











REVIEW

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

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## Abstract

**Background:** The aim of this feasibility study was to adapt and model a behavioural intervention for anxiety with autistic adults with moderate to severe intellectual disabilities.

**Method:** Twenty-eight autistic adults with moderate or severe intellectual disabilities, 37 carers, and 40 therapists took part in this single-group non-randomised feasibility study designed to test intervention feasibility and acceptability, outcome measures, and research processes.

**Results:** The intervention was judged as feasible and acceptable by autistic adults with intellectual disabilities, carers, and therapists. Minor intervention revisions were suggested. Carers completed 100% of outcome measures and the missing data rate was low. Complying with legislation governing the inclusion of participants who lack

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capacity to decide whether they wanted to take part in this study led to an average 5-week enrolment delay.

**Conclusion:** The intervention and associated study processes were judged to be feasible and acceptable and should now be tested within a larger randomised trial.

#### KEYWORDS

anxiety disorders, autism, exposure therapy, feasibility study, learning disabilities, psychological treatment

## 1 | INTRODUCTION

Robust research demonstrates that autistic people are at increased risk of developing mental health problems, including anxiety disorders (Baird et al., 2006; Hofvander et al., 2009; Joshi et al., 2013; Simonoff et al., 2008), and that people with intellectual disabilities are also at an elevated risk of developing mental health problems (Cooper et al., 2007; Einfeld et al., 2011; Einfeld & Tonge, 1996). Those with both autism and intellectual disabilities have an even further increased chance of having mental health problems (Bakken et al., 2010; Dunn et al., 2020; La Malfa et al., 2007; Morgan et al., 2018; Peña-Salazar et al., 2022). Considering this increased risk, especially for those with moderate to severe intellectual disabilities (Hove & Havik, 2010), it is problematic that the evidence supporting the use of psychological therapies with this group is sparse (Tapp et al., 2023; Vereenooghe et al., 2018; Vereenooghe & Langdon, 2013).

Adults with intellectual disabilities frequently have communication and social skills difficulties which become more severe as the level of intellectual disability increases (Smith et al., 2020) such that 'talking' psychological therapies require substantial adaptation if they are to be used successfully. These adaptations can include simplification of communication and materials, attempting to tailor content to developmental level, the inclusion of carers within therapy, and using more directive methods (Jahoda et al., 2024; Surley & Dagnan, 2019), amongst others. However, many of the techniques used in cognitive therapy for anxiety are likely too complex for use with adults with moderate to severe intellectual disabilities, even with adaptation, and there is evidence that these methods may not improve outcomes (Hayes, 2004; Longmore & Worrell, 2007; Sweet & Loizeaux, 1991). This includes outcomes following intervention for anxiety disorders (Borkovec & Costello, 1993; Emmelkamp et al., 1985; Mattick et al., 1989; Vogel et al., 2004).

A focus upon behavioural therapy for anxiety, while reducing or excluding cognitive components, may be advantageous for those with moderate to severe intellectual disabilities as this would reduce the need for verbal communication and the teaching of complex abstract concepts. There is some limited evidence to support this conclusion. Rosen et al. (2016) completed a systematic review that included seven studies using single case experimental designs with autistic people with moderate or severe intellectual disabilities. A variety of behavioural interventions with adaptations were used, such as the inclusion of parents or carers within therapy. The interventions tested

included: systematic desensitisation and the use of fear hierarchies (Koegel et al., 2004; Love et al., 1990; Luscre & Center, 1996), video modelling and mastery techniques (Luscre & Center, 1996), stimulus fading (Shabani & Fisher, 2006), positive reinforcement to support behaviour change (Luscre & Center, 1996; Schmidt et al., 2013; Shabani & Fisher, 2006; Wolff & Symons, 2013), and exposure techniques (Allison et al., 2013; Schmidt et al., 2013; Shabani & Fisher, 2006; Wolff & Symons, 2013). Rosen et al. (2016) indicated that behavioural interventions had the potential to reduce anxiety, but no randomised controlled trials were found. Therefore, modelling and feasibility studies are needed to inform the decision as to whether to proceed to larger randomised controlled trials (RCTs).

We established an Intervention Adaptation Group (IAG) and collaboratively adapted an existing psychological intervention, developed a programme theory and logic model, fidelity checklist, and therapist training package for use with autistic adults with moderate to severe intellectual disabilities prior to completing a single-group feasibility study. The objectives of the single-group feasibility study were: (1) to model the manualised intervention to determine the acceptability and feasibility for all stakeholders, including autistic adults with moderate to severe intellectual disabilities, carers, and clinicians, and adjust as required; (2) to judge the appropriateness, including response rates, of measures of anxiety-related symptomatology for potential use within a later study; (3) to examine the feasibility and acceptability of consent and associated processes; and (4) to describe factors that facilitate or challenge the implementation of the intervention. As this was a feasibility study, we also aimed to estimate key parameters including: (1) recruitment rate; (2) protocol adherence; and (3) outcome data to inform the decision as to whether a future clinical trial was feasible.

## 2 | METHOD

### 2.1 | Intervention adaptation

Prior to our feasibility study, and to adapt the intervention to better meet the needs of autistic adults with intellectual disabilities, an Intervention Adaptation Group (IAG) was established comprised of an autistic collaborator (RS) who chaired the meetings, a representative from the National Autistic Society, a sibling of an autistic person with severe intellectual disability, and five clinicians with experience of

working with autistic adults with intellectual disabilities some of whom had additional caring roles. Members of the research team also attended the IAG and had backgrounds in clinical psychology or speech and language therapy. We made use of methods drawn from action research (Greenwood & Levin, 2006) by focusing upon collaboration and reflection with practitioners and carers to improve the intervention, logic model, fidelity checklist, and make decisions about candidate outcome measures.

Prior to each IAG meeting, documents were circulated to group members. An agenda was set, and discussion and reflection encouraged amongst group members until consensus was reached for each decision. Any disagreements were discussed until the group reached consensus and a recommendation was made. Feedback and reflections were sought from group members about changes and refinements to the manual, logic model, materials, and the fidelity checklist. These changes were then presented to the IAG at the next meeting to ensure that they were enacted as previously recommended and to encourage further reflection. All recommendations were recorded in an Excel spreadsheet which was shared with the IAG for approval. Feedback was also sought on a range of candidate outcome measures, and several candidate measures were presented to the IAG which included a review of the items, psychometric properties, and likely ease of use. The IAG were invited to make the final recommendation as to which outcome measures should be used. The IAG had five meetings that lasted at least 2 h over a 2-month period. Meetings were scheduled every 2 weeks, except for the last two meetings which were 1 week apart. All meetings were online and were recorded.

To develop the initial draft of the intervention manual, we used an existing intervention for anxiety symptoms in autistic adults without intellectual disabilities (Doble et al., 2017; Langdon et al., 2013, 2016). There are number of potential challenges that were considered when delivering psychological interventions for anxiety to autistic adults with moderate to severe intellectual disabilities including different ways of communicating, behaviours that challenge, problems with recognising mental health issues, restricted or repetitive behaviours, and sensory over- or under-responsivity and/or avoidance of some types of sensory input. Keeping these challenges in mind, the adaptations developed collaboratively with the IAG were: (1) involving carers or family members in the delivery of intervention; (2) using methods that are less reliant upon verbal communication, including graded exposure coupled with relaxation and reinforcement; (3) using a person-centred approach to ensure the therapist understood the needs of the person as an individual and tailored delivery to needs; (4) performing a preference and functional assessment, and a thorough exploration of the nature of anxiety, avoidance, accommodation, and sensory issues to develop a psychological formulation; and (5) using adapted ways of communicating such as visual schedules and easier-to-read materials.

The subsequent manualised intervention consisted of 12 sessions that were up to 90 minutes long usually delivered on weekly basis. A description of each of the 12 sessions is found in Table 1, while the logic model can be found within Figure S1. An example of the

intervention fidelity checklist, which was adapted from that used by Jahoda et al. (2018), can be found within Table S1. A description of the content of the therapist training package is found within Table S2. The IAG recommended the chosen outcome measures and eligibility screening measures used within the feasibility study.

## 2.2 | Feasibility study

### 2.2.1 | Participants

#### *Autistic adults with moderate to severe intellectual disabilities*

Recruitment was open to participants with autism and moderate to severe intellectual disabilities who had anxiety disorders and their carers within five NHS Trusts within England. We used a multi-point recruitment strategy, which primarily involved screening existing case-loads of NHS community intellectual disabilities teams for potentially eligible participants and sharing information about the study with those who were thought likely eligible and their carers.

Participants were eligible to take part in the study if they met all the following inclusion criteria: (1) aged over 16 years old; (2) diagnosis of autism confirmed by case note review; (3) existing diagnosis of moderate to severe intellectual disabilities, confirmed at screening; (4) existing diagnosis of an anxiety disorder confirmed or initially made at screening; (5) carer or family member able to support participation in the intervention; and (6) for those who do not have capacity, successful identification of a personal or nominated consultee who provided advice indicating that the person should take part in the project and would likely wish to take part in our study if they had capacity in accordance with the national legal framework in place (Mental Capacity Act 2005). Our single exclusion criterion was: (1) currently receiving another psychological therapy for a mental health problem.

#### *Sample size*

As this was a feasibility study, the purpose was to recruit enough participants to provide estimates of key parameters for a future larger study and not to power the study to detect statistically significant change. An a priori power calculation was not conducted (Arain et al., 2010). We aimed to recruit 30 autistic adults with moderate to severe intellectual disabilities to provide reasonable precision around our estimates of parameters; for example, if 80% of participants complete the intervention, a sample size of 30 participants would allow us to calculate a 95% confidence interval around this estimate to within  $\pm 14.5\%$  (i.e., from 65.5% to 94.5%).

Thirty-four autistic adults with moderate to severe intellectual disabilities were referred for eligibility screening. Five of these were excluded as they declined to participate, did not have a diagnosis of autism, or did not respond to our attempts to contact them. Twenty-nine were assessed for eligibility and one person was excluded due to not having moderate to severe intellectual disabilities.

