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A research study of behavioural activation treatment for depression for adolescents with mild to moderate intellectual disability

Submission date
17/05/2023

Recruitment status
No longer recruiting

Registration date
19/06/2023

Overall study status
Completed

Last Edited
19/06/2023

Condition category
Mental and Behavioural Disorders

[ ] 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
Adolescents with a learning disability (LD) face significant mental health inequalities. Children and adolescents with LD are 4-5 times more likely to have mental health problems compared to children and adolescents without LD. Furthermore, young people with LD are 1.7 times more likely to experience depression than other young people. Psychological therapies, such as cognitive behavioural therapy (CBT), are recommended as the best treatment for most people with depression but they require good verbal communication. Studies have shown that people with LD do not have the communication skills to participate in most available psychological therapies. The aim of this study is to work with adolescents with LD, carers and family members, and therapists to adapt an existing treatment for depression in adolescents with mild/moderate LD. The study team will also complete a feasibility study to try out our treatment and get feedback from participants and their families. Information will also be collected about what treatment people are currently receiving, and test out some measures.

Who can participate
Adolescents (age 12 – 17 years old) with mild/moderate LDs, carers and family members

What does the study involve
A study of the treatment will be undertaken with up to 20 participants who will receive the treatment plus support as usual (SAU). Half the participants will take part in the treatment group, and half will receive SAU. Adolescents who choose to take part will be involved for a maximum of six months. The study will take place in special education settings in the UK. Parents and therapists will be interviewed about their experiences of taking part in the study. This will allow the team to understand the acceptability and experience of receiving the treatment

What are the possible benefits and risks of participating
While it is not known whether the treatment is likely to be beneficial for adolescents with mild to moderate LDs, there is a possibility that the treatment may result in an improvement in depressive symptoms. The aim of this study is to try out the treatment and seek feedback from

participants and their families to decide if a larger trial is needed. The study is not expected to cause any side effects or risks from participation. There is a chance a participant might feel some discomfort as a result of talking about how they feel or completing the questions, either during or after completion of the survey

Where is the study run from?
CEDAR (Centre for Educational Development Appraisal and Research), University of Warwick (UK)

When is the study starting and how long it is expected to run for
January 2020 to December 2023

Who is funding the study?
The University of Warwick, Monash Warwick Alliance (UK)

Who is the main contact
Andreas Paris (Beat-D@warwick.ac.uk)

Contact information

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Public

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Additional identifiers

Protocol serial number
1.4

Study information

Scientific Title
Behavioural activation for depression (BEAT-D) in adolescents with mild to moderate learning disabilities: A feasibility randomised controlled study of BEAT-D versus support as usual

Acronym
BEAT-D

Study objectives
The study will examine the effectiveness of the Behavioural Activation intervention that has been slightly adapted for adolescents with mild to moderate LD and depression (Beat-D). It furthermore aims to comprehensively evaluate the feasibility of a treatment trial for depression in adolescents with mild to moderate LD.
Hypotheses:
1. How acceptable is the intervention to the adolescents with LD, their parents/carers, and practitioners? Do practitioners feel the intervention processes were appropriate for adolescents and their parents/carers?
2. What is the rate of recruitment of adolescents with depression and mild-moderate LD to the study?
3. What is the retention rate of the recruited adolescents with LD six-months post-randomisation?
4. Which outcome measures (potential primary and secondary outcome measures) have greatest utility to detect meaningful change in the participants with LD, and their parents/carers?
5. Are there any adverse events associated with the intervention in this study population?
6. What are the reasons for non-completion of the intervention?
7. Is behavioural activation delivered with fidelity to the manual/model (according to the manual' s fidelity checklist), and what is the adherence of participants to the intervention?
8. What is support as usual (SAU) for adolescents with LD and depression?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/08/2022, University of Warwick, Humanities and Social Sciences Research Ethics Committee (Kirby Corner Road, Coventry, CV4 8UW, United Kingdom; +44 (0) 2476575732; hssrec@warwick.ac.uk), ref: HSSREC 192/22-23 AM01

Study design

Single-centre single-blind feasibility randomized controlled trial and qualitative investigation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of depression in adolescents with mild to moderate learning disability

Interventions
This trial will be a single-centre, single-blind, two-armed feasibility RCT (RCT) of Beat-D delivered in special education settings, compared to support as usual (SAU). Beat-D (treatment) is a structured, time-limited, manualised psychological therapy, developed to treat those with an intellectual disability and depressive symptoms. It is delivered over 8-12 (one-hour) sessions, held weekly or every two weeks, spanning approximately 4 months. The treatment can be delivered in person, or using video conferencing. Support as usual (SAU) includes any current interventions that any given school is already offering to their students.

