set-backs and problem solve
- Social support to help participants to try new ideas and approaches to address lifestyle behaviours

The coaching is available in multiple languages with the assistance of the national interpreter service.

Assessing the implementation fidelity of the intervention

Implementation of the intervention will be assessed by the following measures:

- % of GPs and PNs who complete the online training modules
- % of intervention patients who receive baseline, and 6-week clinical review by a PN
- % of patients who receive a health check at 12-weeks by a GP
- Usage of the lifestyle App determined by app-analytics (% of patients with documented goals related to lifestyle change)
- % who received assisted referral to Get Healthy telephone coaching
- % of patients who take up and complete Get Healthy telephone coaching program

Methods and analysis

Trial Design

The trial is a pragmatic, two-arm, practice-level cluster randomised controlled trial evaluating impacts and outcomes of a m-health enhanced preventive intervention in primary care.

Setting

Australian general practice. The study will be conducted in two regions of Sydney (South West Sydney and Central and Eastern Sydney) and Adelaide, in collaboration with the local Primary Health Networks (PHNs).

Randomisation

Randomisation of practices into intervention or control groups (providing usual care) will be performed using an internet-based randomisation service (RANDOMIZE.NET). Practice randomisation was chosen because of the risk of contamination if individual patients were randomised within practices. Randomisation will be performed in two waves. Practices will be stratified according to the size of the practice (less than 5 GPs and 5 or more GPs) and location (NSW/SA) prior to randomisation. GPs and Practice Nurses (PNs) will be delivering the intervention and are not blinded to the intervention.

Eligibility and Exclusion Criteria

General Practices

Eligibility for practices is based on meeting the following inclusion criteria. Practices should:

- Be situated in Local Government Areas (LGAs) with a low Socio-economic (SEIFA[1]) score equal to and below the 6th decile (usually associated with lower health literacy (5)
- Use clinical software compatible with the data extraction and recruitment tool *Doctors Control Panel* (DCP). This includes *Medical Director, MediNet, PracSoft and Best Practice* and associated compatible billing software (*Pracsoft and Best Practice Management*).
- Agree to the installation of DCP for the purposes of clinical audit and to identify eligible patients for the study
- Have access to an active internet connection
- Have at least one practice nurse who is prepared to conduct the HeLP- GP intervention with eligible and consenting patients and complete data management relating to these patients
- Agree to provide GP follow up health checks to participating patients at 12 weeks and 12-month time points
- Can make their staff available to distribute study materials to potential study participants when they register with reception prior to seeing a GP

Practice patients

Eligible patients are those who are:

- Aged 40-74 years
- Overweight or obese (BMI≥28 recorded in last 12 months)[2]
- With BP recorded in the clinical software within the previous 12 months
- Speaking English and/or Arabic [3]
- With access to a smart phone or tablet device

[1] Australian Bureau of Statistics Socioeconomic Indexes for Areas (SEIFA) http://www.abs.gov.au/websitedbs/censushome.nsf/home/seifahelpansuis?opendocument&navpos=260&#01

[2] 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.

[3] Arabic was chosen as many recently arrived immigrants in the geographical areas are Arabic speaking

Exclusion criteria:

- Experiencing recent weight loss (>5% in past 3 months)
- A diagnosis of Diabetes requiring insulin or a current prescription for insulin
- A diagnosis of Cardiovascular disease (includes angina, myocardial infarction, heart failure, heart valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident))
- Taking medication for weight loss (Orlistat or Phenteremine)
- Cognitive impairment
- Physical impairment which prohibits engaging in moderate level physical activity

Recruitment

The recruitment process for practices and patients is outlined in Figure 3. The target practice recruitment is 24 practices from two regions in Sydney (South West Sydney and Central and Eastern Sydney) and 16 practices from Adelaide, South Australia.

The primary source of practice recruitment will be through participating Primary Health Networks (PHNs) in the target locations. PHNs will approach potentially eligible practices using mail, fax and practice visits to ascertain their interest. Practices will be provided with a study outline and asked to complete an Expression of Interest (EOI). A face to face practice visit will provide detailed information about practice tasks and confirm eligibility.

