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The CASPER-PLUS trial: collaborative care in screen positive elders with major depressive disorder

Submission date
13/06/2012

Recruitment status
No longer recruiting

Registration date
24/07/2012

Overall study status
Completed

Last Edited
17/11/2020

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 the most common of all mental health problems. Around 1 in 7 older people (aged over 75) suffer from depression. Depression in older people is associated with poor quality of life and increased health and social care use. As the ageing population grows, solutions are needed to meet the specific needs of older people. CASPER PLUS is a study of a primary care-based psychological treatment, called collaborative care, for older people with depression. The aim of the study is to establish the clinical effectiveness and cost effectiveness of collaborative care for older people with depression.

Who can participate?
All patients aged 65 and over in participating GP practices will be invited to take part in the study.

What does the study involve?
Eligible participants who consent to take part are allocated into one of two groups: the Collaborative Care group or Usual GP Care. This is done through a computerised process called randomisation, which means participants are allocated to groups purely by chance, in a similar way to using the toss of a coin.
Collaborative Care participants are assigned to a specialist health worker, called a Case Manager. They work closely with the participant for a period of 8 to 10 weeks, providing support and information to help them recover from depression, to improve their mental wellbeing and to keep well in future.
Collaborative care may also involve medication management, in cases where the participant has been prescribed medication. The case manager liaises with the participants GP regarding their care.
Collaborative Care has shown promising trial results in the United States of America (USA). However the transferability of this model of service to the UK NHS cannot be assumed. The National Institute for Health and Clinical Excellence (NICE) has identified this as an important intervention that should be subject to further studies.

What are the possible benefits and risks of participating?
The possible benefits are that participants may be offered collaborative care, which may not be currently available in their GP practice. A large study in the USA using collaborative care has shown positive results in improving levels of depression among older adults. The CASPER Plus trial is conducted through the National Health Service (NHS). All NHS research is approved by of an independent Research Ethics Committee, to protect the safety, rights, wellbeing and dignity of participants. There are no expected risks in participating in the study.

Where is the study run from?
The main centre of the trial is York. A number of GP practices in and around the area will invite patients over 65 to take part in the study. We also expect to recruit participants from GP practices in and around Leeds, Durham and Newcastle.

When is the study starting and how long is it expected to run for?
August 2012 to June 2015

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

Who is the main contact?
Prof. Simon Goodbody
simon.gilbody@york.ac.uk
(updated 17/11/2020, previously: Dr Helen Lewis
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Study website
https://www.york.ac.uk/healthsciences/research/mental-health/projects/casper/who/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 10/57/43, Protocol number: R12237

Study information

Scientific Title
The CASPER-PLUS trial: CollAborative care in Screen Positive EldeRs with major depressive disorder - a pragmatic randomised controlled trial

Acronym
CASPER-PLUS

Study objectives
CASPER-PLUS is a sub study of the wider CASPER study (ISRCTN02202951), a cohort study and randomised controlled trial (RCT) looking at the effectiveness of collaborative care in older patients with sub-threshold depression, using a database screening approach in rectuiting patients.

CASPER-PLUS aims to establish the clinical and cost effectiveness of a collaborative care intervention for older people with screen-positive above-threshold depression ('major depressive episode') within a definitive RCT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & Humber - Leeds East, 20/04/2012, ref: 10/H1306/61

Study design
Pragmatic multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
http://www.york.ac.uk/healthsciences/trials-unit/casper/participants/

Health condition(s) or problem(s) studied
Depression / mental well-being

Interventions
Eligible participants who have consented to be in the trial will be randomised into one of two intervention groups: 1. Collaborative Care (including Behavioural Activation) intervention with medication monitoring and management
2. Usual care

This psychological intervention is a bespoke collaborative care designed and delivered specifically for those aged 65 or over with above threshold, case-level depression over 8-10 weekly sessions. 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 are 'stepped up' from low intensity care to a more intensive form of management including medication monitoring.