Participants will be randomly assigned to either the Beat-D intervention plus support as usual or 'support as usual' (control) groups. For the control group, each setting's support in terms of depressive symptomatology will be offered as normal. Eligible participants will receive the Beat-D intervention including access to their schools 'support as usual'.

Following baseline testing, participants will be allocated to the intervention or control groups through a process of stratified random blocks. This ensures that intervention arms are balanced with respect to the number of participants in each group and in each school. It will additionally allow researchers to immediately notify participating schools of participant allocation, thus facilitating planning and minimising waiting times. The randomisation process will individually allocate participants to one of the groups. Randomisation will be completed by a member of the Research team who will remain independent from delivery and testing. All members of the research team will remain blinded to participant allocation throughout the trial, apart from the study's Research Assistant who will be offering supervision to the Beat-D implemented and will thus be aware of participant allocation. Any incidents of unblinding will be reported to the study' s Principal Investigator and this will be recorded in the study database and final evaluation report.
The study includes a process evaluation phase that will collect qualitative data from parents, adolescents, and practitioners. The interview questions will address the participants' views and experiences of the Beat-D intervention to develop a better understanding of the change process.

The trial's Primary Investigator is Professor Kylie Gray, based at the Centre for Educational Development Appraisal and Research (CEDAR), University of Warwick. Professor Gray has a background in psychology and is an international leading expert in mental health in children and adolescents with intellectual disabilities, with an established international track record.

The trial's Co-Investigator is Professor Richard Hastings, Head of Department at the Centre for Educational Development Appraisal and Research (CEDAR), University of Warwick, and is an international leading expert in mental health in children and adolescents with intellectual disabilities, with an established international track record.

The project's collaborator is Professor Andrew Jahoda from Glasgow University, a leading expert on Behavioural Activation for people with intellectual disabilities, and one of the developers of the Beat-It. He has more than 25 years of clinical experience, specialising in the mental health of people with intellectual disabilities, and has an extensive track record in clinical trial research.

The study's research assistant is Andreas Paris, based at the Centre for Educational Development Appraisal and Research (CEDAR), University of Warwick. Andreas has a background in Clinical Psychology and Applied Behavioural Analysis, is a PhD student at CEDAR currently in the final year of his studies and has been working with individuals with intellectual disabilities for more than 15 years.

Beat-D Practitioners consist of one Clinical Psychologist with more than 20 years of experience in working with people with intellectual disabilities; one qualified counsellor with experience in mental health first aid; one designated safeguarding lead and mental health coordinator with experience in delivering social and emotional support to students as well as training staff; one assistant headteacher with experience in offering emotional support to students; four Teaching Assistants and two Mentors with experience is providing mental health support (Mental Health First-Aiders) in 1:1 and small group formats, as well as providing support focusing on students' emotional well-being

The Beat-D digital training course (offered online via the NHS) was provided to all implementers. Contingent on its completion, implementers received a copy of the Beat-D adapted manual and a subsequent three-hour workshop was delivered for a discussion around its different components. A further three-hour workshop was delivered by one of the authors of the Beat-D intervention. Throughout the delivery of the intervention, weekly supervision sessions will be provided by the Research Assistant on an individual basis and according to the Beat-D manual and guidelines. Implementation fidelity will also be explored through the supervision sessions. The Beat-D implementers will be in close contact with the research team and will be able to ask for ad-hoc supervision meetings to discuss implementation challenges.

The intervention will be provided on an individual basis. Beat-D practitioners will be meeting with each participant and their support person individually, in an isolated room within each special education setting. An option for some sessions to be provided online (via Microsoft Teams) is also available to account for any potential covid-19 factors. Some sessions will be delivered face to face, whilst others will be delivered remotely and depending on each family's preference, thus offering flexibility in their delivery.