Recruitment of Practice Patients

Patients will be recruited at the point of presentation using the *Doctors' Control Panel* software (DCP) which has also been used in previous research [12]. This software will be programmed according to the inclusion and exclusion criteria to identify potential participants as they present to the practice. These patients will be flagged and information on patients BMI, lipids and blood

pressure will be extracted from the medical record and printed. This information will be attached to information and consent forms by the practice receptionist and given to patients to read and discuss with the GP or practice nurse. The practice will be reimbursed for the time spent by the reception staff.

[Insert Figure 3 about here].

Patient and public involvement.

The development of the research question and outcome measures was informed by previous research conducted in general practice on preventive care, health literacy and obesity management. This included extensive qualitative study with patients about their experience of care in general practice and the influence of their culture and health literacy (24, 34, 43, 55). Patients were not involved in the design of this study and will not be involved in the recruitment to and conduct of the study. We will conduct qualitative interviews with participants on their experience of the intervention. A summary report will be made available to participants via the study website.

Outcomes

All primary outcomes are changes at the level of the individual patient. These include change in:

- Domains of health literacy from the Health Literacy Questionnaire (56) from self-report in telephone interviews between baseline, 6 and 12 months
- e-health literacy assessed using the e-Health Literacy Scale (eHeals) (57); from self-report in telephone interviews between baseline, 6 12 and 18 months
- Biomedical risk factors (weight, height, BMI, waist circumference, blood pressure) through audit of clinical records, between baseline, 6 12 and 18 months.

Secondary outcomes include change in :-

- Behavioural risk factors (daily fruit and vegetable consumption and physical activity level) assessed from self-report in telephone interviews between baseline and 6 months (58-60).
- total cholesterol extracted from the medical record at baseline and 12 months
- health related quality of life measured using the EQ-5D-5L(61) administered by telephone survey at baseline and 12 months,
- cost of intervention including service use assessed from linked data from public medical insurance (Medical Benefits Schedule), Pharmaceutical Benefits Scheme (PBS) and hospital data at 12 months.
- Receipt of advice given by the GP or practice nurse(30) assessed by patient interview at baseline and 6 months for:
    - Smoking cessation
    - Diet
    - Physical activity and
    - Weight management.

Data collection (See Figure 4)

Practice: A practice assessment survey will be conducted by the research team at baseline to determine organization and staffing, use of health education materials and links to other services. *Providers*: GPs and PNs involved in the study will complete a questionnaire at baseline and 12 months. This will ask about their existing preventive practices and referral pattern, approach to and confidence with health literacy and health education, previous training and education (43, 62). *Patient surveys:* All patients will participate in a survey administered by research staff by telephone at baseline, 6 and 12 months to assess diet and physical activity behaviours, health literacy and e-health literacy. The interview will include questions about education received in general practice and referral for lifestyle or weight interventions at baseline and 6 months and quality of life at

baseline and 12 months. Intervention group patients will be interviewed at 18 months about lifestyle behaviours.

Medical record audits: These will be conducted at baseline, 6 months, 12 months and 18 months.

Administrative health service data: All patients will be asked to consent to provision of health service and medication use from routinely collected data from Australia's national health insurance and pharmaceutical benefits authorities (MBS and PBS).

Qualitative interviews: A sample of up to 25 patients and 20 providers stratified by state and practice size will be interviewed between 3 and 6 months post intervention. The interviews will explore patient and provider perceptions of how preventive care is influenced by health literacy and provide feedback on the fidelity and barriers to the adoption of the intervention.

[Insert Figure 4 about here]

Data will be collected on all participants who discontinue or are excluded.

Control Practices

After the initial audit of recording of risk factors, which will be fed back to control practices to improve recording, they will recruit patients in the same way as intervention practices. They will provide usual care (the clinical practice routinely offered to patients by the GP and PN). Data from patients attending control practices will be collected from their medical records at baseline and 12 months and they will receive the same telephone questionnaire as patients in the intervention group which includes the frequency of advice and referral at baseline and 12 months. Control practices will be offered the intervention after 12 months.