Twenty-eight (82%) participants who were referred for eligibility screening received the intervention alongside treatment-as-usual (TAU), Figure 1. Their average age was,  $M = 26.79$ ,  $SD = 8.39$ , 95%

**TABLE 1** Structure of the BEAMS-ID intervention.

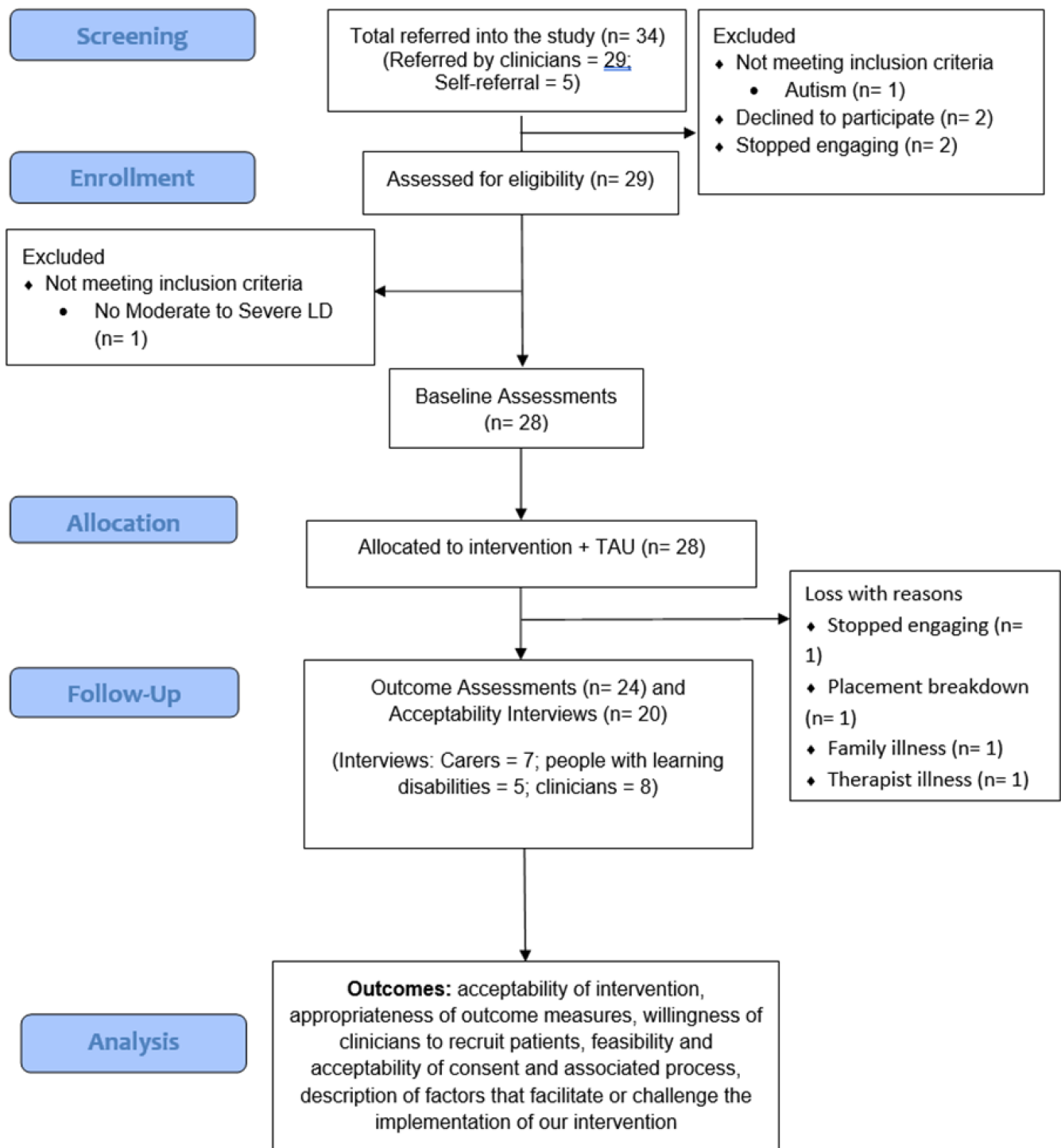
Session	Main focus	Key activities/focus points
1	Psychoeducation on behaviour change CARER ONLY SESSION	<ul style="list-style-type: none"> <li>• Provide an overview of the structure of the intervention and explain the role of the carer.</li> <li>• Build rapport with the carer.</li> <li>• Develop understanding of person's anxiety and potential maintaining factors.</li> <li>• Provide psychoeducation on principles of behaviour and behaviour change.</li> <li>• Provide further psychoeducation on anxiety disorders and maintaining factors.</li> <li>• Introduce ABC chart.</li> </ul>
2	Building rapport	<ul style="list-style-type: none"> <li>• Provide an overview of the structure of the intervention and explain the role of the carer.</li> <li>• Build rapport with the person (autistic adult with moderate to severe learning disabilities participating in the BEAMS-ID intervention).</li> <li>• Conduct a Preference Assessment.</li> <li>• Explore expectations of the person and their carer.</li> </ul>
3	Psychoeducation on anxiety, autism, and learning disability	<ul style="list-style-type: none"> <li>• Provide psychoeducation on autism and learning disability.</li> <li>• Provide psychoeducation on anxiety.</li> <li>• Develop further understanding of person's traits and anxiety.</li> <li>• Key vocabulary training for the person.</li> </ul>
4	Relaxation training	<ul style="list-style-type: none"> <li>• Introduce relaxation techniques.</li> <li>• Practise relaxation techniques.</li> </ul>
5	Design of individualised intervention plan CARER ONLY SESSION	<ul style="list-style-type: none"> <li>• Analyse ABC charts.</li> <li>• Describe the person's key behaviours, areas of strength and challenges, and sources of motivation.</li> <li>• Design individualised Intervention Plan including green, amber, and red strategies.</li> </ul>
6	Building fear ladders CARER ONLY SESSION	<ul style="list-style-type: none"> <li>• Provide psychoeducation on Fear Ladders and their role in Graded Exposure.</li> <li>• Explore anxiety provoking situations.</li> <li>• Come up with a Fear Ladder.</li> <li>• Explore potential barriers to Graded Exposure.</li> <li>• Discuss generalisation.</li> </ul>
7	Graded exposure	<ul style="list-style-type: none"> <li>• Explain rationale of Graded Exposure (Systematic Desensitisation).</li> <li>• Explain how relaxation strategies can be used when exposed to anxiety provoking situations.</li> </ul>
8	Graded exposure	<ul style="list-style-type: none"> <li>• Continue with Graded Exposure.</li> </ul>
9	Graded exposure	<ul style="list-style-type: none"> <li>• Continue with Graded Exposure.</li> </ul>
10	Graded exposure	<ul style="list-style-type: none"> <li>• Continue with Graded Exposure.</li> </ul>
11	Wrap up	<ul style="list-style-type: none"> <li>• Continue with Graded Exposure.</li> <li>• Prepare for end of intervention.</li> </ul>
12	Wrap up	<ul style="list-style-type: none"> <li>• Summarise the intervention.</li> <li>• Encourage reflection on the initial intervention goals.</li> <li>• Review individualised Intervention Plan and set maintenance and generalisation goals.</li> </ul>

