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A Comprehensive Evaluation of the Implementation and Impact of Telecare and Telehealth across Health and Social Care - the Whole System Demonstrator (WSD) Project

Submission date
28/05/2010

Recruitment status
No longer recruiting

Registration date
28/05/2010

Overall study status
Completed

Last Edited
08/08/2014

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Shashivadan Hirani

Contact details
Charles Bell House
67-73 Riding House Street
London
United Kingdom
W1W 7EJ
s.hirani@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

4635

Study information

Scientific Title

Acronym
WSD

Study objectives
The care of individuals with long-term conditions (such as heart failure and diabetes) and those who need help from social care services (such as frail older people) is very important. The government wants to improve services for these people, by helping health and social care services to work together more effectively. It is hoped that this will lead to better outcomes, with people able to live at home longer, reducing the risk of ill health and providing more support for informal carers. To make this possible, it is also important that these new services do not increase costs.

The Whole System Demonstrator Project:
In a government initiative known as the Whole System Demonstrator project (WSD), it is planned to help health and social services to work together by introducing new technologies into three pilot sites (Cornwall, Kent and Newham). These technologies fall into two general groups:
1. Telecare packages monitor people in their homes and send alerts when required, e.g., sensors to detect falls
2. Telehealth interventions will allow people to communicate at a distance with their health care professional (e.g. sending blood glucose results)

Evaluation:
Although these technologies have been evaluated, published evaluations have been small and insufficiently rigorous. At present it is not clear whether these new technologies are effective and a good use of public money. We intend to test the value of these technologies using a number of different research methods. To achieve this we are using a randomised controlled trial to compare patients using these new technologies with those who receive usual care. We will also use qualitative studies to examine other issues in more detail.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 08/H1005/4)

Study design
Multicentre randomised interventional process of care trial with qualitative component

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
1. Telecare assistive devices: Telecare assistive devices and support for individuals receiving social care, controls will receive usual care
2. Telehealth assistive devices: Telehealth assistive devices and support for individuals with long term condition (heart failure, chronic obstructive pulmonary disease [COPD] and diabetes)
3. Control: controls will receive usual care

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. 36-item Short Form Health Survey (SF-36)
2. EuroQoL questionnaire (EQ-5D)
3. Generic heart-failure, diabetes and COPD quality of life (QoL) questionnaires
4. Center for Epidemiologic Studies Depression Scale (CES-D)
5. 6-Item Short-Form of the State Scale of the Spielberger State Trait Anxiety Inventory (STAI-6)

All measured at 3 and 12 months.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/05/2008

Completion date
30/09/2009

Eligibility

Key inclusion criteria
The eligibility criteria for the trial have been broadly determined by the policy focus of the funder, the Department of Health, on people with long term conditions and social care needs. They have been reached through discussions with both the Department of Health and the three

participating sites. They have also been derived partly from existing evidence about which populations are mostly likely to benefit from the delivery of telecare and telehealth devices but also maximise reliance on professional judgement about which groups are most likely to benefit.

Detailed inclusion criteria:
Individuals aged 18 years or over fulfilling criteria A and B:

Criteria A:
At least one of three long-term index conditions as defined using Quality and Outcomes Framework (QOF) criteria:
1. Heart failure: diagnosis confirmed by echocardiogram or by specialist assessment
2. Diabetes: those with a diagnosis of Type 1 or Type 2 diabetes and:
2.1. A recorded HbA1c in the previous 15 months
2.2. Excluding those in whom the last HbA1c is 7.4 or less
3. Chronic obstructive pulmonary disease (COPD): diagnosis confirmed by spirometry (COPD is diagnosed if the individual has a forced expiratory volume in one second [FEV1] of less than 70% of predicted normal and has an FEV1/forced vital capacity [FVC] ratio less than 70%)
4. Additional physical co-morbidities may be present; these individuals will still be eligible

Criteria B:
5. At least one unplanned admission to hospital relating to their long term condition(s)in the previous year, or has had at least one episode of care in the past year from intermediate care services, rapid response services, ambulance services, Accident and Emergency relating to their long term condition
6. Individuals aged 18 years and over with social care needs who would benefit from telecare. They must meet one or more of the following criteria:
6.1. Currently in receipt of, or considered to have a need for night sitting
6.2. Receiving 7 or more hours per week of home care or 3.5 or more hours per week of home care plus a meals service (defined by individual not household)
6.3. Receiving 1 or more days per week of day care
6.4. Have had a fall or who are considered at high risk of falling
6.5. A live-in or nearby informal carer facing difficulties carrying their current burden of responsibilities
6.6. Cognitive impairment/confusion (people fulfilling this criterion who are unable to provide written informed consent and do not have a primary informal caregiver available or an advocate will not be approached to participate in the questionnaire study)

The following definition of an informal carer will be used:
Someone who is seeing and helping their family member, relative or friend at least once a week.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 6000; UK sample size: 6000

Key exclusion criteria
General exclusion criteria:
1. Lack of ability to understand English (the devices are not currently tailored to support non-English language speakers)
2. Inability to complete the questionnaire with support from a researcher (applies to questionnaire study only - Themes 2 and 3)

Telehealth exclusion criteria:
3. People with one or more of the three index conditions (above) and cognitive impairment /confusion but insufficient informal caregiver support available to enable regular readings to be taken using telehealth equipment. This group will still be eligible to receive telecare.
4. Individuals without an appropriate power supply or telephone line in their place of residence (Telehealth requires an appropriate power supply or telephone line so if this is not available it cannot be installed)
5. Telehealth already installed (this exclusion criteria is likely to only apply to the Kent site where some pilot work has already been undertaken with telehealth equipment - individuals who already have telehealth equipment will need to be excluded to reduce learning effects)

Telecare exclusion criteria:
6. Telecare already installed (excluding pendant alarms)

Date of first enrolment
01/05/2008

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Charles Bell House
London
United Kingdom
W1W 7EJ

Sponsor information

Organisation

Department of Health (UK)

Sponsor details
Policy Research Programme
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NS

Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/08/2011		Yes	No
Results article	secondary care and mortality results	21/06/2012		Yes	No

Other publications	cost-effectiveness	20/03/2013	Yes	No
Results article	health and social care services results	01/07/2013	Yes	No
Results article	general practice contacts results	08/10/2013	Yes	No
Results article	quality of life results	01/05/2014	Yes	No
Results article	type 2 diabetes results	06/08/2014	Yes	No
Results article	cost-effectiveness results	01/11/2014	Yes	No