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

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2 health literacy using eHealth and teamwork in

3 primary health care: Protocol for a cluster

4 Randomised controlled trial

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38

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 \geq 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

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76 Introduction

77 Rationale

78 Reducing the burden of chronic disease is an important public health priority in Australia (1).
79 Overweight and obesity account for 7% of the burden of disease (2) as a risk factor for 11 types of
80 cancer, three cardiovascular conditions, chronic kidney disease, diabetes, dementia, gallbladder
81 disease, fatty liver, gout, back pain and osteoarthritis (2) Currently around 63% of the Australian
82 population are overweight or obese (BMI 25 kg/m2 or more) and the prevalence is increasing (3).
83 The burden of overweight is unequally distributed with a 13% higher prevalence of overweight in the
84 lowest compared with the highest socioeconomic group in females (4). There is an urgent need to
85 find effective strategies at both the population and individual level to prevent and manage this
86 condition.
87
88 Low functional health literacy (i.e., health related reading and numeracy) is present in approximately
89 59% of the population and is more common in socioeconomically disadvantaged populations (5). It
90 is a potential barrier to the uptake and effectiveness of a range of preventive interventions (6).
91 Aspects of health literacy have also been associated with poorer uptake of screening programs and
92 immunisation (7, 8). Conversely higher health literacy has been associated with greater
93 improvements in response to physical activity interventions in disadvantaged populations(9).
94 Patients with low health literacy are less likely to engage in health promoting behaviours (10-12),
95 receive and understand preventive advice, and attend or complete programs that they are referred
96 to (13, 14). A systematic review of interventions in primary care to improve health literacy for
97 chronic disease behavioural risk factors found that interventions with multiple components were
98 more effective at improving nutritional health literacy (15).
99

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).

109

110 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.

123

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

1
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3 126 literacy around weight loss found limited information as to the effect of weight loss interventions on
4
5 127 health literacy primarily because this is an outcome not frequently reported (30). We have
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7 128 evaluated a structured, nurse delivered health check intervention based on 5As that includes a brief
8
9 129 assessment of health literacy, tailoring advice and the use of “teach-back”; goal setting that involves
10
11 130 specific, time-bound goals that are set collaboratively and involve feedback; assisted navigation to
12
13 131 referral services and pro-active follow up visits (30-33). This has proven feasible to implement (34),
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15 132 however, consistent with other studies, the impact on risk behaviours and weight have been small
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17 133 (23). This may be due to the limited capacity within primary care to provide interventions based on
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19 134 evidence that are of sufficient intensity and length.
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24 136 We have concluded that there is a need to supplement weight management consultations in primary
25
26 137 care with specific components that continue to operate outside the consultation such as coaching
27
28 138 programs and other support services. There is some evidence of barriers to uptake of these
29
30 139 components such as cost and accessibility (27, 35), although the evidence for health coaching
31
32 140 suggests it is an accessible, affordable and effective method to change health behaviours (36, 37).
33
34 141 Moreover an evaluation of a government funded telephone coaching service in NSW suggested that
35
36 142 it could be effective in reaching disadvantaged population groups (38). Another promising approach
37
38 143 is the use of e-health to supplement both clinical care and referral programs in supporting behaviour
39
40 144 change. Previous research has demonstrated the effectiveness of mobile health (m-health) text
41
42 145 messages as part of a lifestyle program to prevent unhealthy weight gain in young adults (39). This
43
44 146 adds to the emerging evidence of the efficacy of using mobile apps and SMS text messaging in
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46 147 supporting change in health behaviours (40). However, the optimal form and role of this technology
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48 148 for patients with low health or e-health literacy is still unclear.
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53 150 This paper describes the protocol for the development and evaluation of an intervention which
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55 151 combines face to face consultation in general practice with these digital health approaches based on
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152 previous research which has demonstrated both feasibility of implementation and highlighted the
153 potential for health gains.

154

155 Intervention Development

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

158

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

171

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

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

181
182 **Aims and research questions**

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

189
190 **Methods**

191 **Trial Design**

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

194
195 **Setting**

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

200 Randomisation

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

209 Eligibility and Exclusion Criteria

210 General Practices

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

- 212 • Be situated in Local Government Areas (LGAs) with a low Socio-economic (SEIFA¹) score
 213 equal to and below the 6th decile (usually associated with lower health literacy (5)
- 214 • Use clinical software compatible with the data extraction and recruitment tool *Doctors*
 215 *Control Panel* (DCP). This includes *Medical Director*, *MediNet*, *PracSoft* and *Best Practice* and
 216 associated compatible billing software (*Pracsoft* and *Best Practice Management*).
- 217 • Agree to the installation of DCP for the purposes of clinical audit and to identify eligible
 218 patients for the study
- 219 • Have access to an active internet connection
- 220 • Have at least one practice nurse who is prepared to conduct the HeLP- GP intervention with
 221 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>

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

227 Practice patients

228 Eligible patients are those who are:

- 229 - Aged 40-74 years
- 230 - Overweight or obese (BMI \geq 28 recorded in last 12 months)²
- 231 - With BP recorded in the clinical software within the previous 12 months
- 232 - Speaking English and/or Arabic³
- 233 - With access to a smart phone or tablet device
- 234
- 235 *Exclusion criteria:*
- 236 - Experiencing recent weight loss (>5% in past 3 months)
- 237 - A diagnosis of Diabetes requiring insulin or a current prescription for insulin
- 238 - A diagnosis of Cardiovascular disease (includes angina, myocardial infarction, heart failure, heart
- 239 valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident))
- 240 - Taking medication for weight loss (Orlistat or Phentermine)
- 241 - Cognitive impairment
- 242 - Physical impairment which prohibits engaging in moderate level physical activity
- 243

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

244 Recruitment

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

248

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

254

255 Recruitment of Practice Patients

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

264 *[Insert Figure 1 about here].*

265

266 Ethics

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

270

271 Practice and Provider consent

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

275

276 Patient Consent

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

287 Withdrawal

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

291 Trial Registration

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

294

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

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

323

324 c) Facilitation visits conducted by CIs and PHNs

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

330

331 2. Clinical intervention

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

336

337 a) Practice nurse health check and follow up.

338 Eligible patients will attend a health check visit with the PN within 4 weeks of recruitment. The
339 content of the nurse consult is based on the 5As (Table 2). The content of the consultation is
340 consistent with the Australian Guidelines for the management of overweight and obesity [28, 48, 49]
341 and will include assessment of health literacy, brief advice, use of “teachback” to determine if the
342 patient has understood the advice given, goal setting (using *my snapp* or recorded using a health
343 check form) and offering referral to telephone coaching (Get Healthy). The nurse will be alerted to
344 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)

<i>Assess</i>	Review baseline BMI, waist circumference, blood pressure and lipids. Briefly assess diet, physical activity, health literacy and e-health literacy.
<i>Advise/ Agree</i>	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.
<i>Assist</i>	Introduce and provide referral to the Get Healthy telephone coaching program to the patient, (outline purpose of the program and details about participation).
<i>Arrange</i>	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

1
2
3 399 practice nurse(30) and health service use and costs from routinely collected data by Australia's
4
5 400 health insurance agency and pharmaceutical benefits service (MBS and PBS).
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9 402 Data collection (See Figure 4)
10
11 403 *Practice:* A practice assessment survey will be conducted by the research team at baseline to
12
13 404 determine organization and staffing, use of health education materials and links to other services.
14
15 405 *Providers:* GPs and PNs involved in the study will complete a questionnaire at baseline and 12
16
17 406 months. This will ask about their existing preventive practices and referral pattern, approach to and
18
19 407 confidence with health literacy and health education, previous training and education (43, 61).
20
21 408 *Patient surveys:* All patients will participate in a survey administered by research staff by telephone
22
23 409 at baseline, 6 and 12 months to assess diet and physical activity behaviours, health literacy and e-
24
25 410 health literacy. The interview will include questions about education received in general practice
26
27 411 and referral for lifestyle or weight interventions at baseline and 6 months and quality of life at
28
29 412 baseline and 12 months. Intervention group patients will be interviewed at 18 months about lifestyle
30
31 413 behaviours.
32
33 414 *Medical record audits:* These will be conducted at baseline, 6 months, 12 months and 18 months.
34
35 415 *Administrative health service data:* All patients will be asked to consent to provision of health service
36
37 416 and medication use from routinely collected data from Australia's national health insurance and
38
39 417 pharmaceutical benefits authorities (MBS and PBS).
40
41 418 *Qualitative interviews:* A sample of up to 25 patients and 20 providers stratified by state and practice
42
43 419 size will be interviewed between 3 and 6 months post intervention. The interviews will explore
44
45 420 patient and provider perceptions of how preventive care is influenced by health literacy and provide
46
47 421 feedback on the fidelity and barriers to the adoption of the intervention.
48
49 422 [Insert Figure 4 about here]
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51 423 Data will be collected on all participants who discontinue or are excluded.
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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 $\alpha=0.05$. $\beta=0.8$ 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