CI [23.54, 30.05], and 64.3%,  $n = 18$ , were male. Just under 79% were white British, and 18% were from other ethnic backgrounds. Just under 54% had severe intellectual disabilities; the remainder had moderate intellectual disabilities. The majority (71.4%) lived at home with their family, Table 2. Twenty-two participants (79%) were judged to lack capacity to decide whether they wanted to take part in our study in accordance with the Mental Capacity Act, 2005, in England and Wales. In addition to a diagnosis of autism and intellectual disabilities, participants also had diagnoses of attention-deficit-hyperactivity disorder,  $n = 1$ , Tourette syndrome,  $n = 1$ , Down syndrome,  $n = 1$ , microcephaly,  $n = 1$ , and other conditions such as hypothyroidism,  $n = 1$ , poor peripheral vision,  $n = 1$ , and skin conditions,  $n = 2$ . The majority (71.4%) were taking medication with the most frequently prescribed for diabetes and thyroid problems. The most frequently prescribed psychotropic medications were antidepressants,

following by antipsychotics, Table 2. Four participants were lost to follow-up. There were four different reasons for this loss associated with each individual participant: (1) did not respond to our attempts to make contact; (2) placement breakdown; (3) illness within their family; and (4) therapist illness leading to participant disengagement, Figure 1. This was an attrition rate of 14% over time. Five participants took part in our post-intervention interviews using Talking Mats®.

#### Carers

Thirty-seven carers (19 family members, 18 paid carers) also took part in our study and supported autistic participants with moderate to severe intellectual disabilities. We recruited more carers than the number of autistic participants with moderate to severe intellectual disabilities because we included paid carers. Different carers supported participants when attending different intervention sessions.



**FIGURE 1** Participant flow diagram.

Following the completion of the intervention, seven carers took part in post-intervention interviews.

#### Therapists

Forty therapists were also recruited and trained to deliver the intervention across five NHS Trusts. Seven therapists (18%) did not complete their mandatory Good Clinical Practice (GCP) training and therefore could not move forward to act as a therapist during this study even though they completed their intervention training. A

further seven (18%) also did not work as a therapist during the duration of this study. In total, 14 (35%) of those trained did not deliver the intervention. Therapists who did not deliver the intervention most frequently cited that they were too busy with their existing workload to take part in research or did not respond to further attempts to contact them even though they had volunteered to work as a therapist in the research study. One therapist was re-deployed into another role and was not able to work as a therapist. Twenty-six therapists delivered the intervention to participants. Most therapists were registered

**TABLE 2** Participant demographics.

	N	Percent
<b>Ethnicity</b>		
White—British	22	78.6
Mixed—White and Asian	2	7.1
Asian or Asian British—Pakistani	1	3.6
Asian or Asian British—Indian	1	3.6
Black or Black British—African	1	3.6
Prefer not to say	1	3.6
<b>Participant's primary place of residence</b>		
Family home	20	71.4
Supported living	5	17.9
Residential placement	2	7.1
<b>Degree of learning disability</b>		
Moderate	13	46.4
Severe	15	53.6
<b>Medication</b>		
Antihistamines	10	35.7
Antidepressants	10	35.7
Antipsychotics	8	28.6
Constipation/stomach medication	7	25
Benzodiazepines	6	21.4
Antiepileptic	5	17.9
Vitamins/supplements	5	17.9
Contraceptive pill	4	14.3
Painkillers	4	14.3
Melatonin/sleeping tablet	4	14.3
Proton pump inhibitor	4	14.3
Other (including antidiabetic and thyroid treatments)	12	42.9

psychologists (37%), followed by assistant psychologists (23%), nurses (20%), occupational therapists (7%), psychiatrists (7%), trainee clinical psychologists (3%), and behaviour specialists (3%). Eight therapists (31%) took part in post-intervention semi-structured interviews. All had experience of working with people with intellectual disabilities.

### 2.2.2 | Design and procedure

All participants received the intervention alongside TAU within this single group non-randomised feasibility study. Both quantitative and qualitative research methods were used to address study aims. Participants were in the study for approximately 6-months, and all were assessed at three time points: (1) eligibility screening; (2) baseline assessment within 4 weeks before commencement of the intervention; and (3) follow up assessment within 4 weeks of completing of the intervention.

