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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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1  
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3 39 **Abstract**  
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5

6 40 **Background**  
7

8 41 Adults with lower levels of health literacy are less likely to engage in health promoting behaviours.

9  
10 42 Our trial evaluates the impacts and outcomes of a mobile health enhanced preventive intervention  
11  
12 43 in primary care for people who are overweight or obese.  
13

14 44 **Methods/Design**  
15

16 45 A two-arm pragmatic practice-level cluster randomised trial will be conducted in 40 practices in low  
17  
18 46 socioeconomic areas in Sydney and Adelaide, Australia. Forty patients aged 40-70 years with a BMI  $\geq$   
19  
20 47 28 will be enrolled per practice. The HeLP-GP intervention includes a practice-level quality  
21  
22 48 improvement intervention (medical record audit and feedback, staff training and practice facilitation  
23  
24 49 visits) to support practices to implement the clinical intervention for patients. The clinical  
25  
26 50 intervention involves a health check visit with a practice nurse based on the 5As framework (assess,  
27  
28 51 advise, agree, assist and arrange), the use of a purpose-built patient-facing app, *my snapp*, and  
29  
30 52 referral for telephone coaching. The primary outcomes are change in health literacy, lifestyle  
31  
32 53 behaviours, weight, waist circumference and blood pressure. The study will also evaluate changes in  
33  
34 54 quality of life and health service use to determine the cost effectiveness of the intervention and  
35  
36 55 examine the experiences of practices in implementing the program.  
37  
38  
39

40 56 **Discussion**  
41

42 57 Our trial will provide evidence to inform the role of primary health care in preventive care for  
43  
44 58 overweight and obese adults and addressing the barriers of low health literacy.  
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## 60 Strengths and Limitations of this study

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

## 70 Trial Registration

71 This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12617001508369).  
72 Date registered 30 October 2017.

## 73 Keywords

74 Overweight, obesity, primary care, preventive medicine, health literacy, m-health  
75

## 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/m<sup>2</sup> 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

1  
2  
3 100 Primary care is well positioned to contribute to the prevention and management of overweight and  
4  
5 101 obesity. Over 86% of the population of Australia visit a general practitioner at least once a year (16).  
6  
7 102 Almost a third of patients presenting in general practice are obese and two thirds are overweight or  
8  
9 103 obese, which are rates similar to the prevalence in the general community (17). Behavioural  
10  
11 104 interventions in primary care have been demonstrated to achieve a 5-7% improvement in weight,  
12  
13 105 blood pressure or lipids for patients, potentially preventing or delaying the onset of Type 2 diabetes  
14  
15 106 and cardiovascular disease (18-20). However these interventions tend to have lower uptake by low  
16  
17 107 socioeconomic groups (21, 22) and, overall, most weight loss interventions in primary care achieve  
18  
19 108 only small reductions in weight (23).

20  
21  
22 109

#### 23 24 110 Preliminary work leading up to this study

25  
26 111 Over the past decade we have sought to develop more effective interventions to prevent disease in  
27  
28 112 primary care which target disadvantaged populations who are more likely to have low health  
29  
30 113 literacy. In previous research we have found that ethnicity and language interact with health  
31  
32 114 literacy to influence uptake of preventive interventions especially those for weight loss (24). This  
33  
34 115 accords with the findings of others that health literacy differentials are greater among older people,  
35  
36 116 for those born overseas, those who do not speak English at home and those with low educational  
37  
38 117 attainment (25). In these groups patient-provider communication tends to be less effective, leading  
39  
40 118 providers to incorrectly assume that patients with low health literacy are poorly motivated and they  
41  
42 119 are therefore less likely to offer lifestyle interventions (26, 27). Organisational and practitioner  
43  
44 120 barriers also contribute to low frequency and effectiveness of assessment, advice, goal setting, and  
45  
46 121 referral of patients with low health literacy (6, 28). These barriers include time available for  
47  
48 122 consultations and competing demands on primary care staff.

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51 123

52  
53 124 We have also identified a need to tailor prevention and management of excess weight to a patients'  
54  
55 125 level of health literacy (29). Our review of primary health care level interventions targeting health



1  
2  
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  
6  
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),  
14  
15 132 however, consistent with other studies, the impact on risk behaviours and weight have been small  
16  
17 133 (23). This may be due to the limited capacity within primary care to provide interventions based on  
18  
19 134 evidence that are of sufficient intensity and length.  
20

21  
22 135  
23  
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  
45  
46 147 supporting change in health behaviours (40). However, the optimal form and role of this technology  
47  
48 148 for patients with low health or e-health literacy is still unclear.  
49

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51 149  
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53 150 This paper describes the protocol for the development and evaluation of an intervention which  
54  
55 151 combines face to face consultation in general practice with these digital health approaches based on  
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1  
2  
3 152 previous research which has demonstrated both feasibility of implementation and highlighted the  
4  
5 153 potential for health gains.  
6

7 154

## 9 155 Intervention Development

11  
12 156 The various components of the HeLP-GP intervention have been developed and piloted over the past  
13  
14 157 five years.  
15

16 158

18  
19 159 The brief primary care intervention which is designed to support practices to improve the quality of  
20  
21 160 preventive care for the SNAP (smoking, nutrition, alcohol and physical activity) risk behaviours and  
22  
23 161 weight management is based on behavioural theory and is structured on the 5As framework which  
24  
25 162 encompasses assessment, advice, agreeing on goals, assisting with motivational counselling and  
26  
27 163 referral options and arranging follow up (13, 41). Progress along the pathway from assessment to  
28  
29 164 follow up is associated with increased patient motivation and behaviour change (42). This has been  
30  
31 165 trialled in general practice and found to be feasible and acceptable and to lead to improvement in  
32  
33 166 the quality of preventive care (30, 43, 44). This intervention was adapted for use by practice nurses  
34  
35 167 and modified for patients with low health literacy to include brief screening for low health literacy,  
36  
37 168 tailored communication and referral navigation to local lifestyle programs and piloted (45). It was  
38  
39 169 subsequently evaluated in a trial which demonstrated its feasibility and acceptability to providers  
40  
41 170 and patients (30).  
42  
43

44 171

46 172 The app used in this study is supported by *Healthy.me*, a personally controlled health management  
47  
48 173 platform designed to help patients and consumers manage their health (46). This has been shown to  
49  
50 174 improve uptake of preventive services (47, 48) and strong consumer acceptance has been  
51  
52 175 demonstrated in Australia across different healthcare settings including primary care (49). This  
53  
54 176 platform was modified to create the mobile application used in this study (*my snapp*). This was  
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1  
2  
3 177 informed by research that interventions based on theory and those involving goal-setting and self-  
4  
5 178 monitoring as well as providing additional methods to interact with patients, particularly text  
6  
7 179 messages, were more effective (50-53). Other research suggests that patients with low health  
8  
9 180 literacy prefer apps or text messages to other sources of online information (54).  
10

11 181

## 12 182 Aims and research questions

13  
14  
15  
16 183 The aim of this study is to evaluate the implementation and effectiveness of a preventive  
17  
18 184 intervention in primary care structured around the 5As framework supported by a patient-facing  
19  
20 185 mobile app, consultations with the practice nurse and/or referral to a telephone coaching service.  
21  
22 186 The intervention aims to develop the knowledge and skills of overweight or obese patients with low  
23  
24 187 health literacy. The trial will assess the impact of the intervention on preventive care received,  
25  
26 188 patients' health and e-health literacy, physical and behavioural risk factors, quality of life and costs.  
27

28 189

## 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60

## 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).

199

## 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<sup>NET</sup>). 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 (SEIFA<sup>1</sup>) score  
213 equal to and below the 6<sup>th</sup> 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

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53 <sup>1</sup> Australian Bureau of Statistics Socioeconomic Indexes for Areas (SEIFA)  
54 <http://www.abs.gov.au/websitedbs/censushome.nsf/home/seifahelpansuis?opendocument&navpos=260&#0>  
55 [1](#)

- 1  
2  
3 222 • Agree to provide GP follow up health checks to participating patients at 12 weeks and 12-  
4  
5 223 month time points  
6  
7 224 • Can make their staff available to distribute study materials to potential study participants  
8  
9 225 when they register with reception prior to seeing a GP  
10  
11  
12 226

13 227 **Practice patients**

14  
15 228 Eligible patients are those who are:

- 16  
17 229 - Aged 40-74 years  
18  
19 230 - Overweight or obese (BMI $\geq$ 28 recorded in last 12 months)<sup>2</sup>  
20  
21 231 - With BP recorded in the clinical software within the previous 12 months  
22  
23 232 - Speaking English and/or Arabic<sup>3</sup>  
24  
25 233 - With access to a smart phone or tablet device  
26  
27  
28 234

29  
30 235 **Exclusion criteria:**

- 31  
32 236 - Experiencing recent weight loss (>5% in past 3 months)  
33  
34 237 - A diagnosis of Diabetes requiring insulin or a current prescription for insulin  
35  
36 238 - A diagnosis of Cardiovascular disease (includes angina, myocardial infarction, heart failure, heart  
37  
38 239 valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident))  
39  
40 240 - Taking medication for weight loss (Orlistat or Phentermine)  
41  
42 241 - Cognitive impairment  
43  
44 242 - Physical impairment which prohibits engaging in moderate level physical activity  
45  
46  
47 243

51  
52  
53 <sup>2</sup> The cut point for BMI was chosen to target people at higher risk and to capture people from Asian  
54 backgrounds who have a lower equivalent BMI.

55 <sup>3</sup> Arabic was chosen as many recently arrived immigrants in the geographical areas are Arabic speaking  
56  
57

## 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.

1  
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3 270  
4

5 271 Practice and Provider consent

7 272 Written consent will be obtained from all participating practices including consent to conduct the  
8  
9 273 study in the practice and access practice data, and individual consent from all participating GPs and  
10  
11 274 PNs.  
12

13  
14 275

15  
16 276 Patient Consent

17  
18 277 Patients will be given information and consent forms in English or Arabic language and be able to ask  
19  
20 278 further questions of the GP or PN. The patient will provide their written consent by filling in the  
21  
22 279 consent form and either placing it in a collection box at reception, or by returning it in a 'reply paid'  
23  
24 280 envelope to the research team. To increase comprehension and meaningful consent within our  
25  
26 281 target population of patients with low health literacy, we have shortened and simplified the  
27  
28 282 Participant Information Statement and Consent forms. Patient eligibility will be confirmed by the GP  
29  
30 283 and at subsequent interview. They will be invited by mail at 6 months to separately consent to the  
31  
32 284 use of routinely collected data on health service use (from Medicare (MBS) Australia's national  
33  
34 285 health insurance program), pharmaceutical use (from the Pharmaceutical Benefits Scheme (PBS))  
35  
36 286 and hospitalisation data (from State admitted patient data collections).  
37

38  
39 287 Withdrawal

40  
41 288 Practices or patients may withdraw from the study at any time. If patients commence weight loss  
42  
43 289 medication or develop cognitive impairment or severe illness they will be withdrawn from the study.  
44  
45 290 Withdrawals and reasons for withdrawal will be recorded.  
46

47  
48 291 Trial Registration

49  
50  
51 292 The HeLP trial is prospectively registered with the Australian Clinical Trials Registry (ANZCTR):  
52  
53 293 ACTRN12617001508369 <http://www.ANZCTR.org.au/ACTRN12617001508369.aspx>  
54

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## 295 Description of the intervention

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

### 298 1. Practice intervention

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

#### 302 a) Medical record audit

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

312 *[Insert Figure 2 about here]*

313

#### 314 b) GP and Nurse training to deliver intervention

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



1  
2  
3 320 to participating GPs and PNs. An on-line post training questionnaire and evaluation form will be  
4  
5 321 completed by GP and PN participants and will provide information to evaluate the training and its  
6  
7 322 impact.

8  
9 323

#### 10 11 324 c) Facilitation visits conducted by CIs and PHNs

12  
13 325 Facilitation visits will be made up to three times over three months to each intervention practice  
14  
15 326 during the beginning of intervention phase to support PNs and the practice. The aim of the practice  
16  
17 327 facilitation is to support each intervention practice to implement the HeLP-GP intervention including  
18  
19 328 making improvements in recording based on the initial de-identified clinical audit and prepare for  
20  
21 329 the health check visits.

22  
23  
24 330

## 25 26 331 2. Clinical intervention

27  
28 332 The clinical intervention has three components, each of which will be offered to all patients in the  
29  
30 333 intervention group: a health check visit with the PN; a patient-facing app - *my snapp*; and referral to  
31  
32 334 telephone coaching. Patients may receive any concomitant care indicated for their medical  
33  
34 335 conditions.

35  
36  
37 336

#### 38 39 337 a) Practice nurse health check and follow up.

40  
41 338 Eligible patients will attend a health check visit with the PN within 4 weeks of recruitment. The  
42  
43 339 content of the nurse consult is based on the 5As (Table 2). The content of the consultation is  
44  
45 340 consistent with the Australian Guidelines for the management of overweight and obesity [28, 48, 49]  
46  
47 341 and will include assessment of health literacy, brief advice, use of “teachback” to determine if the  
48  
49 342 patient has understood the advice given, goal setting (using *my snapp* or recorded using a health  
50  
51 343 check form) and offering referral to telephone coaching (Get Healthy). The nurse will be alerted to  
52  
53 344 those patients who have low e-health literacy (from the baseline assessment) and will spend extra  
54  
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345 time demonstrating and checking the use of *my snapp* (over one or two consultations). Patients will  
 346 be reviewed by the PN at 6 weeks and by the GP at 12 weeks.

347

348 **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

349

350 **b) my snapp**

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

357 **Table 2: *my snapp* content**

<b>Section</b>	<b>Description</b>
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.