443 Data management

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

446 Adverse events

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

449 Analysis

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

459 Economic evaluation

460 Information on resource use associated with the intervention will be collected by research staff,
461 including the cost of setting up the intervention: practice staff education, practice support visits and
462 materials and web support. Other relevant resource use includes GP and PN visits, referrals, hospital
463 attendances and prescribing. We will request patient consent to access their medical records, MBS
464 and PBS data, and public hospital data from the State Health Departments. The MBS, PBS and State
465 data will capture most primary care and hospital costs. The cost of PN visits for health checks will be
466 assigned an hourly rate based on PN salary levels plus on-costs. Questions on patient use of lifestyle
467 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

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

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

509

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

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

520

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

For peer review only

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523 Acknowledgements

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539

540 Trial Sponsor

541 Centre for Primary Health Care and Equity, UNSW. Contact Professor Mark Harris +61 2 93858384 or

542 m.f.harris@unsw.edu.au

543

544 Committees

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

546 oversees the project.

547 Contribution

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

551

552 Competing interests

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

554

555 Data statement

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

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559 Dissemination

560 The findings of the study will be made available to participants and the public via the Centre for
561 Primary Health Care web page 25and through conference presentations and research publications.
562 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

- 780 Patient Inclusion criteria: Aged 40-74 years; Overweight or obese (BMI \geq 28 recorded in last 12
- 781 months) ; BP recorded in the clinical software within the previous 12 months; Speaking English
- 782 and/or Arabic; access to a smart phone or tablet device.
- 783 Patient Exclusion criteria: Experiencing recent weight loss (>5% in past 3 months); diagnosis of
- 784 Diabetes requiring insulin or a current prescription for insulin; diagnosis of Cardiovascular
- 785 disease (includes angina, myocardial infarction, heart failure, heart valve disease (rheumatic
- 786 or non-rheumatic), stroke (cerebrovascular accident)); Taking medication for weight loss
- 787 (Orlistat or Phentermine); Cognitive impairment; Physical impairment prohibiting the patient
- 788 from undertaking moderate level physical activity.
- 789 15. Anticipated date of first enrolment: 1st May 2018.
- 790 16. Sample size: Planned: 1600
- 791 17. Sample size: Current: 0 patients
- 792 18. Recruitment Status: Pending: participants are not yet being recruited or enrolled at any site
- 793 19. Primary Outcome(s):
- 794 i) Health literacy. Measure Health Literacy Questionnaire: Timepoints: Baseline, 6 and 12
- 795 months
- 796 ii) e-health literacy. Measure eHeals. Timepoints: Baseline, 6, 12 and 18 months
- 797 v) Body Mass Index. Calculated from measured weight in Kg and height in cm. Timepoints:
- 798 Baseline, 6 , 12 and 18 months.
- 799 vi) Waist circumference. Measured in cm. Timepoints: Baseline, 6 , 12 and 18 months.
- 800 vii) Blood pressure. Measured in mmHg using automated sphygmomanometer. Timepoints:
- 801 Baseline, 6 , 12 and 18 months
- 802 20. Secondary outcomes
- 803 i) Daily fruit and vegetable consumption. Measure: questions adapted from NSW Population
- 804 Health Survey and CSIRO Healthy diet score. Timepoints: Baseline and 6 months
- 805 ii) Physical activity level. Measure: Self-reported minutes of vigorous and moderate activity.
- 806 Calculated as score. Timepoints: Baseline and 6 months.
- 807 iii) Health related quality of life. Measure: EQ-5D-5L. Baseline and 12 months.
- 808 ii) Total Cholesterol. Measure: Recorded total cholesterol from medical records. Up to 2 years
- 809 prior to baseline and 12 months.
- 810 iii) Advice and Referral. Measure: Patient questionnaire on reported advice or referral given by
- 811 GP for smoking, diet, physical activity or weight management in previous 6 months.
- 812 Timepoints: Baseline, 6 months
- 813 iv) Cost. Measure: Practice nurse time plus Medical Benefits Schedule and Pharmaceutical
- 814 Benefits Schedule data. Timepoints: 12 months.
- 815 21. Ethics Review
- 816 i) Status: Approved (HC17474)
- 817 ii) Date of approval: 27 July 2017

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- iii)
- Name and contact details of Ethics committee(s): University of New South Wales Human
- 819
- Research Ethics Committee. Phone P: +61 2 9385 6222, + 61 2 9385 7257 or + 61 2 9385 7007.
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- Email: humanethics@unsw.edu.au
- 821
22.
- Completion date: Unknown
- 822
23.
- Summary Results: Not yet available
- 823
24.
- IPD sharing statement: Plan to share IPD: No