Additional components of feasibility (e.g., acceptability) were assessed using recorded semi-structured interviews after follow-up assessments were complete with carers and therapists. These recordings were transcribed. This information was integrated to create a

description of factors that promote or challenge the implementation of the intervention with reference to the logic model and research procedures. We also completed interviews with autistic participants with intellectual disabilities to explore their experience of the intervention and taking part in our research study using Talking Mats® which is a structured approach to help people with communication difficulties to organise and express their views. Talking Mats® have been used previously with this population (Bradshaw et al., 2018). Members of the research team were trained in using the Talking Mats®. This interview included 13 questions, all represented by assigned visuals. Participants were asked to tell us how they felt about various parts of the intervention by putting corresponding visuals in one of the three categories—like, unsure, and do not like. After the interview, the interviewer took a photograph of the completed mat, but the process was not videoed. The Effectiveness Framework which guides the interviewer's reflections on the Talking Mats® interview process was then completed (Murphy & Cameron, 2008).

#### *Eligibility screening*

Eligibility screening involved initially reviewing medical records to check inclusion criteria were met and the exclusion criterion were not met; this was completed by NHS staff. For those who wished to take part in the study, the following measures were also completed together with a carer and administered by a member of the research team: (1) a diagnostic checklist for anxiety based on the Diagnostic Manual—Intellectual Disability-2 (National Association for the Dually Diagnosed, 2016) which was developed for this study by the research team and administered as a semi-structured interview to confirm whether symptoms associated with one or more anxiety disorders were present, (2) the Vineland Adaptive Behaviour Scales—Third Edition (Sparrow et al., 2016) which is a standardised assessment of adaptive behaviour. The Domain Level form was completed with a carer and the Communication, Daily Living Skills, and Socialisation Standard Scores, along with the Adaptive Behaviour Composite calculated to confirm that the participant had a level of adaptive behaviour that was consistent with having a moderate to severe intellectual disability, and (3) the Social Responsiveness Scale 2 (Constantino et al., 2003) which is a proxy-rated measure of autistic symptoms.

#### *Candidate outcome measures*

The four candidate proxy-rated outcome measures chosen by the IAG were: (1) the Developmental Behaviour Checklist-2 Adult (DBC2-A) (Gray et al., 2018): this is a standardised assessment of emotional and behavioural problems comprised of 107 items completed by family members or someone who knows the person well. The DBC2-A has good reliability and validity (Mohr et al., 2004, 2005, 2011) and higher scores indicate greater difficulties; (2) The Behaviour Problems Inventory for Individuals with Intellectual Disabilities—Short Form (BPI-S, Rojahn et al., 2012a) is a short measure of challenging behaviour that also has good reliability and validity (Mascitelli et al., 2015; Rojahn et al., 2012b). Higher scores are associated with increased frequency or severity of challenging behaviour; (3) the Psychopathology in Autism Checklist (PAC) (Helverschou et al., 2009) was developed specifically for use with autistic adults with intellectual disabilities and

has good reliability and validity capturing symptoms of psychosis, obsessive-compulsive disorder, depression, anxiety, and general adjustment (Helverschou et al., 2021). Higher scores are associated with increased symptoms, and (4) the Index of Community Involvement (Raynes, 1994) which is a measure of engagement within domestic leisure, social and community activities by people with intellectual disabilities. This measure has been used in a previous clinical trial involving adults with intellectual disabilities (Jahoda et al., 2015; Jahoda et al., 2017; Jahoda et al., 2018). These measures were completed by carers either online, using paper via the postal system, or with a member of the research team.

### Analysis

The study is reported in accordance with the CONSORT extension for pilot and feasibility studies and adaptations for non-randomised pilot and feasibility studies (Lancaster & Thabane, 2019). A detailed statistical analysis plan was written and agreed by the study statistician and an independent statistician prior to the analysis. As this was a feasibility study, the analysis was descriptive in nature. Continuous data were reported as means and standard deviations, and we additionally calculated the within-group effect size while recognising that this effect size cannot be used to draw conclusions about intervention efficacy or effectiveness. Categorical data were reported as frequencies and proportions. Outcomes were estimated with their associated 95% confidence intervals. No formal hypothesis testing took place. We also calculated and reported our accrual and attrition rate and the percentage of missing data across our outcome measures along with the number of sessions attended and session fidelity data.

We used framework analysis (Gale et al., 2013) to analyse the data generated from our semi-structured interviews with carers and therapists. Framework analysis is a pragmatic method which is advantageous within this context because it allows researchers to investigate key issues of interest, rather than analyse data for all emergent themes. We examined the views of carers and therapists on several key areas, including: (a) the accessibility and acceptability of the intervention; (b) helpful and unhelpful aspects, including barriers to change; (c) the value of our adaptations; (d) relationships with professionals within the intervention; (e) acceptability of outcome measures; and (f) acceptability of consent and associated processes, including randomisation in a future trial. We used Excel spreadsheets for data organisation and management. Data captured using Talking Mats<sup>®</sup> were presented as frequency counts of the number of participants who said they liked, were unsure, or did not like aspects of the intervention and research processes.

### Progression criteria

As this was a feasibility study, key parameters to inform the decision to progress to a future clinical trial were estimated. The following criteria were used to determine the feasibility of a future trial within the following domains: (a) recruitment; (b) protocol adherence; and (c) outcome data leading to three possible recommendations for trial progression (Avery et al., 2017) as found in Table 3.