358

359 *[Insert Figure 3 about here]*

## 360 c) Telephone Coaching

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

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

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

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3 375 Assessing the implementation fidelity of the intervention  
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5 376 Implementation of the intervention will be assessed by the following measures:  
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- 7 377 • % of GPs and PNs who complete the online training modules  
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9 378 • % of intervention patients who receive baseline, and 6-week clinical review by a PN  
10  
11 379 • % of patients who receive a health check at 12-weeks by a GP  
12  
13 380 • Usage of the lifestyle App determined by app-analytics (% of patients with documented  
14  
15 381 goals related to lifestyle change)  
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17 382 • % who received assisted referral to Get Healthy telephone coaching  
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19 383 • % of patients who take up and complete Get Healthy telephone coaching program  
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24 385 Evaluation  
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27 386 Outcomes  
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29 387 All primary outcomes are changes at the level of the individual patient between baseline and 12  
30  
31 388 months. These include change in:

- 32  
33 389 • Two domains of health literacy from the Health Literacy Questionnaire (55) (Ability to find good  
34  
35 390 health information and Understand health information well enough to know what to do) and e-  
36  
37 391 health literacy (using the eHeals) (56);  
38  
39 392 • Lifestyle behaviours including portions of fruit and vegetables, soft drink, high fat and snack food  
40  
41 393 consumed per day, use of a dietary plan and the level of physical activity adapted from existing  
42  
43 394 instruments (57-59).  
44  
45 395 • Weight, height, BMI, waist circumference, blood pressure extracted from patient medical  
46  
47 396 records.  
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50 397 Secondary outcomes include health related quality of life using the EQ-5D-5L(60) , total cholesterol  
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52 398 extracted from the medical record and patient reported advice and referral given by the GP or  
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399 practice nurse(30) and health service use and costs from routinely collected data by Australia's  
400 health insurance agency and pharmaceutical benefits service (MBS and PBS).

401

402 **Data collection (See Figure 4)**

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

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

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

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

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

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

422 *[Insert Figure 4 about here]*

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

## 424 Control Practices

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

## 433 Sample size calculation

434 We aim to recruit 40 practices (24 NSW; 16 SA); 20 practices intervention and 20 practices control.  
 435 We are aiming to consent 40 patients per practice (1600 total) based on previous research [30]. We  
 436 anticipate a loss of approximately 20-25% at follow up (12 months). We will seek mobile numbers  
 437 and alternative contacts to improve follow up. Estimates for sample size based on intra-cluster  
 438 correlation coefficients, prevalence, variance and effect sizes from our previous research are in table  
 439 3, based on a two-sided test of significance at  $\alpha=0.05$ .  $\beta=0.8$  and 20% loss to follow up [40] (Table  
 440 3).

441 **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

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3 443 Data management

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5 444 Data will be cleaned and coded and stored in a secure environment according to the data  
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7 445 management protocol.

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10 446 Adverse events

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12 447 An independent adverse events committee will monitor and if necessary investigate any reports of  
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14 448 possible adverse events or harms.

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17 449 Analysis

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19 450 We will examine differences in the change in the primary and secondary outcomes between  
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21 451 intervention and control practices at six months for health literacy and patient behaviours and 12  
22  
23 452 months for all outcomes. Analyses will be conducted on an intention-to-treat basis and adjusted for  
24  
25 453 baseline differences in any characteristics (e.g. age, gender) between groups. We will analyse  
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27 454 outcome variables (health literacy, e-health literacy, diet and physical activity behaviours, BMI, waist  
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29 455 circumference, BP, total cholesterol, quality of life and health service use) using multilevel linear and  
30  
31 456 logistic regression techniques that adjust for clustering by practice with multiple imputation for  
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33 457 missing values.

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38 459 Economic evaluation

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40 460 Information on resource use associated with the intervention will be collected by research staff,  
41  
42 461 including the cost of setting up the intervention: practice staff education, practice support visits and  
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44 462 materials and web support. Other relevant resource use includes GP and PN visits, referrals, hospital  
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46 463 attendances and prescribing. We will request patient consent to access their medical records, MBS  
47  
48 464 and PBS data, and public hospital data from the State Health Departments. The MBS, PBS and State  
49  
50 465 data will capture most primary care and hospital costs. The cost of PN visits for health checks will be  
51  
52 466 assigned an hourly rate based on PN salary levels plus on-costs. Questions on patient use of lifestyle  
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54 467 services and programs, and non-Medicare funded allied health will also be included in the patient

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3 468 questionnaire. Cost estimates will be generated for referrals to community-based programs. In the  
4  
5 469 base case analysis, undertaken from a health service perspective, referrals to allied health  
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7 470 professionals will only be costed if supported by a Medicare claim. The incremental costs of the  
8  
9 471 intervention, will be presented alongside the consequences with respect to changes in quality of life  
10  
11 472 (including the estimation of QALY gains informed by the EQ5D-5L) and differences in health literacy,  
12  
13 473 behavioural outcomes, and clinical measures (BMI, blood pressure and Lipids). Deterministic and  
14  
15 474 bootstrapped sensitivity analyses will be undertaken to identify key uncertain parameters and  
16  
17 475 represent uncertainty around the mean estimates, respectively.  
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## 477 Qualitative analysis

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24 478 The qualitative interviews will be transcribed and analysed thematically using the program NVivo  
25  
26 479 (QSR NVivo 11). This will use an inductive approach based on the data as well as deductively based  
27  
28 480 on health literacy and health information theory (13, 62).  
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## 482 Discussion

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35 483 This trial evaluates a comprehensive intervention which is designed to support better preventive  
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37 484 care for overweight and obese patients with low health literacy. It builds on previous work by the  
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39 485 investigators and others to develop feasible interventions in primary care that address both patient  
40  
41 486 and practice barriers to adoption, implementation and effectiveness. If successful, it will inform  
42  
43 487 policy and practice including the role of primary care in addressing the challenge of overweight and  
44  
45 488 obesity and the often-conflicting information that is available to practitioners and the public.  
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49 490 The complexity of the intervention and evaluation poses potential threats to internal and external  
50  
51 491 validity. Recruiting and engaging a large number of practices to a trial such as this is becoming  
52  
53 492 increasingly difficult. We have addressed this by working in partnership with Primary Health  
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3 493 Networks (district level organisations of general practice and allied health services) to identify,  
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5 494 approach and brief practice principals and practitioners on the study. Practice costs will be  
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7 495 reimbursed, and practitioners will be able to access continuing professional development points  
8  
9 496 through the clinical audit and training. However, the main incentive is the value of the research  
10  
11 497 itself and how it will inform policy and practice in the long run and this needs to be carefully  
12  
13 498 discussed.

14  
15 499 Problems with recruitment, retention or engagement of patients with the intervention and data  
16  
17 500 collection have the potential to reduce statistical power and therefore the ability to detect the  
18  
19 501 primary outcomes with adequate precision. In this setting, recruitment procedures need to avoid  
20  
21 502 pressure from the research team and patient's own GP to ensure that eligible patients are  
22  
23 503 approached and provided with sufficient information to make an informed decision about  
24  
25 504 participation. We will work with practices to set up software and systems to make this possible. A  
26  
27 505 significant part of the burden on participants will be from the telephone interviews by the research  
28  
29 506 team. Although telephone interviews are preferred by most patients, they are onerous if they are  
30  
31 507 too long. We have thus had to balance this burden against our desire to collect as much information  
32  
33 508 as possible using robust instruments.

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37  
38 510 A further risk is that the clinical intervention will not be implemented in practice as we planned.  
39  
40 511 Again, addressing this requires close work with the practices. The implementation measures and  
41  
42 512 qualitative evaluation will provide some insight, but this may be too late to correct. We have thus  
43  
44 513 built into the practice level intervention several measures to improve fidelity. These include  
45  
46 514 feedback mechanisms in the online training, reflective feedback from practices on the audits and  
47  
48 515 practice discussion during the facilitation visits. These will be tracked regularly during the  
49  
50 516 implementation of the trial. A further risk is that some health and e-health literacy will both be  
51  
52 517 required for adoption of the App by patients and is expected to improve as a result of the

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3 518 intervention use. This will be addressed by the support provided to patients by practice nurses and  
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5 519 general practitioners.

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9 521 The fieldwork for the study is planned to be completed by December 2018 with follow-up completed  
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11 522 by mid-2019. We anticipate circulation of the main findings from the study by 2020.

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539

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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.

1  
2  
3 547 **Contribution**  
4

5 548 MH, SP and LT drafted the paper and the protocol documents on which it was based. All authors  
6  
7 549 reviewed the paper and made extensive comments and edits to it. The paper and protocol are  
8  
9 550 based on the grant application submitted to and peer reviewed by the NHMRC in 2016.  
10

11 551

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13  
14 552 **Competing interests**  
15

16 553 The investigators have no competing interests to declare relevant to this study.  
17

18 554  
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20  
21 555 **Data statement**  
22

23 556 Data and Meta-data will be stored in a repository at the University of New South Wales. De-  
24  
25 557 identified data will be made available subject to ethics committee approval.  
26

27 558  
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30 559 **Dissemination**  
31

32 560 The findings of the study will be made available to participants and the public via the Centre for  
33  
34 561 Primary Health Care web page 25and through conference presentations and research publications.  
35  
36 562 There are no restricts on publication.  
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740 **Appendix 1: Trial Registration Data Set**

- 741 1. Primary Registry and Trial Identifying Number: Australian New Zealand Clinical Trials Registry  
742 (ACTRN 12617001508369).
- 743 2. Date of Registration in Primary Registry: 26 October 2017 (Updated 20 March 2018)
- 744 3. Secondary Identifying Numbers: Australian National Health and Medical Research Council  
745 Project Number: APP1125681.
- 746 4. Source(s) of Monetary or Material Support: Australian National Health and Medical Research  
747 Council
- 748 5. Primary Sponsor: University of New South Wales, NSW 2052 Australia.
- 749 6. Secondary Sponsors: University of Adelaide, University of Sydney, University of Wollongong,  
750 CSIRO Health and Biosecurity, Macquarie University.
- 751 7. Contact for Public Queries: Ms Sharon Parker, Email: sharon.parker@unsw.edu.au;  
752 telephone: +61 (2) 9385 8396; and postal address: Centre for Primary Health Care and Equity,  
753 UNSW SYDNEY NSW 2052 AUSTRALIA..
- 754 8. Contact for Scientific Queries: Professor Mark Harris, email: m.f.harris@unsw.edu.au;  
755 telephone: +61 2 9385 8384; Postal address: Centre for Primary Health Care and Equity UNSW  
756 SYDNEY NSW 2052 AUSTRALIA.
- 757 9. Public Title: Health eLiteracy for Prevention in General Practice .
- 758 10. Scientific Title: Preventing chronic disease in patients with low health literacy using eHealth  
759 and teamwork in primary health care: Protocol for a cluster Randomised controlled trial.  
760 Acronym: HeLP-GP.
- 761 11. Countries of Recruitment: Australia
- 762 12. Health Condition(s) or Problem(s) Studied: Overweight and obesity.
- 763 13. Intervention(s): The HeLP-GP intervention includes a practice-level quality improvement  
764 intervention (medical record audit and feedback, staff training and practice facilitation visits)  
765 to support practices to implement the clinical intervention for patients. The clinical  
766 intervention involves a health check visit with a practice nurse based on the 5As framework  
767 (assess, advise, agree, assist and arrange), the use of a purpose-built patient-facing app, my  
768 snapp, and referral for telephone coaching. The aim of the intervention is to support patients  
769 to change diet and physical activity. Practices are randomly allocated to intervention and  
770 control groups. Patients recruited by control group practices will receive usual care (the  
771 clinical practice routinely offered to patients by the GP and PN).
- 772 14. Key Inclusion and Exclusion Criteria:
- 773 Practice Inclusion criteria: Situated in Local Government Areas (LGAs) with a SEIFA score  
774 equal to or below the 6th decile. Using Medical Director PracSoft or Best Practice software  
775 and allocate patients to individual GPs within this software. Agree to the use of Doctors  
776 Control Panel (DCP) linked with their software to identify eligible patients for the study; Have  
777 access to an active internet connection; Have at least one practice nurse who is prepared to  
778 conduct the HeLP intervention with eligible patients and complete data management relating  
779 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)