For peer review only

Figure 1. Practice and patient recruitment

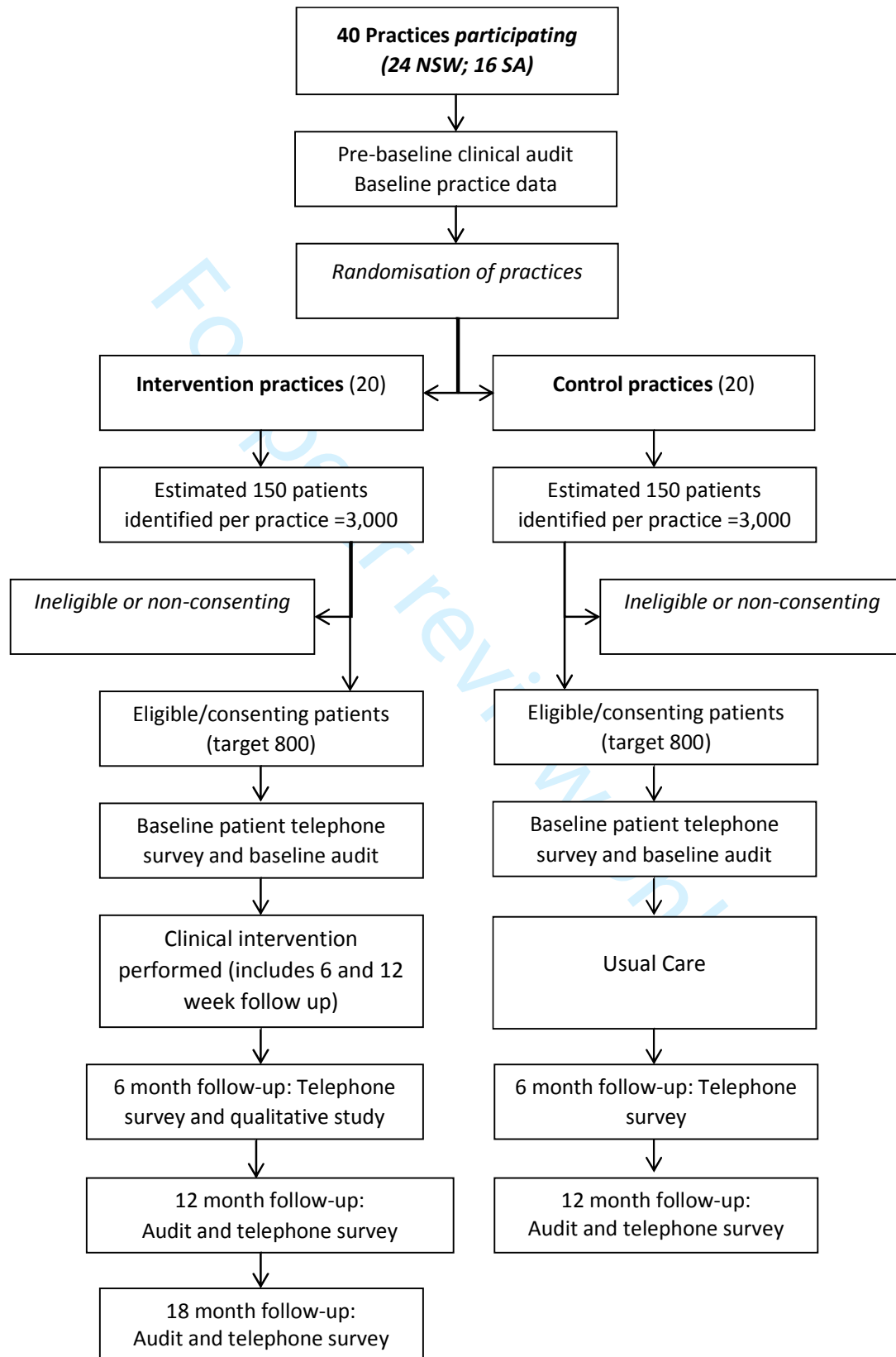


Figure 2: Clinical audit reports

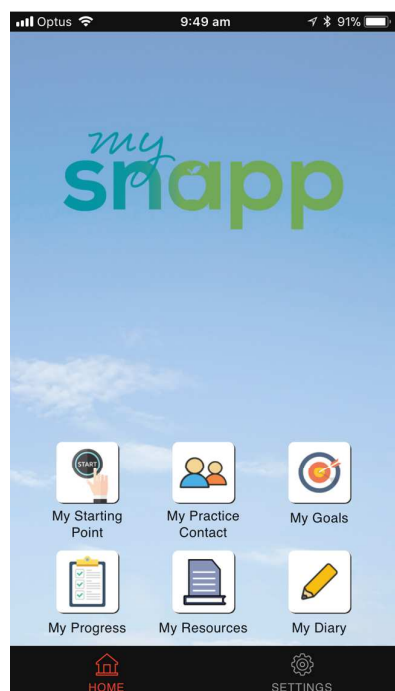
Baseline deidentified audit report for patients aged 40-74 years

	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

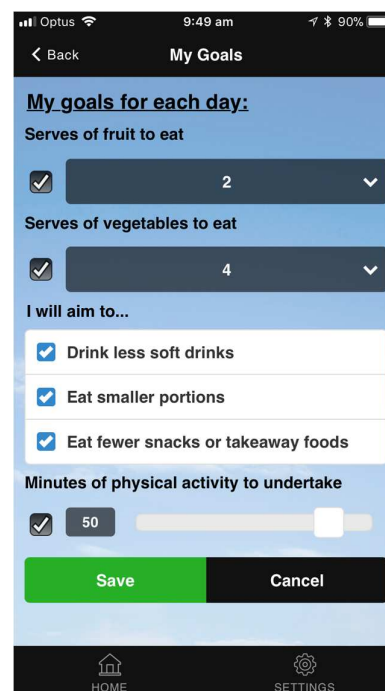
* Recommended frequency because sample includes patients with type 2 diabetes and patients on medication.

Identified audit report for patients enrolled in study

[illegible]

Figure 3: *My Snapp* screens

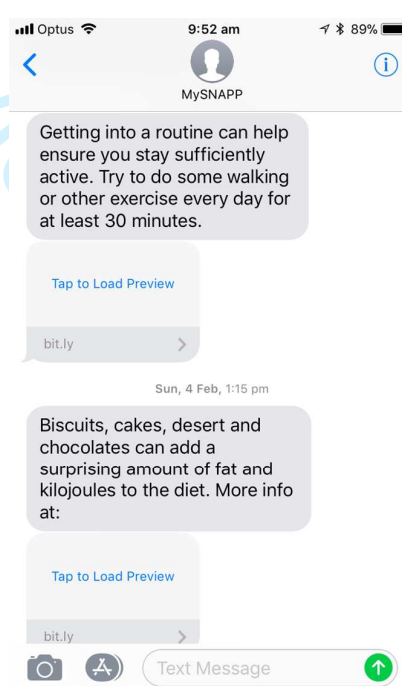
Landing Page



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

1	sponsor contact			
2	information			
3				
4	Roles and	#5c	Role of study sponsor and funders, if any, in study design;	24
5	responsibilities:		collection, management, analysis, and interpretation of	
6	sponsor and funder		data; writing of the report; and the decision to submit the	
7			report for publication, including whether they will have	
8			ultimate authority over any of these activities	
9				
10				
11				
12	Roles and	#5d	Composition, roles, and responsibilities of the coordinating	24
13	responsibilities:		centre, steering committee, endpoint adjudication	
14	committees		committee, data management team, and other individuals or	
15			groups overseeing the trial, if applicable (see Item 21a for	
16			data monitoring committee)	
17				
18				
19				
20	Background and	#6a	Description of research question and justification for	5-9
21	rationale		undertaking the trial, including summary of relevant studies	
22			(published and unpublished) examining benefits and harms	
23			for each intervention	
24				
25				
26				
27	Background and	#6b	Explanation for choice of comparators	10
28	rationale: choice of			
29	comparators			
30				
31				
32	Objectives	#7	Specific objectives or hypotheses	9
33				
34				
35	Trial design	#8	Description of trial design including type of trial (eg, parallel	9
36			group, crossover, factorial, single group), allocation ratio,	
37			and framework (eg, superiority, equivalence, non-inferiority,	
38			exploratory)	
39				
40				
41				
42	Study setting	#9	Description of study settings (eg, community clinic,	9
43			academic hospital) and list of countries where data will be	
44			collected. Reference to where list of study sites can be	
45			obtained	
46				
47				
48				
49	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable,	10,11
50			eligibility criteria for study centres and individuals who will	
51			perform the interventions (eg, surgeons, psychotherapists)	
52				
53				
54	Interventions:	#11a	Interventions for each group with sufficient detail to allow	14-17
55	description		replication, including how and when they will be	
56			administered	
57				
58				
59				
60				

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: adherence	#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

1	mechanism		envelopes), describing any steps to conceal the sequence	
2			until interventions are assigned	
3				
4	Allocation:	#16c	Who will generate the allocation sequence, who will enrol	10
5	implementation		participants, and who will assign participants to	
6			interventions	
7				
8				
9	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg,	10
10			trial participants, care providers, outcome assessors, data	
11			analysts), and how	
12				
13				
14	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is	10
15	emergency		permissible, and procedure for revealing a participant's	
16	unblinding		allocated intervention during the trial	
17				
18				
19				
20	Data collection plan	#18a	Plans for assessment and collection of outcome, baseline,	19-20
21			and other trial data, including any related processes to	
22			promote data quality (eg, duplicate measurements, training	
23			of assessors) and a description of study instruments (eg,	
24			questionnaires, laboratory tests) along with their reliability	
25			and validity, if known. Reference to where data collection	
26			forms can be found, if not in the protocol	
27				
28				
29				
30				
31	Data collection plan:	#18b	Plans to promote participant retention and complete follow-	20
32	retention		up, including list of any outcome data to be collected for	
33			participants who discontinue or deviate from intervention	
34			protocols	
35				
36				
37				
38	Data management	#19	Plans for data entry, coding, security, and storage, including	21
39			any related processes to promote data quality (eg, double	
40			data entry; range checks for data values). Reference to	
41			where details of data management procedures can be	
42			found, if not in the protocol	
43				
44				
45				
46	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary	21
47			outcomes. Reference to where other details of the statistical	
48			analysis plan can be found, if not in the protocol	
49				
50				
51				
52	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and	21
53	analyses		adjusted analyses)	
54				
55				
56	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	21
57	population and		adherence (eg, as randomised analysis), and any statistical	
58	missing data		methods to handle missing data (eg, multiple imputation)	
59				
60				

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Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

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

1			and disclosure of contractual agreements that limit such	
2			access for investigators	
3				
4	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	n/a
5	trial care		compensation to those who suffer harm from trial	
6			participation	
7				
8				
9	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial	26
10	trial results		results to participants, healthcare professionals, the public,	
11			and other relevant groups (eg, via publication, reporting in	
12			results databases, or other data sharing arrangements),	
13			including any publication restrictions	
14				
15				
16				
17	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of	n/a
18	authorship		professional writers	
19				
20				
21	Dissemination policy:	#31c	Plans, if any, for granting public access to the full protocol,	n/a
22	reproducible		participant-level dataset, and statistical code	
23	research			
24				
25				
26	Informed consent	#32	Model consent form and other related documentation given	n/a
27	materials		to participants and authorised surrogates	
28				
29				
30	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of	n/a
31			biological specimens for genetic or molecular analysis in the	
32			current trial and for future use in ancillary studies, if	
33			applicable	
34				
35				
36				
37	The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution License CC-			
38	BY-ND 3.0. This checklist was completed on 27. March 2018 using http://www.goodreports.org/ , a			
39	tool made by the EQUATOR Network in collaboration with Penelope.ai			
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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:	<i>BMJ Open</i>
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 Medicine
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

