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Self-management supported by assistive, rehabilitation and telecare technologies

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

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)
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