The five core components of the intervention are described below:
1. Patient-centred assessment and engagement: Patients are first assessed in their own residential setting. The severity of depression and associated behavioural and social deficits are assessed and patient information materials are given.
2. Symptom measurement and monitoring: A standardised assessment of symptom severity is made. Symptom tracking (to judge response, failure to respond or deterioration) is then made at all subsequent patient contacts.
3. Medication management: The prescription of anti-depressant medication is entirely at the discretion of the General Practitioner. We will encourage GPs to consider NICE guidance in their prescribing decisions. The concordant use of medication by patients will be encouraged by the case manager if a prescription has been initiated by the GP. Patient concerns (such as addiction) and non-compliance will be addressed during sessions. There will be active liaison with GPs to encourage follow up patient appointments with the GP if poor concordance is noted.
4. Active follow-up: All patients are followed up by the CM for eight weeks using face to face meetings or telephone contacts.
5. Delivery of behavioural activation (BA): Patients are offered the option of behavioural activation delivered over eight sessions by their case manager. BA consists of a structured programme of reducing the frequency of negatively reinforced avoidant behaviours in parallel with increasing the frequency of positively reinforcing behaviours to improve functioning and raise mood. During this time patients will remain under the medical care of their GP.

The additional elements of collaborative care include: telephone support; symptom monitoring and active surveillance (facilitated by computerised case management systems PC-MIS); medication monitoring; low intensity psychosocial intervention (behavioural activation). The work of case managers is supervised by an older persons mental health specialist (old age psychiatrist or psychologist).

Control intervention
Participants allocated to the control condition will receive usual primary care management of case level depression offered by their GP, in line with NICE depression guidance and local service provision.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measure as of 17/11/2020:

Primary outcome measure is depression severity measured by the PHQ9. The primary time point for the primary outcome measure is 4 months. PHQ9 also measured at 12 and 18 months to examine any sustained impact of the intervention

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Previous primary outcome measure:

Depression severity measured by the PHQ9 at 4,12 and 18 months

Secondary outcome measures
Current secondary outcome measures as of 17/11/2020:

1. Quality of Life measured by SF-12 at 4, 12 and 18 months
2. Anxiety measured by GAD-7 at 4, 12 and 18 months
3. Somatic symptoms measured using PHQ-15 at 4, 12 and 18 months
4. Resilience using the CD-RISC2 at 4, 12 and 18 months
5. Cost-effectiveness including the EQ-5D, prescribed medication and health and social care use

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Previous secondary outcome measures:

Presence/absence of depression diagnosis as ascertained by interview

Overall study start date
15/08/2012

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. CASPER participants will be identified by comprehensive screening strategies in primary care (replicating that which is incentivised in QOF-compliant case finding for those with CHD and diabetes).
2. Older people (aged 65 and above)
3. Who screen-positive for depression on the recommended QOF 2 question brief depression screen (sometimes referred to as the "Whooley" questions after their initial validation study), but who on further assessment have Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) Major Depressive Disorder (MDD)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
450

Key exclusion criteria
1. Known alcohol dependency (as recorded on GP records)
2. Any known co-morbidity that would in the GPs opinion make entry to the trial inadvisable (e.g. recent evidence of self harm, known current thoughts of self harm, significant cognitive impairment)
3. Other factors that would make an invitation to participate in the trial inappropriate (e.g. recent bereavement; terminal malignancy)
4. Known to be experiencing psychotic symptoms (as recorded on GP records)

Date of first enrolment
15/08/2012

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of York
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York (UK)

Sponsor details

c/o Sue Final
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Sponsor type
University/education

Website
http://www.york.ac.uk/

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	19/11/2014		Yes	No
Results article	qualitative study results	19/10/2015		Yes	No
Other publications	erratum	27/04/2016		Yes	No
Funder report results	report to funder	01/11/2017		No	No