Sample size calculation

We aim to recruit 40 practices (24 NSW; 16 SA); 20 practices intervention and 20 practices control. We are aiming to consent 40 patients per practice (1600 total) based on previous research [30]. We anticipate a loss of approximately 20-25% at follow up (12 months). We will seek mobile numbers and alternative contacts to improve follow up. Estimates for sample size based on intra-cluster

correlation coefficients, prevalence, variance and effect sizes from our previous research are in table 3, based on a two-sided test of significance at α=0.05. β= 0.8 and 20% loss to follow up [40] (Table 3).

Table 3: ICC and sample size estimates for primary outcomes

Outcome	Intra-cluster Correlation Coefficient	Design effect (30-40 patients per practice)	Effect size or difference in proportions	Sample size per group
Mean Health Literacy Score	0.014	1.43	0.4	140
Mean Diet score	0.001	1.03	0.21	367
Mean PA score	0.018	1.56	0.28	312
Mean BMI	0.042	2.30	0.30	401
Mean Systolic BP	0.057	2.77	0.39	285

Data management

Data will be cleaned and coded and stored in a secure environment according to the data management protocol.

Adverse events

An independent adverse events committee will monitor and if necessary investigate any reports of possible adverse events or harms.

Analysis

We will examine differences in the change in the primary and secondary outcomes between intervention and control practices at six months for health literacy and patient behaviours and 12 months for all outcomes. Analyses will be conducted on an intention-to-treat basis and adjusted for baseline differences in any characteristics (e.g. age, gender) between groups. We will analyse outcome variables (health literacy, e-health literacy, diet and physical activity behaviours, BMI, waist circumference, BP, total cholesterol, quality of life and health service use) using multilevel linear and

logistic regression techniques that adjust for clustering by practice with multiple imputation for missing values.

Economic evaluation

Information on resource use associated with the intervention will be collected by research staff, including the cost of setting up the intervention: practice staff education, practice support visits and materials and web support. Other relevant resource use includes GP and PN visits, referrals, hospital attendances and prescribing. We will request patient consent to access their medical records, MBS and PBS data, and public hospital data from the State Health Departments. The MBS, PBS and State data will capture most primary care and hospital costs. The cost of PN visits for health checks will be assigned an hourly rate based on PN salary levels plus on-costs. Questions on patient use of lifestyle services and programs, and non-Medicare funded allied health will also be included in the patient questionnaire. Cost estimates will be generated for referrals to community-based programs. In the base case analysis, undertaken from a health service perspective, referrals to allied health professionals will only be costed if supported by a Medicare claim. The incremental costs of the intervention, will be presented alongside the consequences with respect to changes in quality of life (including the estimation of QALY gains informed by the EQ5D-5L) and differences in health literacy, behavioural outcomes, and clinical measures (BMI, blood pressure and Lipids). Deterministic and bootstrapped sensitivity analyses will be undertaken to identify key uncertain parameters and represent uncertainty around the mean estimates, respectively.

Qualitative analysis

The qualitative interviews will be transcribed and analysed thematically using the program NVivo (QSR NVivo 11). This will use an inductive approach based on the data as well as deductively based on health literacy and health information theory (13, 63).

Ethics and dissemination

Approval

The study has been approved by the University of New South Wales Human Research Ethics Committee (HC17474). The University of Adelaide Human Research Ethics committee has ratified this approval.

Practice and Provider consent

Written consent will be obtained from all participating practices including consent to conduct the study in the practice and access practice data, and individual consent from all participating GPs and PNs.

