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Behavioural interventions to treat anxiety in adults with autism and moderate to severe intellectual disabilities

Submission date
08/02/2021

Recruitment status
No longer recruiting

Registration date
11/02/2021

Overall study status
Completed

Last Edited
04/11/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study is about autistic adults who have moderate to severe intellectual disabilities and problems with anxiety. There are good therapies for anxiety, but these have not been tried with autistic adults with moderate to severe intellectual disabilities. In order to meet the needs of autistic adults with moderate to severe intellectual disabilities, these therapies need to change. This study has two aims: (1) the researchers will work with autistic adults, carers and family members, and professionals to adapt an existing therapy for anxiety disorders that was developed for autistic adults without intellectual disabilities, and (2) complete a study to try out the therapy and seek feedback from participants and their families. The researchers will also collect information about what sort of therapy people are currently getting, along with testing out some good ways to measure anxiety.

Who can participate?
Autistic adults (16 years and older) who have moderate to severe learning disabilities, have difficulties with anxiety and who have a carer or family member that can also take part in the study

What does the study involve?
The study has two parts. In the first part, the researchers will change their existing therapy together with autistic adults with intellectual disabilities, parents, carers and clinicians. This work will be led by an autistic person and members of the research team. The researchers will use something called action research methods and consensus development meetings to change the treatment and figure out the best way to measure anxiety. This means that they will repeatedly spend time with autistic adults with intellectual disabilities, parents, carers and clinicians, working together to make changes to therapy. At the same time, the researchers will do a national survey to find out what treatments or therapies people are getting now. In the second phase, the researchers will try out the therapy with 30 autistic adults with moderate to severe intellectual disabilities. They will also try to interview participants, carers and clinicians

about their experiences of doing our study. This will help them to work out whether people like the therapy, can use the measures of anxiety, and whether there is anything that they need to change to help people better.

What are the possible benefits and risks of participating?
While the researchers do not know whether the treatment is likely to be beneficial for autistic adults with moderate to severe learning disabilities, there is a possibility that the treatment may result in a reduction in anxiety. The aim of this study is to try out the therapy and seek feedback from participants and their families to decide if a larger trial is needed. Since the treatment involves exposure-based elements, there is a risk of temporary distress to the participants. This will be minimised by carefully planning the intervention. The study has been categorised as low risk.

Where is the study run from?
The University of Warwick with help from the National Autistic Society, Cardiff University, University of Glasgow, University of East Anglia and University of Bristol (UK)

When is the study starting and how long is it expected to run for?
January 2021 to May 2023

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
292402

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 48095, IRAS 292402

Study information

Scientific Title
Behavioural interventions to treat anxiety in adults with autism and moderate to severe intellectual disabilities (BEAMS-ID)

Acronym
BEAMS-ID

Study objectives
To examine the feasibility of conducting a definitive trial of the BEAMS-ID intervention to reduce anxiety in autistic adults with moderate to severe intellectual disabilities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/02/2021, Wales REC 6 (Meeting Room, Level 2, Wales National Pool, Sketty Lane, Swansea SA2 8QG, UK; +44 (0)7920 565 664, +44 (0)1874 615950; Wales.REC6@wales.nhs.uk), REC ref: 21/WA/0013

Study design
Non-randomized; Both; Design type: Treatment, Psychological & Behavioural, Cross-sectional

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety in adults with autism and moderate to severe intellectual disabilities

Interventions
Phase 1a (Intervention Adaptation)
The researchers will establish an Intervention Adaptation Group (IAG) comprised of 6 to 8 key stakeholders who will be representatives from their PPI partners, carers and family members, people with autism and/or intellectual disabilities, and clinicians, along with members of the research team. This group will be led by a person with autism who has a history of difficulties with anxiety together with members of the research team. The researchers will use co-production, and working together with stakeholders, they will use action research over a series of five meetings over 4 months to: (a) define the needs and problems that are to be addressed for people with autism and moderate to severe intellectual disabilities, (b) define the intervention objectives, with reference to the likely barriers, (c) adapt the existing manualised intervention, develop the fidelity checklist, and consider candidate primary and secondary outcome measures, including measures of social care, making a recommendation for use within Phase 2, (e) consider any additional methods to identify users of the intervention, clarification of how to measure outcomes, and further development of implementation protocols as needed, and (f) further consideration of any challenges or barriers to the evaluation plan, including likely to solutions, coupled with the decision as to how to measure outcomes.