### Ethical opinion

This study was granted a favourable ethical opinion by Wales REC 6 and associated NHS Health Research Authority Approval (Ref: 21/WA/0013) was given. Our Participant Information Sheet and

**TABLE 3** Progression criteria.

#### Green

If all of the following criteria are met a recommendation that a pilot or internal pilot-full trial was considered warranted: (a) Recruitment: (i) accrual rate is at least three patients per site per month on average, and (ii) attrition rate is 30% or lower; (b) protocol adherence: (i) fidelity ratings indicate therapist adherence to the intervention of at least 70%, (ii) at least 70% of carers and clinicians report that the intervention and consent procedures were acceptable, (iii) participants received an average of 70% or more intervention sessions; and (c) Outcome data: (i) at least 70% of participants and carers complete outcome data at each time point, (ii) at least 75% of items within each outcome measure for each participant are complete, and (iii) at least 70% of carers judge our outcome measures to be acceptable.

#### Amber

If green criteria were not met but the following criteria were met, then the research team examined the reasons for this, carefully considered what remedial action could be taken to improve the likelihood that a larger trial should take place. For example, difficulties could have been related to a delay in research ethics or governance approvals or a longer than expected time to build relationships with referrers which could be managed effectively within a larger trial: (a) recruitment: (i) accrual rate is less than 3 but greater than two patients per site per month on average, or builds up to 3 per month in the latter months of recruitment and (ii) attrition rate is greater than 30% but less than 50%; (b) protocol adherence: (i) fidelity ratings indicate therapist adherence to the intervention is less than 70% but greater than 60%, (ii) less than 70% but greater than 55% of carers and clinicians report that the intervention and consent procedures were acceptable, (iii) participants received an average of less than 70% but greater than 55% or more intervention sessions; and (c) outcome data: (i) less than 70% but greater than 60% of participants and carers complete outcome data at each time point, (ii) less than 75% but greater than 60% of items within each outcome measure for each participant are complete, and (iii) less than 70% but greater than 65% of carers judge our outcome measures to be acceptable.

#### Red

If green or amber criteria are not met, and following a thorough review of the reasons for this, including consideration as to whether remedial action could be taken, a recommendation to proceed to a larger trial could not be made: (a) Recruitment: (i) accrual rate is less than 2 patients per site per month on average, and (ii) attrition rate is greater than 40%, (b) Protocol adherence: (i) fidelity ratings indicate therapist adherence to the intervention is less than 50%, (ii) less than 55% of carers and clinicians report that the intervention, and consent procedures were acceptable, (iii) participants received an average of less than 55% or more intervention sessions, and (iv) less than 60% of participants received their allocated intervention, and (c) Outcome data: (i) less than 50% of participants and carers complete outcome measures at each time point, (ii) less than 50% of items within each outcome measure for each participant are complete, and (iii) less than 65% of carers judge our outcome measures to be acceptable.

Consent Form for people with intellectual disabilities was presented in an easier-to-read format, Table S3. All participants were assumed to have capacity to decide whether they wished to take part, and those who wished to take part provided signed informed consent. Where there was evidence to suggest that a participant did not have capacity to make a decision about taking part in this study, the provisions within the Mental Capacity Act, 2005, were followed. Carers of participants were approached and invited to take part in this study. If interested, they were given a Carer Information Sheet and an associated consent form which they were asked to sign. Finally, therapists were also invited to take part as research participants. Again, those who were interested were given a Therapist Information Sheet and associated consent form which they were asked to sign.

### 3 | RESULTS

#### 3.1 | Participant accrual

Participants were recruited from five NHS Trusts in England. Recruitment opened on 02 December 2021 just as the Omicron variant of SARS-CoV-2 was spreading throughout England leading to a series of measures to curtail spread by working from home and wearing facemasks. This had been preceded by two previous lockdowns and increasing pressure on the NHS. Two sites were also affected by a ransomware attack on Advanced, an NHS provider of electronic patient records systems which made screening difficult. Consequently, our accrual rates were negatively affected initially, but improved with

time, and especially during the summer of 2022. The overall accrual rate was,  $M = 2.80$ , 95% CI [1.86, 4.05], participants per month. During the final 3 months of our recruitment period, across all our sites, this increased to,  $M = 6.33$ , 95% CI [3.81, 9.89], participants per month.

##### 3.1.1 | Eligibility screening

Participants most frequently fulfilled diagnostic criteria for generalised anxiety disorder (60.71%), followed by specific phobia (57.14%), social anxiety (25%), and agoraphobia (21.42%). The average Adaptive Behaviour Composite score for participants enrolled in our study was,  $M = 38.21$ ,  $SD = 11.20$ ,  $Min = 20$ ,  $Max = 53$ , which was within the range expected for individuals with moderate to severe intellectual disabilities. The SRS Total score average was,  $M = 121.76$ ,  $SD = 20.33$ ,  $Min = 76$ ,  $Max = 149$ , which is in the range associated with the presence of autism; all participants scoring above the cutoff of 75. The percentage of missing items across the subscales of each measure was very low and ranged from 0% to 0.42%, Table 4.