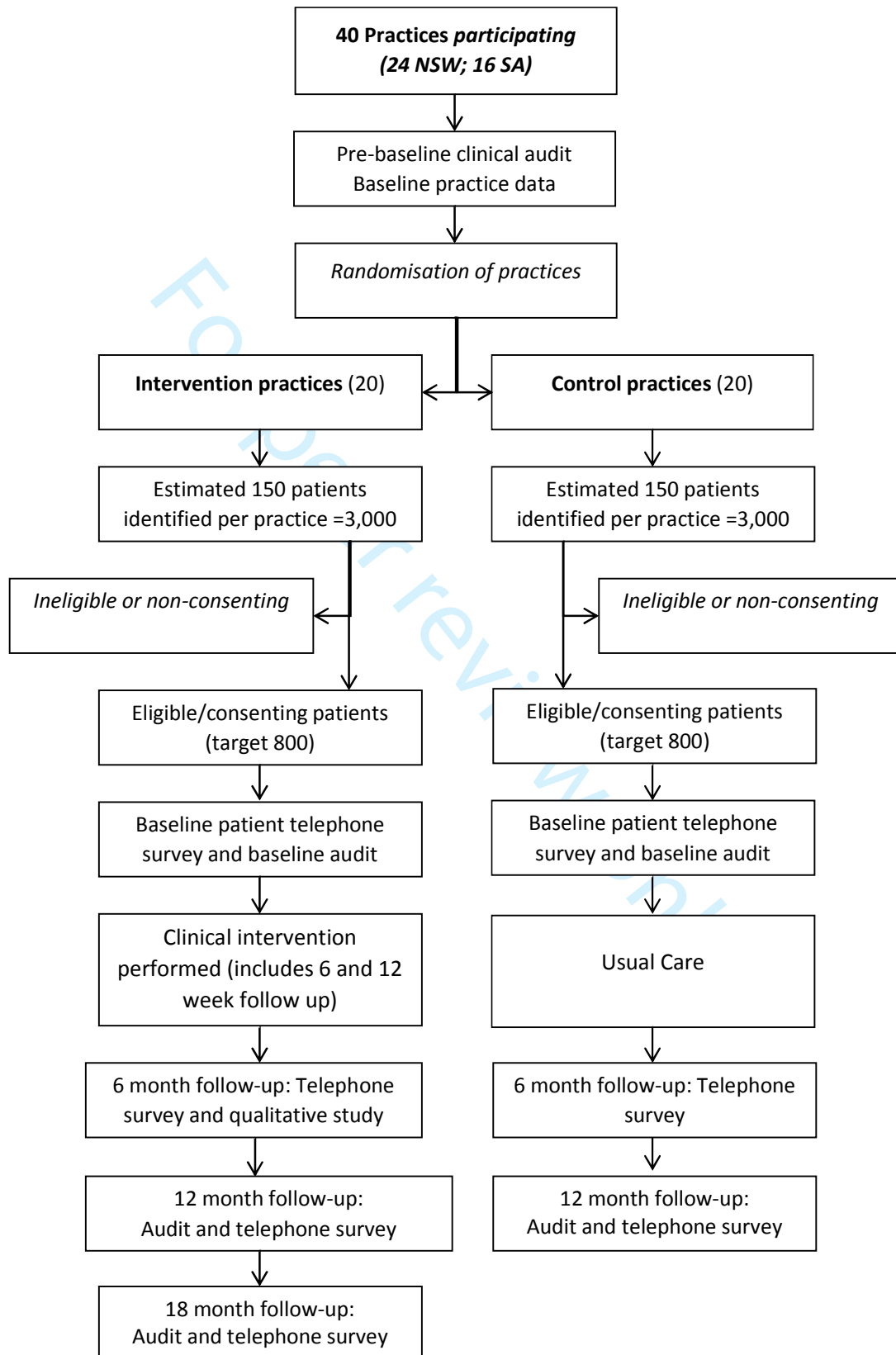
817 ii) Date of approval: 27 July 2017

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- 818 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.
- 820 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

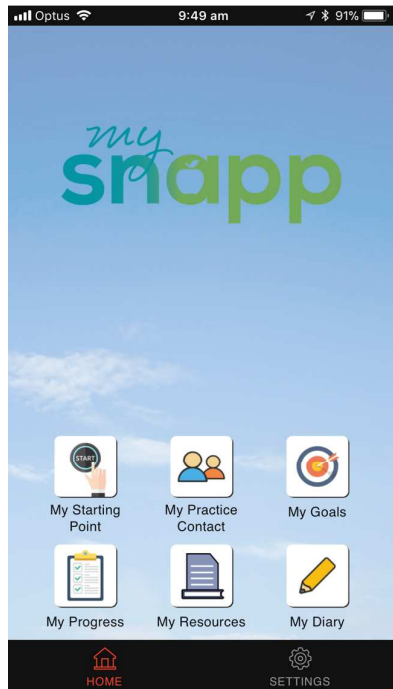
	Proportion of patients in your practice n (%)		Min Standards %	
a) Smoking status Recorded in past 2 years			85	
b) Alcohol intake Recorded in past 2 years			70	
c) BMI Recorded in past 12 months*			85	
d) Waist Circumference Recorded in 2 years			70	
e) Blood Pressure Recorded in past 12 months*	On 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.

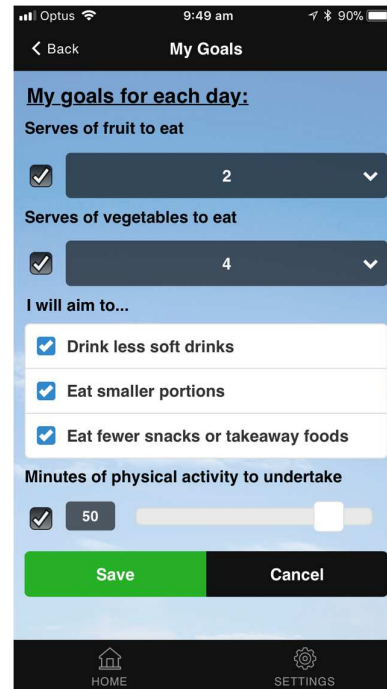
### Identified audit report for patients enrolled in study

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

Figure 3: My Snapp screens



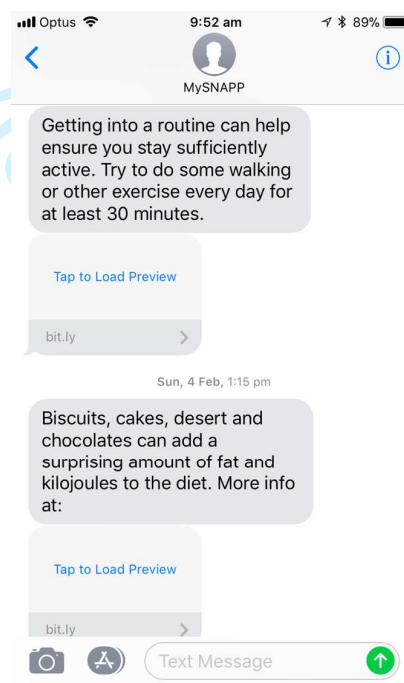
Landing Page



Goal Setting



Weekly self-monitoring



Text message

**Figure 4: Outcomes and Data collection**

Outcome	Source	Baseline	6 months	12 months	18 months (interv only)
<b>Primary</b>					
Health literacy e-health literacy	Patient questionnaire				
Diet and physical activity	Patient questionnaire				
BMI, waist circumference, BP	Record audit				
<b>Secondary</b>					
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	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable,	10,11
49			eligibility criteria for study centres and individuals who will	
50			perform the interventions (eg, surgeons, psychotherapists)	
51				
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				

1	Interventions:	#11b	Criteria for discontinuing or modifying allocated	13
2	modifications		interventions for a given trial participant (eg, drug dose	
3			change in response to harms, participant request, or	
4			improving / worsening disease)	
5				
6				
7				
8	Interventions:	#11c	Strategies to improve adherence to intervention protocols,	18
9	adherence		and any procedures for monitoring adherence (eg, drug	
10			tablet return; laboratory tests)	
11				
12				
13	Interventions:	#11d	Relevant concomitant care and interventions that are	15
14	concomitant care		permitted or prohibited during the trial	
15				
16				
17	Outcomes	#12	Primary, secondary, and other outcomes, including the	18-19
18			specific measurement variable (eg, systolic blood pressure),	
19			analysis metric (eg, change from baseline, final value, time	
20			to event), method of aggregation (eg, median, proportion),	
21			and time point for each outcome. Explanation of the clinical	
22			relevance of chosen efficacy and harm outcomes is strongly	
23			recommended	
24				
25				
26				
27				
28	Participant timeline	#13	Time schedule of enrolment, interventions (including any	18-19
29			run-ins and washouts), assessments, and visits for	
30			participants. A schematic diagram is highly recommended	
31			(see Figure)	
32				
33				
34				
35	Sample size	#14	Estimated number of participants needed to achieve study	20-21
36			objectives and how it was determined, including clinical and	
37			statistical assumptions supporting any sample size	
38			calculations	
39				
40				
41				
42	Recruitment	#15	Strategies for achieving adequate participant enrolment to	12
43			reach target sample size	
44				
45				
46	Allocation: sequence	#16a	Method of generating the allocation sequence (eg,	10
47	generation		computer-generated random numbers), and list of any	
48			factors for stratification. To reduce predictability of a random	
49			sequence, details of any planned restriction (eg, blocking)	
50			should be provided in a separate document that is	
51			unavailable to those who enrol participants or assign	
52			interventions	
53				
54				
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56				
57	Allocation	#16b	Mechanism of implementing the allocation sequence (eg,	10
58	concealment		central telephone; sequentially numbered, opaque, sealed	
59				
60				

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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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	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and	21
52	analyses		adjusted analyses)	
53				
54				
55	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	21
56	population and		adherence (eg, as randomised analysis), and any statistical	
57	missing data		methods to handle missing data (eg, multiple imputation)	
58				
59				
60				

1	Data monitoring:	#21a	Composition of data monitoring committee (DMC); summary	n/a
2	formal committee		of its role and reporting structure; statement of whether it is	
3			independent from the sponsor and competing interests; and	
4			reference to where further details about its charter can be	
5			found, if not in the protocol. Alternatively, an explanation of	
6			why a DMC is not needed	
7				
8				
9				
10				
11	Data monitoring:	#21b	Description of any interim analyses and stopping guidelines,	n/a
12	interim analysis		including who will have access to these interim results and	
13			make the final decision to terminate the trial	
14				
15				
16	Harms	#22	Plans for collecting, assessing, reporting, and managing	21
17			solicited and spontaneously reported adverse events and	
18			other unintended effects of trial interventions or trial conduct	
19				
20				
21	Auditing	#23	Frequency and procedures for auditing trial conduct, if any,	n/a
22			and whether the process will be independent from	
23			investigators and the sponsor	
24				
25				
26				
27	Research ethics	#24	Plans for seeking research ethics committee / institutional	12
28	approval		review board (REC / IRB) approval	
29				
30				
31	Protocol	#25	Plans for communicating important protocol modifications	n/a
32	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	
33			relevant parties (eg, investigators, REC / IRBs, trial	
34			participants, trial registries, journals, regulators)	
35				
36				
37	Consent or assent	#26a	Who will obtain informed consent or assent from potential	13
38			trial participants or authorised surrogates, and how (see	
39			Item 32)	
40				
41				
42				
43	Consent or assent:	#26b	Additional consent provisions for collection and use of	13
44	ancillary studies		participant data and biological specimens in ancillary	
45			studies, if applicable	
46				
47				
48	Confidentiality	#27	How personal information about potential and enrolled	13
49			participants will be collected, shared, and maintained in	
50			order to protect confidentiality before, during, and after the	
51			trial	
52				
53				
54				
55	Declaration of	#28	Financial and other competing interests for principal	26
56	interests		investigators for the overall trial and each study site	
57				
58				
59	Data access	#29	Statement of who will have access to the final trial dataset,	26
60				

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				

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 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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7 2 health literacy using eHealth and teamwork in  
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11 3 primary health care: Protocol for a cluster  
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1  
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3 39 **Abstract**  
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6 40 **Background**  
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8 41 Adults with lower levels of health literacy are less likely to engage in health promoting behaviours.

9  
10 42 Our trial evaluates the impacts and outcomes of a mobile health enhanced preventive intervention  
11  
12 43 in primary care for people who are overweight or obese.  
13

14 44 **Methods/Design**  
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16 45 A two-arm pragmatic practice-level cluster randomised trial will be conducted in 40 practices in low  
17  
18 46 socioeconomic areas in Sydney and Adelaide, Australia. Forty patients aged 40-70 years with a BMI  $\geq$   
19  
20 47 28 will be enrolled per practice. The HeLP-GP intervention includes a practice-level quality  
21  
22 48 improvement intervention (medical record audit and feedback, staff training and practice facilitation  
23  
24 49 visits) to support practices to implement the clinical intervention for patients. The clinical  
25  
26 50 intervention involves a health check visit with a practice nurse based on the 5As framework (assess,  
27  
28 51 advise, agree, assist and arrange), the use of a purpose-built patient-facing app, *my snapp*, and  
29  
30 52 referral for telephone coaching. The primary outcomes are change in health literacy, lifestyle  
31  
32 53 behaviours, weight, waist circumference and blood pressure. The study will also evaluate changes in  
33  
34 54 quality of life and health service use to determine the cost effectiveness of the intervention and  
35  
36 55 examine the experiences of practices in implementing the program.  
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40 56 **Discussion**  
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42 57 Our trial will provide evidence to inform the role of primary health care in preventive care for  
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44 58 overweight and obese adults and addressing the barriers of low health literacy.  
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## 60 Strengths and Limitations of this study

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

## 70 Trial Registration

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

72 Date registered 30 October 2017.

## 73 Keywords

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

75

## 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/m<sup>2</sup> 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

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3 100 Primary care is well positioned to contribute to the prevention and management of overweight and  
4  
5 101 obesity. Over 86% of the population of Australia visit a general practitioner at least once a year (16).  
6  
7 102 Almost a third of patients presenting in general practice are obese and two thirds are overweight or  
8  
9 103 obese, which are rates similar to the prevalence in the general community (17). Behavioural  
10  
11 104 interventions in primary care have been demonstrated to achieve a 5-7% improvement in weight,  
12  
13 105 blood pressure or lipids for patients, potentially preventing or delaying the onset of Type 2 diabetes  
14  
15 106 and cardiovascular disease (18-20). However these interventions tend to have lower uptake by low  
16  
17 107 socioeconomic groups (21, 22) and, overall, most weight loss interventions in primary care achieve  
18  
19 108 only small reductions in weight (23).  
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#### 23 24 110 Preliminary work leading up to this study

25  
26 111 Over the past decade we have sought to develop more effective interventions to prevent disease in  
27  
28 112 primary care which target disadvantaged populations who are more likely to have low health  
29  
30 113 literacy. In previous research we have found that ethnicity and language interact with health  
31  
32 114 literacy to influence uptake of preventive interventions especially those for weight loss (24). This  
33  
34 115 accords with the findings of others that health literacy differentials are greater among older people,  
35  
36 116 for those born overseas, those who do not speak English at home and those with low educational  
37  
38 117 attainment (25). In these groups patient-provider communication tends to be less effective, leading  
39  
40 118 providers to incorrectly assume that patients with low health literacy are poorly motivated and they  
41  
42 119 are therefore less likely to offer lifestyle interventions (26, 27). Organisational and practitioner  
43  
44 120 barriers also contribute to low frequency and effectiveness of assessment, advice, goal setting, and  
45  
46 121 referral of patients with low health literacy (6, 28). These barriers include time available for  
47  
48 122 consultations and competing demands on primary care staff.  
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53 124 We have also identified a need to tailor prevention and management of excess weight to a patients'  
54  
55 125 level of health literacy (29). Our review of primary health care level interventions targeting health  
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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  
6  
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),  
14  
15 132 however, consistent with other studies, the impact on risk behaviours and weight have been small  
16  
17 133 (23). This may be due to the limited capacity within primary care to provide interventions based on  
18  
19 134 evidence that are of sufficient intensity and length.  
20

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23  
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  
45  
46 147 supporting change in health behaviours (40). However, the optimal form and role of this technology  
47  
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  
54  
55 151 combines face to face consultation in general practice with these digital health approaches based on  
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3 152 previous research which has demonstrated both feasibility of implementation and highlighted the  
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5 153 potential for health gains.

