# Self-management supported by assistive, rehabilitation and telecare technologies

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
18/06/2010	No longer recruiting	<pre>Protocol</pre>
Registration date	Overall study status	<ul><li>Statistical analysis plan</li></ul>
18/06/2010	Completed	Results
Last Edited	Condition category	Individual participant data
11/05/2017	Other	<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Prof Mark Hawley

#### Contact details

Health Services Research
School of Health & Related Research (ScHARR)
Regents Court
30 Regent Street
Sheffield
United Kingdom
S1 4DA
+44 114 222 0682
mark.hawley@sheffield.ac.uk

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

4912

# Study information

#### Scientific Title

Multicentre non-randomised interventional process of care trial of self-management of chronic conditions supported by assistive, rehabilitation and telecare technology

#### **Acronym**

**SMART 2** 

#### **Study objectives**

The overall aim of this project is to deepen understanding of the potential for technology support of self management. The use of technology for this purpose is now attracting attention, but there are some fundamental issues that need to be researched. These include how information on changes in chronic conditions can be collated and fed back to users in a meaningful and usable way to help them to understand their condition; how such information, remote from a clinician, can be presented to promote behaviour change and how this information can allow people to adjust life goals to accommodate and aid acceptance of their condition.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Leeds East REC, 03/06/2008, ref: 08/H1306/46

## Study design

Multicentre non-randomised interventional process of care trial

# Primary study design

Interventional

# Secondary study design

Non randomised study

# Study setting(s)

Hospital

# Study type(s)

Treatment

# Participant information sheet

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

# Health condition(s) or problem(s) studied

Topic: Generic Health Relevance and Cross Cutting Themes, Primary Care Research Network for England; Subtopic: Not Assigned, Generic Health Relevance (all Subtopics); Disease: All Diseases, Other

#### **Interventions**

A series of focus groups will be carried out during the first 3 - 6 months of the study. Home visits with up to five volunteer participants will take place after these focus groups (months 4 - 7). In year 2 and 3 we will undertake evaluation sessions at approximately 6-monthly intervals when elements of the PSMS will be delivered to the clinical research teams by technologists working at the University of Ulster. A series of focus groups exclusively for clinicians specialising in treatment and rehabilitation of each of the three conditions will be conducted from month 6 onwards.

#### **Intervention Type**

Other

#### Phase

Not Applicable

#### Primary outcome measure

To investigate how technology can be used to construct tailored plans of interventions to be undertaken

#### Secondary outcome measures

- 1. To examine the extent to which behaviour change is promoted through personalised feedback
- 2. To identify how information on signs, symptoms and lifestyle consequences can be fed back to users in a usable way
- 3. To identify how relevant signs, symptoms and lifestyle consequences of long-term conditions can be effectively monitored and modelled

# Overall study start date

01/01/2008

#### Completion date

31/12/2011

# **Eligibility**

#### Key inclusion criteria

User participants with one of the following conditions:

- 1. Stroke, congestive heart failure (CHF) and chronic pain
- 2. People with stroke up to 2 years post stroke
- 3. People diagnosed with chronic heart failure (CHF) (New York Heart Association [NYHA]) 2, 3 or 4
- 4. Living in the community
- 5. Access to a telephone line
- 6. Sufficient English language skills in order to understand and express themselves verbally

#### Carer participants:

7. Co-resident with patient participant or in very frequent contact with them

#### Clinician participants:

8. Currently involved in delivery of services to people with one of the three conditions

#### Participant type(s)

#### **Patient**

#### Age group

Other

#### Sex

Both

## Target number of participants

Planned sample size: 150

#### Key exclusion criteria

User participants:

- 1. Co-morbid cognitive or physical impairment to the extent that it will hinder participants from giving informed consent and/or talking in a group setting
- 2. In-patient in a hospital or other residential setting

#### Carer participants:

3. Not having a large amount of contact with a patient who has agreed to participate in the study

#### Date of first enrolment

01/01/2008

#### Date of final enrolment

31/12/2011

# Locations

#### Countries of recruitment

England

United Kingdom

# Study participating centre Health Services Research

Sheffield United Kingdom S1 4DA

# Sponsor information

#### Organisation

University of Sheffield (UK)

#### Sponsor details

Royal Hallamshire Hospital Glossop Road Sheffield England United Kingdom S10 2JF

#### Sponsor type

University/education

#### Website

http://www.sheffield.ac.uk/

#### **ROR**

https://ror.org/05krs5044

# Funder(s)

### Funder type

Research council

#### **Funder Name**

Engineering and Physical Sciences Research Council (EPSRC) (UK)

# Alternative Name(s)

EPSRC Engineering & Physical Sciences Research Council, UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, The Engineering and Physical Sciences Research Council (EPSRC), EPSRC

# **Funding Body Type**

Government organisation

# **Funding Body Subtype**

National government

#### Location

**United Kingdom** 

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

# Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary