Behavioural interventions to treat anxiety in adults with autism and moderate to severe intellectual disabilities: the BEAMS-ID feasibility study

Peter E Langdon,[1,2,3*] Magdalena M Apanasionok,[1] Emma Scripps,[1] Karen Bunning,[4] Malwina Filipczuk,[1] David Gillespie,[5] Richard P Hastings,[1] Andrew Jahoda,[6] Rachel McNamara,[5] Dheeraj Rai[7] and Kylie M Gray[1]

[1]Centre for Research in Intellectual and Developmental Disabilities (CIDD), University of Warwick, Coventry, UK
[2]Brooklands Hospital, Coventry and Warwickshire Partnership NHS Trust, Birmingham, UK
[3]Herefordshire and Worcestershire Health and Care NHS Trust, Worcester, UK
[4]School of Health Sciences, University of East Anglia, Norwich, UK
[5]Centre for Trials Research, College of Biomedical and Life Sciences, Cardiff University, Cardiff, UK
[6]Psychological Medicine, University of Glasgow, Glasgow, UK
[7]Centre for Academic Mental Health, Population Health Sciences, Bristol Medical School, Bristol, UK and National Institute for Health and Care Research - Bristol Biomedical Research Centre, Bristol, UK

[*]Corresponding author Peter.Langdon@warwick.ac.uk

Published October 2024
DOI: 10.3310/MWTQ5721

Scientific summary

Behavioural interventions to treat anxiety in adults with autism and moderate to severe intellectual disabilities: the BEAMS-ID feasibility study

Health Technology Assessment 2024; Vol. 28: No. 72
DOI: 10.3310/MWTQ5721

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

A large number of people with autism and learning disabilities have problems with anxiety. There is evidence that talking psychological therapies are an effective intervention for anxiety, but many of these interventions have not been tested with people who have both autism and learning disabilities. These interventions need to be adapted before they can be used with this population because of their difficulties with verbal communication, restricted and repetitive behaviours, and behaviours that challenge.

Objectives

We aimed to (1) work with our patient and public involvement (PPI) partners to adapt an existing intervention manual for anxiety disorders for use with autistic adults with moderate to severe learning disabilities and (2) complete a feasibility study to try out our intervention and seek feedback from participants, families and therapists. In addition, we collected information about what interventions people are currently receiving to characterise treatment-as-usual (TAU) and test out some outcome measures.

Phase 1a: adaptation

Our objectives were:

- to establish an intervention adaptation group (IAG) and, during a series of meetings, adapt an existing intervention to treat anxiety symptoms in autistic adults who have moderate to severe learning disabilities
- to develop an intervention fidelity checklist that can be used alongside the intervention manual
- to appraise and consider several candidate outcome measures of anxiety-related symptoms and make a recommendation for use within Phase 2
- to develop an intervention logic model.

Phase 1b: description of treatment-as-usual

Our objective was to complete a national survey of existing interventions for adults with anxiety disorders who have moderate to severe learning disabilities. The survey was constructed using items adapted from the Template for Intervention Description and Replication (TIDieR) checklist to ensure a clear description of TAU. This phase ran concurrently with Phase 1a and Phase 2. This allowed for the capture of data to allow for the characterisation of TAU, including any specific interventions offered. We invited participation from all community-based services for people with autism and/or learning disabilities across the United Kingdom.

Phase 2: feasibility study

Our objectives were:

- to model the manualised intervention to determine the acceptability and feasibility for all stakeholders, including autistic adults with moderate to severe learning disabilities, carers, and clinicians, and adjust as required
- to judge the appropriateness, including response rates, of our measures of anxiety-related symptomatology for use within a larger study
- to examine the feasibility and acceptability of consent and associated processes in the context of the Mental Capacity Act, 2005 and
- to describe factors that facilitate or challenge the implementation of our intervention.

Methods

Study design

Phase 1a (intervention adaptation)
An IAG was established, and during a series of five meetings an existing intervention used to treat anxiety symptoms in adults with autism was adapted for use with people who also have moderate to severe learning disabilities.

Phase 1b (treatment-as-usual survey)
A national survey of existing community-based interventions for adults with anxiety disorders who have moderate to severe learning disabilities was conducted. The TIDieR checklist was used to inform the development of our survey questions to ensure a clear description of TAU.

Phase 2 (feasibility study)
This study was a single-arm, non-randomised, feasibility study, with autistic people who have moderate to severe learning disabilities. Participants and their carers received the adapted intervention developed in Phase 1a, in conjunction with any other intervention they were receiving. Both qualitative and quantitative research methods were used to address key components of feasibility.

