

1 **Appendix 1: Trial Registration Data Set**

- 2 1. Primary Registry and Trial Identifying Number: Australian New Zealand Clinical Trials
3 Registry (ACTRN 12617001508369).
- 4 2. Date of Registration in Primary Registry: 26 October 2017 (Updated 20 March 2018)
- 5 3. Secondary Identifying Numbers: Australian National Health and Medical Research Council
6 Project Number: APP1125681.
- 7 4. Source(s) of Monetary or Material Support: Australian National Health and Medical Research
8 Council
- 9 5. Primary Sponsor: University of New South Wales, NSW 2052 Australia.
- 10 6. Secondary Sponsors: University of Adelaide, University of Sydney, University of Wollongong,
11 CSIRO Health and Biosecurity, Macquarie University.
- 12 7. Contact for Public Queries: Ms Sharon Parker, Email: sharon.parker@unsw.edu.au; telephone:
13 +61 (2) 9385 8396; and postal address: Centre for Primary Health Care and Equity, UNSW
14 SYDNEY NSW 2052 AUSTRALIA..
- 15 8. Contact for Scientific Queries: Professor Mark Harris, email: m.f.harris@unsw.edu.au;
16 telephone: +61 2 9385 8384; Postal address: Centre for Primary Health Care and Equity UNSW
17 SYDNEY NSW 2052 AUSTRALIA.
- 18 9. Public Title: Health eLiteracy for Prevention in General Practice .
- 19 10. Scientific Title: Preventing chronic disease in patients with low health literacy using eHealth
20 and teamwork in primary health care: Protocol for a cluster Randomised controlled trial.
21 Acronym: HeLP-GP.
- 22 11. Countries of Recruitment: Australia
- 23 12. Health Condition(s) or Problem(s) Studied: Overweight and obesity.
- 24 13. Intervention(s): The HeLP-GP intervention includes a practice-level quality improvement
25 intervention (medical record audit and feedback, staff training and practice facilitation visits) to
26 support practices to implement the clinical intervention for patients. The clinical intervention
27 involves a health check visit with a practice nurse based on the 5As framework (assess, advise,
28 agree, assist and arrange), the use of a purpose-built patient-facing app, my snapp, and referral
29 for telephone coaching. The aim of the intervention is to support patients to change diet and
30 physical activity. Practices are randomly allocated to intervention and control groups. Patients
31 recruited by control group practices will receive usual care (the clinical practice routinely
32 offered to patients by the GP and PN).
- 33 14. Key Inclusion and Exclusion Criteria:
34 Practice Inclusion criteria: Situated in Local Government Areas (LGAs) with a SEIFA score
35 equal to or below the 6th decile. Using Medical Director PracSoft or Best Practice software and
36 allocate patients to individual GPs within this software. Agree to the use of Doctors Control
37 Panel (DCP) linked with their software to identify eligible patients for the study; Have access to
38 an active internet connection; Have at least one practice nurse who is prepared to conduct the
39 HeLP intervention with eligible patients and complete data management for these patients
40 Patient Inclusion criteria: Aged 40-74 years; Overweight or obese (BMI \geq 28 recorded in last 12
41 months) ; BP recorded in the clinical software within the previous 12 months; Speaking English
42 and/or Arabic; access to a smart phone or tablet device.

- 43 Patient Exclusion criteria: Experiencing recent weight loss (>5% in past 3 months); diagnosis
44 of Diabetes requiring insulin or a current prescription for insulin; diagnosis of Cardiovascular
45 disease (includes angina, myocardial infarction, heart failure, heart valve disease (rheumatic or
46 non-rheumatic), stroke (cerebrovascular accident)); Taking medication for weight loss (Orlistat
47 or Phentermine); Cognitive impairment; Physical impairment prohibiting the patient from
48 undertaking moderate level physical activity.
- 49 15. Anticipated date of first enrolment: 1st May 2018.
- 50 16. Sample size: Planned: 1600
- 51 17. Sample size: Current: 0 patients
- 52 18. Recruitment Status: Pending: participants are not yet being recruited or enrolled at any site
- 53 19. Primary Outcome(s):
- 54 i) Health literacy. Measure Health Literacy Questionnaire: Timepoints: Baseline, 6 and 12 months
- 55 ii) e-health literacy. Measure eHeals. Timepoints: Baseline, 6, 12 and 18 months
- 56 v) Body Mass Index. Calculated from measured weight in Kg and height in cm. Timepoints:
57 Baseline, 6, 12 and 18 months.
- 58 vi) Waist circumference. Measured in cm. Timepoints: Baseline, 6, 12 and 18 months.
- 59 vii) Blood pressure. Measured in mmHg using automated sphygmomanometer. Timepoints:
60 Baseline, 6, 12 and 18 months
- 61 20. Secondary outcomes
- 62 i) Daily fruit and vegetable consumption. Measure: questions adapted from NSW Population
63 Health Survey and CSIRO Healthy diet score. Timepoints: Baseline and 6 months
- 64 ii) Physical activity level. Measure: Self-reported minutes of vigorous and moderate activity.
65 Calculated as score. Timepoints: Baseline and 6 months.
- 66 iii) Health related quality of life. Measure: EQ-5D-5L. Baseline and 12 months.
- 67 ii) Total Cholesterol. Measure: Recorded total cholesterol from medical records. Up to 2 years
68 prior to baseline and 12 months.
- 69 iii) Advice and Referral. Measure: Patient questionnaire on reported advice or referral given by
70 GP for smoking, diet, physical activity or weight management in previous 6 months.
71 Timepoints: Baseline, 6 months
- 72 iv) Cost. Measure: Practice nurse time plus Medical Benefits Schedule and Pharmaceutical
73 Benefits Schedule data. Timepoints: 12 months.
- 74 21. Ethics Review
- 75 i) Status: Approved (HC17474)
- 76 ii) Date of approval: 27 July 2017
- 77 iii) Name and contact details of Ethics committee(s): University of New South Wales Human
78 Research Ethics Committee. Phone P: +61 2 9385 6222, + 61 2 9385 7257 or + 61 2 9385
79 7007. Email: humanethics@unsw.edu.au
- 80 22. Completion date: Unknown
- 81 23. Summary Results: Not yet available
- 82 24. IPD sharing statement: Plan to share IPD: No