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Collaborative care in screen-positive elders (CASPER) trial

Submission date
01/06/2009

Recruitment status
No longer recruiting

Registration date
03/06/2009

Overall study status
Completed

Last Edited
17/08/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression is one of the most common mental disorders worldwide. The symptoms of depression can vary greatly from person to person, but generally include low mood, problems with sleeping and/or eating, and a general loss of interest in life. Around 1 in 7 older people suffer from depression. Depression in this age group is associated with poor quality of life along with increased health and social care use. The CASPER trial is a study of a primary care based psychological treatment called collaborative care for older adults with sub-threshold depression. Sub-threshold depression is when patients suffer from a few depressive symptoms but insufficient to meet formal diagnostic criteria for major depression. The aim of the study is to test whether or not collaborative care is effective at preventing symptoms of depression from getting worse, and to see if it would be value for money for the National Health Service (NHS).

Who can participate?
Adults showing signs of low mood, who are aged 75 and over for the first phase of the study and 65 and over for the main part of the study.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive six to eight weekly sessions of low intensity collaborative care, delivered by a specialist health worker (case manager). Collaborative care may also involve medication management, in cases where the participant has been prescribed medication. Participants in this group also receive telephone support, symptom monitoring (so that action can be taken if symptoms of depression appear or get worse) and behavioural activation (a type of therapy which focuses on changing behaviour to improve symptoms). Those in the second group receive standard care, delivered by their GP. At the start of the study and then again after 4 and 12 months, participants in both groups complete a number of questionnaires in order to assess their general and mental well-being.

What are the possible benefits and risks of participating?
Being offered collaborative care is a possible benefit for participants as it may not be currently available in their GP practice. There are no notable risks involved with taking part in the study.

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

When is the study starting and how long is it expected to run for?
October 2009 to November 2014

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Professor Simon Gilbody
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Study website
http://www.york.ac.uk/healthsciences/research/mental-health/projects/casper/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 08/19/04

Study information

Scientific Title
Collaborative care and active surveillance for screen-positive elders with sub-clinical depression: a pilot study and definitive and randomised evaluation

Acronym
CASPER

Study objectives
1. To develop a low intensity collaborative care intervention based upon evidence-supported models of care for older adults with screen-positive sub-threshold depression
2. To establish the acceptability and uptake of this service by older adults with screen-positive sub-threshold depression in primary and residential care settings
3. To test the feasibility of conducting a successful trial of low intensity collaborative care intervention for older adults with screen-positive sub-threshold depression
4. To establish the clinical effectiveness of low intensity collaborative care intervention for older adults with screen-positive sub-threshold depression
5. To examine the cost effectiveness of a low intensity collaborative care intervention for older adults with screen-positive sub-threshold depression across a range of health and social care costs

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Leeds East Research Ethics Committee, 28/09/2010, 10/H1306/61

Study design
Randomised controlled trial, including a prospective economic and qualitative evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
http://www.york.ac.uk/healthsciences/research/mental-health/projects/casper/participants/

Health condition(s) or problem(s) studied
Sub-clinical depression

Interventions
Active intervention:
Low intensity form of collaborative care delivered by a case manager of 6 - 8 weekly sessions. Collaborative care is the most effective and efficient way of organising and delivering depression care in primary care settings. The defining features of collaborative care include a case manager, working with the patient, with access to the GP and a mental health specialist (old age psychiatrist or psychologist). Collaborative care will be delivered by a case manager (a

primary care mental health worker) within a 'stepped care framework', such that those whose depression deteriorates (moving from sub-threshold to threshold) are 'stepped up' from low intensity care to a more intensive form of management (including anti-depressant medication). The additional elements of collaborative care include:
1. Telephone support
2. Symptom monitoring and active surveillance
3. Brief psycho-social intervention (behavioural activation)

Control intervention:
The comparator technology will be general primary care management of sub-threshold depression, in line with National Institute for Health and Clinical Excellence (NICE) depression guidance and with due reference to local service provision.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Self reported depression severity (as measured by the 9-item Patient Health Questionnaire [PHQ-9]) at 4 months as a continuous measure.