Patient Consent

Patients will be given information and consent forms in English or Arabic language and be able to ask further questions of the GP or PN. The patient will provide their written consent by filling in the consent form and either placing it in a collection box at reception, or by returning it in a 'reply paid' envelope to the research team. To increase comprehension and meaningful consent within our target population of patients with low health literacy, we have shortened and simplified the Participant Information Statement and Consent forms. Patient eligibility will be confirmed by the GP and at subsequent interview. They will be invited by mail at 6 months to separately consent to the use of routinely collected data on health service use (from Medicare (MBS) Australia's national health insurance program), pharmaceutical use (from the Pharmaceutical Benefits Scheme (PBS)) and hospitalisation data (from State admitted patient data collections).

Withdrawal

Practices or patients may withdraw from the study at any time. If patients commence weight loss medication or develop cognitive impairment or severe illness they will be withdrawn from the study. Withdrawals and reasons for withdrawal will be recorded.

Data deposition

Data and Meta-data will be stored in a repository at the University of New South Wales. De-identified data will be made available subject to ethics committee approval.

Dissemination

The findings of the study will be made available to participants and the public via the Centre for Primary Health Care web and through conference presentations and research publications. There are no restrictions on publication.

Discussion

This trial evaluates a comprehensive intervention which is designed to support better preventive care for overweight and obese patients with low health literacy. It builds on previous work by the investigators and others to develop feasible interventions in primary care that address both patient and practice barriers to adoption, implementation and effectiveness. If successful, it will inform policy and practice including the role of primary care in addressing the challenge of overweight and obesity and the often-conflicting information that is available to practitioners and the public.

The complexity of the intervention and evaluation poses potential threats to internal and external validity. Recruiting and engaging a large number of practices to a trial such as this is becoming increasingly difficult. We have addressed this by working in partnership with Primary Health Networks (district level organisations of general practice and allied health services) to identify, approach and brief practice principals and practitioners on the study. Practice costs will be reimbursed, and practitioners will be able to access continuing professional development points through the clinical audit and training. However, the main incentive is the value of the research itself and how it will inform policy and practice in the long run and this needs to be carefully discussed.

Problems with recruitment, retention or engagement of patients with the intervention and data collection have the potential to reduce statistical power and therefore the ability to detect the primary outcomes with adequate precision. In this setting, recruitment procedures need to avoid pressure from the research team and patient's own GP to ensure that eligible patients are approached and provided with sufficient information to make an informed decision about participation. We will work with practices to set up software and systems to make this possible. A significant part of the burden on participants will be from the telephone interviews by the research team. Although telephone interviews are preferred by most patients, they are onerous if they are too long. We have thus had to balance this burden against our desire to collect as much information as possible using robust instruments.

A further risk is that the clinical intervention will not be implemented in practice as we planned. Again, addressing this requires close work with the practices. The implementation measures and qualitative evaluation will provide some insight, but this may be too late to correct. We have thus built into the practice level intervention several measures to improve fidelity. These include feedback mechanisms in the online training, reflective feedback from practices on the audits and practice discussion during the facilitation visits. These will be tracked regularly during the implementation of the trial. A further risk is that some health and e-health literacy will both be required for adoption of the App by patients and is expected to improve as a result of the intervention use. This will be addressed by the support provided to patients by practice nurses and general practitioners.

The fieldwork for the study is planned to be completed by December 2018 with follow-up completed by mid-2019. We anticipate circulation of the main findings from the study by 2020.

Figure Legends

Figure 1: Clinical audit reports

Figure 2: My Snapp screens

Figure 3. Practice and patient recruitment

Figure 4: Outcomes and Data collection

Acknowledgements

The authors would like to acknowledge the partnership of the Central and Eastern, South West Sydney and Adelaide Primary Health Networks and the other HeLP-GP investigators and research staff especially An Tran in Sydney and Carmel McNamara in SA. We also thank Paige Martin, Jason Dalmazzo, Abir Khurshied, Rattapon Kevin Deeraviset for their efforts in the development of *my snapp*; staff in the New South Wales and South Australian Ministry of Health and Get-Healthy (especially Ruth Chesser-Hawkins, Lyndall Thomas and Kate Reid) for their support in providing access to the telephone coaching program and collection of data associated with its use; and Anton Knieriemen, Colin Sheppard and Oliver Frank who developed a tailored version of the DCP program to facilitate patient recruitment and clinical audits. We would like to acknowledge the general practices involved in piloting for this for the project and the consumers linked to Adelaide PHN for piloting *my snapp*.