##### 3.2 | Intervention adherence and fidelity

Participants completed,  $M = 9.64$ ,  $SD = 3.65$ , 95% CI [8.13, 11.15],  $Min = 1$ ,  $Max = 12$ , sessions. On average, participants who started the intervention attended 80% of sessions. Therapists completed a fidelity checklist following the completion of each of the 12 sessions. These

**TABLE 4** Descriptive data for the eligibility measures.

Measures	N	% items missing	M (SD)	95% CI
<i>Vineland Adaptive Behaviour Scale-3 Standard Scores</i>				
Communication	28	0.18	35.04 (13.81)	[29.68, 40.39]
Daily living skills	28	0.27	32.54 (9.91)	[28.69, 36.38]
Socialisation	28	0.8	37.86 (11.26)	[33.49, 42.22]
Adaptive behaviour composite	28	0.42	38.21 (11.20)	[33.87, 42.56]
<i>Social Responsiveness Scale, Second Edition (SRS-2)</i>				
Social awareness	28	0	14.11 (3.47)	[12.76, 15.45]
Social cognition	28	0.3	23.39 (5.39)	[21.30, 25.48]
Social motivation	28	0	20.75 (7.15)	[17.98, 23.52]
Social communication	28	0	40.04 (8.22)	[36.85, 43.22]
Restricted interests and repetitive behaviour	28	0.3	24.46 (6.33)	[22.01, 26.92]
SRS-R total score	28	0.11	121.76 (20.33)	[113.37, 130.15]
<b>Anxiety diagnostic checklist</b>			% Meeting diagnostic criteria	
Specific phobia	16	0	57.1	
Separation anxiety	2	0	7.1	
Social anxiety	7	0	25.0	
Panic	1	0	3.6	
Agoraphobia	6	0	21.4	
Generalised anxiety	17	0	60.7	



data are summarised in Table 5 for each section of the fidelity checklist. The data indicated that the average number of total items endorsed ranged from 88.23 to 99.54 within each section of the checklist.

### 3.3 | Candidate outcome measures

Outcome data across all our measures are found within Table 6. The missing data rate across our candidate outcome measures was low at baseline, ranging from 0% to 2.38%, and low at follow up, ranging from 0 to 1.56% of items. At follow up, scores were lower (compared with baseline) on the DBC-2 Self-Absorbed subscale,  $d = 0.63$ , 95% CI [0.19, 1.07], and the PAC Total score,  $d = 0.45$ , 95% CI [0.03, 0.87], and the PAC Depression,  $d = 0.65$ , 95% CI [0.20, 1.07], subscale. Further, the frequency of aggressive and destructive behaviour,  $d = 0.65$ , 95% CI [0.20, 1.09], and stereotyped behaviour,  $d = 0.50$ , 95% CI [0.07, 0.92], as measured by the BPI-S was also lower. No adverse or serious adverse events were observed.

### 3.4 | Semi-structured interviews

#### 3.4.1 | Participants

Ratings using the Talking Mats® effectiveness framework indicated that participants were engaged and understood the issues being discussed, Table S4. The results of the Talking Mats® interviews are shown in Table S5. A majority of participants liked the participant information booklets they were given, their carer helping, and coming to sessions. A majority also liked the fear ladder, making choices, meeting new people during the intervention, and using the ratings scales. All participants said they liked relaxation and the visual schedules used. A majority disliked experiencing anxiety, but one participant indicated that they liked talking about things that made them anxious. Most did not recognise the BEAMS-ID study logo, and one person said they did not like coming to their appointment, while another was unsure.

**TABLE 5** Summary of the frequency of items endorsed within each section of the BEAMS-ID intervention fidelity checklist.

	M percentage items endorsed (SD)	Mdn percentage items endorsed
General session preparation	92.41 (6.44)	94.10
Coverage of the session plan	91.64 (7.17)	94.10
Understanding and accessibility	98.80 (2.39)	100.00
Interpersonal effectiveness	99.54 (1.45)	100.00
Engaging participants	99.08 (2.58)	100.00
Session content	88.23 (10.09)	90.00
Inter-session tasks	87.82 (9.16)	88.20

#### 3.4.2 | Carers

A summary of the results of our qualitative analysis and supportive quotes are found within Tables S6–S10.

##### *Acceptability of research procedures*

Carers were positive about the process for gaining consent and the participant information sheets which were seen as straightforward and helpful. A majority were also of the view that the research procedures met the needs of autistic adults with moderate to severe intellectual disabilities and were appropriately adapted. One carer did comment that the intervention did not meet participant need due to the complexity of the participant. A majority also indicated that outcome measures were acceptable, but they did comment that some of the questions appeared repetitive or were difficult to answer. Carers reported no barriers associated with research procedures. They also saw randomisation as acceptable within a future clinical trial, but some carers commented about the potential time taken to take part in a future study, or other reason (e.g., their age). In terms of facilitating factors, they spoke about having an interest in the study, wanting to help others, and to learn more. They did not describe any barriers, Table S6.

##### *Acceptability of the intervention*

Carers were positive about therapy and considered the intervention had been adapted successfully to meet need. Intervention facilitators were said to be the carer learning, appropriate materials and adaptations, such as including participant interests in therapy, along with relationship with the therapist. They commented that the materials used were accessible and the therapeutic techniques were appropriate to meet both participant and carer need. When asked about barriers, participants reported practical challenges including illness, holidays, and time. They also spoke about some difficulties with accessing appropriate materials and whether therapy could be adapted further to meet need, amongst other reasons, Table S7.