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## 8 9 155 Intervention Development

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12 156 The various components of the HeLP-GP intervention have been developed and piloted over the past  
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14 157 five years.

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19 159 The brief primary care intervention which is designed to support practices to improve the quality of  
20  
21 160 preventive care for the SNAP (smoking, nutrition, alcohol and physical activity) risk behaviours and  
22  
23 161 weight management is based on behavioural theory and is structured on the 5As framework which  
24  
25 162 encompasses assessment, advice, agreeing on goals, assisting with motivational counselling and  
26  
27 163 referral options and arranging follow up (13, 41). Progress along the pathway from assessment to  
28  
29 164 follow up is associated with increased patient motivation and behaviour change (42). This has been  
30  
31 165 trialled in general practice and found to be feasible and acceptable and to lead to improvement in  
32  
33 166 the quality of preventive care (30, 43, 44). This intervention was adapted for use by practice nurses  
34  
35 167 and modified for patients with low health literacy to include brief screening for low health literacy,  
36  
37 168 tailored communication and referral navigation to local lifestyle programs and piloted (45). It was  
38  
39 169 subsequently evaluated in a trial which demonstrated its feasibility and acceptability to providers  
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41  
42 170 and patients (30).

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45  
46 172 The app used in this study is supported by *Healthy.me*, a personally controlled health management  
47  
48 173 platform designed to help patients and consumers manage their health (46). This has been shown to  
49  
50 174 improve uptake of preventive services (47, 48) and strong consumer acceptance has been  
51  
52 175 demonstrated in Australia across different healthcare settings including primary care (49). This  
53  
54 176 platform was modified to create the mobile application used in this study (*my snapp*). This was

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2  
3 177 informed by research that interventions based on theory and those involving goal-setting and self-  
4  
5 178 monitoring as well as providing additional methods to interact with patients, particularly text  
6  
7 179 messages, were more effective (50-53). Other research suggests that patients with low health  
8  
9 180 literacy prefer apps or text messages to other sources of online information (54).  
10

11 181

## 12 182 Aims and research questions

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16 183 The aim of this study is to evaluate the implementation and effectiveness of a preventive  
17  
18 184 intervention in primary care structured around the 5As framework supported by a patient-facing  
19  
20 185 mobile app, consultations with the practice nurse and/or referral to a telephone coaching service.  
21  
22 186 The intervention aims to develop the knowledge and skills of overweight or obese patients with low  
23  
24 187 health literacy. The trial will assess the impact of the intervention on preventive care received,  
25  
26 188 patients' health and e-health literacy, physical and behavioural risk factors, quality of life and costs.  
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## 29 190 Methods

### 30 191 Trial Design

31  
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35 192 The trial is a pragmatic, two-arm, practice-level cluster randomised controlled trial evaluating  
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37 193 impacts and outcomes of a m-health enhanced preventive intervention in primary care.  
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### 40 195 Setting

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46 196 Australian general practice. The study will be conducted in two regions of Sydney (South West  
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48 197 Sydney and Central and Eastern Sydney) and Adelaide, in collaboration with the local Primary Health  
49  
50 198 Networks (PHNs).  
51

52 199

## 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<sup>NET</sup>). 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 (SEIFA<sup>1</sup>) score  
213 equal to and below the 6<sup>th</sup> 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

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53 <sup>1</sup> Australian Bureau of Statistics Socioeconomic Indexes for Areas (SEIFA)  
54 <http://www.abs.gov.au/websitedbs/censushome.nsf/home/seifahelpansuis?opendocument&navpos=260&#0>  
55 [1](#)



- 1  
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3 222 • Agree to provide GP follow up health checks to participating patients at 12 weeks and 12-  
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5 223 month time points  
6  
7 224 • Can make their staff available to distribute study materials to potential study participants  
8  
9 225 when they register with reception prior to seeing a GP  
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11 226

12  
13 227 **Practice patients**

14  
15 228 Eligible patients are those who are:

- 16  
17 229 - Aged 40-74 years  
18  
19 230 - Overweight or obese (BMI $\geq$ 28 recorded in last 12 months)<sup>2</sup>  
20  
21 231 - With BP recorded in the clinical software within the previous 12 months  
22  
23 232 - Speaking English and/or Arabic<sup>3</sup>  
24  
25 233 - With access to a smart phone or tablet device  
26  
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29  
30 235 **Exclusion criteria:**

- 31  
32 236 - Experiencing recent weight loss (>5% in past 3 months)  
33  
34 237 - A diagnosis of Diabetes requiring insulin or a current prescription for insulin  
35  
36 238 - A diagnosis of Cardiovascular disease (includes angina, myocardial infarction, heart failure, heart  
37  
38 239 valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident))  
39  
40 240 - Taking medication for weight loss (Orlistat or Phentermine)  
41  
42 241 - Cognitive impairment  
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44 242 - Physical impairment which prohibits engaging in moderate level physical activity  
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53 <sup>2</sup> The cut point for BMI was chosen to target people at higher risk and to capture people from Asian  
54 backgrounds who have a lower equivalent BMI.

55 <sup>3</sup> Arabic was chosen as many recently arrived immigrants in the geographical areas are Arabic speaking  
56  
57

## 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.

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5 271 **Practice and Provider consent**

7 272 Written consent will be obtained from all participating practices including consent to conduct the  
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9 273 study in the practice and access practice data, and individual consent from all participating GPs and  
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11 274 PNs.  
12

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16 276 **Patient Consent**

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18 277 Patients will be given information and consent forms in English or Arabic language and be able to ask  
19  
20 278 further questions of the GP or PN. The patient will provide their written consent by filling in the  
21  
22 279 consent form and either placing it in a collection box at reception, or by returning it in a 'reply paid'  
23  
24 280 envelope to the research team. To increase comprehension and meaningful consent within our  
25  
26 281 target population of patients with low health literacy, we have shortened and simplified the  
27  
28 282 Participant Information Statement and Consent forms. Patient eligibility will be confirmed by the GP  
29  
30 283 and at subsequent interview. They will be invited by mail at 6 months to separately consent to the  
31  
32 284 use of routinely collected data on health service use (from Medicare (MBS) Australia's national  
33  
34 285 health insurance program), pharmaceutical use (from the Pharmaceutical Benefits Scheme (PBS))  
35  
36 286 and hospitalisation data (from State admitted patient data collections).  
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38

39 287 **Withdrawal**

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41 288 Practices or patients may withdraw from the study at any time. If patients commence weight loss  
42  
43 289 medication or develop cognitive impairment or severe illness they will be withdrawn from the study.  
44  
45 290 Withdrawals and reasons for withdrawal will be recorded.  
46  
47

48  
49 291 **Patient and public involvement.**

50  
51 292 The development of the research question and outcome measures was informed by previous  
52  
53 293 research conducted in general practice on preventive care, health literacy and obesity management.  
54  
55 294 This included extensive qualitative study with patients about their experience of care in general  
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3 295 practice and the influence of their culture and health literacy (24, 34, 43, 55). Patients were not  
4  
5 296 involved in the design of this study and will not be involved in the recruitment to and conduct of the  
6  
7 297 study. We will conduct qualitative interviews with participants on their experience of the  
8  
9 298 intervention. A summary report will be made available to participants via the study website.

## 10 11 299 Trial Registration

12  
13  
14 300 The HeLP trial is prospectively registered with the Australian Clinical Trials Registry (ANZCTR):

15  
16 301 ACTRN12617001508369 <http://www.ANZCTR.org.au/ACTRN12617001508369.aspx>

## 17 18 19 302 Description of the intervention

20  
21  
22 303 The HeLP GP intervention includes a practice level quality improvement (QI) intervention and a  
23  
24 304 clinical intervention. A logic model for the intervention can be found in Appendix 1.

### 25 26 305 1. Practice intervention

27  
28  
29 306 This includes a de-identified medical record audit, training of practice staff (GPs and PNs) and a  
30  
31 307 series of three practice facilitation visits.

#### 32 33 34 35 309 a) Medical record audit

36  
37 310 A de-identified medical record audit will be conducted by research staff using the DCP program pre-  
38  
39 311 baseline in both intervention and control patients aged 40-74 years (who have not had a heart  
40  
41 312 attack or stroke or do not have diabetes requiring insulin), on the recording of smoking status,  
42  
43 313 alcohol consumption, BMI, waist circumference, blood pressure and total cholesterol. In  
44  
45 314 intervention practices an identified medical audit of the records of consenting patients participating  
46  
47 315 in the trial will be conducted at baseline and 12 months. This will include assessing the control of  
48  
49 316 their risk factors and cardiovascular risk. Audit reports will be fed back to practitioners (GPs and  
50  
51 317 PNs), who will reflect on the reports and be supported to make improvements in the practice  
52  
53 318 facilitation visits (See below and Figure 2).

54  
55  
56 319 *[Insert Figure 2 about here]*

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5 321 b) GP and Nurse training to deliver intervention  
6

7 322 Three comprehensive online training modules will cover study processes, the health risks of obesity,  
8  
9 323 benefits of weight loss, the role of GPs and nurses in weight management, the components of the  
10  
11 324 HeLP-GP intervention, tailoring care to the needs of people with low health literacy, processes to be  
12  
13 325 followed for the health check visits and the use of the App with patients. Online videos will reinforce  
14  
15 326 the GPs' and PNs' use of the App and referral to telephone coaching. Links to these will be provided  
16  
17 327 to participating GPs and PNs. An on-line post training questionnaire and evaluation form will be  
18  
19 328 completed by GP and PN participants and will provide information to evaluate the training and its  
20  
21 329 impact.  
22

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24 330  
25

26 331 c) Facilitation visits conducted by CIs and PHNs  
27

28 332 Facilitation visits will be made up to three times over three months to each intervention practice  
29  
30 333 during the beginning of intervention phase to support PNs and the practice. The aim of the practice  
31  
32 334 facilitation is to support each intervention practice to implement the HeLP-GP intervention including  
33  
34 335 making improvements in recording based on the initial de-identified clinical audit and prepare for  
35  
36 336 the health check visits.  
37

38  
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40

41 338 2. Clinical intervention  
42

43 339 The clinical intervention has three components, each of which will be offered to all patients in the  
44  
45 340 intervention group: a health check visit with the PN; a patient-facing app - *my snapp*; and referral to  
46  
47 341 telephone coaching. Patients may receive any concomitant care indicated for their medical  
48  
49 342 conditions.  
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344 a) Practice nurse health check and follow up.

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

354

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

356	<i>Assess</i>	Review baseline BMI, waist circumference, blood pressure and lipids. Briefly assess diet, physical activity, health literacy and e-health literacy.
357	<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.
358	<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).
359	<i>Arrange</i>	Arrange follow up visit at 6 weeks and a further visit with the GP at 12 weeks

356

357 b) my snapp

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

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

364 **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.

365

366 *[Insert Figure 3 about here]*

### 367 c) Telephone Coaching

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

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

- 1  
2  
3 375 • Resources and tools to develop and maintain motivation for a healthier lifestyle  
4  
5 376 • Assistance to deal with set-backs and problem solve  
6  
7 377 • Social support to help participants to try new ideas and approaches to address lifestyle  
8  
9 378 behaviours

10  
11 379 The coaching is available in multiple languages with the assistance of the national interpreter  
12  
13 380 service.

14  
15 381

## 16 382 Assessing the implementation fidelity of the intervention

17  
18  
19 383 Implementation of the intervention will be assessed by the following measures:

- 20  
21  
22 384 • % of GPs and PNs who complete the online training modules  
23  
24 385 • % of intervention patients who receive baseline, and 6-week clinical review by a PN  
25  
26 386 • % of patients who receive a health check at 12-weeks by a GP  
27  
28 387 • Usage of the lifestyle App determined by app-analytics (% of patients with documented  
29  
30 388 goals related to lifestyle change)  
31  
32 389 • % who received assisted referral to Get Healthy telephone coaching  
33  
34 390 • % of patients who take up and complete Get Healthy telephone coaching program  
35  
36

37 391

## 38 392 Evaluation

### 39 393 Outcomes

40  
41  
42 394 All primary outcomes are changes at the level of the individual patient between baseline and 12  
43  
44 395 months. These include change in:

- 45  
46  
47 396 • Two domains of health literacy from the Health Literacy Questionnaire (56) (Ability to find good  
48  
49 397 health information and Understand health information well enough to know what to do) and e-  
50  
51 398 health literacy (using the eHeals) (57);  
52  
53  
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1  
2  
3 399 • Lifestyle behaviours including portions of fruit and vegetables, soft drink, high fat and snack food  
4  
5 400 consumed per day, use of a dietary plan and the level of physical activity adapted from existing  
6  
7 401 instruments (58-60).

8  
9 402 • Weight, height, BMI, waist circumference, blood pressure extracted from patient medical  
10  
11 403 records.

12  
13 404 Secondary outcomes include health related quality of life using the EQ-5D-5L(61) , total cholesterol  
14  
15 405 extracted from the medical record and patient reported advice and referral given by the GP or  
16  
17 406 practice nurse(30) and health service use and costs from routinely collected data by Australia's  
18  
19 407 health insurance agency and pharmaceutical benefits service (MBS and PBS).

20  
21  
22 408

23  
24 409 Data collection (See Figure 4)

25  
26 410 *Practice:* A practice assessment survey will be conducted by the research team at baseline to  
27  
28 411 determine organization and staffing, use of health education materials and links to other services.