Setting and participants

Phase 1a (intervention adaptation)
The IAG included eight key stakeholders who were representatives from our PPI partners, carers and family members, people with autism and/or learning disabilities, and clinicians, along with members of the research team.

Phase 1b (treatment-as-usual survey)
All services for adults with autism and learning disabilities (and learning disabilities services providing support to those who also have autism); this included NHS mental health and learning disabilities services, and the independent and charitable sector, including social enterprises within the UK. The total of number of survey responses was $N = 76$.

Phase 2 (feasibility study)
This single-arm non-randomised feasibility study took place within the NHS health services in England. We aimed to recruit up to 30 participants from the following NHS services across England: Coventry and Warwickshire Partnership NHS Trust, Herefordshire and Worcestershire Health and Care NHS Trust, Leicestershire Partnership NHS Trust, Solent NHS Trust, and Mersey Care NHS Foundation Trust. A total of 28 participants were enrolled, and 18% were from a non-white background, while 53.6% had severe learning disabilities.

Intervention
Participants within this study received up to 12 sessions of individual and manualised behaviour therapy, each lasting between 60 and 90 minutes with support from carers. The intervention was exposure therapy and was adapted for use with this population and manualised.

Assessment of feasibility of delivery and acceptability of the intervention
We examined the views of participants, parents/carers, and therapists to address (1) intervention accessibility and acceptability, (2) helpful/unhelpful aspects, including barriers to change, (3) the value of our adaptations, (4) relationships with therapists, (5) acceptability of consent processes, (6) acceptability of outcome measures and (7) acceptability of randomisation within a future trial. We completed semistructured interviews with seven parents/carers and eight therapists. Interviews using Talking Mats®

were also completed with five autistic adults with moderate to severe learning disabilities who received the intervention to explore their experience of the intervention and their outcomes.

Collection of outcome data

Phase 1a (intervention adaptation)

We held five meetings with the IAG and made use of consensus methods following discussion to make decisions about intervention adaptations, the content of our fidelity checklist, and our selection of candidate outcome measures.

Phase 1b

Questions for the TAU survey included the type of support/intervention, who, how and where it is delivered, along with dose and any modifications adapted from the TIDieR checklist. The online survey was delivered using Qualtrics (Qualtrics, Provo, UT, USA) or as a telephone interview. This phase lasted 14 months, running concurrently with Phase 1a and Phase 2.

Phase 2

Participants were enrolled in the study for approximately 6 months. Participants were assessed at three times points: (1) screening for eligibility, (2) baseline assessment within 4 weeks before commencement of the intervention and (3) within 4 weeks following the completion of the intervention. Eligibility assessments included measures of adaptive behaviour, autistic symptoms, and symptoms of anxiety disorders. Our outcome assessments included measures of anxiety, emotional and behavioural problems, behaviours that challenge, and engagement within the community.

Patient and public involvement and engagement

Patient and public involvement and engagement was firmly and genuinely an integral part of our methodology. We partnered with the National Autistic Society (NAS), who worked collaboratively with us to adapt our intervention, along with carers, autistic people, and clinicians. They helped prepare study documentation, recruit participants, and collaboratively disseminate information about this study. Autistic people, carers and clinicians were members of the Study Steering Group and shared oversight of our project progress. Our IAG was formed of carers, autistic people and clinicians who are experienced with working with autistic people with moderate to severe learning disabilities.

Results

Phase 1a

We successfully adapted the intervention, developed a logic model and intervention fidelity checklist, and chose outcome measures collaboratively with the IAG.

Phase 1b

Seventy-eight health and social care professionals responded to our survey and 76 provided data about TAU. The majority worked for the NHS. The most frequently offered anxiety intervention was described as psychological interventions, but exposure therapy was said to be infrequently provided. Respondents also described the adaptations they made to psychological interventions for use with adults with learning disability. These adaptations included: providing communication support, adjusting session content or activities, adjusting the timing, duration, frequency and number of sessions, involving carers within the intervention, or making changes to a person's environment. The next most offered intervention was medication. Respondents also described less frequently offered interventions including speech and language therapy, occupational therapy, sensory strategies, communication training, increased staff support, touch therapy and music therapy. Four respondents indicated that physical health support was also offered as an intervention for anxiety.

