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NOTEPAD: third sector workers supporting depressed and anxious older people to do social activities

Submission date
02/11/2016

Recruitment status
No longer recruiting

Registration date
10/11/2016

Overall study status
Completed

Last Edited
29/11/2022

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 a major global public health threat and by 2030 levels are predicted to be the second leading cause of disease burden and disability worldwide. Anxiety and depression commonly over-lap or co-exist and are prevalent amongst older people with up to 20% of older people reporting symptoms of depression. Depression and anxiety in older people often go undetected and are poorly managed in primary care, particularly in people with other long term health problems. One barrier to being able to spot depression and anxiety is that older people may not go to their GP with depression because of the stigma (negative associations) they have about mental health problems. It has been found that older people prefer to have talking therapies rather than taking antidepressant medications. Behavioural activation (BA) is a short form of cognitive behavioural therapy (a type of talking therapy that helps people change the way they think and behave). It has previously been found to be effective in the management of depression and can be given by non-mental health trained practitioners. The aim of this study is to find out whether it is possible and practical; for non-traditional providers (NTPs) to deliver BA to older people with anxiety and/or depression.

Who can participate?
Adults aged 65 and over who have symptoms of anxiety and depression

What does the study involve?
At the start of the study, participants are visited at home by a Research Nurse where they are asked to confirm that they are happy to take part and fill in some questionnaires. The participants are then randomly allocated to one of two groups. Those in the first group are advised to go to their GP so that they can receive usual care. Those in the second group are contacted by a worker from Age UK and arrange 4-6 one-to-one appointments with them. The appointments can take place at a time and a place convenient to the participant (in their home for example) or over the telephone and last for approximately 30-60 minutes. During the appointments, the Age UK worker discusses strategies to help with low mood or stress with the participant. The Age UK worker also discusses types of activities that participants may be interested in, and then tries to help them to attend and take part in that activity or join a group,

and attend with them if the participant wishes. At the start of the study and then again after four months, participants in both groups complete a number of questionnaires to assess their mental wellbeing. In addition, the number of participants who have taken part is recorded to see if conducting a larger study would be possible.

What are the possible benefits and risks of participating?
Participants who receive the BA may benefit from receiving the one-to-one support and taking part in group activities which could help improve their symptoms. There is a risk that some participants may find the visits with the Research Nurse tiring or upsetting.

Where is the study run from?
1. Research Institute for Primary Care and Health Sciences, Keele University (UK)
2. Age UK North Staffordshire (UK)

When is the study starting and how long is it expected to run for?
September 2015 to August 2017

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

Who is the main contact?
Dr Heather Burroughs
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32442

Study information

Scientific Title
NOTEPAD: a feasibility study for NOn-Traditional providers to support the management of Elderly People with Anxiety and Depression

Acronym
NOTEPAD

Study objectives
The aim of this study is to test whether it is possible and practical for non-traditional providers (NTPs) to deliver a simple psychosocial intervention, which has been developed by members of the research team, to older people with anxiety and/or depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committee North West – GM West, 16/08/2016, ref: 16/NW/0552

Study design
Single-centre randomised controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Depression, anxiety and loneliness in older adults

Interventions
Eligible participants will be visited at home by a Research Nurse at a time and date to suit them. The participant will be asked to complete a consent form and a number of baseline

questionnaires. This visit will last approximately 90 minutes. Participants will then be randomised by computer to the control or intervention group.

Intervention group: Participants will be offered an individual appointment with the third sector worker (NTP) at a local third sector service or in the participant's home (depending on participant preference). The NTP will work as a mentor or 'befriender' to the participant and deliver an intervention developed from the team's previous work. Four-six contacts between the participant and the NTP are anticipated, utilising a combination of face to face and telephone contact. The intervention is intended to be tailored to patient preference so there is some flexibility regarding the precise number of sessions, interval, mode of delivery and format.

Control group: Participants will be advised to see their own doctor (GP) so that they can receive the usual care.

For all participants, a follow up interview will take place 4 months after the baseline interview, during which the baseline questionnaires will be repeated.

Intervention Type
Other

Primary outcome measure
1. Engagement of GP practices is measured by recording the number of GP practices that agree to participate of those approached
2. Recruitment, training and retention of NTPs is measured by monitoring how many NTPs undergo full training and are retained to the end of the study
3. Response rates to the screening questionnaire is measured by recording the number of target participants that will respond to screening as a percentage of the number mailed and invited to participate in the study
4. Participant recruitment rate is measured by the number of eligible participant who consent to participate in the study as a percentage of all eligible participants
5. Response rates to follow-up questionnaire is measured recording the number of participants who consent to participate that remain in the study until the end of follow-up at 4 months
6. Adherence to intervention is measured by reviewing NTP notes at 4 months, recording of sessions and qualitative interviews with NTPs and a sample of participants

Primary outcome:
Depression is measured using the Computerised Clinical Interview Schedule Revised (CIS-R) Score at baseline and 4 months.

Secondary outcome measures
1. Quality of life is measured using the CASP-12 questionnaire at baseline and 4 months
2. Loneliness is measured using the Adult Attitude to Loneliness questionnaire at baseline and 4 months
3. Vulnerability is measured using the Adult Attitude to Loneliness (AAG) at baseline and 4 months
4. Health-related quality of life is measured using the EQ-5D-5L at baseline and 4 months
5. Social participation is measured using the Social participation questionnaire at baseline and 4 months
6. Self-efficacy is measured using the Self Efficacy questionnaire at baseline and 4 months
7. Participant burden is measured using a question by the research nurse at baseline and 4 months

Overall study start date
01/09/2015

Completion date
31/08/2017

Eligibility

Key inclusion criteria
1. Aged over 65
2. Registered at 1 of the 6 recruited practices
3. A score of 10 or higher on the PHQ9 and/or GAD7 (as indicated on a postal screening questionnaire and a pre-baseline telephone call)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
100

Total final enrolment
36

Key exclusion criteria
1. People at risk of self-harm/suicide
2. Alcohol/substance abuse
3. People in the palliative phase of an illness
4. Lacking capacity to consent
5. Living in a care home

Date of first enrolment
01/12/2016

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Research Institute for Primary Care and Health Sciences
Keele University
Keele
United Kingdom
ST5 5BG

Study participating centre
Age UK North Staffordshire
19 Stafford Street
Stoke-on-Trent
United Kingdom
ST1 1JW

Sponsor information

Organisation
Keele University

Sponsor details
Directorate of Engagement and Partnerships
iC2 Building
Keele
England
United Kingdom
ST5 5NH

Sponsor type
University/education

ROR
https://ror.org/00340yn33

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
Feasibility study results to be published by end July 2018.

Intention to publish date
31/07/2018

Individual participant data (IPD) sharing plan
The current 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?
Protocol article	protocol	07/03/2018		Yes	No
Results article	qualitative results	19/01/2019	12/02/2020	Yes	No
Results article		01/07/2019	29/11/2022	Yes	No
HRA research summary			28/06/2023	No	No