29  
30 412 *Providers:* GPs and PNs involved in the study will complete a questionnaire at baseline and 12  
31  
32 413 months. This will ask about their existing preventive practices and referral pattern, approach to and  
33  
34 414 confidence with health literacy and health education, previous training and education (43, 62).

35  
36 415 *Patient surveys:* All patients will participate in a survey administered by research staff by telephone  
37  
38 416 at baseline, 6 and 12 months to assess diet and physical activity behaviours, health literacy and e-  
39  
40 417 health literacy. The interview will include questions about education received in general practice  
41  
42 418 and referral for lifestyle or weight interventions at baseline and 6 months and quality of life at  
43  
44 419 baseline and 12 months. Intervention group patients will be interviewed at 18 months about lifestyle  
45  
46 420 behaviours.

47  
48 421 *Medical record audits:* These will be conducted at baseline, 6 months, 12 months and 18 months.

49  
50 422 *Administrative health service data:* All patients will be asked to consent to provision of health service  
51  
52 423 and medication use from routinely collected data from Australia's national health insurance and  
53  
54 424 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

	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

449

450 **Data management**

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

453 **Adverse events**

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

456 **Analysis**

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

465

## 466 Economic evaluation

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

483

## 484 Qualitative analysis

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

488

## 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

1  
2  
3 514 too long. We have thus had to balance this burden against our desire to collect as much information  
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5 515 as possible using robust instruments.

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8  
9 517 A further risk is that the clinical intervention will not be implemented in practice as we planned.

10  
11 518 Again, addressing this requires close work with the practices. The implementation measures and

12  
13 519 qualitative evaluation will provide some insight, but this may be too late to correct. We have thus

14  
15 520 built into the practice level intervention several measures to improve fidelity. These include

16  
17 521 feedback mechanisms in the online training, reflective feedback from practices on the audits and

18  
19 522 practice discussion during the facilitation visits. These will be tracked regularly during the

20  
21 523 implementation of the trial. A further risk is that some health and e-health literacy will both be

22  
23 524 required for adoption of the App by patients and is expected to improve as a result of the

24  
25 525 intervention use. This will be addressed by the support provided to patients by practice nurses and

26  
27 526 general practitioners.

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31  
32 528 The fieldwork for the study is planned to be completed by December 2018 with follow-up completed

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34 529 by mid-2019. We anticipate circulation of the main findings from the study by 2020.

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3 531 **Figure Legends**  
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5 532 **Figure 1. Practice and patient recruitment**  
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8 533 **Figure 2: Clinical audit reports**  
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11 534 **Figure 3: My Snapp screens**  
12

13 535 **Figure 4: Outcomes and Data collection**  
14

15 536  
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17  
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41  
42  
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4

5 555 Centre for Primary Health Care and Equity, UNSW. Contact Professor Mark Harris +61 2 93858384 or  
6  
7 556 m.f.harris@unsw.edu.au  
8

9 557  
10

11  
12 558 **Committees**  
13

14 559 The trial has a steering committee comprised on the project manager and investigators that  
15  
16 560 oversees the project.  
17

18 561  
19

20  
21 562 **Contribution**  
22

23 563 SP co-drafted the paper and protocol documents on which it was based  
24

25 564 NS contributed to and was CI on the peer reviewed funding proposal and commented on the paper  
26  
27 565 and protocol documents on which it was based specially data collection and intervention in general  
28  
29 566 practice  
30

31 567 DN contributed to and was CI on the peer reviewed funding proposal and contributed to the overall  
32  
33 568 design of the study and intervention and content of the paper and protocol documents on which it  
34  
35 569 was based  
36

37 570 LT co-drafted the paper and protocol documents on which it was based  
38

39  
40 571 ED-W contributed to and was CI on the peer reviewed funding proposal and contributed to the  
41  
42 572 design of the study and content of the paper and protocol documents on which it was based  
43  
44 573 especially in the education components of the intervention  
45

46 574 NZ contributed to and was CI on the peer reviewed funding proposal and commented on the paper  
47  
48 575 and protocol documents on which it was based especially in relation to the role of general practice  
49

50 576 JK contributed to and was CI on the peer reviewed funding proposal especially the health economic  
51  
52 577 component and commented on the paper and protocol documents on which it was based  
53  
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1  
2  
3 578 JL contributed to and was AI on the peer reviewed funding proposal especially the health economic

4  
5 579 component and commented on the paper and protocol documents on which it was based

6  
7 580 MN contributed to and was CI on the peer reviewed funding proposal especially the nutrition

8  
9 581 component and commented on the paper.

10  
11 582 STL contributed to and was CI on the peer reviewed funding proposal especially the informatics

12  
13 583 component and commented on the paper and protocol documents on which it was based

14  
15 584 AL contributed to and was CI on the peer reviewed funding proposal especially the m-health

16  
17 585 component and commented on the paper and protocol documents on which it was based

18  
19 586 RO contributed to and was AI on the peer reviewed funding proposal especially the health literacy

20  
21 587 component and commented on the paper and protocol documents on which it was based

22  
23 588 MFH developed and led the peer reviewed funding proposal including the design of the study and

24  
25 589 intervention and co-drafted the paper and protocol documents on which it was based.

26  
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29  
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31  
32 592 NHMRC in 2016.

### 33 34 593 **Competing interests**

35  
36  
37 594 The investigators have no competing interests to declare relevant to this study.

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### 40 41 596 **Data statement**

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44 597 Data and Meta-data will be stored in a repository at the University of New South Wales. De-

45  
46 598 identified data will be made available subject to ethics committee approval.

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3 600 **Dissemination**  
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5 601 The findings of the study will be made available to participants and the public via the Centre for  
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7 602 Primary Health Care web page 25and through conference presentations and research publications.  
8

9 603 There are no restricts on publication.  
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For peer review only

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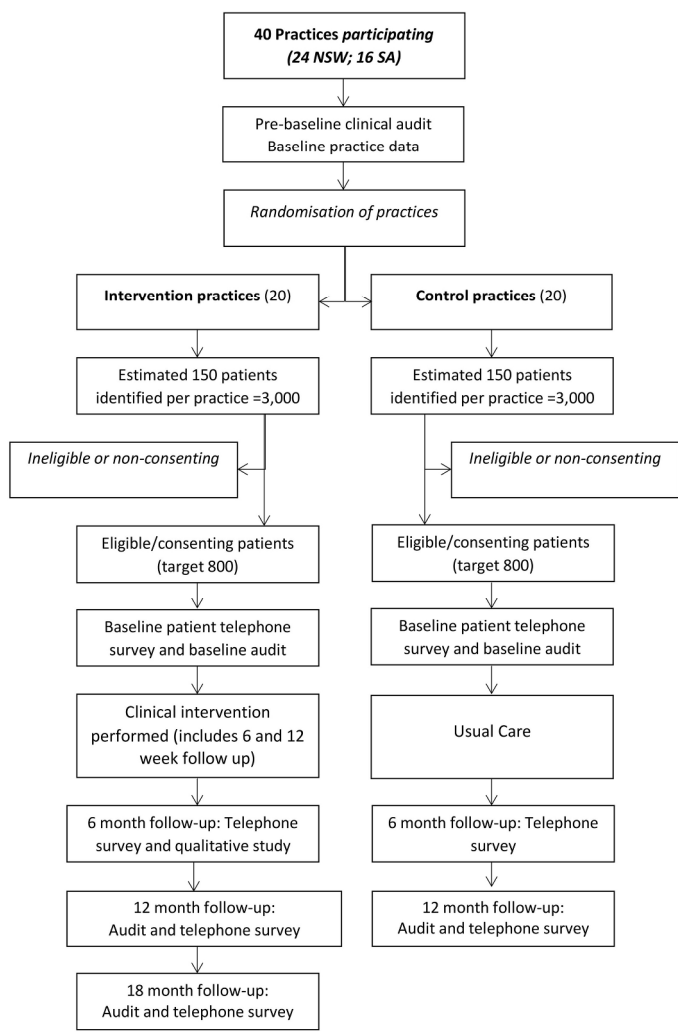


Figure 1

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

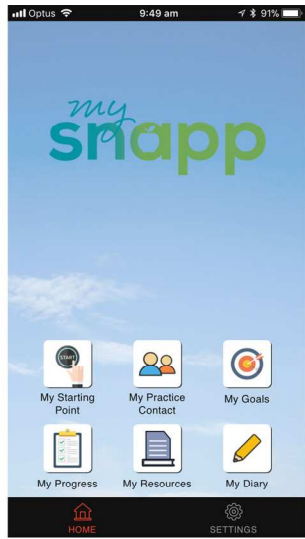
Patient Name	Gen der	Age	Smoking Status <i>Current, Ex- or Never</i>	BMI	Systolic BP		Total cholesterol		Absolute risk
					<i>On Medic</i>	<i>Not on Meds</i>	<i>On Meds</i>	<i>Not on Meds</i>	
<i>Target</i>			<i>Non or Ex</i>	<i>BMI ≤ 25</i>	<i>Systolic BP &lt;140 mmHg</i>		<i>Total Cholesterol &lt;4mMol/L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

Figure 2

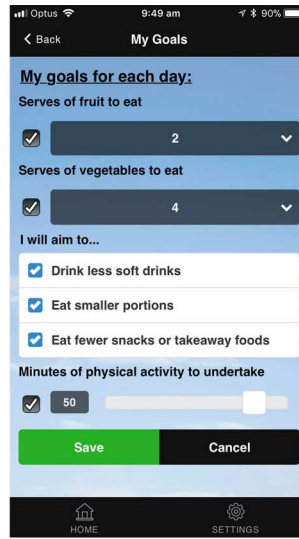
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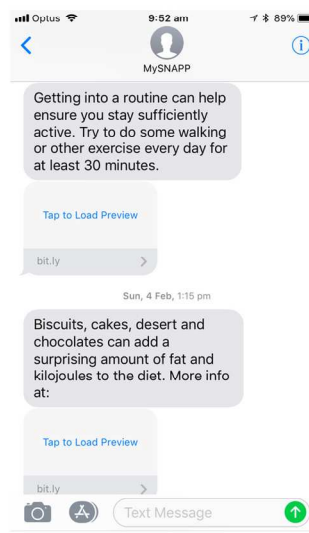
Landing Page



Goal Setting



Weekly self-monitoring



Text message

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

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3 41 Patient Inclusion criteria: Aged 40-74 years; Overweight or obese (BMI $\geq$ 28 recorded in last 12  
4 42 months) ; BP recorded in the clinical software within the previous 12 months; Speaking English  
5 43 and/or Arabic; access to a smart phone or tablet device.

6  
7 44 Patient Exclusion criteria: Experiencing recent weight loss (>5% in past 3 months); diagnosis of  
8 45 Diabetes requiring insulin or a current prescription for insulin; diagnosis of Cardiovascular  
9 46 disease (includes angina, myocardial infarction, heart failure, heart valve disease (rheumatic  
10 47 or non-rheumatic), stroke (cerebrovascular accident)); Taking medication for weight loss  
11 48 (Orlistat or Phentermine); Cognitive impairment; Physical impairment prohibiting the patient  
12 49 from undertaking moderate level physical activity.

13  
14 50 15. Anticipated date of first enrolment: 1st May 2018.

15  
16 51 16. Sample size: Planned: 1600

17 52 17. Sample size: Current: 0 patients

18  
19 53 18. Recruitment Status: Pending: participants are not yet being recruited or enrolled at any site

20  
21 54 19. Primary Outcome(s):

22 55 i) Health literacy. Measure Health Literacy Questionnaire: Timepoints: Baseline, 6 and 12  
23 56 months

24  
25 57 ii) e-health literacy. Measure eHeals. Timepoints: Baseline, 6, 12 and 18 months

26 58 v) Body Mass Index. Calculated from measured weight in Kg and height in cm. Timepoints:  
27 59 Baseline, 6 , 12 and 18 months.

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29 60 vi) Waist circumference. Measured in cm. Timepoints: Baseline, 6 , 12 and 18 months.

30  
31 61 vii) Blood pressure. Measured in mmHg using automated sphygmomanometer. Timepoints:  
32 62 Baseline, 6 , 12 and 18 months

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34 63 20. Secondary outcomes

35 64 i) Daily fruit and vegetable consumption. Measure: questions adapted from NSW Population  
36 65 Health Survey and CSIRO Healthy diet score. Timepoints: Baseline and 6 months

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38 66 ii) Physical activity level. Measure: Self-reported minutes of vigorous and moderate activity.  
39 67 Calculated as score. Timepoints: Baseline and 6 months.

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41 68 iii) Health related quality of life. Measure: EQ-5D-5L. Baseline and 12 months.

42 69 ii) Total Cholesterol. Measure: Recorded total cholesterol from medical records. Up to 2 years  
43 70 prior to baseline and 12 months.

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45 71 iii) Advice and Referral. Measure: Patient questionnaire on reported advice or referral given by  
46 72 GP for smoking, diet, physical activity or weight management in previous 6 months.  
47 73 Timepoints: Baseline, 6 months

48  
49 74 iv) Cost. Measure: Practice nurse time plus Medical Benefits Schedule and Pharmaceutical  
50 75 Benefits Schedule data. Timepoints: 12 months.

