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CLASSIC Proactive Telephone Coaching and Tailored Support (PROTECTS)

Submission date
19/06/2014

Recruitment status
No longer recruiting

Registration date
19/06/2014

Overall study status
Completed

Last Edited
31/05/2018

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The Salford Integrated Care Programme (SICP) is a large scale project to improve care for older people with long-term conditions and social care needs in Salford. The aim of this study is to test the effectiveness of telephone health coaching for older patients (aged 65+) with multiple long-term conditions (multi-morbidity), compared to usual care.

Who can participate?
Patients aged 65+ with two or more existing long-term conditions and assessed as needing some assistance with self-management.

What does the study involve?
Patients receive a 20-minute phone call once a month for 6 months which is delivered by experienced health advisers. The health advisers and the patient agree a plan for management of their long-term conditions, including advice on healthier diet, exercise, reduction of smoking and alcohol consumption and increased social activity, as well as support for low mood (if applicable).

What are the possible benefits and risks of participating?
Previous evidence suggests that health coaching may be effective in improving outcomes, including self-management and quality of life. However, these benefits have not been confirmed for older patients with multi-morbidity in the UK NHS. The trialists are not aware of any adverse effects from health coaching

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
July 2014 to September 2016

Who is funding the study?
NIHR Health Services and Delivery Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
16717

Study information

Scientific Title
CLASSIC Proactive Telephone Coaching and Tailored Support (PROTECTS): a pragmatic, two-arm, patient-level, randomised trial of the effectiveness of telephone coaching and support for older people with multimorbidity

Acronym
CLASSIC Proactive Telephone Coaching and Tailored Support (PROTECTS)

Study objectives
The Salford Integrated Care Programme (SICP) is a large scale transformational project to improve care for older people with long-term conditions and social care needs in Salford. SICP will deliver improved care through 3 core mechanisms:
1. Improved access to community resources and targeted support for self-management
2. Better integration of care through multidisciplinary health and social care groups providing structured, population based care.
3. An 'Integrated contact centre' to support navigation and self-management

The Comprehensive Longitudinal Assessment of Salford Integrated Care (CLASSIC) is an evaluation framework designed to provide a rigorous test of the ability of the SICP to deliver enhanced experience of care, improved well-being and quality of life, and reduced costs of care and improved cost effectiveness. The CLASSIC evaluation framework will adopt the cohort

multiple randomised controlled trial, where a large population cohort is recruited and followed over time, with subgroups of the cohort used to evaluate the outcomes of particular SICP components.

An important component of the SICP is a contact centre providing 'health coaching'. Health coaching involves 'a regular series of phone calls between patient and health professional...to provide support and encouragement to the patient, and promote healthy behaviours such as treatment control, healthy diet, physical activity and mobility, rehabilitation, and good mental health'.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. First MREC approval date 29/04/2014, ref: 14/NW/0206
2. Health Coaching Sub Project (Leeds East), approval date 26/05/2015, ref: 15/YH/0129

Primary study design
Interventional

Study design
Both; Interventional and Observational; Design type: Process of Care, Treatment, Cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care, Ageing; Subtopic: Not Assigned, Ageing; Disease: All Diseases, All Ageing

Interventions
Current interventions as of 10/03/2016:
The CLASSIC framework includes a large cohort of patients, which we will sample to recruit patients for a trial using the cohort multiple randomised controlled trial methodology (Relton et al 2010). The trial is called CLASSIC PROTECTS (Proactive Telephone Coaching and Tailored Support), which tests the effectiveness of telephone health coaching on the outcomes of older patients (aged 65+) with multiple long-term conditions, compared to usual care. 1306 eligible patients in the CLASSIC cohort will be randomly selected and 504 asked if they would take part in a trial of health coaching for multiple long-term conditions – a 20-minute phone call each month for 6 months. The remaining 802 will act as controls for the study, and will be followed up as part of the CLASSIC cohort.

Previous interventions:
The CLASSIC framework includes a large cohort of patients, which we will sample to recruit patients for a trial using the cohort multiple randomised controlled trial methodology (Relton et al 2010). The trial is called CLASSIC PROTECTS (Proactive Telephone Coaching and Tailored Support), which tests the effectiveness of telephone health coaching on the outcomes of older patients (aged 65+) with multiple long-term conditions, compared to usual care. 504 eligible patients in the CLASSIC cohort will be randomly selected and 50% (n=252) asked if they would take part in a trial of health coaching for multiple long-term conditions – a 20-minute phone call each month for 6 months. The remaining 50% will act as controls for the study, and will be followed up as part of the CLASSIC cohort.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 13/12/2016:
1. Ability to self-manage, measured using the 13-item version of the Patient Activation Measure
2. Quality of life, measured using the physical health domain of the World Health Organization Quality of Life (WHOQOL-BREF) instrument
Timepoint(s): Month 0, 20

Previous primary outcome measures from 10/03/2016 to 13/12/2016:
Health outcomes; Timepoint(s): Month 0, 6

Original primary outcome measures:
Health outcomes; Timepoint(s): Month 0, 6, 12, 18, 24

Key secondary outcome(s)
Current secondary outcome measures as of 13/12/2016:
1. Depression, assessed using the Mental Health Inventory-5
2. Ability to self-manage, assessed using the Summary of Diabetes Self-Care Activities (SDSCA) measure
3. Health economic analyses using the EQ5D-L measure and healthcare utilisation data
Timepoint(s): Month 0, 20

Previous secondary outcome measures from 10/03/2016 to 13/12/2016:
1. Costs; Timepoint(s): Month 0, 6
2. Patient experience; Timepoint(s): Month 0, 6

Original secondary outcome measures:
1. Costs; Timepoint(s): Month 0, 6, 12, 18, 24
2. Patient experience; Timepoint(s): Month 0, 6, 12, 18, 24

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Aged 65+
2. 2 or more existing long-term conditions
3. Assessed as needing some assistance with self-management (defined in terms of scores on the Patient Activation Measure)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Senior

Sex
All

Key exclusion criteria
1. Patients in the palliative care stage of condition
2. Those with conditions which reduce capacity to consent and participate

Date of first enrolment
01/07/2015

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Manchester
5th Floor, Williamson Building
Manchester
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M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Health Services and Delivery Research Programme (Grant Codes: 12/130/33)

Alternative Name(s)
Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Results article	results	20/07/2017		Yes	No
Results article	trial within a cohort results	30/05/2018		Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			26/07/2023	No	No