ISRCTN23278208 https://doi.org/10.1186/ISRCTN23278208

Preventing depression study: PERSUADE

Submission date
20/11/2017

Recruitment status
No longer recruiting

Registration date
28/11/2017

Overall study status
Completed

Last Edited
22/10/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The number of people with depression is increasing across the world; depression is set to become the leading cause of disability worldwide by 2030. Treatments for depression have limited usefulness and have only led to a 35% reduction of cases of depression, as compared to those receiving no treatment. People with untreated depression symptoms are at an increased risk of persistent depression with poor outcomes. There is a need to develop treatments that can be delivered at the very early stage of the illness thus preventing progression into full blown symptoms of depression. One of the major risk factors for depression is sub-threshold depression. Sub-threshold depression is a condition where the person has developed some of the symptoms of stress and low mood but the number of symptoms, and their severity, is lower than the threshold that we would use to diagnose someone with depression. In routine clinical practice we use a score of 10 or above on a depression questionnaire (Personal Health Questionnaire PHQ 9) to diagnose depression. This study uses a score of between 5 and 9 on the PHQ 9 to indicate sub-threshold depression. Experience tells us that it can be difficult to engage people with mild depression into preventive treatments that may require ongoing commitment. So, we plan to use user involvement to adapt and evaluate a psychological therapy program which is acceptable. It will be based on Cognitive Behaviour Therapy (CBT) principles. The aim of this study is to reduce depression symptom scores and prevent development of depression in people with sub-threshold depression defined as PHQ score 5-9.

Who can participate?
Adults aged 18 to 60 who have score between a 5 to 9 on the PHQ 9 scale.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive a specially developed CBT based intervention manual and will be required to attend a one full-day or two half-day workshops to support the manual. Those in the second group receive the usual care (no treatment). All participants are asked to complete a short questionnaire three months after the study to assess their symptoms. Some participants in the treatment group are also invited to take part in an interview over the telephone, to talk about their experiences during the study.

What are the possible benefits and risks of participating?
The model being used in the intervention has been used in many previous studies and shown

effectiveness in helping people to manage their mood better. We do not anticipate the self-help intervention to pose a risk to participants and it does not prevent them accessing other more traditional health care through their GP if needed.

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

When is the study starting and how long is it expected to run for?
July 2017 to June 2018

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36210

Study information

Scientific Title
Preventing depression in the community by voluntary sector providers

Acronym
PERSUADE

Study objectives
The primary aim is to reduce depression symptom scores and prevent development of depression in people with sub-threshold depression defined as PHQ score 5-9.

The objectives of the study are:
1. To adapt a low intensity community based depression prevention intervention based upon Cognitive Behaviour Therapy (CBT) model for adults with sub-threshold depression deliverable by voluntary sector organisations
2. To establish the acceptability and uptake of this model by adults with sub-threshold depression
3. To test the feasibility of conducting a successful trial of community based depression prevention intervention for adults with sub-threshold depression

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West- Greater Manchester East REC, 23/11/2017, ref: 17/NW/0604

Study design
Randomised; Interventional; Design type: Prevention, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Primary care, Primary sub-specialty: Mental Health; UKCRC code/ Disease: Mental Health/ Organic, including symptomatic, mental disorders

Interventions

Participants are randomised to either the intervention group or to usual care (no treatment). Participants in the intervention group receive a specially developed CBT based intervention manual and are required to attend a one full-day (or 2 half-days) workshop to support the manual. Motivational techniques are incorporated at the beginning of the workshop to help engage participants, based on previous research and our own experience of conducting social groups. Group exercises, role-play demonstrations and discussions of case vignettes will be participatory to maintain participant's interest and motivation.

All participants are followed up 3 months post randomisation.

Engagement, attendance of workshops and retention to the study are recorded.

Phone or face-to-face interviews are conducted with a sample of the participants in the intervention group (n=15) on completion of the intervention, looking at acceptability. Interviews are also be carried out with the specially trained facilitators at the end of the study to assess training, support and intervention delivery.

Intervention Type
Other

Primary outcome measure
Feasibility and acceptability are assessed using:
1. Recruitment methods - a number of different recruitment strategies are tried and assessed to see how much time each takes and the yields.
2. Engagement, attendance of workshops and retention to the study
3. Phone or face-to-face interviews are conducted with a sample of the participants in the intervention group
4. Interviews are carried out with the specially trained facilitators at the end of the study to assess training, support and intervention delivery

Secondary outcome measures
1. Depression is measured using PHQ-9 at baseline and 3 months.
2. Health status is measured using EQ-5D-3L at baseline and 3 months
3. Healthcare utilisation is measured using (CSRI) at baseline and 3 months
4. Client Satisfaction is measured using Client Satisfaction Questionnaire (CSQ-8) at baseline and 3 months

Overall study start date
01/07/2017

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. Patients from primary care or the general community
2. Male and female
3. Aged between 18 years and 60 years of age
4. Score between 5-9 on the PHQ 9

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 64; UK Sample Size: 64

Key exclusion criteria
1. Depression (score higher than 9 on PHQ-9, or formal diagnosis of depression)
2. Psychosis
3. Drug or alcohol use as primary diagnosis
4. Suicidal ideations
5. Non-English language speakers

Date of first enrolment
01/01/2018

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The University of Manchester
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
The University of Manchester

Sponsor details
Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A protocol paper has been written and will be submitted once ethical approval has been confirmed.
This will be followed by a process evaluation paper and a results paper at the end of the study in 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	31/10/2017	28/11/2017	No	Yes
Protocol article	protocol	03/10/2019	22/10/2020	Yes	No
HRA research summary			28/06/2023	No	No