Funding Statement

This work is supported by National Health and Medical Research Council (NHMRC) of Australia project grant number APP1125681 (2017). RO is funded in part through a NHMRC Senior Research Fellowship (APP1059122). The funder played no role in the design of this study.

Trial Sponsor

Centre for Primary Health Care and Equity, UNSW. Contact Professor Mark Harris +61 2 93858384 or m.f.harris@unsw.edu.au

Committees

The trial has a steering committee comprised on the project manager and investigators that oversees the project.

Contribution

SP co-drafted the paper and protocol documents on which it was based

NS contributed to and was CI on the peer reviewed funding proposal and commented on the paper and protocol documents on which it was based specially data collection and intervention in general practice

DN contributed to and was CI on the peer reviewed funding proposal and contributed to the overall design of the study and intervention and content of the paper and protocol documents on which it was based

LT co-drafted the paper and protocol documents on which it was based

ED-W contributed to and was CI on the peer reviewed funding proposal and contributed to the design of the study and content of the paper and protocol documents on which it was based especially in the education components of the intervention

NZ contributed to and was CI on the peer reviewed funding proposal and commented on the paper and protocol documents on which it was based especially in relation to the role of general practice

JK contributed to and was CI on the peer reviewed funding proposal especially the health economic component and commented on the paper and protocol documents on which it was based

JL contributed to and was AI on the peer reviewed funding proposal especially the health economic component and commented on the paper and protocol documents on which it was based

MN contributed to and was CI on the peer reviewed funding proposal especially the nutrition component and commented on the paper.

STL contributed to and was CI on the peer reviewed funding proposal especially the informatics component and commented on the paper and protocol documents on which it was based

AL contributed to and was CI on the peer reviewed funding proposal especially the m-health component and commented on the paper and protocol documents on which it was based

RO contributed to and was AI on the peer reviewed funding proposal especially the health literacy component and commented on the paper and protocol documents on which it was based

MFH developed and led the peer reviewed funding proposal including the design of the study and intervention and co-drafted the paper and protocol documents on which it was based.

The paper and protocol are based on the grant application submitted to and peer reviewed by the NHMRC in 2016.

Competing interests

The investigators have no competing interests to declare relevant to this study.

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Baseline deidentified audit report for patients aged 40-74 years

		Proportion of patients in your practice n (%)		Min Standards %
a) Smoking status Recorded *in past 2 years*				85
b) Alcohol intake Recorded in past 2 years				70
c) BMI *Recorded in past 12 months**				85
d) Waist Circumference *Recorded in 2 years*				70
e) Blood Pressure *Recorded in past 12 months**		*On antihypertensive medication*	*Not on antihypertensive Medication*	90
g) Fasting Blood Lipids *Recorded in past 12 months**		*On Lipid medication*	*Not on Lipid Medication*	
	Total cholesterol			85
	LDL-C			85
	HDL-C			85
	TG			85

* Recommended frequency because sample includes patients with type 2 diabetes and patients on medication.

Identified audit report for patients enrolled in study

Patient Name	Gender	Age	Smoking Status	BMI	Systolic BP		Total cholesterol		Absolute risk
			Current, Ex- or Never		*On Medic*	*Not on Meds*	*On Meds*	*Not on Meds*	
Target			*Non or Ex*	*BMI≤ 25*	*Systolic BP <140 mmHg*		*Total Cholesterol <4mMol/L*		*<15%*
Total meeting standards									

Figure 1

150x226mm (300 x 300 DPI)