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52 76 21. Ethics Review

53 77 i) Status: Approved (HC17474)

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55 78 ii) Date of approval: 27 July 2017

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- 79 iii) Name and contact details of Ethics committee(s): University of New South Wales Human
- 80 Research Ethics Committee. Phone P: +61 2 9385 6222, + 61 2 9385 7257 or + 61 2 9385 7007.
- 81 Email: humanethics@unsw.edu.au
- 82 22. Completion date: Unknown
- 83 23. Summary Results: Not yet available
- 84 24. IPD sharing statement: Plan to share IPD: No
- 85

For peer review only

# 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				
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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	
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27	Background and	#6b	Explanation for choice of comparators	10
28	rationale: choice of			
29	comparators			
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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				
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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	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable,	10,11
49			eligibility criteria for study centres and individuals who will	
50			perform the interventions (eg, surgeons, psychotherapists)	
51				
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				
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1	Interventions:	#11b	Criteria for discontinuing or modifying allocated	13
2	modifications		interventions for a given trial participant (eg, drug dose	
3			change in response to harms, participant request, or	
4			improving / worsening disease)	
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8	Interventions:	#11c	Strategies to improve adherence to intervention protocols,	18
9	adherence		and any procedures for monitoring adherence (eg, drug	
10			tablet return; laboratory tests)	
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12				
13	Interventions:	#11d	Relevant concomitant care and interventions that are	15
14	concomitant care		permitted or prohibited during the trial	
15				
16				
17	Outcomes	#12	Primary, secondary, and other outcomes, including the	18-19
18			specific measurement variable (eg, systolic blood pressure),	
19			analysis metric (eg, change from baseline, final value, time	
20			to event), method of aggregation (eg, median, proportion),	
21			and time point for each outcome. Explanation of the clinical	
22			relevance of chosen efficacy and harm outcomes is strongly	
23			recommended	
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28	Participant timeline	#13	Time schedule of enrolment, interventions (including any	18-19
29			run-ins and washouts), assessments, and visits for	
30			participants. A schematic diagram is highly recommended	
31			(see Figure)	
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34				
35	Sample size	#14	Estimated number of participants needed to achieve study	20-21
36			objectives and how it was determined, including clinical and	
37			statistical assumptions supporting any sample size	
38			calculations	
39				
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41				
42	Recruitment	#15	Strategies for achieving adequate participant enrolment to	12
43			reach target sample size	
44				
45				
46	Allocation: sequence	#16a	Method of generating the allocation sequence (eg,	10
47	generation		computer-generated random numbers), and list of any	
48			factors for stratification. To reduce predictability of a random	
49			sequence, details of any planned restriction (eg, blocking)	
50			should be provided in a separate document that is	
51			unavailable to those who enrol participants or assign	
52			interventions	
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57	Allocation	#16b	Mechanism of implementing the allocation sequence (eg,	10
58	concealment		central telephone; sequentially numbered, opaque, sealed	
59				
60				



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

1	Data monitoring:	#21a	Composition of data monitoring committee (DMC); summary	n/a
2	formal committee		of its role and reporting structure; statement of whether it is	
3			independent from the sponsor and competing interests; and	
4			reference to where further details about its charter can be	
5			found, if not in the protocol. Alternatively, an explanation of	
6			why a DMC is not needed	
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11	Data monitoring:	#21b	Description of any interim analyses and stopping guidelines,	n/a
12	interim analysis		including who will have access to these interim results and	
13			make the final decision to terminate the trial	
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15				
16	Harms	#22	Plans for collecting, assessing, reporting, and managing	21
17			solicited and spontaneously reported adverse events and	
18			other unintended effects of trial interventions or trial conduct	
19				
20				
21	Auditing	#23	Frequency and procedures for auditing trial conduct, if any,	n/a
22			and whether the process will be independent from	
23			investigators and the sponsor	
24				
25				
26				
27	Research ethics	#24	Plans for seeking research ethics committee / institutional	12
28	approval		review board (REC / IRB) approval	
29				
30				
31	Protocol	#25	Plans for communicating important protocol modifications	n/a
32	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	
33			relevant parties (eg, investigators, REC / IRBs, trial	
34			participants, trial registries, journals, regulators)	
35				
36				
37	Consent or assent	#26a	Who will obtain informed consent or assent from potential	13
38			trial participants or authorised surrogates, and how (see	
39			Item 32)	
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43	Consent or assent:	#26b	Additional consent provisions for collection and use of	13
44	ancillary studies		participant data and biological specimens in ancillary	
45			studies, if applicable	
46				
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48	Confidentiality	#27	How personal information about potential and enrolled	13
49			participants will be collected, shared, and maintained in	
50			order to protect confidentiality before, during, and after the	
51			trial	
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55	Declaration of	#28	Financial and other competing interests for principal	26
56	interests		investigators for the overall trial and each study site	
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59	Data access	#29	Statement of who will have access to the final trial dataset,	26
60				

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	
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36				

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 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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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

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3 1 Title: Preventing chronic disease in patients with low  
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7 2 health literacy using eHealth and teamwork in  
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11 3 primary health care: Protocol for a cluster  
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16 4 Randomised controlled trial  
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38

## 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  $\geq$   
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

## 64 Strengths and Limitations of this study

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

## 72 Keywords

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

74



## 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/m<sup>2</sup> 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

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3 99 Primary care is well positioned to contribute to the prevention and management of overweight and  
4  
5 100 obesity. Over 86% of the population of Australia visit a general practitioner at least once a year (16).  
6  
7 101 Almost a third of patients presenting in general practice are obese and two thirds are overweight or  
8  
9 102 obese, which are rates similar to the prevalence in the general community (17). Behavioural  
10  
11 103 interventions in primary care have been demonstrated to achieve a 5-7% improvement in weight,  
12  
13 104 blood pressure or lipids for patients, potentially preventing or delaying the onset of Type 2 diabetes  
14  
15 105 and cardiovascular disease (18-20). However these interventions tend to have lower uptake by low  
16  
17 106 socioeconomic groups (21, 22) and, overall, most weight loss interventions in primary care achieve  
18  
19 107 only small reductions in weight (23).  
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22 108

#### 23 24 109 Preliminary work leading up to this study

25  
26 110 Over the past decade we have sought to develop more effective interventions to prevent disease in  
27  
28 111 primary care which target disadvantaged populations who are more likely to have low health  
29  
30 112 literacy. In previous research we have found that ethnicity and language interact with health  
31  
32 113 literacy to influence uptake of preventive interventions especially those for weight loss (24). This  
33  
34 114 accords with the findings of others that health literacy differentials are greater among older people,  
35  
36 115 for those born overseas, those who do not speak English at home and those with low educational  
37  
38 116 attainment (25). In these groups patient-provider communication tends to be less effective, leading  
39  
40 117 providers to incorrectly assume that patients with low health literacy are poorly motivated and they  
41  
42 118 are therefore less likely to offer lifestyle interventions (26, 27). Organisational and practitioner  
43  
44 119 barriers also contribute to low frequency and effectiveness of assessment, advice, goal setting, and  
45  
46 120 referral of patients with low health literacy (6, 28). These barriers include time available for  
47  
48 121 consultations and competing demands on primary care staff.  
49  
50 122

51  
52  
53 123 We have also identified a need to tailor prevention and management of excess weight to a patients'  
54  
55 124 level of health literacy (29). Our review of primary health care level interventions targeting health  
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57

1  
2  
3 125 literacy around weight loss found limited information as to the effect of weight loss interventions on  
4  
5 126 health literacy primarily because this is an outcome not frequently reported (30). We have  
6  
7 127 evaluated a structured, nurse delivered health check intervention based on 5As that includes a brief  
8  
9 128 assessment of health literacy, tailoring advice and the use of “teach-back”; goal setting that involves  
10  
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),  
14  
15 131 however, consistent with other studies, the impact on risk behaviours and weight have been small  
16  
17 132 (23). This may be due to the limited capacity within primary care to provide interventions based on  
18  
19 133 evidence that are of sufficient intensity and length.  
20

21  
22 134

23  
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  
27  
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  
39  
40 143 change. Previous research has demonstrated the effectiveness of mobile health (m-health) text  
41  
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  
45  
46 146 supporting change in health behaviours (40). However, the optimal form and role of this technology  
47  
48 147 for patients with low health or e-health literacy is still unclear.  
49

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53 149 This paper describes the protocol for the development and evaluation of an intervention which  
54  
55 150 combines face to face consultation in general practice with these digital health approaches based on  
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2  
3 151 previous research which has demonstrated both feasibility of implementation and highlighted the  
4  
5 152 potential for health gains.

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7 153

## 8 9 154 Intervention Development

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11  
12 155 The various components of the HeLP-GP intervention have been developed and piloted over the past  
13  
14 156 five years.

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17 157

18  
19 158 The brief primary care intervention which is designed to support practices to improve the quality of  
20  
21 159 preventive care for the SNAP (smoking, nutrition, alcohol and physical activity) risk behaviours and  
22  
23 160 weight management is based on behavioural theory and is structured on the 5As framework which  
24  
25 161 encompasses assessment, advice, agreeing on goals, assisting with motivational counselling and  
26  
27 162 referral options and arranging follow up (13, 41). Progress along the pathway from assessment to  
28  
29 163 follow up is associated with increased patient motivation and behaviour change (42). This has been  
30  
31 164 trialled in general practice and found to be feasible and acceptable and to lead to improvement in  
32  
33 165 the quality of preventive care (30, 43, 44). This intervention was adapted for use by practice nurses  
34  
35 166 and modified for patients with low health literacy to include brief screening for low health literacy,  
36  
37 167 tailored communication and referral navigation to local lifestyle programs and piloted (45). It was  
38  
39 168 subsequently evaluated in a trial which demonstrated its feasibility and acceptability to providers  
40  
41 169 and patients (30).

42  
43  
44 170

45  
46 171 The app used in this study is supported by *Healthy.me*, a personally controlled health management  
47  
48 172 platform designed to help patients and consumers manage their health (46). This has been shown to  
49  
50 173 improve uptake of preventive services (47, 48) and strong consumer acceptance has been  
51  
52 174 demonstrated in Australia across different healthcare settings including primary care (49). This  
53  
54 175 platform was modified to create the mobile application used in this study (*my snapp*). This was

1  
2  
3 176 informed by research that interventions based on theory and those involving goal-setting and self-  
4  
5 177 monitoring as well as providing additional methods to interact with patients, particularly text  
6  
7 178 messages, were more effective (50-53). Other research suggests that patients with low health  
8  
9 179 literacy prefer apps or text messages to other sources of online information (54).  
10

11 180

## 12 13 181 **Aims and research questions**

14  
15  
16 182 The aim of this study is to evaluate the implementation and effectiveness of a preventive  
17  
18 183 intervention in primary care structured around the 5As framework supported by a patient-facing  
19  
20 184 mobile app, consultations with the practice nurse and/or referral to a telephone coaching service.  
21  
22 185 The intervention aims to develop the knowledge and skills of overweight or obese patients with low  
23  
24 186 health literacy. The trial will assess the impact of the intervention on preventive care received,  
25  
26 187 patients' health and e-health literacy, physical and behavioural risk factors, quality of life and costs.  
27

## 28 29 188 **Description of the intervention**

30  
31  
32 189 The HeLP GP intervention includes a practice level quality improvement (QI) intervention and a  
33  
34 190 clinical intervention. A logic model for the intervention can be found in Appendix 1.  
35

### 36 37 191 **1. Practice intervention**

38  
39 192 This includes a de-identified medical record audit, training of practice staff (GPs and PNs) and a  
40  
41 193 series of three practice facilitation visits.  
42

43 194

#### 44 45 195 **a) Medical record audit**

46  
47  
48 196 A de-identified medical record audit will be conducted by research staff using the DCP program pre-  
49  
50 197 baseline in both intervention and control patients aged 40-74 years (who have not had a heart  
51  
52 198 attack or stroke or do not have diabetes requiring insulin), on the recording of smoking status,  
53  
54 199 alcohol consumption, BMI, waist circumference, blood pressure and total cholesterol. In  
55  
56 200 intervention practices an identified medical audit of the records of consenting patients participating  
57

1  
2  
3 201 in the trial will be conducted at baseline and 12 months. This will include assessing the control of  
4  
5 202 their risk factors and cardiovascular risk. Audit reports will be fed back to practitioners (GPs and  
6  
7 203 PNs), who will reflect on the reports and be supported to make improvements in the practice  
8  
9 204 facilitation visits (See below and Figure 1).

10  
11 205 *[Insert Figure 1 about here]*  
12

13 206  
14

#### 15 207 b) GP and Nurse training to deliver intervention

16  
17 208 Three comprehensive online training modules will cover study processes, the health risks of obesity,  
18  
19 209 benefits of weight loss, the role of GPs and nurses in weight management, the components of the  
20  
21 210 HeLP-GP intervention, tailoring care to the needs of people with low health literacy, processes to be  
22  
23 211 followed for the health check visits and the use of the App with patients. Online videos will reinforce  
24  
25 212 the GPs' and PNs' use of the App and referral to telephone coaching. Links to these will be provided  
26  
27 213 to participating GPs and PNs. An on-line post training questionnaire and evaluation form will be  
28  
29 214 completed by GP and PN participants and will provide information to evaluate the training and its  
30  
31 215 impact.  
32  
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35

#### 36 217 c) Facilitation visits conducted by CIs and PHNs

37  
38 218 Facilitation visits will be made up to three times over three months to each intervention practice  
39  
40 219 during the beginning of intervention phase to support PNs and the practice. The aim of the practice  
41  
42 220 facilitation is to support each intervention practice to implement the HeLP-GP intervention including  
43  
44 221 making improvements in recording based on the initial de-identified clinical audit and prepare for  
45  
46 222 the health check visits.  
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## 51 224 2. Clinical intervention

52  
53  
54 225 The clinical intervention has three components, each of which will be offered to all patients in the  
55  
56 226 intervention group: a health check visit with the PN; a patient-facing app - *my snapp*; and referral to  
57

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)**

242	<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

242

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2  
3 243 b) *my snapp*

4  
5 244 The components of the App are described in Table 2 and Figure 2. The PN explains the App, supports  
6  
7 245 the patient to register and download the App, enters information on risk factors (BMI, WC, BP) and  
8  
9 246 the practice and helps the patient to set goals and navigate the App. There is also a patient website  
10  
11 247 where participants can get further information and communicate any problems or issues with the  
12  
13 248 App. The content of *my snapp* aligns with both the nurse health check and the telephone coaching  
14  
15 249 (Table 2).

16  
17  
18 250 **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.

