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Comparing a behavioural activation treatment for depression in adults with learning disabilities with an attention control

Submission date
08/11/2012

Recruitment status
No longer recruiting

Registration date
13/11/2012

Overall study status
Completed

Last Edited
01/10/2018

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
Adults with learning disabilities are as likely to have depression as adults who do not have learning disabilities. However, not much is known about what treatments help adults with learning disabilities and depression. Behavioural activation is a psychological therapy for depression that has been shown to work as well as other psychological treatments like cognitive behavioural therapy. The advantage of behavioural activation for adults with learning disabilities is that people do not need to have good verbal communication skills. Behavioural activation gets people with depressioninvolved in positive activities. This includes everyday activities which they may have stopped doing because of their low mood. The proposed study would investigate whether a behavioural activation treatment adapted for adults with learning disabilities and depression works.

Who can participate?
The study aims to recruit 166 men and women with mild learning disabilities and depression. All the participants will be 18 years of age and above.

What does the study involve?
Over a period of two years, participants will be invited to take part in behavioural activation treatment for depression or supported self-help treatment. The treatment that the participant gets will be decided by a process called randomisation, which is like the toss of a coin. The treatments last for between 8 - 12 weeks. At the end of the study we will compare the mood and sense of well-being of participants who had received the behavioural activation treatment with those given guided self-help.

What are the possible risks and benefits of participating?
The possible benefit to participants is that their level of distress will reduce. They may also take part in more purposeful activity, enjoy better relationships with others, and have more opportunity for social inclusion. There are no anticipated major risks from taking part in the

study, based on the findings from pilot work trying out the interventions. However, those taking part in the study are depressed and their condition will sometimes become worse. Therefore, a close watch will be kept in case taking part in the study has caused any harm

Where is the study run from?
The Universities of Glasgow, Bangor and Lancaster (UK)

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in mid-2013 in Scotland. If recruitment is successful in the first year then recruitment will also start England and Wales in 2014. Participants will be enrolled in the study for a year, so that they can be followed-up after their treatment has finished.

Who is funding the study?
NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 10/104/34

Study information

Scientific Title
A randomised controlled trial comparing a behavioural activation treatment for depression in adults with learning disabilities with an attention control

Study objectives
To assess the clinical (reduction in depressive symptoms) and cost effectiveness of a behavioural activation intervention for adults with learning disabilities.

Secondary objectives:
Evaluate whether behavioural activation, compared to an attention control intervention leads to:
1. A greater reduction in anxiety symptoms
2. Higher levels of activity
3. Greater improvement in quality of life
4. Improved carers' sense of self-efficacy in supporting depressed adults
5. improved carers' relationships with the depressed adults

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/1010434
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0004/81724/PRO-10-104-34.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multi-centre single-blind randomized controlled design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Interventions
Behavioural Activation: The treatment is designed to be delivered to individuals alongside a carer who provides regular support to them. It is a structured, time limited, manualised psychological therapy, developed to treat those with a learning disability and depressive symptoms.

The treatment is divided into two phases, starting with an assessment period (4 sessions), where the patient with learning disabilities and their carer are socialised into the model and an individual formulation is developed. The subsequent 5-10 active treatment sessions focus on: (i) Recovering lost skills and interests, and new skills training, (ii) Graded exposure to reduce avoidant behaviours, and (iii) Targeting inherently reinforcing activity, and activity likely to increase access to other positive reinforcers. The final two sessions (11-12) after the active treatment phase have a future focus, and are concerned with helping the patient and carer to maintain and build on progress they have made.

Guided self-help: The self-help resources were designed to be used by patients with learning disabilities along with the support of a carer. There will be an initial meeting, with the patient and carer to explain the materials and provide coaching in their use, then 8 sessions to support the dyads in their use of the self-help materials. Although the materials were designed to be accessible, carer support is essential for their delivery as the patients themselves are expected to have few, if any, literacy skills. The focus is psycho-educational and the first two sessions with the patient begin by looking at the nature of depression, before going on to outline how depressive symptoms can be tackled. The materials focus on key topics including feeling down, sleep, exercise, and problem solving.

The treatment duration for both arms of the trial is approximately 4 months, with a 12 month follow-up period following randomisation.

Intervention Type
Behavioural

Primary outcome measure
Self-report of depressive symptoms, using the Glasgow Depression Scale, an instrument validated for use with adults who have Learning Disabilities. Data will be at collected at baseline, 4 months post randomisation and 12 months post randomisation.

Secondary outcome measures
1. Self-reports of anxiety
2. Carer proxy reports of depression
3. Activity/engagement in community life
4. An economic analysis will compare the costs of the treatment with the quality of life benefits as measured by the EQ-5D

Data will be at collected at baseline, 4 months post randomisation and 12 months post randomisation.

Overall study start date
01/01/2013

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. A learning disability
2. Over 18 years old
3. Clinically significant depression
4. Is able to give informed consent to participate
5. A level of expressive and receptive communication skill in English (reading skills not required) to allow participation in the treatment
6. Has a family member or paid carer who has supported them for a minimum of six months, is available for weekly-fortnightly treatment sessions with the practitioner, and who currently provides a minimum of 2 hours support per week to the patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
166

Key exclusion criteria
1. Suicidal
2. A measured IQ of >75
3. Factors that prevent the patient from interacting with the carer and therapist or retaining information from the therapy (e.g. dementia, significant agitation, withdrawal arising from psychosis)
4. Does not consent to her/his GP being contacted about their participation in the study

Date of first enrolment
01/07/2013

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Glasgow
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Sponsor information

Organisation
NIHR Health Technology Assessment Programme (UK)

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Sponsor type
Government

ROR
https://ror.org/0187kwz08

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	30/12/2015		Yes	No
Results article	results	01/12/2017		Yes	No
Results article	results	01/09/2018		Yes	No