ISRCTN95270332 https://doi.org/10.1186/ISRCTN95270332

Self-help for those at risk of depression: The SHARD Trial

Submission date
17/02/2014

Recruitment status
No longer recruiting

Registration date
21/02/2014

Overall study status
Completed

Last Edited
19/01/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
We are carrying out a study of a primary care based self-help workbook for older people with low level depression. Our study is part of a larger study called CASPER (http://www.casperstudy.org.uk) which is looking at ways to improve the care that older people receive for different levels of depression. The aim of the study is to see if a self-help workbook designed to help older people with lower level symptoms of depression will improve those symptoms and prevent them turning into more severe depression in the future.

Who can participate?
We are looking for people aged 65 years and over who have symptoms of depression or low mood. You may also be invited because you are in a high-risk group, such as suffering from a health complaint or you are a carer to a relative. We know many people suffer but do not seek help for their low mood.

What does the study involve?
We don't yet know if the new type of care is any better than the care already offered by your GP to treat depression and improve the feelings of people who are finding life difficult. We need to compare the two methods of giving care to see if there is a difference. If you agree to take part, you will be asked to fill in a questionnaire about yourself. Once you have sent back your questionnaire, we will look through your replies to see if you fit with our needs for the study. If you do, one of our team will call you to ask you some more questions. We will then randomly allocate you to one of two groups: either a usual GP care group or the self-help workbook group. Both groups will also be sent a questionnaire after 4 months and 12 months. If you are put into the usual care group, your GP care will continue as normal. We will still ask you to fill in and send back the questionnaires mentioned above. If you are put into the self-help workbook group, you will be sent a self-help workbook through the post to read and work through in your own time at a pace that suits you. You will receive up to three telephone calls from a researcher to offer help with the workbook if needed and answer any questions you may have. At the end of the study we will compare the two groups to see if the self-help workbook group show fewer symptoms of depression than the usual GP care group over time.

What are the possible benefits and risks of taking part in this study?
We cannot promise that taking part in this study will help you. Taking part could improve the treatment offered to people suffering from depression in the future. By taking part in this study you may receive help that isn't normally offered to people. The possible disadvantages are that it takes up some of your time. It takes time to complete questionnaires. For those in the self-help workbook group, time will be spent reading the booklet and working through the activities.

Where is the study run from?
The study is being organised by the University of York who is working with teams at different areas around York, Harrogate, Hull, Leeds, Durham and Newcastle and Northumberland, UK.

When is the study starting and how long is it expected to run for?
Recruitment is expected to start in early February 2014 and will continue until the end of July 2014; the follow-up questionnaires will continue until July 2015.

Who is funding the study?
National Institute of Health Research, UK.

Who is the main contact?
Professor Simon Gilbody (Chief Investigator), sg519@york.ac.uk

Study website
https://www.york.ac.uk/healthsciences/research/mental-health/projects/casper/shard/

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
A multi-centred randomised controlled trial to determine whether a specifically designed guided self-help workbook, using behavioural activation principles in addition to GP usual care is more effective than GP usual care alone for older people with sub-threshold depression symptoms

Acronym
SHARD

Study objectives
A low-intensity self-help workbook based on behavioural activation principles alongside usual GP care will reduce depression amongst older people displaying sub-threshold symptoms of depression more effectively than usual care alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - Leeds, 23/12/2013, REC ref: 10/H1306/61

Study design
Pragmatic two-arm randomised controlled multi-site trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Sub-threshold depression in people 65 years and older

Interventions
Eligible and consenting participants will be randomly allocated to one of two comparative arms. This sub-study forms part of a larger funded project supported by the Department of Health's National Institute of Health Research Health Technology Assessment programme (NIHR HTA).

Participants will be identified through the CASPER recruitment process and followed up alongside the main study (CASPER: ISRCTN02202951).

Intervention arm:
BA self-help workbook plus usual primary care
Participants will be sent a specially-designed self-help workbook produced for the purposes of the SHARD trial. This booklet is entitled Helping you to maintain a positive mood in older age: a self-help workbook and is 20 pages long. The workbook is based on clear principles of an evidence-supported psychological treatment (behavioural activation BA) for depression. The core purpose of the workbook is to introduce simple behavioural strategies for improving mood and the rationale is to enable patients to regain functionality lost or reduced as part of low mood. By using principles of BA, participants are encouraged to (1) re-establish their daily routine, (2) increase pleasurable external activities and (3) address necessary issues such as unpaid bills.

The self-help workbook has been tested for readability and designed after extensive consultation with older people with depression and their carers. After consenting to take part, participants to this arm of the trial will be sent a copy of the self-help workbook with an explanatory cover letter. Participants will also receive up to three telephone calls designed to check that the materials have arrived and to offer practical advice and encouragement to use the materials. In addition all participants will receive the usual care of their GP.

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

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patient-reported depression severity (Patient Health Questionnaire 9 - PHQ-9) at 4 months and again at 12 months to examine any sustained impact of the intervention.

Secondary outcome measures
1. Health-related quality of life (physical and mental component of the SF-12) at 4 months and 12 months
2. Health-state utility (EQ-5D) at 4 months and 12 months

Overall study start date
01/02/2014

Completion date
31/07/2015

Eligibility

Key inclusion criteria

Participants will be identified in primary care. Our target population will be older people (aged 65 and above) who screen-positive for depression on a two question brief depression screen (sometimes referred to as the 'Whooley' questions after their initial validation study), but who on further assessment do not fulfil criteria for DSM-IV Major Depressive Disorder (MDD), and therefore have sub-threshold depression.

Inclusion criteria:
Aged 65+ years and with a read code for any one of the following:
1. Depression
2. Anti-depressant medication
3. Ischemic heart disease (IHD)
4. Diabetes
5. Chronic obstructive pulmonary disease (COPD)
6. Arthritis
7. Carer

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
We aimed to recruit 156 participants per arm. Assuming 15% attrition, the trial had 90% power to detect at the 5% significance level a difference of 0.4 standard deviations (approximately 2 PHQ-9 score points) in the PHQ-9 score between the two arms. We recruited 332 participants.

Total final enrolment
332

Key exclusion criteria
1. Not currently experiencing psychotic symptoms
2. No known alcohol dependency (as recorded on GP records)
3. No known significant cognitive impairment; unable to give informed consent (as recorded on GP records)
4. No known recent bereavement (as recorded on GP records)
5. No known terminal malignancy (as recorded on GP records)

Date of first enrolment
10/03/2014

Date of final enrolment
11/08/2014

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)

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c/o Sue Final, University Intellectual Property Manager
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Sponsor type
University/education

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment programme (HTA) (UK) grant ref.: 08/19/04

Results and Publications

Publication and dissemination plan
Not provided at time of registration

2018 abstract in https://gcdp2018.uib.eu/Submitted-Abstracts/ (added 02/09/2020)

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration