HeLP-GP
Health e-Literacy for Prevention in General Practice

UNSW SYDNEY
Centre for Primary Health Care and Equity, UNSW Sydney

THE UNIVERSITY of ADELAIDE

PROVIDER INFORMATION STATEMENT

Health e-Literacy for Prevention in General Practice (HeLP-GP) Study

You are invited to participate in a cluster randomised controlled trial involving general practices in New South Wales and South Australia.

1. What is the research study about?

The intervention we are testing involves a combination of mHealth and telephone coaching provided to overweight and obese patients to assist them to improve their diet, increase the level of physical activity they undertake and generally improve their health. Practice nurses will deliver the intervention through a process where individuals are assessed, receive advice and assistance to set behavioural goals, navigate referral to evidence based preventive programs and maintain their behaviour change.

Practice staff will participate in a Quality Improvement (QI) program. This will involve pre and post clinical audits, and training to practice nurses (PNs) and general practitioners (GPs) to support and work closely with their patients to improve their knowledge and understanding about their health conditions (health literacy).

2. Why am I being approached?

You were selected as a possible participant based on your geographic location within a Local Government Area (LGA) that supports a socioeconomically disadvantaged and diverse population in Sydney or Adelaide.

3. Who is conducting this research?

The study is being carried out by the following researchers and is being funded by the National Health and Medical Research Council (NHMRC). The primary sites for the research are Sydney/Illawarra and Adelaide.

Role	Name	Organisation
Chief Investigator	Professor Mark Harris	Centre for Primary Health Care and Equity, UNSW
Co-Investigator/s	Professor Nigel Stocks; Professor Jon Karnon	University of Adelaide
	Professor Siaw Teng-Liaw; Associate Professor Jane Lloyd; Ms Sharon Parker; Ms Louise Thomas; Dr Jonathon Lim; Ms Shoko Saito	Centre for Primary Health Care and Equity, UNSW
	Professor Nicholas Zwar	University of Wollongong
	Professor Donald Nutbeam; Professor Elizabeth Denney-Wilson	University of Sydney
	Professor Manny Noakes	CSIRO Animal, Food and Health Sciences
	Doctor Annie Lau	Macquarie University

4. General Practice Inclusion/Exclusion Criteria

We are looking for practices which:

- Are situated in Local Government Areas (LGAs) with a SEIFA score equal to or below the 6th decile
- Use Medical Director, Medinet or Best Practice and associated billing software Pracsoft or Best Practice Management, 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 PN who is prepared to conduct the HeLP intervention with eligible patients and complete data management relating to these patients
- Agree to provide GP follow up health checks to participating patients at 12 weeks and 12 month time points
- Can make their reception staff available to distribute study materials to potential study participants as they present to the practice

5. Do I have to take part in this research study?

Participation in this research study is entirely voluntary. If you decide to take part and later change your mind, you are free to withdraw from the study at any time by notifying the research team.

6. What does participation in this research require?

If you decide to participate, your practice will be randomised to either the intervention or control arm of the study.

The following tasks are requested regardless of this allocation:

- A de-identified pre-baseline clinical audit of your patients aged 40-74 years and feedback on recording
- A practice assessment profile to help us understand how your practice is organised, what roles different staff members have, what information systems are used, and the particular needs of your patients.
- A survey from each GP and PN about assessment and management of overweight patients. This will be collected at both baseline and 12 months.
- DCP will be installed on the local drive of the computer/s in your reception area and programmed to identify potentially eligible patients as they present to your practice. Your reception staff will be requested to hand the print-out from DCP plus an information sheet and consent form in either English or Arabic to patients in the waiting room who have been flagged by DCP.
- The GP/PN will be asked to check the eligibility of patients against a checklist and answer patient's questions about the research. GPs/PNs will **NOT** be required to consent patients. Patients can either take the research information away with them to consider, or fill out the consent form and leave it at reception or mail it to the research team. The Patient Information sheet will also provide patients with details of who they can contact from the research team if they would like to discuss participation in the study in more detail before making a decision.

Based on the allocation of practices to study groups through randomisation the following additional tasks will apply:

Intervention practices:

- GPs and PNs will be provided with 60-80 minutes of training (broken down into three modules of online training) covering the research processes, information regarding lifestyle change and the conduct of a health check. Instructional videos will assist staff to implement the intervention.
- PNs will be asked to deliver a 40-minute health check based on the 5As (Assess, Advise/Agree, Assist and Arrange). During this session PNs will discuss and set up for patients their individual lifestyle app (MySnapp) and provide assisted referral to the Get Healthy coaching service offered as part of the intervention.
- PNs and GPs will be asked to follow up their patients at 6 weeks, 12 weeks and 12 months.
- A sample of GPs, PNs and practice managers or administrative staff will also be invited to participate in a qualitative interview to explore enablers and barriers to implementation of the intervention.

Control practices:

- Control practices will be asked to provide usual care throughout the study period. For the purposes of this study, usual care refers to the clinical practice routinely offered to patients by the general practitioner and the practice nurse. Between 12 and 18 months, control practices will have the opportunity to conduct health assessments on their patients and complete the online training requirements as part of their CPD activity.

7. If I am interested in participating what should I do?

If you decide you want to take part in the research study, you should:

- Read this information carefully and clarify any questions with the research team
- All participating GPs and PNs should sign and return the consent form
- Take a copy of this form with you to keep.

8. Are there any risks involved?

There are no foreseeable risks for you through participation.

9. What are the possible benefits to participation?

- Increased understanding of the factors that influence patient health behaviour.
- Continuing professional development incentives: a) Category One points for participating in the review of your practice via the clinical audits and b) Category Two points for participation in the online training and
- Two payments to reimburse you for the administrative staff time ($600 in the first year and $400 in the second year). This is paid regardless of allocation and on the receipt of a tax invoice and completion of study tasks
- Additional support and payments for PN involvement if allocated to the intervention group

10. What will happen to information about me?

By signing the attached consent form you consent to the research team collecting and using information about you and your clinical practice for this research study.
These researchers are the only people who will have access to your data. Your information will never be used in any way that identifies you. At the end of the study, your data will be archived at the University of NSW (ResData). This secure storage is permanent.

11. How and when will I find out what the results of the research study are?

We will publish the results of the study in Australian and international medical journals. All information published will be done in a way that will not identify you.

If you would like to receive a copy of the results of this study you can contact the UNSW Research Centre for Primary Health Care and Equity: cphce@unsw.edu.au or (02) 9385 1547.

12. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw this consent at any time. Withdrawal of participation should be indicated on the 'Withdrawal of Participation Form'.
Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney, the University of Adelaide or their research partners.

If you decide to leave the research study, the researchers will not collect additional information from you. You can also choose to withdraw all the information you have previously provided by indicating this preference on the Withdrawal of Participation Form.

13. What should I do if I have further questions about my involvement in the research study?

If you require further information regarding this study or if you have any problems related to your involvement in the study, you can contact:

Research Team Contact Details

Name	Professor Mark Harris
Position	Executive Director, Centre for Primary Health Care and Equity
Telephone	02 9385 8384
Email	m.f.harris@unsw.edu.au

What if I have a complaint or any concerns about the research study?

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Complaints Contact

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC17474

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