

Self-management supported by assistive, rehabilitation and telecare technologies

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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)

UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, 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
Not provided at time of registration