Secondary outcome measures
Updated secondary outcome measures:
Note: The secondary outcome measures were updated to the following prior to recruitment of the first participant into the study.
1. Depression severity and symptomatology is measured using the 9-item Patient Health Questionnaire (PHQ-9) at baseline and 12 months
2. Binary depression severity at 4 and 12 months is measured using the 9-item Patient Health Questionnaire (PHQ-9) using scores ≥ 10 to designate moderate depression caseness at 4 and 12 months
3. Health state utility is measured using European Quality of Life-5 Dimensions (EQ-5D) at 4 and 12 months
4. Physical health and somatic complaints is measured using a 15-item scale using Patient Health Questionnaire-15 items (PHQ-15) at baseline, 4 and 12 months
5. Quality of life is measured using Short Form questionnaire-12 items (SF-12) and EQ-5D at baseline, 4 and 12 months
6. Psychological anxiety is measured using the Generalized Anxiety Disorder 7-item (GAD-7) scale at baseline, 4 and 12 months
7. Resilience and the ability to bounce back is measured using the Connor–Davidson Resilience Scale two-item version (CD-RISC 2) at baseline, 4 and 12 months
8. Self-report medication data at baseline, 4 and 12 months (Not applicable to participants who fully withdraw from the study)
9. Healthcare resource use data obtained from GP practices measures:
9.1. Participants’ contacts with GPs (appointments, home visits or telephone consultations)
9.2. Participants’ contacts with practice nurses (appointments or telephone consultations)
9.3. Prescriptions across each participant's follow up period of 12 months (or up until they leave the practice/die)

10. Mortality across the follow up period is measured using a data linkage service established with the Health and Social Care Information Centre to provide regular updates from the Office for National Statistics mortality data on any trial participants who had died while in the study

Original secondary outcome measures:
1. ICD depression status at 4 and 12 months
2. Health related quality of life is measured using the 36-item Short Form Health Survey (SF-36) at 4 and 12 months
3. Health-state utility is measured using the European Quality of Life-5 Dimensions (EQ-5D) questionnaire at 4 and 12 months

Overall study start date
01/10/2009

Completion date
14/11/2014

Eligibility

Key inclusion criteria
Inclusion criteria as of 10/03/2016:
1. Age ≥ 75 years during the pilot phase or ≥ 65 years during the main trial
2. Identified by a GP practice as being able to take part in collaborative care

Original inclusion criteria:
Elderly people (aged 75 years and older, either sex) with screen-positive depression on the Quality Outcomes Framework Depression 1 (QOF DEP1) - compliant 'two depression screening questions', but do not reach the threshold for International Classification of Disease, version 10 (ICD 10) moderate depressive disorder

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
486 patients (243 in each group). Allowing for a potential loss to follow-up of 10% the final sample size needed is 540 patients (270 in each group). The target sample size was revised upwards in view of higher than anticipated loss to follow- up and to enable us to retain the original statistical power estimate. The total sample size required was 658 patients (329 in each arm).

Key exclusion criteria
Exclusion criteria as of 10/03/2016:
Those identified by a primary care clinician as:
1. Having a known alcohol dependency (as recorded on GP records)

2. Experiencing psychotic symptoms (as recorded on GP records)
3. Having any known comorbidity that would, in the GP's opinion, make entry to the trial inadvisable (e.g. recent evidence of suicidal risk/self-harm, significant cognitive impairment)
4. Being affected by other factors that would make an invitation to participate in the trial inappropriate (e.g. recent bereavement, terminal malignancy)

Original exclusion criteria:
1. Reached threshold for ICD 10 moderate depressive disorder
2. Patients with alcohol dependence
3. Patients with dementia

Date of first enrolment
24/05/2011

Date of final enrolment
09/07/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of York
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Sponsor information

Organisation
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ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/10/2011		Yes	No
Results article	results	15/03/2016		Yes	No

Results article	results	01/02/2017		Yes	No
Results article	results	21/02/2017		Yes	No
Results article	study within a trial (SWAT) results	21/05/2020	17/08/2020	Yes	No