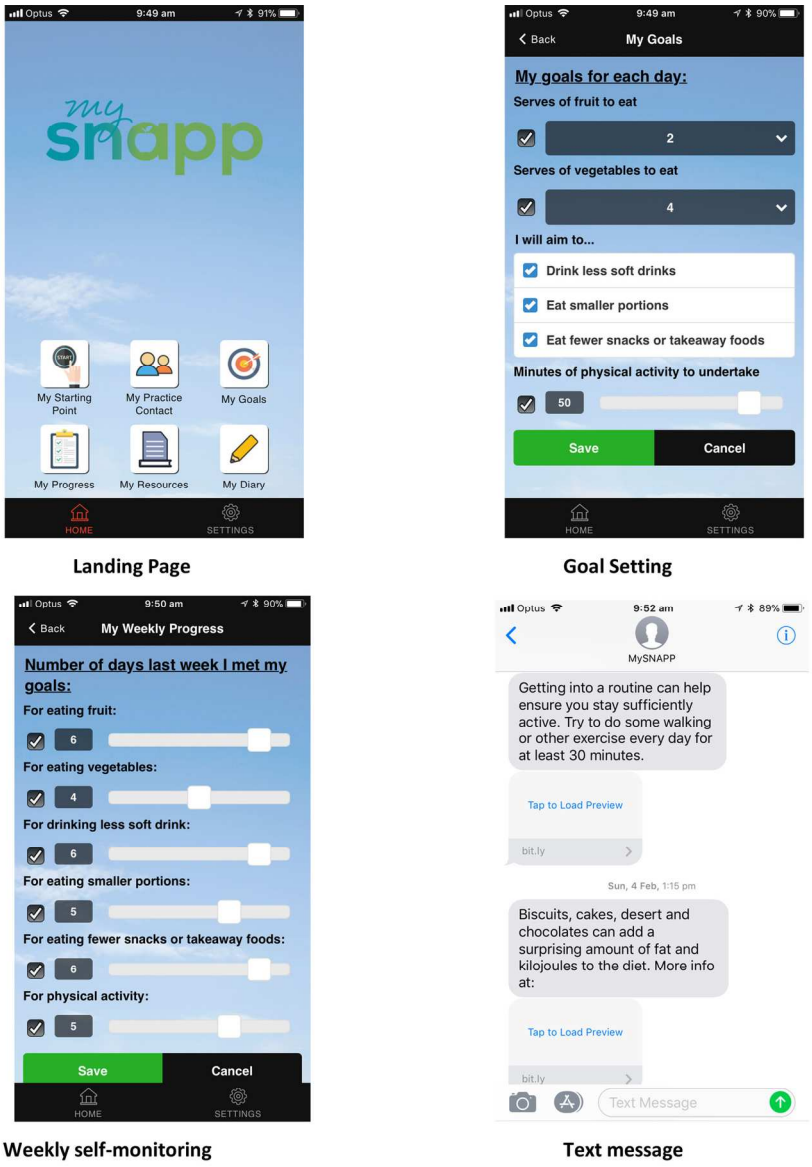

Figure 1

138x193mm (300 x 300 DPI)

