

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

<b>Submission date</b> 10/08/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/11/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
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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