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45  
46  
47 252 *[Insert Figure 2 about here]*



1  
2  
3 253 c) Telephone Coaching  
4

5 254 The telephone coaching program recommended to patients is “Get Healthy” which is supported by  
6  
7 255 the relevant state government and provided free of charge. Get Healthy delivers 10 free coaching  
8  
9 256 calls over 10 weeks which provide:

- 11 257 • Review of lifestyle goals (diet and physical activity) and ways to address barriers to achieving  
12  
13 258 these goals  
14  
15 259 • Practical health information  
16  
17  
18 260 • Support and resources to promote self-monitoring of diet, physical activity and weight  
19  
20 261 • Resources and tools to develop and maintain motivation for a healthier lifestyle  
21  
22 262 • Assistance to deal with set-backs and problem solve  
23  
24 263 • Social support to help participants to try new ideas and approaches to address lifestyle  
25  
26 264 behaviours

27  
28 265 The coaching is available in multiple languages with the assistance of the national interpreter  
29  
30 266 service.  
31

32  
33 267

34  
35 268 Assessing the implementation fidelity of the intervention  
36

37 269 Implementation of the intervention will be assessed by the following measures:

- 38  
39 270 • % of GPs and PNs who complete the online training modules  
40  
41 271 • % of intervention patients who receive baseline, and 6-week clinical review by a PN  
42  
43 272 • % of patients who receive a health check at 12-weeks by a GP  
44  
45 273 • Usage of the lifestyle App determined by app-analytics (% of patients with documented  
46  
47 274 goals related to lifestyle change)  
48  
49 275 • % who received assisted referral to Get Healthy telephone coaching  
50  
51 276 • % of patients who take up and complete Get Healthy telephone coaching program  
52  
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## 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<sup>NET</sup>). 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:

- 1  
2  
3 300 • Be situated in Local Government Areas (LGAs) with a low Socio-economic (SEIFA<sup>1</sup>) score  
4  
5 301 equal to and below the 6<sup>th</sup> decile (usually associated with lower health literacy (5)  
6  
7 302 • Use clinical software compatible with the data extraction and recruitment tool *Doctors*  
8  
9 303 *Control Panel* (DCP). This includes *Medical Director, MediNet, PracSoft and Best Practice* and  
10  
11 304 associated compatible billing software (*Pracsoft and Best Practice Management*).  
12  
13 305 • Agree to the installation of DCP for the purposes of clinical audit and to identify eligible  
14  
15 306 patients for the study  
16  
17 307 • Have access to an active internet connection  
18  
19 308 • Have at least one practice nurse who is prepared to conduct the HeLP- GP intervention with  
20  
21 309 eligible and consenting patients and complete data management relating to these patients  
22  
23 310 • Agree to provide GP follow up health checks to participating patients at 12 weeks and 12-  
24  
25 311 month time points  
26  
27 312 • Can make their staff available to distribute study materials to potential study participants  
28  
29 313 when they register with reception prior to seeing a GP  
30  
31  
32  
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34

### 315 Practice patients

316 Eligible patients are those who are:

- 317 - Aged 40-74 years  
318 - Overweight or obese (BMI $\geq$ 28 recorded in last 12 months)<sup>2</sup>  
319 - With BP recorded in the clinical software within the previous 12 months  
320 - Speaking English and/or Arabic<sup>3</sup>  
321 - With access to a smart phone or tablet device

<sup>1</sup> Australian Bureau of Statistics Socioeconomic Indexes for Areas (SEIFA)

<http://www.abs.gov.au/websitedbs/censushome.nsf/home/seifahelpansuis?opendocument&navpos=260&#0>

<sup>2</sup>

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.

<sup>3</sup> Arabic was chosen as many recently arrived immigrants in the geographical areas are Arabic speaking

1  
2  
3 322

4  
5 323 *Exclusion criteria:*

- 6  
7 324 - Experiencing recent weight loss (>5% in past 3 months)
- 8  
9 325 - A diagnosis of Diabetes requiring insulin or a current prescription for insulin
- 10  
11 326 - A diagnosis of Cardiovascular disease (includes angina, myocardial infarction, heart failure, heart
- 12  
13 327 valve disease (rheumatic or non-rheumatic), stroke (cerebrovascular accident))
- 14  
15 328 - Taking medication for weight loss (Orlistat or Phentermine)
- 16  
17 329 - Cognitive impairment
- 18  
19 330 - Physical impairment which prohibits engaging in moderate level physical activity
- 20  
21

22 331

23  
24 332 *Recruitment*

25  
26 333 The recruitment process for practices and patients is outlined in Figure 3. The target practice

27  
28 334 recruitment is 24 practices from two regions in Sydney (South West Sydney and Central and Eastern

29  
30 335 Sydney) and 16 practices from Adelaide, South Australia.

31  
32 336

33  
34 337 The primary source of practice recruitment will be through participating Primary Health Networks

35  
36 338 (PHNs) in the target locations. PHNs will approach potentially eligible practices using mail, fax and

37  
38 339 practice visits to ascertain their interest. Practices will be provided with a study outline and asked to

39  
40 340 complete an Expression of Interest (EOI). A face to face practice visit will provide detailed

41  
42 341 information about practice tasks and confirm eligibility.

43  
44 342

45  
46 343 *Recruitment of Practice Patients*

47  
48 344 Patients will be recruited at the point of presentation using the *Doctors' Control Panel* software

49  
50 345 (DCP) which has also been used in previous research [12]. This software will be programmed

51  
52 346 according to the inclusion and exclusion criteria to identify potential participants as they present to

53  
54 347 the practice. These patients will be flagged and information on patients BMI, lipids and blood

55  
56  
57

1  
2  
3 348 pressure will be extracted from the medical record and printed. This information will be attached to  
4  
5 349 information and consent forms by the practice receptionist and given to patients to read and discuss  
6  
7 350 with the GP or practice nurse. The practice will be reimbursed for the time spent by the reception  
8  
9 351 staff.

10  
11 352 *[Insert Figure 3 about here].*  
12

13 353  
14

### 15 354 Patient and public involvement.

16  
17  
18 355 The development of the research question and outcome measures was informed by previous  
19  
20 356 research conducted in general practice on preventive care, health literacy and obesity management.  
21  
22 357 This included extensive qualitative study with patients about their experience of care in general  
23  
24 358 practice and the influence of their culture and health literacy (24, 34, 43, 55). Patients were not  
25  
26 359 involved in the design of this study and will not be involved in the recruitment to and conduct of the  
27  
28 360 study. We will conduct qualitative interviews with participants on their experience of the  
29  
30 361 intervention. A summary report will be made available to participants via the study website.  
31

32 362  
33

### 34 363 Outcomes

35  
36  
37 364 All primary outcomes are changes at the level of the individual patient. These include change in:  
38  
39 365 • Domains of health literacy from the Health Literacy Questionnaire (56) from self-report in  
40  
41 366 telephone interviews between baseline, 6 and 12 months  
42  
43 367 • e-health literacy assessed using the e-Health Literacy Scale (eHeals) (57); from self-report in  
44  
45 368 telephone interviews between baseline, 6 12 and 18 months  
46  
47 369 • Biomedical risk factors (weight, height, BMI, waist circumference, blood pressure) through audit  
48  
49 370 of clinical records, between baseline, 6 12 and 18 months.  
50

51  
52 371 Secondary outcomes include change in :-  
53  
54  
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- 1  
2  
3 372 • Behavioural risk factors (daily fruit and vegetable consumption and physical activity level)  
4  
5 373 assessed from self-report in telephone interviews between baseline and 6 months (58-60).  
6  
7 374 • total cholesterol extracted from the medical record at baseline and 12 months  
8  
9 375 • health related quality of life measured using the EQ-5D-5L(61) administered by telephone survey  
10  
11 376 at baseline and 12 months,  
12  
13 377 • cost of intervention including service use assessed from linked data from public medical  
14  
15 378 insurance (Medical Benefits Schedule), Pharmaceutical Benefits Scheme (PBS) and hospital data  
16  
17 379 at 12 months.  
18  
19  
20 380 • Receipt of advice given by the GP or practice nurse(30) assessed by patient interview at baseline  
21  
22 381 and 6 months for:  
23  
24 382 ○ Smoking cessation  
25  
26 383 ○ Diet  
27  
28 384 ○ Physical activity and  
29  
30 385 ○ Weight management.  
31  
32  
33

34 387 **Data collection (See Figure 4)**

35  
36  
37 388 *Practice:* A practice assessment survey will be conducted by the research team at baseline to  
38  
39 389 determine organization and staffing, use of health education materials and links to other services.

40  
41 390 *Providers:* GPs and PNs involved in the study will complete a questionnaire at baseline and 12  
42  
43 391 months. This will ask about their existing preventive practices and referral pattern, approach to and  
44  
45 392 confidence with health literacy and health education, previous training and education (43, 62).

46  
47 393 *Patient surveys:* All patients will participate in a survey administered by research staff by telephone  
48  
49 394 at baseline, 6 and 12 months to assess diet and physical activity behaviours, health literacy and e-  
50  
51 395 health literacy. The interview will include questions about education received in general practice  
52  
53 396 and referral for lifestyle or weight interventions at baseline and 6 months and quality of life at  
54  
55  
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57  
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59  
60

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.

417

#### 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

423 correlation coefficients, prevalence, variance and effect sizes from our previous research are in table  
 424 3, based on a two-sided test of significance at  $\alpha=0.05$ .  $\beta=0.8$  and 20% loss to follow up [40] (Table  
 425 3).

426 **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

#### 428 Data management

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

#### 431 Adverse events

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

#### 434 Analysis

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



1  
2  
3 441 logistic regression techniques that adjust for clustering by practice with multiple imputation for  
4  
5 442 missing values.

6  
7 443

#### 8 9 444 Economic evaluation

10  
11 445 Information on resource use associated with the intervention will be collected by research staff,  
12  
13 446 including the cost of setting up the intervention: practice staff education, practice support visits and  
14  
15 447 materials and web support. Other relevant resource use includes GP and PN visits, referrals, hospital  
16  
17 448 attendances and prescribing. We will request patient consent to access their medical records, MBS  
18  
19 449 and PBS data, and public hospital data from the State Health Departments. The MBS, PBS and State  
20  
21 450 data will capture most primary care and hospital costs. The cost of PN visits for health checks will be  
22  
23 451 assigned an hourly rate based on PN salary levels plus on-costs. Questions on patient use of lifestyle  
24  
25 452 services and programs, and non-Medicare funded allied health will also be included in the patient  
26  
27 453 questionnaire. Cost estimates will be generated for referrals to community-based programs. In the  
28  
29 454 base case analysis, undertaken from a health service perspective, referrals to allied health  
30  
31 455 professionals will only be costed if supported by a Medicare claim. The incremental costs of the  
32  
33 456 intervention, will be presented alongside the consequences with respect to changes in quality of life  
34  
35 457 (including the estimation of QALY gains informed by the EQ5D-5L) and differences in health literacy,  
36  
37 458 behavioural outcomes, and clinical measures (BMI, blood pressure and Lipids). Deterministic and  
38  
39 459 bootstrapped sensitivity analyses will be undertaken to identify key uncertain parameters and  
40  
41 460 represent uncertainty around the mean estimates, respectively.

42  
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44  
45 461

#### 46 462 Qualitative analysis

47  
48  
49 463 The qualitative interviews will be transcribed and analysed thematically using the program NVivo  
50  
51 464 (QSR NVivo 11). This will use an inductive approach based on the data as well as deductively based  
52  
53 465 on health literacy and health information theory (13, 63).

## 466 Ethics and dissemination

### 467 Approval

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

### 471 Practice and Provider consent

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

### 475 Patient Consent

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

### 486 Withdrawal

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

## 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.

497

## 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.

1  
2  
3 515 Problems with recruitment, retention or engagement of patients with the intervention and data  
4  
5 516 collection have the potential to reduce statistical power and therefore the ability to detect the  
6  
7 517 primary outcomes with adequate precision. In this setting, recruitment procedures need to avoid  
8  
9 518 pressure from the research team and patient's own GP to ensure that eligible patients are  
10  
11 519 approached and provided with sufficient information to make an informed decision about  
12  
13 520 participation. We will work with practices to set up software and systems to make this possible. A  
14  
15 521 significant part of the burden on participants will be from the telephone interviews by the research  
16  
17 522 team. Although telephone interviews are preferred by most patients, they are onerous if they are  
18  
19 523 too long. We have thus had to balance this burden against our desire to collect as much information  
20  
21 524 as possible using robust instruments.  
22

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24 525

25  
26 526 A further risk is that the clinical intervention will not be implemented in practice as we planned.  
27  
28 527 Again, addressing this requires close work with the practices. The implementation measures and  
29  
30 528 qualitative evaluation will provide some insight, but this may be too late to correct. We have thus  
31  
32 529 built into the practice level intervention several measures to improve fidelity. These include  
33  
34 530 feedback mechanisms in the online training, reflective feedback from practices on the audits and  
35  
36 531 practice discussion during the facilitation visits. These will be tracked regularly during the  
37  
38 532 implementation of the trial. A further risk is that some health and e-health literacy will both be  
39  
40 533 required for adoption of the App by patients and is expected to improve as a result of the  
41  
42 534 intervention use. This will be addressed by the support provided to patients by practice nurses and  
43  
44 535 general practitioners.  
45

46  
47 536

48  
49 537 The fieldwork for the study is planned to be completed by December 2018 with follow-up completed  
50  
51 538 by mid-2019. We anticipate circulation of the main findings from the study by 2020.  
52

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60

## 540 **Figure Legends**

541 **Figure 1: Clinical audit reports**

542 **Figure 2: My Snapp screens**

543 **Figure 3. Practice and patient recruitment**

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

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561

1  
2  
3 562 **Trial Sponsor**  
4

5 563 Centre for Primary Health Care and Equity, UNSW. Contact Professor Mark Harris +61 2 93858384 or  
6  
7 564 m.f.harris@unsw.edu.au  
8