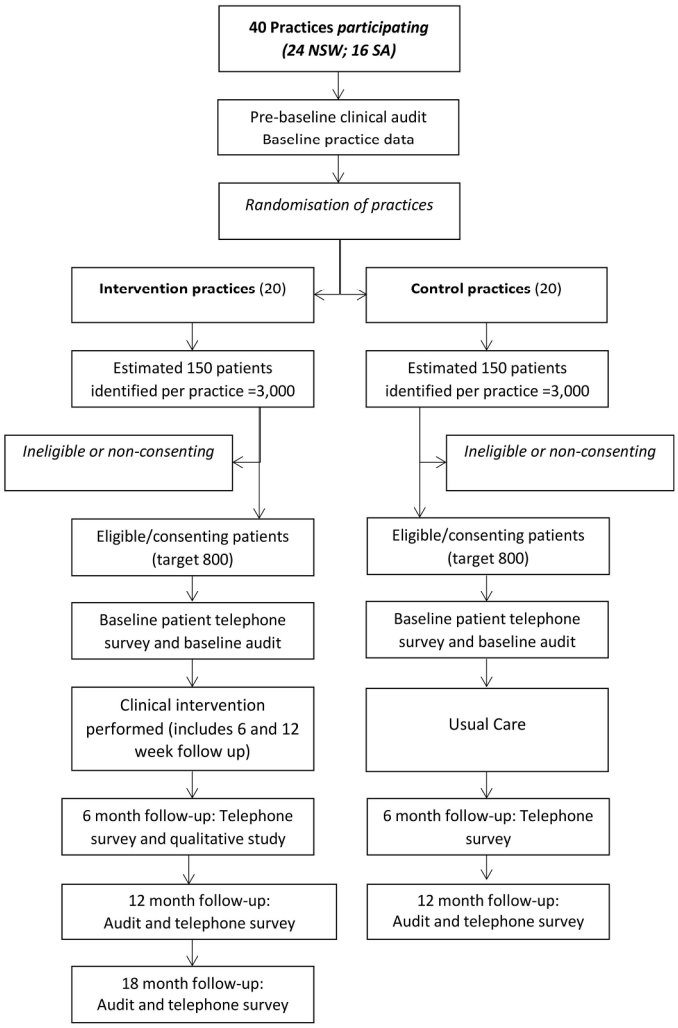

Figure 3

170x289mm (300 x 300 DPI)

Outcome	Source	Baseline	6 months	12 months	18 months (interv only)
Primary					
Health literacy e-health literacy	Patient questionnaire	■	■	■	
Diet and physical activity	Patient questionnaire	■	■	■	■
BMI, waist circumference, BP	Record audit	■		■	■
Secondary					
Total cholesterol	Record audit	■		■	
Quality of life (EQ-5D-5L)	Patient questionnaire	■		■	
Health service and medication use	Patient questionnaire MBS and PBS	■ 6 m prior 12 m prior		■ 6 m prior 12 m prior	

Figure 4

99x63mm (300 x 300 DPI)

Appendix 1: Trial Registration Data Set

1. Primary Registry and Trial Identifying Number: Australian New Zealand Clinical Trials Registry (ACTRN 12617001508369).

2. Date of Registration in Primary Registry: 26 October 2017 (Updated 20 March 2018)

3. Secondary Identifying Numbers: Australian National Health and Medical Research Council Project Number: APP1125681.

4. Source(s) of Monetary or Material Support: Australian National Health and Medical Research Council

5. Primary Sponsor: University of New South Wales, NSW 2052 Australia.

6. Secondary Sponsors: University of Adelaide, University of Sydney, University of Wollongong, CSIRO Health and Biosecurity, Macquarie University.

7. Contact for Public Queries: Ms Sharon Parker, Email: sharon.parker@unsw.edu.au; telephone: +61 (2) 9385 8396; and postal address: Centre for Primary Health Care and Equity, UNSW SYDNEY NSW 2052 AUSTRALIA..

8. Contact for Scientific Queries: Professor Mark Harris, email: m.f.harris@unsw.edu.au; telephone: +61 2 9385 8384; Postal address: Centre for Primary Health Care and Equity UNSW SYDNEY NSW 2052 AUSTRALIA.

9. Public Title: Health eLiteracy for Prevention in General Practice .

10. Scientific Title: Preventing chronic disease in patients with low health literacy using eHealth and teamwork in primary health care: Protocol for a cluster Randomised controlled trial. Acronym: HeLP-GP.

11. Countries of Recruitment: Australia

12. Health Condition(s) or Problem(s) Studied: Overweight and obesity.

13. Intervention(s): The HeLP-GP intervention includes a practice-level quality improvement intervention (medical record audit and feedback, staff training and practice facilitation visits) to support practices to implement the clinical intervention for patients. The clinical intervention involves a health check visit with a practice nurse based on the 5As framework (assess, advise, agree, assist and arrange), the use of a purpose-built patient-facing app, my snapp, and referral for telephone coaching. The aim of the intervention is to support patients to change diet and physical activity. Practices are randomly allocated to intervention and control groups. Patients recruited by control group practices will receive usual care (the clinical practice routinely offered to patients by the GP and PN).