SCHOLARONE™
Manuscripts

1 Title: Preventing chronic disease in patients with low

2 health literacy using eHealth and teamwork in

3 primary health care: Protocol for a cluster

4 Randomised controlled trial

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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 \geq 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

76 Introduction

77 Rationale

78 Reducing the burden of chronic disease is an important public health priority in Australia (1).
79 Overweight and obesity account for 7% of the burden of disease (2) as a risk factor for 11 types of
80 cancer, three cardiovascular conditions, chronic kidney disease, diabetes, dementia, gallbladder
81 disease, fatty liver, gout, back pain and osteoarthritis (2) Currently around 63% of the Australian
82 population are overweight or obese (BMI 25 kg/m² or more) and the prevalence is increasing (3).
83 The burden of overweight is unequally distributed with a 13% higher prevalence of overweight in the
84 lowest compared with the highest socioeconomic group in females (4). There is an urgent need to
85 find effective strategies at both the population and individual level to prevent and manage this
86 condition.
87
88 Low functional health literacy (i.e., health related reading and numeracy) is present in approximately
89 59% of the population and is more common in socioeconomically disadvantaged populations (5). It
90 is a potential barrier to the uptake and effectiveness of a range of preventive interventions (6).
91 Aspects of health literacy have also been associated with poorer uptake of screening programs and
92 immunisation (7, 8). Conversely higher health literacy has been associated with greater
93 improvements in response to physical activity interventions in disadvantaged populations(9).
94 Patients with low health literacy are less likely to engage in health promoting behaviours (10-12),
95 receive and understand preventive advice, and attend or complete programs that they are referred
96 to (13, 14). A systematic review of interventions in primary care to improve health literacy for
97 chronic disease behavioural risk factors found that interventions with multiple components were
98 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).

109

110 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.

123

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

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

154

155 Intervention Development

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

158

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

171

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

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

181
182 **Aims and research questions**

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

189
190 **Methods**

191 **Trial Design**

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

194
195 **Setting**

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

200 Randomisation

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

209 Eligibility and Exclusion Criteria

210 General Practices

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

- 212 • Be situated in Local Government Areas (LGAs) with a low Socio-economic (SEIFA¹) score
 213 equal to and below the 6th decile (usually associated with lower health literacy (5)
- 214 • Use clinical software compatible with the data extraction and recruitment tool *Doctors*
 215 *Control Panel* (DCP). This includes *Medical Director*, *MediNet*, *PracSoft* and *Best Practice* and
 216 associated compatible billing software (*Pracsoft* and *Best Practice Management*).
- 217 • Agree to the installation of DCP for the purposes of clinical audit and to identify eligible
 218 patients for the study
- 219 • Have access to an active internet connection
- 220 • Have at least one practice nurse who is prepared to conduct the HeLP- GP intervention with
 221 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>

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

227 Practice patients

228 Eligible patients are those who are:

- 229 - Aged 40-74 years
- 230 - Overweight or obese (BMI \geq 28 recorded in last 12 months)²
- 231 - With BP recorded in the clinical software within the previous 12 months
- 232 - Speaking English and/or Arabic³
- 233 - With access to a smart phone or tablet device
- 234
- 235 *Exclusion criteria:*
- 236 - Experiencing recent weight loss (>5% in past 3 months)
- 237 - A diagnosis of Diabetes requiring insulin or a current prescription for insulin
- 238 - A diagnosis of Cardiovascular disease (includes angina, myocardial infarction, heart failure, heart
- 239 valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident))
- 240 - Taking medication for weight loss (Orlistat or Phentermine)
- 241 - Cognitive impairment
- 242 - Physical impairment which prohibits engaging in moderate level physical activity
- 243

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

244 Recruitment

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

248

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

254

255 Recruitment of Practice Patients

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

264 *[Insert Figure 1 about here].*

265

266 Ethics

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

270

271 Practice and Provider consent

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

275

276 Patient Consent

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

287 Withdrawal

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

291 Patient and public involvement.

292 The development of the research question and outcome measures was informed by previous
293 research conducted in general practice on preventive care, health literacy and obesity management.
294 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]

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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)

<i>Assess</i>	Review baseline BMI, waist circumference, blood pressure and lipids. Briefly assess diet, physical activity, health literacy and e-health literacy.
<i>Advise/ Agree</i>	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.
<i>Assist</i>	Introduce and provide referral to the Get Healthy telephone coaching program to the patient, (outline purpose of the program and details about participation).
<i>Arrange</i>	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

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3 362 App. The content of *my snapp* aligns with both the nurse health check and the telephone coaching

4

5 363 (Table 2).

6

7 364 **Table 2: *my snapp* content**

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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.

34 365

35

36 366 *[Insert Figure 3 about here]*

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38

39 367 **c) Telephone Coaching**

40

41 368 The telephone coaching program recommended to patients is “Get Healthy” which is supported by

42

43 369 the relevant state government and provided free of charge. Get Healthy delivers 10 free coaching

44

45

46 370 calls over 10 weeks which provide:

- 47
- 48 371
 - Review of lifestyle goals (diet and physical activity) and ways to address barriers to achieving
- 49
- 50 372 these goals
- 51
- 52 373
 - Practical health information
- 53
- 54 374
 - Support and resources to promote self-monitoring of diet, physical activity and weight
- 55
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- 375 • Resources and tools to develop and maintain motivation for a healthier lifestyle
- 376 • Assistance to deal with set-backs and problem solve
- 377 • Social support to help participants to try new ideas and approaches to address lifestyle
- 378 behaviours

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

381

382 Assessing the implementation fidelity of the intervention

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

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

391

392 Evaluation

393 Outcomes

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

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

399 • Lifestyle behaviours including portions of fruit and vegetables, soft drink, high fat and snack food
400 consumed per day, use of a dietary plan and the level of physical activity adapted from existing
401 instruments (58-60).

402 • Weight, height, BMI, waist circumference, blood pressure extracted from patient medical
403 records.

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

409 Data collection (See Figure 4)

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

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

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

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

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

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

429 *[Insert Figure 4 about here]*

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

431 Control Practices

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

439

440 Sample size calculation

441 We aim to recruit 40 practices (24 NSW; 16 SA); 20 practices intervention and 20 practices control.
 442 We are aiming to consent 40 patients per practice (1600 total) based on previous research [30]. We
 443 anticipate a loss of approximately 20-25% at follow up (12 months). We will seek mobile numbers
 444 and alternative contacts to improve follow up. Estimates for sample size based on intra-cluster
 445 correlation coefficients, prevalence, variance and effect sizes from our previous research are in table
 446 3, based on a two-sided test of significance at $\alpha=0.05$. $\beta=0.8$ and 20% loss to follow up [40] (Table
 447 3).

448 **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
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	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).

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489 Discussion

490 This trial evaluates a comprehensive intervention which is designed to support better preventive
491 care for overweight and obese patients with low health literacy. It builds on previous work by the
492 investigators and others to develop feasible interventions in primary care that address both patient
493 and practice barriers to adoption, implementation and effectiveness. If successful, it will inform
494 policy and practice including the role of primary care in addressing the challenge of overweight and
495 obesity and the often-conflicting information that is available to practitioners and the public.
496
497 The complexity of the intervention and evaluation poses potential threats to internal and external
498 validity. Recruiting and engaging a large number of practices to a trial such as this is becoming
499 increasingly difficult. We have addressed this by working in partnership with Primary Health
500 Networks (district level organisations of general practice and allied health services) to identify,
501 approach and brief practice principals and practitioners on the study. Practice costs will be
502 reimbursed, and practitioners will be able to access continuing professional development points
503 through the clinical audit and training. However, the main incentive is the value of the research
504 itself and how it will inform policy and practice in the long run and this needs to be carefully
505 discussed.
506 Problems with recruitment, retention or engagement of patients with the intervention and data
507 collection have the potential to reduce statistical power and therefore the ability to detect the
508 primary outcomes with adequate precision. In this setting, recruitment procedures need to avoid
509 pressure from the research team and patient’s own GP to ensure that eligible patients are
510 approached and provided with sufficient information to make an informed decision about
511 participation. We will work with practices to set up software and systems to make this possible. A
512 significant part of the burden on participants will be from the telephone interviews by the research
513 team. Although telephone interviews are preferred by most patients, they are onerous if they are

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

516

517 A further risk is that the clinical intervention will not be implemented in practice as we planned.

518 Again, addressing this requires close work with the practices. The implementation measures and

519 qualitative evaluation will provide some insight, but this may be too late to correct. We have thus

520 built into the practice level intervention several measures to improve fidelity. These include

521 feedback mechanisms in the online training, reflective feedback from practices on the audits and

522 practice discussion during the facilitation visits. These will be tracked regularly during the

523 implementation of the trial. A further risk is that some health and e-health literacy will both be

524 required for adoption of the App by patients and is expected to improve as a result of the

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

526 general practitioners.