A logic model will be developed, feedback will be sought at each meeting, and following reflection, subsequent refinements will be made to the manual and fidelity checklist by the research team which will be presented to the IAG at the next meeting leading to a final version. This will ensure that the approach is problem-focused and cyclical, allowing for repeated episodes of reflection and action during and between meetings (Leykum, Pugh, Lanham, Harmon, & McDaniel, 2009).

The researchers will make use of their existing intervention that was previously developed for the treatment of anxiety disorders amongst people with autism who do not have intellectual disabilities (Doble et al., 2017; Langdon et al., 2016; Langdon et al., 2013), and adapt it for use with those who have moderate to severe intellectual disabilities by focusing on the behavioural components. This is because many of the patients will have marked difficulties with verbal communication because they have moderate to severe intellectual disabilities and are not able to take part in traditional “talking” psychological therapies. The existing intervention was also developed with strong PPI input from adults with autism and their parents as part of a previously funded NIHR grant (RfPB: PB-PG-1208-18024). The previously developed modularised intervention (Langdon et al., 2016; Langdon et al., 2013) included the following modules: (a) psychoeducation about anxiety and autism, (b) cognitive-based interventions for anxiety, (c) social skills training, (d) relaxation training, (e) building fear hierarchies, (f) exposure therapy and systematic desensitisation, and (g) behavioural experiments.

During Phase 1 of this project, the researchers aim to focus upon the following modules: (a) relaxation training, (b) building fear hierarchies, (c) exposure therapy and systematic desensitisation, and (d) behavioural experiments for use with those who have both autism and moderate to severe intellectual disabilities. This intervention has previously been tested within a successful pilot trial with patients with autism who have anxiety disorders (Doble et al., 2017; Langdon et al., 2016; Langdon et al., 2013).

The outcomes from Phase 1 will be: (a) logic model, (b) an adapted intervention manual that can be tested within a feasibility study, (c) a fidelity checklist, and (d) candidate outcome measures for use within the feasibility study.

Phase 1b (TAU Survey)
Design. This will be an online survey of existing community-based services within the United Kingdom to characterise TAU. The survey will include questions that are informed by the Template for Intervention Description and Replication (TIDieR) checklist. The TIDieR checklist is used to provide a description of an intervention, including the use of any associated materials. Who, how and where an intervention is delivered is also described as well as the associated dose and modifications. The online survey will be delivered using Qualtrics.

Setting. All services for adults with autism and intellectual disabilities (and intellectual disabilities services providing support to those who also have autism) within the United Kingdom will be invited to take part in this study with an aim of recruiting at least 20 community teams; this includes NHS mental health and learning disabilities services, and the independent and charitable sector, including social enterprises. The researchers will make use of the Research in Developmental Neuropsychiatry (RADiANT) consortium of NHS providers and their existing network of twenty-nine NHS Trusts and private sector providers who participated in the mATCH study (RfPB: PB-PG-0214-33040) to help ensure successful recruitment. RADiANT is a consortium of NHS service providers which works in collaboration with academics in a number of universities. It seeks advice from service users, patients, families, charities, community leaders and a range of statutory bodies and organisations. RADiANT focuses on mental health and behavioural issues associated with five developmental conditions- intellectual disabilities, autism, attention deficit hyperactivity disorder, epilepsy and acquired brain injury. It is hosted by Hertfordshire Partnership University NHS Foundation Trust (HPFT), and multiple NHS Trusts are partners who have committed to actively supporting and taking part in research studies within the aforementioned five developmental conditions, including the lead NHS Trust for the current application, Coventry and Warwickshire Partnership NHS Trust. Worcestershire Health and Care NHS Trust are an additional partner in this project and a full member of RADiANT (https://radiant.nhs.uk).

Phase 2 (Feasibility Study)
Design. The researchers will make use of their existing treatment manual, which will have been adapted within Phase 1 of the current study, and complete a feasibility study to model the behavioural intervention and determine its acceptability and feasibility for stakeholders including service users, carers and clinicians who are delivering the intervention in according with the MRC Framework for developing and assessing the feasibility of complex interventions (Medical Research Council, 2006; O'Cathain et al., 2019). Further refinements to the manual are anticipated.