14. Key Inclusion and Exclusion Criteria:

Practice Inclusion criteria: Situated in Local Government Areas (LGAs) with a SEIFA score equal to or below the 6th decile. Using Medical Director PracSoft or Best Practice software and allocate patients to individual GPs within this software. Agree to the use of Doctors Control Panel (DCP) linked with their software to identify eligible patients for the study; Have access to an active internet connection; Have at least one practice nurse who is prepared to conduct the HeLP intervention with eligible patients and complete data management for these patients

Patient Inclusion criteria: Aged 40-74 years; Overweight or obese (BMI≥28 recorded in last 12 months) ; BP recorded in the clinical software within the previous 12 months; Speaking English and/or Arabic; access to a smart phone or tablet device.

Patient Exclusion criteria: Experiencing recent weight loss (>5% in past 3 months); diagnosis of Diabetes requiring insulin or a current prescription for insulin; diagnosis of Cardiovascular disease (includes angina, myocardial infarction, heart failure, heart valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident)); Taking medication for weight loss (Orlistat or Phenteremine); Cognitive impairment; Physical impairment prohibiting the patient from undertaking moderate level physical activity.

15. Anticipated date of first enrolment: 1st May 2018.

16. Sample size: Planned: 1600

17. Sample size: Current: 0 patients

18. Recruitment Status: Pending: participants are not yet being recruited or enrolled at any site

19. Primary Outcome(s):

i) Health literacy. Measure Health Literacy Questionnaire: Timepoints: Baseline, 6 and 12 months

ii) e-health literacy. Measure eHeals. Timepoints: Baseline, 6, 12 and 18 months

v) Body Mass Index. Calculated from measured weight in Kg and height in cm. Timepoints: Baseline, 6 , 12 and 18 months.

vi) Waist circumference. Measured in cm. Timepoints: Baseline, 6 , 12 and 18 months.

vii) Blood pressure. Measured in mmHg using automated sphygmomanometer. Timepoints: Baseline, 6 , 12 and 18 months

20. Secondary outcomes

i) Daily fruit and vegetable consumption. Measure: questions adapted from NSW Population Health Survey and CSIRO Healthy diet score. Timepoints: Baseline and 6 months

ii) Physical activity level. Measure: Self-reported minutes of vigorous and moderate activity. Calculated as score. Timepoints: Baseline and 6 months.

iii) Health related quality of life. Measure: EQ-5D-5L. Baseline and 12 months.

ii) Total Cholesterol. Measure: Recorded total cholesterol from medical records. Up to 2 years prior to baseline and 12 months.

iii) Advice and Referral. Measure: Patient questionnaire on reported advice or referral given by GP for smoking, diet, physical activity or weight management in previous 6 months. Timepoints: Baseline, 6 months

iv) Cost. Measure: Practice nurse time plus Medical Benefits Schedule and Pharmaceutical Benefits Schedule data. Timepoints: 12 months.

21. Ethics Review

i) Status: Approved (HC17474)

ii) Date of approval: 27 July 2017

iii) Name and contact details of Ethics committee(s): University of New South Wales Human Research Ethics Committee. Phone P: +61 2 9385 6222, + 61 2 9385 7257 or + 61 2 9385 7007. Email: humanethics@unsw.edu.au

22. Completion date: Unknown

23. Summary Results: Not yet available

24. IPD sharing statement: Plan to share IPD: No

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

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

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

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	29
Protocol version	#3	Date and version identifier	29
Funding	#4	Sources and types of financial, material, and other support	24
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1 and 2
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	29

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	24
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	24
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-9
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	10
Objectives	#7	Specific objectives or hypotheses	9
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	9
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	9
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10,11
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	14-17

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	13
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	18
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	15
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	18-19
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	18-19
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	20-21
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	12
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	10

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	10
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	19-20
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	20
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	21
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	21
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	21

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	21
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	12
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	13
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	26
Data access	#29	Statement of who will have access to the final trial dataset,	26

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	26
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a