527

528 The fieldwork for the study is planned to be completed by December 2018 with follow-up completed

529 by mid-2019. We anticipate circulation of the main findings from the study by 2020.

530

531 Figure Legends

532 **Figure 1. Practice and patient recruitment**

533 **Figure 2: Clinical audit reports**

534 **Figure 3: My Snapp screens**

535 **Figure 4: Outcomes and Data collection**

536

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539 Sydney and Adelaide Primary Health Networks and the other HeLP-GP investigators and research
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542 *snapp*; staff in the New South Wales and South Australian Ministry of Health and Get-Healthy
543 (especially Ruth Chessier-Hawkins, Lyndall Thomas and Kate Reid) for their support in providing
544 access to the telephone coaching program and collection of data associated with its use; and Anton
545 Knieriemen, Colin Sheppard and Oliver Frank who developed a tailored version of the DCP program
546 to facilitate patient recruitment and clinical audits. We would like to acknowledge the general
547 practices involved in piloting for this for the project and the consumers linked to Adelaide PHN for
548 piloting *my snapp*.

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552 The funder played no role in the design of this study.

553

554 Trial Sponsor

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

557

558 Committees

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

561

562 Contribution

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

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

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

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

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

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

576 JK contributed to and was CI on the peer reviewed funding proposal especially the health economic
577 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.

600 **Dissemination**

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

For peer review only

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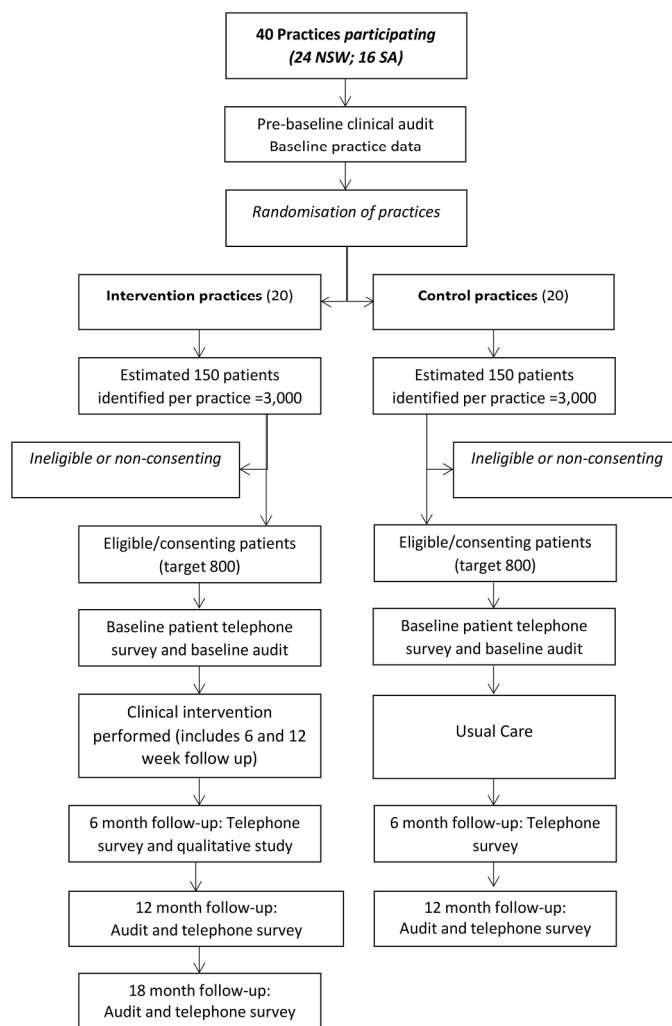


Figure 1

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	Gen der	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)

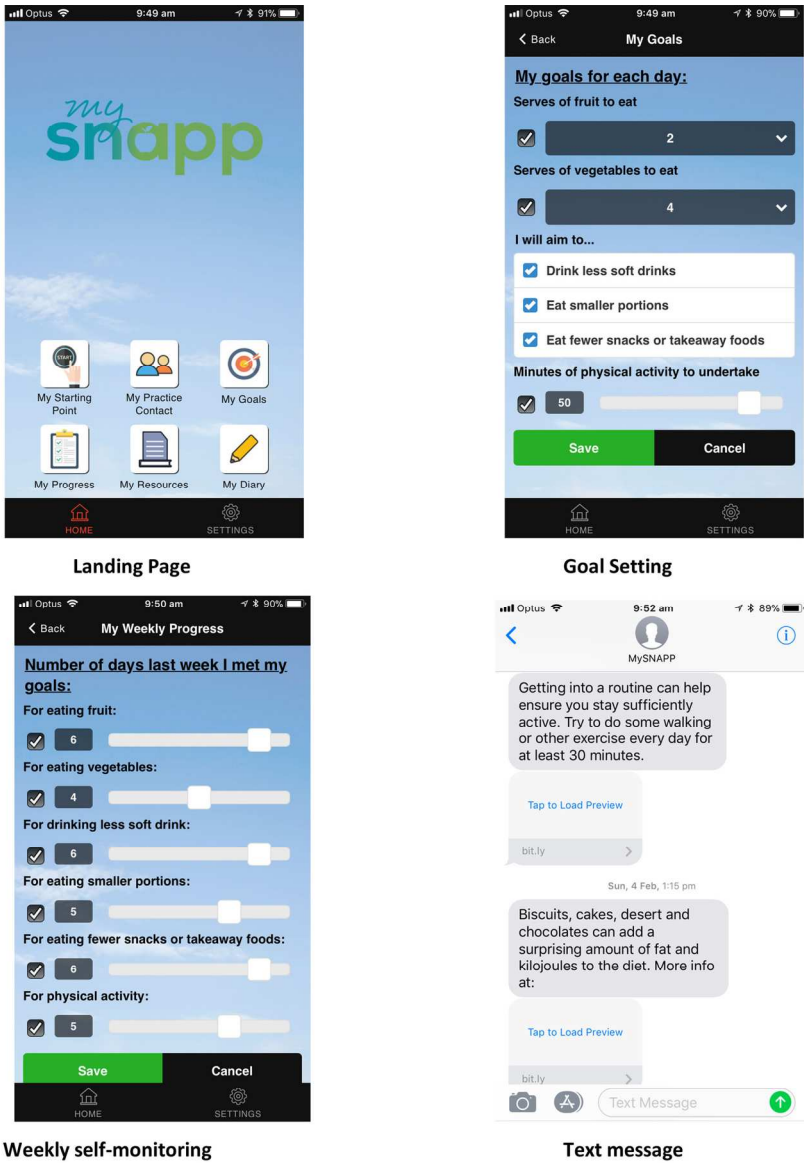


Figure 3

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

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

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

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

51 16. Sample size: Planned: 1600

52 17. Sample size: Current: 0 patients

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

54 19. Primary Outcome(s):

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

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

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

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

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

63 20. Secondary outcomes

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

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

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

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

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

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

76 21. Ethics Review

77 i) Status: Approved (HC17474)

78 ii) Date of approval: 27 July 2017

- 1
- 2
- 379 iii) Name and contact details of Ethics committee(s): University of New South Wales Human
- 480 Research Ethics Committee. Phone P: +61 2 9385 6222, + 61 2 9385 7257 or + 61 2 9385 7007.
- 581 Email: humanethics@unsw.edu.au
- 6
- 782 22. Completion date: Unknown
- 883 23. Summary Results: Not yet available
- 9
- 1084 24. IPD sharing statement: Plan to share IPD: No
- 1185
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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