The researchers will include a single-arm non-randomised feasibility study of behavioural intervention plus TAU for the treatment of anxiety disorders amongst people with autism who have moderate to severe intellectual disabilities, and the use of qualitative and quantitative research methods to help address key components of feasibility. Recruitment will be open to

participants with autism and moderate to severe intellectual disabilities who have anxiety disorders within England. The researchers anticipate that family or paid carers will actively be involved in treatment in some capacity (extent and nature of involvement to be determined during Phase 1 of the research). Treatment will be delivered by trained therapists (e.g. nurses, assistant psychologists, allied health professionals) who work with people with autism and intellectual disabilities who have received additional training in the behavioural intervention. Participants will be assessed at three times points: (1) screening, (2) assessment within 4-weeks before the commencement of the intervention, and (3) assessment within 4-weeks of the completion of the intervention.

Setting, Context, and Study Pathway. The study will take place within NHS mental health and learning disabilities services in England (Coventry and Warwickshire Partnership NHS Trust; Worcestershire Health and Care NHS Trust, and other Trusts if necessary, to reach recruitment targets). The researchers will nest their project within the RADiANT consortium of NHS providers working in collaboration with a number of universities. The researchers will make use of this network to help facilitate the timely recruitment and participants into this study. For the current project, the researchers will use a multi-point recruitment strategy incorporating specialist community teams for people with autism or intellectual disabilities, advocacy and family support groups, mental health teams, the voluntary and charitable sector, special education settings that include young adults (some schools, special education colleges), self-referral, and through their PPI partners associated networks, specifically the National Autistic Society. The steps in the pathway for the feasibility study are as follows: (a) all participants who provide consent, or participants where a Consultee, in accordance with the Mental Capacity Act, 2005, has provided advice that the participant can be included, will be screened by research staff to ensure they meet the eligibility criteria for the study, (b) following baseline assessment, participants who meet eligibility criteria will be assigned to receive the behavioural intervention plus TAU, and the researchers aim to provide the treatment within existing services within their sites, (c) participants who receive the behavioural intervention plus TAU will have regular scheduled contact with a therapist, and the researchers have allocated between 8 to 12 individual sessions of the intervention per participant within their current timetable, (d) participants will then be assessed using the outcome measures within 4-weeks following the completion of the intervention, (e) a subsample of participants and their carers and clinicians will be asked to take part in semi-structured interviews following the intervention process to further ascertain acceptability and the experience of the intervention the study pathway, and procedures, consent, and associated factors to create a description of factors that promote or challenge the implementation of the intervention, recognising that those with severe intellectual disabilities may not be able to take part in these interviews, meaning that the researchers will have to rely on carers and family members, and (f) through the Study Steering Committee, make a recommendation to the funders for their consideration as to whether a future clinical trial is feasible. This decision will be made by the funder once the study results are available.

Intervention Type
Behavioural

Primary outcome(s)
1. Accrual rate recorded as the number of eligible participants who consent to participate in the study per month over 5 months
2. Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of follow up
3. Response rate recorded as the number of completed assessments per measure at baseline

and follow up (within 4 weeks of completion of the intervention)
4. Therapist adherence to the intervention manual measured with fidelity ratings after each treatment session
5. Acceptability of the intervention and associated study procedures to carers and/or participants assessed using semi-structured interviews after the intervention is complete

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/05/2023

Eligibility

Key inclusion criteria
Phase 2:
1. Diagnosis of ASD confirmed by case note review
2. Existing diagnosis of moderate to severe intellectual disabilities, confirmed at screening
3. Existing diagnosis of an anxiety disorder confirmed or initially made at screening
4. Carer or family member able to support participation in the intervention (assuming this is one of the key adaptations incorporated)
5. For those who do not have capacity, permission for inclusion in accordance with the Mental Capacity Act (2005)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
28

Key exclusion criteria
Phase 2:
1. Currently receiving another psychological therapy for a mental health problem

Date of first enrolment
01/09/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Coventry and Warwickshire Partnership NHS Trust
Wayside House
Wilsons Lane
Coventry
United Kingdom
CV6 6NY

Study participating centre
Worcestershire Health and Care NHS Trust
Unit 2 Kings Court
Charles Hastings Way
Worcester
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WR5 1JR

Sponsor information

Organisation
Coventry and Warwickshire Partnership NHS Trust

ROR
https://ror.org/01gh80505

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR129804

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (University of Warwick and NHS servers). It may be placed in the public domain as required by either the funder or a peer review journal in an anonymised format.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2024	07/10/2024	Yes	No
Results article		31/10/2024	04/11/2024	Yes	No
HRA research summary			26/07/2023	No	No