ISRCTN70714356 https://doi.org/10.1186/ISRCTN70714356

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

Submission date 10/08/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 10/08/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 30/11/2017	**Condition category** Circulatory System	[_] Individual participant data [_] 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
http://orcid.org/0000-0003-3664-1873

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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Mean change in systolic blood pressure after 3 months

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2011

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 155; UK Sample Size: 155 - to include both phases

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
England

United Kingdom

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 Surgery
SO51 7QN

Study participating centre
Woolston Lodge
SO19 9AL

Study participating centre
Regents Park Surgery
SO15 3UA

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Research Governance Office
Highfield
Southampton
England
United Kingdom
SO17 1BJ

Sponsor type
University/education

Website
http://www.soton.ac.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

Publication and dissemination plan
This was a very small pilot and development study that mainly concentrated on the development of the website, and was used as the basis for arguing for a much larger Programme grant subsequently funded by NIHR PGfAR: the trial from that Programme will be published and the data will be made available.

Intention to publish date

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