1	sponsor contact			
2	information			
3				
4	Roles and	#5c	Role of study sponsor and funders, if any, in study design;	24
5	responsibilities:		collection, management, analysis, and interpretation of	
6	sponsor and funder		data; writing of the report; and the decision to submit the	
7			report for publication, including whether they will have	
8			ultimate authority over any of these activities	
9				
10				
11				
12	Roles and	#5d	Composition, roles, and responsibilities of the coordinating	24
13	responsibilities:		centre, steering committee, endpoint adjudication	
14	committees		committee, data management team, and other individuals or	
15			groups overseeing the trial, if applicable (see Item 21a for	
16			data monitoring committee)	
17				
18				
19				
20	Background and	#6a	Description of research question and justification for	5-9
21	rationale		undertaking the trial, including summary of relevant studies	
22			(published and unpublished) examining benefits and harms	
23			for each intervention	
24				
25				
26				
27	Background and	#6b	Explanation for choice of comparators	10
28	rationale: choice of			
29	comparators			
30				
31				
32	Objectives	#7	Specific objectives or hypotheses	9
33				
34				
35	Trial design	#8	Description of trial design including type of trial (eg, parallel	9
36			group, crossover, factorial, single group), allocation ratio,	
37			and framework (eg, superiority, equivalence, non-inferiority,	
38			exploratory)	
39				
40				
41				
42	Study setting	#9	Description of study settings (eg, community clinic,	9
43			academic hospital) and list of countries where data will be	
44			collected. Reference to where list of study sites can be	
45			obtained	
46				
47				
48				
49	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable,	10,11
50			eligibility criteria for study centres and individuals who will	
51			perform the interventions (eg, surgeons, psychotherapists)	
52				
53				
54	Interventions:	#11a	Interventions for each group with sufficient detail to allow	14-17
55	description		replication, including how and when they will be	
56			administered	
57				
58				
59				
60				

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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: adherence	#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

1	mechanism		envelopes), describing any steps to conceal the sequence	
2			until interventions are assigned	
3				
4	Allocation:	#16c	Who will generate the allocation sequence, who will enrol	10
5	implementation		participants, and who will assign participants to	
6			interventions	
7				
8				
9	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg,	10
10			trial participants, care providers, outcome assessors, data	
11			analysts), and how	
12				
13				
14	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is	10
15	emergency		permissible, and procedure for revealing a participant's	
16	unblinding		allocated intervention during the trial	
17				
18				
19				
20	Data collection plan	#18a	Plans for assessment and collection of outcome, baseline,	19-20
21			and other trial data, including any related processes to	
22			promote data quality (eg, duplicate measurements, training	
23			of assessors) and a description of study instruments (eg,	
24			questionnaires, laboratory tests) along with their reliability	
25			and validity, if known. Reference to where data collection	
26			forms can be found, if not in the protocol	
27				
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31	Data collection plan:	#18b	Plans to promote participant retention and complete follow-	20
32	retention		up, including list of any outcome data to be collected for	
33			participants who discontinue or deviate from intervention	
34			protocols	
35				
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37				
38	Data management	#19	Plans for data entry, coding, security, and storage, including	21
39			any related processes to promote data quality (eg, double	
40			data entry; range checks for data values). Reference to	
41			where details of data management procedures can be	
42			found, if not in the protocol	
43				
44				
45				
46	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary	21
47			outcomes. Reference to where other details of the statistical	
48			analysis plan can be found, if not in the protocol	
49				
50				
51				
52	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and	21
53	analyses		adjusted analyses)	
54				
55				
56	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	21
57	population and		adherence (eg, as randomised analysis), and any statistical	
58	missing data		methods to handle missing data (eg, multiple imputation)	
59				
60				

1 Data monitoring: 2 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
11 Data monitoring: 12 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
16 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
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
27 Research ethics 28 approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	12
31 Protocol 32 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
37 Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13
43 Consent or assent: 44 ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	13
48 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
55 Declaration of 56 interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	26
58 Data access	#29	Statement of who will have access to the final trial dataset,	26

1			and disclosure of contractual agreements that limit such	
2			access for investigators	
3				
4	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	n/a
5	trial care		compensation to those who suffer harm from trial	
6			participation	
7				
8				
9	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial	26
10	trial results		results to participants, healthcare professionals, the public,	
11			and other relevant groups (eg, via publication, reporting in	
12			results databases, or other data sharing arrangements),	
13			including any publication restrictions	
14				
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16				
17	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of	n/a
18	authorship		professional writers	
19				
20				
21	Dissemination policy:	#31c	Plans, if any, for granting public access to the full protocol,	n/a
22	reproducible		participant-level dataset, and statistical code	
23	research			
24				
25				
26				
27	Informed consent	#32	Model consent form and other related documentation given	n/a
28	materials		to participants and authorised surrogates	
29				
30				
31	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of	n/a
32			biological specimens for genetic or molecular analysis in the	
33			current trial and for future use in ancillary studies, if	
34			applicable	
35				
36				
37	The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution License CC-			
38	BY-ND 3.0. This checklist was completed on 27. March 2018 using http://www.goodreports.org/ , a			
39	tool made by the EQUATOR Network in collaboration with Penelope.ai			
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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.

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Manuscripts

1 Title: Preventing chronic disease in patients with low

2 health literacy using eHealth and teamwork in

3 primary health care: Protocol for a cluster

4 Randomised controlled trial

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39 **Abstract**

40 **Introduction**

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

44 **Methods and analysis**

45 A two-arm pragmatic practice-level cluster randomised trial will be conducted in 40 practices in low
46 socioeconomic areas in Sydney and Adelaide, Australia. Forty patients aged 40-70 years with a BMI ≥
47 28 will be enrolled per practice. The HeLP-GP intervention includes a practice-level quality
48 improvement intervention (medical record audit and feedback, staff training and practice facilitation
49 visits) to support practices to implement the clinical intervention for patients. The clinical
50 intervention involves a health check visit with a practice nurse based on the 5As framework (assess,
51 advise, agree, assist and arrange), the use of a purpose-built patient-facing app, *my snapp*, and
52 referral for telephone coaching. The primary outcomes are change in health literacy, lifestyle
53 behaviours, weight, waist circumference and blood pressure. The study will also evaluate changes in
54 quality of life and health service use to determine the cost effectiveness of the intervention and
55 examine the experiences of practices in implementing the program.

56 **Ethics and dissemination**

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

62 **Trial Registration**

63 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

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75 Introduction

76 Rationale

77 Reducing the burden of chronic disease is an important public health priority in Australia (1).
78 Overweight and obesity account for 7% of the burden of disease (2) as a risk factor for 11 types of
79 cancer, three cardiovascular conditions, chronic kidney disease, diabetes, dementia, gallbladder
80 disease, fatty liver, gout, back pain and osteoarthritis (2) Currently around 63% of the Australian
81 population are overweight or obese (BMI 25 kg/m2 or more) and the prevalence is increasing (3).
82 The burden of overweight is unequally distributed with a 13% higher prevalence of overweight in the
83 lowest compared with the highest socioeconomic group in females (4). There is an urgent need to
84 find effective strategies at both the population and individual level to prevent and manage this
85 condition.
86
87 Low functional health literacy (i.e., health related reading and numeracy) is present in approximately
88 59% of the population and is more common in socioeconomically disadvantaged populations (5). It
89 is a potential barrier to the uptake and effectiveness of a range of preventive interventions (6).
90 Aspects of health literacy have also been associated with poorer uptake of screening programs and
91 immunisation (7, 8). Conversely higher health literacy has been associated with greater
92 improvements in response to physical activity interventions in disadvantaged populations(9).
93 Patients with low health literacy are less likely to engage in health promoting behaviours (10-12),
94 receive and understand preventive advice, and attend or complete programs that they are referred
95 to (13, 14). A systematic review of interventions in primary care to improve health literacy for
96 chronic disease behavioural risk factors found that interventions with multiple components were
97 more effective at improving nutritional health literacy (15).
98