Beat-D sessions will be delivered in each participant's special education setting. An isolated and purposefully prepared room will be used for the sessions, including a laptop (for sharing some of the intervention resources or exercises) and any appropriate material (photos, cards, post boxes) that are needed for the intervention. Participating schools' Senior Leadership Teams are supportive of the trial and in agreement to provide the infrastructure and resources necessary to support implementation including timetabling time, IT support and availability, the motivation of Beat-D implementers to deliver the intervention, and the motivation and ability of the participants and their families to participate in the intervention. The implementation support is designed to monitor and address issues in relation to these assumptions, or within the family's home depending on what is convenient for them.

Intervention Type
Behavioural

Primary outcome(s)

Change in depressive symptoms measured using the self-reported Glasgow Depression Scale for People with Intellectual Disability (GDS) at baseline and 4 months post-randomisation

Key secondary outcome(s))
1. Change in depressive symptoms measured using the Glasgow Depression Scale for People with Intellectual Disability Carer Supplement (GDS-CS). The GDS-CS will be completed by parents /carers at baseline and at 4 months post-randomisation.
2. Behavioural activation and functional engagement with activities measured using the Behavioural Activation for Depression Scale: Short Form (BADS), adapted for adolescents with intellectual disability at baseline and at 4 months post-randomisation
3. Change in anxiety symptoms measured using the self-report Glasgow Anxiety Scale for People with Intellectual Disability (GAS) at baseline and 4 months post-randomisation
4. Change in anxiety symptoms measured using the Spence Children's Anxiety Scale (Spence; parent/carer report) at baseline and at 4 months post-randomisation.
5. Carer self-efficacy measured using the Emotional Difficulties Self-Efficacy Scale (EDSE). The EDSE will be completed by parents/carers at baseline and 4 months post-randomisation.
6. Change in quality of life measured using the EQ-5D-Y self-report version at baseline and 4 months post-randomisation
7. Change in quality of life measured using the EQ-5D-Y proxy (parent) version at baseline and 4 months post-randomisation

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Adolescents with a mild to moderate intellectual disability, defined by a score of 70 or below on standardised assessments and deficits in adaptive functioning, and/or administratively defined as having an intellectual disability, for example, enrolled in a special school for children /adolescents with mild intellectual disability
2. Adolescents with the capacity to assent/consent to take part in the research (and therefore would have sufficient communication and understanding to take part in the treatment)
3. Aged 12-17 years
4. Clinically significant unipolar depression as determined using information gathered through clinical interview (Anxiety Disorder Interview Schedule for Children)
5. Has support from a family member or paid carer who can support them throughout the treatment
6. If on medication for depressive symptoms, have been on a stable dose for 4 weeks prior to commencement of intervention

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit

12 years

Upper age limit
17 years

Sex
All

Key exclusion criteria
1. A suicide attempt in the past 6 months
2. Intensive inpatient treatment for mental illness in the past 6 months
3. Factors that prevent the young person from interacting with the supporter and therapist or retaining information from the therapy (for example, severe psychosis, degenerative condition)
4. Currently receiving any psychological therapy for a mental health problem
5. Insufficient English language skills to complete the measures or participate in the treatment.

Date of first enrolment
28/04/2023

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Warwick
Centre for Educational Development Appraisal and Research
New Education Building
Westwood Campus
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United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
University/education

Funder Name
University of Warwick

Alternative Name(s)
The University of Warwick, Warwick

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets (individual deidentified participant data, including data dictionaries) generated during and/or analysed during the current study are not expected to be made available as this is a feasibility study and participants have not consented to this. The datasets will be stored in a non-publicly available repository (University of Warwick). These data will be stored securely using a password-protected database on the University's secure server, for 10 years after the completion of the study and by the policy of the University of Warwick.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.4	28/03/2023	19/06/2023	No	Yes
Participant information sheet	version 1.4	28/03/2023	19/06/2023	No	Yes
Protocol file	version 1.4	16/03/2023	19/06/2023	No	No