9  
10 565 **Committees**  
11

12 566 The trial has a steering committee comprised on the project manager and investigators that  
13  
14 567 oversees the project.  
15

16 568 **Contribution**  
17

18  
19 569 SP co-drafted the paper and protocol documents on which it was based  
20

21 570 NS contributed to and was CI on the peer reviewed funding proposal and commented on the paper  
22  
23 571 and protocol documents on which it was based specially data collection and intervention in general  
24  
25 572 practice  
26

27 573 DN contributed to and was CI on the peer reviewed funding proposal and contributed to the overall  
28  
29 574 design of the study and intervention and content of the paper and protocol documents on which it  
30  
31 575 was based  
32

33  
34 576 LT co-drafted the paper and protocol documents on which it was based  
35

36 577 ED-W contributed to and was CI on the peer reviewed funding proposal and contributed to the  
37  
38 578 design of the study and content of the paper and protocol documents on which it was based  
39  
40 579 especially in the education components of the intervention  
41

42 580 NZ contributed to and was CI on the peer reviewed funding proposal and commented on the paper  
43  
44 581 and protocol documents on which it was based especially in relation to the role of general practice  
45

46 582 JK contributed to and was CI on the peer reviewed funding proposal especially the health economic  
47  
48 583 component and commented on the paper and protocol documents on which it was based  
49

50 584 JL contributed to and was AI on the peer reviewed funding proposal especially the health economic  
51  
52 585 component and commented on the paper and protocol documents on which it was based  
53  
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1  
2  
3 586 MN contributed to and was CI on the peer reviewed funding proposal especially the nutrition  
4  
5 587 component and commented on the paper.  
6  
7 588 STL contributed to and was CI on the peer reviewed funding proposal especially the informatics  
8  
9 589 component and commented on the paper and protocol documents on which it was based  
10  
11 590 AL contributed to and was CI on the peer reviewed funding proposal especially the m-health  
12  
13 591 component and commented on the paper and protocol documents on which it was based  
14  
15 592 RO contributed to and was AI on the peer reviewed funding proposal especially the health literacy  
16  
17 593 component and commented on the paper and protocol documents on which it was based  
18  
19 594 MFH developed and led the peer reviewed funding proposal including the design of the study and  
20  
21 595 intervention and co-drafted the paper and protocol documents on which it was based.  
22  
23  
24 596  
25  
26 597 The paper and protocol are based on the grant application submitted to and peer reviewed by the  
27  
28 598 NHMRC in 2016.

### 599 **Competing interests**

30  
31  
32  
33 600 The investigators have no competing interests to declare relevant to this study.  
34  
35 601

602 

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Baseline deidentified audit report for patients aged 40-74 years

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

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

Identified audit report for patients enrolled in study

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

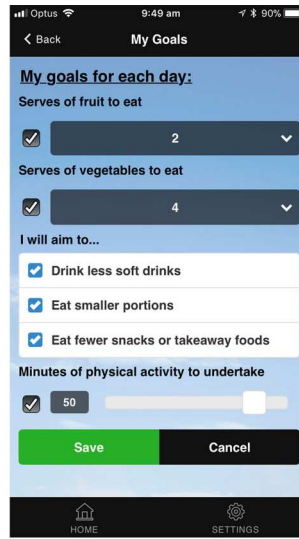
Figure 1

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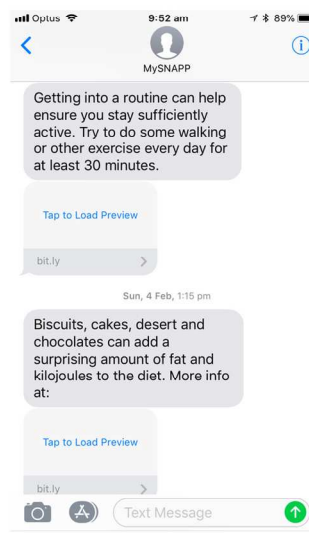
Landing Page



Goal Setting



Weekly self-monitoring



Text message

Figure 1

138x193mm (300 x 300 DPI)

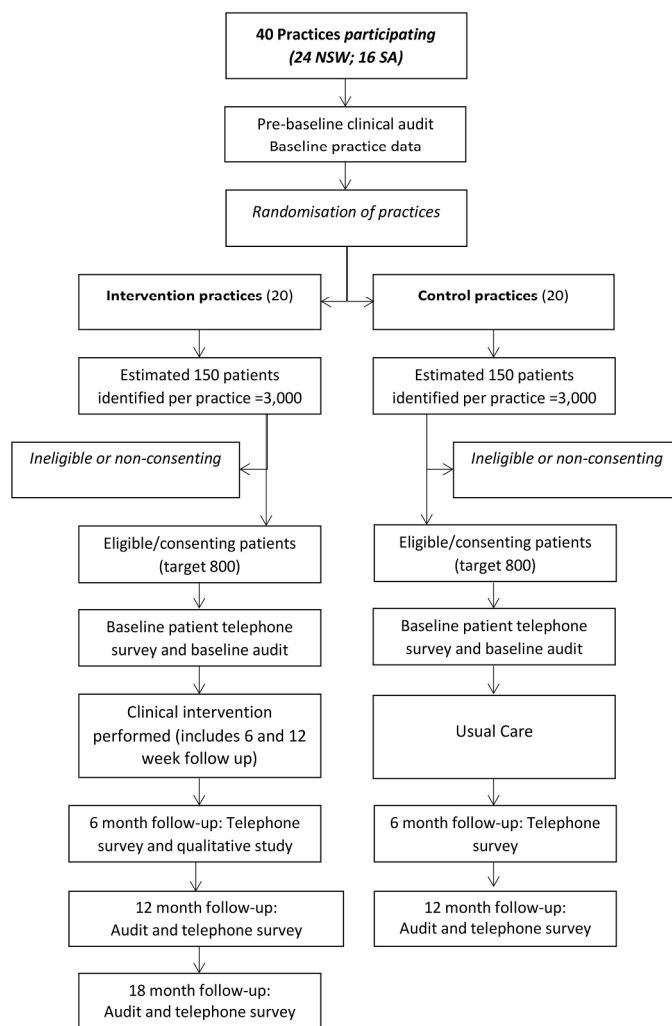


Figure 3

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.



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3 43 Patient Exclusion criteria: Experiencing recent weight loss (>5% in past 3 months); diagnosis  
4 44 of Diabetes requiring insulin or a current prescription for insulin; diagnosis of Cardiovascular  
5 45 disease (includes angina, myocardial infarction, heart failure, heart valve disease (rheumatic or  
6 46 non-rheumatic), stroke (cerebrovascular accident)); Taking medication for weight loss (Orlistat  
7 47 or Phentermine); Cognitive impairment; Physical impairment prohibiting the patient from  
8 48 undertaking moderate level physical activity.
- 9  
10 49 15. Anticipated date of first enrolment: 1st May 2018.
- 11 50 16. Sample size: Planned: 1600
- 12  
13 51 17. Sample size: Current: 0 patients
- 14 52 18. Recruitment Status: Pending: participants are not yet being recruited or enrolled at any site
- 15  
16 53 19. Primary Outcome(s):
- 17 54 i) Health literacy. Measure Health Literacy Questionnaire: Timepoints: Baseline, 6 and 12 months
- 18 55 ii) e-health literacy. Measure eHeals. Timepoints: Baseline, 6, 12 and 18 months
- 19 56 v) Body Mass Index. Calculated from measured weight in Kg and height in cm. Timepoints:  
20 57 Baseline, 6, 12 and 18 months.
- 21  
22 58 vi) Waist circumference. Measured in cm. Timepoints: Baseline, 6, 12 and 18 months.
- 23  
24 59 vii) Blood pressure. Measured in mmHg using automated sphygmomanometer. Timepoints:  
25 60 Baseline, 6, 12 and 18 months
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27 61 20. Secondary outcomes
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29 62 i) Daily fruit and vegetable consumption. Measure: questions adapted from NSW Population  
30 63 Health Survey and CSIRO Healthy diet score. Timepoints: Baseline and 6 months
- 31 64 ii) Physical activity level. Measure: Self-reported minutes of vigorous and moderate activity.  
32 65 Calculated as score. Timepoints: Baseline and 6 months.
- 33  
34 66 iii) Health related quality of life. Measure: EQ-5D-5L. Baseline and 12 months.
- 35  
36 67 ii) Total Cholesterol. Measure: Recorded total cholesterol from medical records. Up to 2 years  
37 68 prior to baseline and 12 months.
- 38  
39 69 iii) Advice and Referral. Measure: Patient questionnaire on reported advice or referral given by  
40 70 GP for smoking, diet, physical activity or weight management in previous 6 months.  
41 71 Timepoints: Baseline, 6 months
- 42 72 iv) Cost. Measure: Practice nurse time plus Medical Benefits Schedule and Pharmaceutical  
43 73 Benefits Schedule data. Timepoints: 12 months.
- 44  
45 74 21. Ethics Review
- 46 75 i) Status: Approved (HC17474)
- 47  
48 76 ii) Date of approval: 27 July 2017
- 49 77 iii) Name and contact details of Ethics committee(s): University of New South Wales Human  
50 78 Research Ethics Committee. Phone P: +61 2 9385 6222, + 61 2 9385 7257 or + 61 2 9385  
51 79 7007. Email: humanethics@unsw.edu.au
- 52  
53 80 22. Completion date: Unknown
- 54  
55 81 23. Summary Results: Not yet available
- 56  
57 82 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				
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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				
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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				
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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				
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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	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable,	10,11
49			eligibility criteria for study centres and individuals who will	
50			perform the interventions (eg, surgeons, psychotherapists)	
51				
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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	
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1	Interventions:	#11b	Criteria for discontinuing or modifying allocated	13
2	modifications		interventions for a given trial participant (eg, drug dose	
3			change in response to harms, participant request, or	
4			improving / worsening disease)	
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8	Interventions:	#11c	Strategies to improve adherence to intervention protocols,	18
9	adherence		and any procedures for monitoring adherence (eg, drug	
10			tablet return; laboratory tests)	
11				
12				
13	Interventions:	#11d	Relevant concomitant care and interventions that are	15
14	concomitant care		permitted or prohibited during the trial	
15				
16				
17	Outcomes	#12	Primary, secondary, and other outcomes, including the	18-19
18			specific measurement variable (eg, systolic blood pressure),	
19			analysis metric (eg, change from baseline, final value, time	
20			to event), method of aggregation (eg, median, proportion),	
21			and time point for each outcome. Explanation of the clinical	
22			relevance of chosen efficacy and harm outcomes is strongly	
23			recommended	
24				
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28	Participant timeline	#13	Time schedule of enrolment, interventions (including any	18-19
29			run-ins and washouts), assessments, and visits for	
30			participants. A schematic diagram is highly recommended	
31			(see Figure)	
32				
33				
34				
35	Sample size	#14	Estimated number of participants needed to achieve study	20-21
36			objectives and how it was determined, including clinical and	
37			statistical assumptions supporting any sample size	
38			calculations	
39				
40				
41				
42	Recruitment	#15	Strategies for achieving adequate participant enrolment to	12
43			reach target sample size	
44				
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46	Allocation: sequence	#16a	Method of generating the allocation sequence (eg,	10
47	generation		computer-generated random numbers), and list of any	
48			factors for stratification. To reduce predictability of a random	
49			sequence, details of any planned restriction (eg, blocking)	
50			should be provided in a separate document that is	
51			unavailable to those who enrol participants or assign	
52			interventions	
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57	Allocation	#16b	Mechanism of implementing the allocation sequence (eg,	10
58	concealment		central telephone; sequentially numbered, opaque, sealed	
59				
60				

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	
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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				
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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				
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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	
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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	
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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	
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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	
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51	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and	21
52	analyses		adjusted analyses)	
53				
54				
55	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	21
56	population and		adherence (eg, as randomised analysis), and any statistical	
57	missing data		methods to handle missing data (eg, multiple imputation)	
58				
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1	Data monitoring:	#21a	Composition of data monitoring committee (DMC); summary	n/a
2	formal committee		of its role and reporting structure; statement of whether it is	
3			independent from the sponsor and competing interests; and	
4			reference to where further details about its charter can be	
5			found, if not in the protocol. Alternatively, an explanation of	
6			why a DMC is not needed	
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11	Data monitoring:	#21b	Description of any interim analyses and stopping guidelines,	n/a
12	interim analysis		including who will have access to these interim results and	
13			make the final decision to terminate the trial	
14				
15				
16	Harms	#22	Plans for collecting, assessing, reporting, and managing	21
17			solicited and spontaneously reported adverse events and	
18			other unintended effects of trial interventions or trial conduct	
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21	Auditing	#23	Frequency and procedures for auditing trial conduct, if any,	n/a
22			and whether the process will be independent from	
23			investigators and the sponsor	
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27	Research ethics	#24	Plans for seeking research ethics committee / institutional	12
28	approval		review board (REC / IRB) approval	
29				
30				
31	Protocol	#25	Plans for communicating important protocol modifications	n/a
32	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	
33			relevant parties (eg, investigators, REC / IRBs, trial	
34			participants, trial registries, journals, regulators)	
35				
36				
37	Consent or assent	#26a	Who will obtain informed consent or assent from potential	13
38			trial participants or authorised surrogates, and how (see	
39			Item 32)	
40				
41				
42				
43	Consent or assent:	#26b	Additional consent provisions for collection and use of	13
44	ancillary studies		participant data and biological specimens in ancillary	
45			studies, if applicable	
46				
47				
48	Confidentiality	#27	How personal information about potential and enrolled	13
49			participants will be collected, shared, and maintained in	
50			order to protect confidentiality before, during, and after the	
51			trial	
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55	Declaration of	#28	Financial and other competing interests for principal	26
56	interests		investigators for the overall trial and each study site	
57				
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59	Data access	#29	Statement of who will have access to the final trial dataset,	26
60				

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				
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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	
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36				

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 39 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)  
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