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

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3 125 literacy around weight loss found limited information as to the effect of weight loss interventions on
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5 126 health literacy primarily because this is an outcome not frequently reported (30). We have
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7 127 evaluated a structured, nurse delivered health check intervention based on 5As that includes a brief
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9 128 assessment of health literacy, tailoring advice and the use of “teach-back”; goal setting that involves
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11 129 specific, time-bound goals that are set collaboratively and involve feedback; assisted navigation to
12
13 130 referral services and pro-active follow up visits (30-33). This has proven feasible to implement (34),
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15 131 however, consistent with other studies, the impact on risk behaviours and weight have been small
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17 132 (23). This may be due to the limited capacity within primary care to provide interventions based on
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19 133 evidence that are of sufficient intensity and length.
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24 135 We have concluded that there is a need to supplement weight management consultations in primary
25
26 136 care with specific components that continue to operate outside the consultation such as coaching
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28 137 programs and other support services. There is some evidence of barriers to uptake of these
29
30 138 components such as cost and accessibility (27, 35), although the evidence for health coaching
31
32 139 suggests it is an accessible, affordable and effective method to change health behaviours (36, 37).
33
34 140 Moreover an evaluation of a government funded telephone coaching service in NSW suggested that
35
36 141 it could be effective in reaching disadvantaged population groups (38). Another promising approach
37
38 142 is the use of e-health to supplement both clinical care and referral programs in supporting behaviour
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40 143 change. Previous research has demonstrated the effectiveness of mobile health (m-health) text
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42 144 messages as part of a lifestyle program to prevent unhealthy weight gain in young adults (39). This
43
44 145 adds to the emerging evidence of the efficacy of using mobile apps and SMS text messaging in
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46 146 supporting change in health behaviours (40). However, the optimal form and role of this technology
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48 147 for patients with low health or e-health literacy is still unclear.
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53 149 This paper describes the protocol for the development and evaluation of an intervention which
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55 150 combines face to face consultation in general practice with these digital health approaches based on
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151 previous research which has demonstrated both feasibility of implementation and highlighted the
152 potential for health gains.

153

154 Intervention Development

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

157

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

170

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

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

180

181 Aims and research questions

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

188 Description of the intervention

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

191 1. Practice intervention

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

194

195 a) Medical record audit

196 A de-identified medical record audit will be conducted by research staff using the DCP program pre-
197 baseline in both intervention and control patients aged 40-74 years (who have not had a heart
198 attack or stroke or do not have diabetes requiring insulin), on the recording of smoking status,
199 alcohol consumption, BMI, waist circumference, blood pressure and total cholesterol. In
200 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

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

228 conditions.

229

230 a) Practice nurse health check and follow up.

231 Eligible patients will attend a health check visit with the PN within 4 weeks of recruitment. The

232 content of the nurse consult is based on the 5As (Table 1). The content of the consultation is

233 consistent with the Australian Guidelines for the management of overweight and obesity [28, 48, 49]

234 and will include assessment of health literacy, brief advice, use of “teachback” to determine if the

235 patient has understood the advice given, goal setting (using *my snapp* or recorded using a health

236 check form) and offering referral to telephone coaching (Get Healthy). The nurse will be alerted to

237 those patients who have low e-health literacy (from the baseline assessment) and will spend extra

238 time demonstrating and checking the use of *my snapp* (over one or two consultations). Patients will

239 be reviewed by the PN at 6 weeks and by the GP at 12 weeks.

240

241 **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

243 **b) my snapp**

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

250 **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.

252 *[Insert Figure 2 about here]*

253 c) Telephone Coaching

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

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

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

268 Assessing the implementation fidelity of the intervention

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

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

278 Methods and analysis

279 Trial Design

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

283 Setting

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

288 Randomisation

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

297 Eligibility and Exclusion Criteria

298 General Practices

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

- 300 • Be situated in Local Government Areas (LGAs) with a low Socio-economic (SEIFA¹) score
- 301 equal to and below the 6th decile (usually associated with lower health literacy (5)
- 302 • Use clinical software compatible with the data extraction and recruitment tool *Doctors*
- 303 *Control Panel* (DCP). This includes *Medical Director*, *MediNet*, *PracSoft* and *Best Practice* and
- 304 associated compatible billing software (*Pracsoft* and *Best Practice Management*).
- 305 • Agree to the installation of DCP for the purposes of clinical audit and to identify eligible
- 306 patients for the study
- 307 • Have access to an active internet connection
- 308 • Have at least one practice nurse who is prepared to conduct the HeLP- GP intervention with
- 309 eligible and consenting patients and complete data management relating to these patients
- 310 • Agree to provide GP follow up health checks to participating patients at 12 weeks and 12-
- 311 month time points
- 312 • Can make their staff available to distribute study materials to potential study participants
- 313 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 Arabic³
- 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>

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

322

323 *Exclusion criteria:*

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

331

332 *Recruitment*

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

336

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

342

343 *Recruitment of Practice Patients*

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

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

352 *[Insert Figure 3 about here].*

353

354 Patient and public involvement.

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

362

363 Outcomes

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

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

371 Secondary outcomes include change in :-

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

387 Data collection (See Figure 4)

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

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

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

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

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

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

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

407 *[Insert Figure 4 about here]*

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

409 Control Practices

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

418 Sample size calculation

419 We aim to recruit 40 practices (24 NSW; 16 SA); 20 practices intervention and 20 practices control.
420 We are aiming to consent 40 patients per practice (1600 total) based on previous research [30]. We
421 anticipate a loss of approximately 20-25% at follow up (12 months). We will seek mobile numbers
422 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 $\alpha=0.05$. $\beta=0.8$ 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.

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490 Data deposition

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

493 Dissemination

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

498 Discussion

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

505
506 The complexity of the intervention and evaluation poses potential threats to internal and external
507 validity. Recruiting and engaging a large number of practices to a trial such as this is becoming
508 increasingly difficult. We have addressed this by working in partnership with Primary Health
509 Networks (district level organisations of general practice and allied health services) to identify,
510 approach and brief practice principals and practitioners on the study. Practice costs will be
511 reimbursed, and practitioners will be able to access continuing professional development points
512 through the clinical audit and training. However, the main incentive is the value of the research
513 itself and how it will inform policy and practice in the long run and this needs to be carefully
514 discussed.

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

525

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

536

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

539

Figure Legends

Figure 1: Clinical audit reports

Figure 2: My Snapp screens

Figure 3. Practice and patient recruitment

Figure 4: Outcomes and Data collection

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562 Trial Sponsor

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

565 Committees

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

568 Contribution

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

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

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

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

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

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

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

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

586 MN contributed to and was CI on the peer reviewed funding proposal especially the nutrition
587 component and commented on the paper.
588 STL contributed to and was CI on the peer reviewed funding proposal especially the informatics
589 component and commented on the paper and protocol documents on which it was based
590 AL contributed to and was CI on the peer reviewed funding proposal especially the m-health
591 component and commented on the paper and protocol documents on which it was based
592 RO contributed to and was AI on the peer reviewed funding proposal especially the health literacy
593 component and commented on the paper and protocol documents on which it was based
594 MFH developed and led the peer reviewed funding proposal including the design of the study and
595 intervention and co-drafted the paper and protocol documents on which it was based.
596
597 The paper and protocol are based on the grant application submitted to and peer reviewed by the
598 NHMRC in 2016.

599 Competing interests

600 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	
			85
			85
			85
			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)

