Self Measurement and management using the Internet for Lowering blood pressure in Everyday practice (SMILE study)

Submission date	Recruitment status	[X] Prospectively registered
10/08/2011	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
10/08/2011	Completed	Results
Last Edited	Condition category	Individual participant data
30/11/2017	Circulatory System	Record updated in last year

Plain English summary of protocol

Background and study aims

This study addresses overlapping issues in patient engagement: a patient support tool to implement a lifestyle intervention that practice nurses currently do not have the time and expertise to implement, and home blood pressure measurements with self-titration (dose adjustment) of medication for lowering blood pressure.

Who can participate?
Patients aged over 18 with high blood pressure

What does the study involve?

The study involves two phases. In Phase 1 the LifeGuide web tool, diet materials, and web pages used in an obesity web intervention (on diet and exercise) are used as the basis for writing the initial web pages for the web intervention. Focus groups and 1:1 interviews with patients and nurses are used to modify the site. In Phase 2 patients are randomly allocated to one of three groups. The first group receive usual care (normal clinic measurement by a GP or nurse). The second group use home blood pressure measurement with telemonitoring. The third group use home blood pressure measurement with telemonitoring and receive access to the lifestyle website with reinforcement by the practice nurse over a 3-month period. After 3 months the changes in blood pressure in the three groups are compared.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? University of Southampton (UK)

When is the study starting and how long is it expected to run for? September 2011 to September 2012

Who is funding the study?
NIHR National School of Primary Care Research (UK)

Who is the main contact? Prof. Paul Little

Contact information

Type(s)

Scientific

Contact name

Prof Paul Little

ORCID ID

https://orcid.org/0000-0003-3664-1873

Contact details

Primary Medical Care Aldermoor Health Centre Aldermoor Close Southampton United Kingdom SO16 5ST

Additional identifiers

Protocol serial number

10176

Study information

Scientific Title

Self Measurement and management using the Internet for Lowering blood pressure in Everyday practice: a randomised controlled trial

Acronym

SMILE

Study objectives

This study addresses overlapping issues in patient engagement:

- 1. A patient support tool to implement lifestyle intervention (the effective and acceptable DASH diet and exercise) that practice nurses currently do not have the time and expertise to implement
- 2. Home blood pressure measurements with self titration of medication

It involves two distinct phases, the initial development of a web intervention followed by a randomised controlled trial to explore the extent to which the interventions can change.

Ethics approval required

Old ethics approval format

Ethics approval(s)

First MREC, 29/03/2011, ref: 11/SC/0051

Study design

Randomised interventional prevention process of care trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Essential hypertension

Interventions

Current interventions as of 30/11/2017:

- 1. Phases:
- 1.1. Phase 1 patient Interviews: 16 + 3 healthcare professionals
- 1.2. Phase 1 focus groups: 8 healthcare professionals
- 1.3. Phase 2 RCT: 50, randomised into 3 groups
- 2. At baseline, weight and blood pressure measured
- 3. End of study, weight and blood pressure measured within GP surgery
- 4. Home measurement, self monitoring of blood pressure by patients
- 5. Follow up after 12 months
- 6. Study entry: registration and one or more randomisations

Previous interventions:

- 1. Phases:
- 1.1. Phase 1 patient Interviews: 30
- 1.2. Phase 1 focus groups: 35
- 1.3. Phase 2 RCT: 90, randomised into 3 groups
- 2. At baseline, weight and blood pressure measured
- 3. End of study, weight and blood pressure measured within GP surgery
- 4. Home measurement, self monitoring of blood pressure by patients
- 5. Follow up after 12 months
- 6. Study entry: registration and one or more randomisations

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Mean change in systolic blood pressure after 3 months

Key secondary outcome(s))

No secondary outcome measures

Completion date

30/09/2012

Eligibility

Key inclusion criteria

- 1. Over 18 years
- 2. Treated essential hypertension
- 3. Poor control blood pressure greater than 140/90 mmHg and less than 200/110 mmHg
- 3. Home access to the internet
- 4. Access to a telephone line

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Inability to self monitor (including diagnosis of of dementia, score of >10 on short orientation memory concentration test)
- 2. Postural hypertension (systolic blood pressure drop >20mmHg)
- 3. More than two antihypertensive medications
- 4. Terminal disease
- 5. Hypertension not managed by family doctor
- 6. Spouse already randomised to the study group

Date of first enrolment

01/09/2011

Date of final enrolment

30/09/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Primary Medical Care

University of Southampton Aldermoor Health Centre Southampton United Kingdom SO16 5ST

Study participating centre Park & St Francis Surgery SO53 4ST

Study participating centre The Clanfield Practice PO8 0QL

Study participating centre Cowplain Family Practice PO8 8DL

Study participating centre The Oaklands Practice GU46 7LS

Study participating centre Rowlands Castle PO9 6BN

Study participating centre Nightingale SurgerySO51 7QN

Study participating centre Woolston Lodge SO19 9AL Study participating centre Regents Park Surgery SO15 3UA

Sponsor information

Organisation

University of Southampton (UK)

ROR

https://ror.org/01ryk1543

Funder(s)

Funder type

Government

Funder Name

NIHR National School of Primary Care Research; Grant Codes: 4.74

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the fact that this was preliminary pilot work.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Part

Participant information sheet 11/11/2025 11/11/2025 No

Yes