Phase 2

(1) Acceptability and feasibility of the intervention: the intervention was feasible to deliver and acceptable to autistic adults with moderate to severe learning disabilities, carers and therapists. Carers and therapists made some suggestions for revisions to the intervention which focused upon reinforcing the importance of consistent carer attendance during the intervention, and the inclusion of further guidance about ensuring that the intervention is person-centred by adapting the timing, frequency, and number of intervention sessions, making use of bespoke or personalised intervention materials, further guidance about delivering relaxation, and strengthening information about the nature and degree of adaptations that can be made by therapists. All suggestions were considered feasible to implement. (2) Appropriateness of outcome measures: percentage of missing data across the outcome measures was low and ranged from 0% to 2.38% and carers completed 100% of all outcome measures. However, carers commented that some of the items were repetitive, and some said they had difficulties answering some questions. However, others said they were acceptable and easy to complete. (3) Feasibility and acceptability of consent and associated processes: carers indicated that the study participant information sheets and associated processes were clear, helpful, and straightforward. Seventy-nine per cent of autistic participants with moderate to severe learning disabilities were judged to lack capacity to make a decision about taking part in this study. On average, it took nearly 5 weeks to seek consultee advice and enrol these participants. (4) Factors that facilitate or challenge the implementation of our intervention: autistic participants with moderate to severe learning disabilities indicated that they liked coming to the intervention sessions and the information booklets that were used during the intervention. They also indicated that they liked some core aspects of the intervention (e.g. fear ladders, relaxation, visual schedules). Carers indicated that the intervention facilitators were adaptations to meet individual needs, the experience of attending therapy and a positive therapeutic relationship with the therapist. Therapists reported that the intervention facilitators were the inclusion of a clear structure, therapist understanding of people with learning disabilities, carer understanding and engagement, effectively meeting carer need, using adapted materials, high-quality training in the intervention, access to supervision, specific aspects of the intervention (e.g. preference assessments, reinforcement, carer-only sessions, positive therapeutic relationship), and intervention flexibility. Carers reported that the key barriers were not directly attributable to the intervention (e.g. illness, holidays, or lack of staff), or were related to challenges accessing intervention material to be used during exposure, or difficulties with using the intervention with some individuals due to additional complexity, the quantity of information provided, and the time commitment required. Therapists suggested that the barriers were challenges adapting relaxation techniques, difficulties with participant engagement and motivation, different carers attending intervention sessions, difficulties with some intervention components with some individuals, quantity of information, and behaviours that challenge.

Conclusions

The BEAMS-ID intervention was judged to be feasible to deliver and acceptable to autistic adults with moderate to severe learning disabilities, carers and therapists. Carers and therapists made some helpful suggestions for revisions which can be easily incorporated into the existing manualised intervention with minor revision. This study took place during the COVID-19 pandemic and the recruitment of participants during Phase 2 was at a lower rate than anticipated, considering that the study was funded prior to the onset of the pandemic. Nevertheless, 93% of the planned sample size was successfully recruited, and it was noted that the accrual rate improved during the summer of 2022 and was higher within sites who joined towards the end of the study period. The participant attrition rate was low and not attributable to the intervention or study processes. This study benefited from genuine patient and public involvement and engagement during the adaptation of the intervention, development of fidelity checklist and logic model, choice of outcome measures and study management. Following minor revisions to the intervention, and further consideration of outcome measures based upon carer feedback, the BEAMS-ID intervention should be tested in a randomised trial.

Protocol

The study protocol is available from https://fundingawards.nihr.ac.uk/award/NIHR129804.

Study registration

This study is registered as ISRCTN12637590.

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR award ref: NIHR129804) and is published in full in *Health Technology Assessment*; Vol. 28, No. 72. See the NIHR Funding and Awards website for further award information.

Health Technology Assessment

ISSN 2046-4924 (Online)

Impact factor: 3.6

A list of Journals Library editors can be found on the NIHR Journals Library website

Launched in 1997, *Health Technology Assessment* (HTA) has an impact factor of 3.6 and is ranked 32nd (out of 105 titles) in the 'Health Care Sciences & Services' category of the Clarivate 2022 Journal Citation Reports (Science Edition). It is also indexed by MEDLINE, CINAHL (EBSCO Information Services, Ipswich, MA, USA), EMBASE (Elsevier, Amsterdam, the Netherlands), NCBI Bookshelf, DOAJ, Europe PMC, the Cochrane Library (John Wiley & Sons, Inc., Hoboken, NJ, USA), INAHTA, the British Nursing Index (ProQuest LLC, Ann Arbor, MI, USA), Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and the Science Citation Index Expanded™ (Clarivate™, Philadelphia, PA, USA).

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta.

Criteria for inclusion in the *Health Technology Assessment* journal
Manuscripts are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

This article

The research reported in this issue of the journal was funded by the HTA programme as award number NIHR129804. The contractual start date was in January 2021. The draft manuscript began editorial review in August 2023 and was accepted for publication in February 2024. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

This article presents independent research funded by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care.

This article was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).