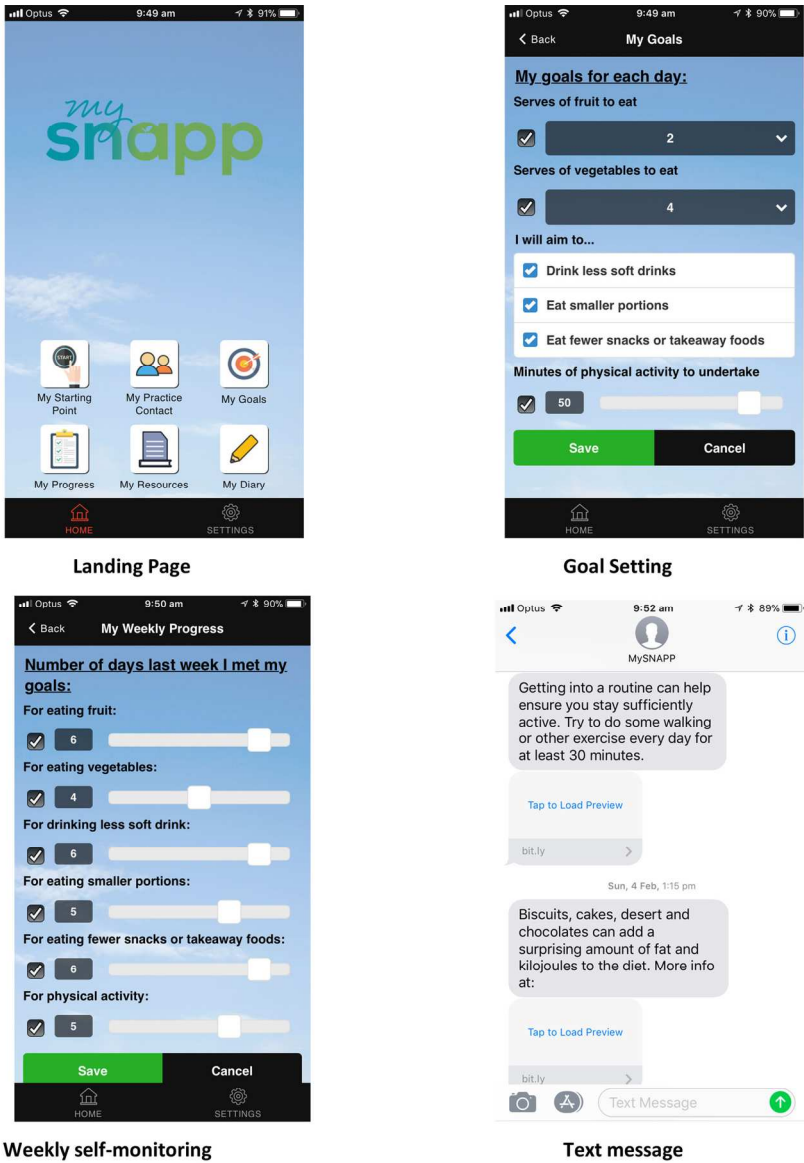


Figure 1

138x193mm (300 x 300 DPI)

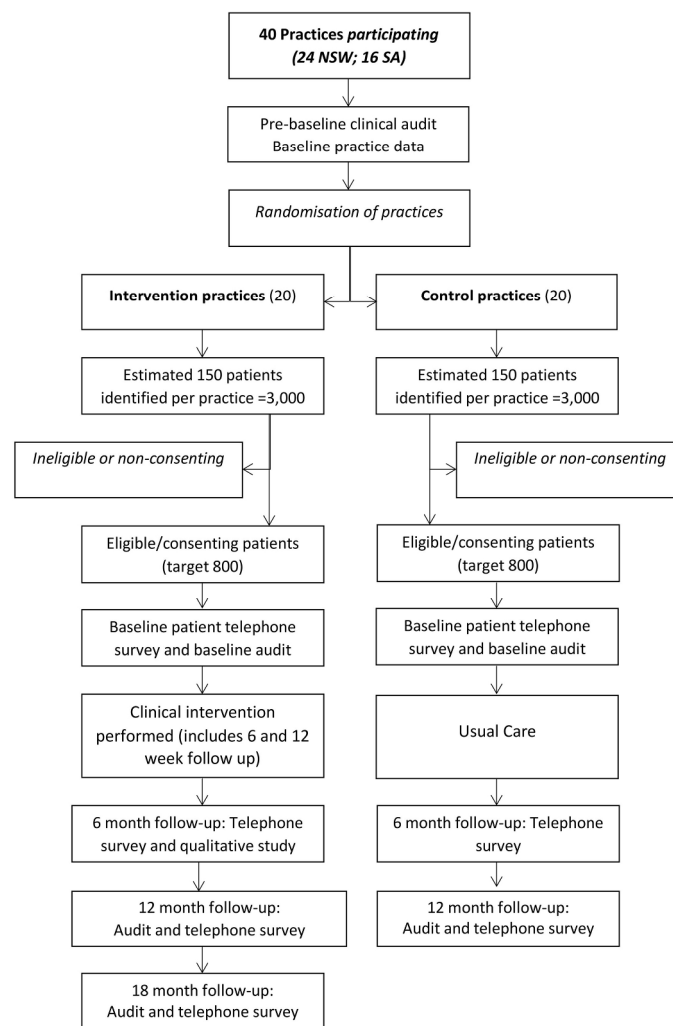


Figure 3

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 \geq 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 Phentermine); 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
- 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
- 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

1	sponsor contact			
2	information			
3				
4	Roles and	#5c	Role of study sponsor and funders, if any, in study design;	24
5	responsibilities:		collection, management, analysis, and interpretation of	
6	sponsor and funder		data; writing of the report; and the decision to submit the	
7			report for publication, including whether they will have	
8			ultimate authority over any of these activities	
9				
10				
11				
12	Roles and	#5d	Composition, roles, and responsibilities of the coordinating	24
13	responsibilities:		centre, steering committee, endpoint adjudication	
14	committees		committee, data management team, and other individuals or	
15			groups overseeing the trial, if applicable (see Item 21a for	
16			data monitoring committee)	
17				
18				
19				
20	Background and	#6a	Description of research question and justification for	5-9
21	rationale		undertaking the trial, including summary of relevant studies	
22			(published and unpublished) examining benefits and harms	
23			for each intervention	
24				
25				
26				
27	Background and	#6b	Explanation for choice of comparators	10
28	rationale: choice of			
29	comparators			
30				
31				
32	Objectives	#7	Specific objectives or hypotheses	9
33				
34				
35	Trial design	#8	Description of trial design including type of trial (eg, parallel	9
36			group, crossover, factorial, single group), allocation ratio,	
37			and framework (eg, superiority, equivalence, non-inferiority,	
38			exploratory)	
39				
40				
41				
42	Study setting	#9	Description of study settings (eg, community clinic,	9
43			academic hospital) and list of countries where data will be	
44			collected. Reference to where list of study sites can be	
45			obtained	
46				
47				
48				
49	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable,	10,11
50			eligibility criteria for study centres and individuals who will	
51			perform the interventions (eg, surgeons, psychotherapists)	
52				
53				
54	Interventions:	#11a	Interventions for each group with sufficient detail to allow	14-17
55	description		replication, including how and when they will be	
56			administered	
57				
58				
59				
60				

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: adherence	#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

1	mechanism		envelopes), describing any steps to conceal the sequence	
2			until interventions are assigned	
3				
4	Allocation:	#16c	Who will generate the allocation sequence, who will enrol	10
5	implementation		participants, and who will assign participants to	
6			interventions	
7				
8				
9	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg,	10
10			trial participants, care providers, outcome assessors, data	
11			analysts), and how	
12				
13				
14	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is	10
15	emergency		permissible, and procedure for revealing a participant's	
16	unblinding		allocated intervention during the trial	
17				
18				
19				
20	Data collection plan	#18a	Plans for assessment and collection of outcome, baseline,	19-20
21			and other trial data, including any related processes to	
22			promote data quality (eg, duplicate measurements, training	
23			of assessors) and a description of study instruments (eg,	
24			questionnaires, laboratory tests) along with their reliability	
25			and validity, if known. Reference to where data collection	
26			forms can be found, if not in the protocol	
27				
28				
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30				
31	Data collection plan:	#18b	Plans to promote participant retention and complete follow-	20
32	retention		up, including list of any outcome data to be collected for	
33			participants who discontinue or deviate from intervention	
34			protocols	
35				
36				
37				
38	Data management	#19	Plans for data entry, coding, security, and storage, including	21
39			any related processes to promote data quality (eg, double	
40			data entry; range checks for data values). Reference to	
41			where details of data management procedures can be	
42			found, if not in the protocol	
43				
44				
45				
46	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary	21
47			outcomes. Reference to where other details of the statistical	
48			analysis plan can be found, if not in the protocol	
49				
50				
51				
52	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and	21
53	analyses		adjusted analyses)	
54				
55				
56	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	21
57	population and		adherence (eg, as randomised analysis), and any statistical	
58	missing data		methods to handle missing data (eg, multiple imputation)	
59				
60				

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

1			and disclosure of contractual agreements that limit such	
2			access for investigators	
3				
4	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	n/a
5	trial care		compensation to those who suffer harm from trial	
6			participation	
7				
8				
9	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial	26
10	trial results		results to participants, healthcare professionals, the public,	
11			and other relevant groups (eg, via publication, reporting in	
12			results databases, or other data sharing arrangements),	
13			including any publication restrictions	
14				
15				
16				
17	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of	n/a
18	authorship		professional writers	
19				
20				
21	Dissemination policy:	#31c	Plans, if any, for granting public access to the full protocol,	n/a
22	reproducible		participant-level dataset, and statistical code	
23	research			
24				
25				
26				
27	Informed consent	#32	Model consent form and other related documentation given	n/a
28	materials		to participants and authorised surrogates	
29				
30				
31	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of	n/a
32			biological specimens for genetic or molecular analysis in the	
33			current trial and for future use in ancillary studies, if	
34			applicable	
35				
36				
37	The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution License CC-			
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39	tool made by the EQUATOR Network in collaboration with Penelope.ai			
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