##### *Intervention improvements*

In terms of improvements, carers suggested that the intervention could be delivered over a longer period, while one carer suggested shorter sessions. Another asked for more information about the intervention to ensure that they understood their expectations, while another suggested that relaxation work could be further adapted. One carer was of the view that no intervention improvements were required, Table S8.

##### *Intervention outcomes*

Carers described a variety of positive outcomes associated with the intervention including an increased understanding of autism and anxiety, developing improved ways of responding to the participant, ability to use relaxation, as well as increased confidence, and improvements in participant anxiety and communication. It is important to note that one carer indicated that the chosen goals were not achieved and another commented that there had been no meaningful changes, Table S9.

**TABLE 6** Descriptive data for all outcome measures.

Measures	Baseline				Follow-up					
	N	% items missing	M (SD)	95% CI	N	% items missing	M (SD)	95% CI	d =	d 95% CI
<b>Developmental Behaviour Checklist-2 Adult</b>										
Total	28	0.13	67.68 (22.63)	[58.90, 76.45]	24	0	57.38 (28.68)	[45.26, 69.48]	0.40	-0.02, 0.81
Disruptive	28	0.14	14.32 (8.82)	[10.9, 17.74]	24	0	12.58 (9.61)	[8.53, 16.64]	0.20	-0.21, 0.60
Communication and anxiety disturbance	28	0.36	14.71 (7.31)	[11.88, 17.55]	24	0	13.13 (7.23)	[10.7, 16.18]	0.29	-0.12, 0.70
Self-absorbed	28	0	16.14 (7.69)	[13.16, 19.13]	24	0	12.38 (7.12)	[9.37, 15.38]	0.63	0.19, 1.1
Depressive	28	0.27	6.54 (3.40)	[5.22, 7.86]	24	0	4.96 (4.58)	[3.02, 6.9]	0.32	-0.10, 0.72
Social Relating	28	0	9.93 (4.59)	[8.15, 11.71]	24	0	8.58 (4.52)	[6.67, 10.49]	0.42	-0.01, 0.83
<b>Psychopathology in Autism Checklist</b>										
Total	28	0.17	79.61 (15.94)	[73.43, 85.79]	24	0.5	73.54 (18.65)	[65.67, 81.41]	0.45	0.03, 0.87
General adjustment problems	28	0.3	26.07 (6.23)	[23.66, 28.49]	24	0	24.71 (7.69)	[21.46, 27.95]	0.33	-0.08, 0.74
Psychosis	28	0	17.53 (4.1)	[15.95, 19.12]	24	0.42	15.67 (4.71)	[13.68, 17.65]	0.41	-0.01, 0.82
OCD	28	0	13 (3.81)	[11.52, 14.48]	24	1.19	12.17 (4.63)	[10.21, 14.12]	0.20	-0.21, 0.60
Depression	28	0	13.36 (4.17)	[11.74, 14.98]	24	0	11.67 (4)	[9.98, 13.35]	0.65	0.20, 1.07
Anxiety	28	0.6	9.64 (2.83)	[8.55, 10.74]	24	1.39	9.33 (2.43)	[8.31, 10.36]	0.05	-0.35, 0.45
<b>Behaviour Problems Inventory Short Form</b>										
Self-injurious behaviour										
Frequency	28	0.45	3.68 (3.53)	[2.31, 5.05]	24	0.52	3.08 (2.83)	[1.89, 4.28]	0.14	-0.26, 0.54
Severity	28	0.45	4.43 (4.09)	[2.84, 6.01]	24	1.56	3.58 (3.49)	[2.11, 5.06]	0.20	-0.20, 0.61
Aggressive-destructive behaviour										
Frequency	28	2.38	4.14 (4.19)	[2.52, 5.77]	24	0.83	2.21 (3.12)	[0.09, 3.53]	0.65	0.20, 1.09
Severity	28	2.38	5.96 (4.85)	[4.08, 7.84]	24	0.42	4.71 (5.63)	[2.33, 7.09]	0.25	-0.16, 0.66
Stereotyped behaviour										
Frequency	28	0.3	12.32 (9.74)	[8.54, 16.1]	24	0	8.83 (8.12)	[5.41, 12.26]	0.50	0.07, 0.92
<b>Index of Community Involvement</b>										
Total	28	0.22	45.9 (25.36)	[36.06, 55.73]	24	0.43	45.83 (20.93)	[37, 54.67]	0.01	-0.39, 0.41
Domestic leisure	28	0	18.54 (7.75)	[15.53, 21.54]	24	0	19.13 (6.39)	[16.43, 21.82]	-0.10	-0.50, 0.31
Social	28	0.65	9.14 (7.15)	[6.37, 11.92]	24	1.14	9.42 (7.34)	[6.32, 12.52]	-0.08	-0.48, 0.32
Community	28	0.12	18.21 (15.57)	[12.17, 24.25]	24	0.29	17.29 (12.42)	[12.05, 22.54]	0.15	-0.25, 0.55

#### Therapeutic relationship

Carers described developing and maintaining a positive therapeutic relationship with therapists. This included feeling comfortable, developing a positive rapport, and positive therapist attributes, Table S10.

### 3.4.3 | Therapists

A summary of the results of the qualitative analysis and supportive quotes are found within Tables S11-S15.

#### Acceptability of the intervention

Therapists indicated that the intervention was acceptable, and carers were engaged, but not consistently across different carers, which may have had an impact upon delivery in some instances. They were of the view that participant need was met, and the intervention was appropriately adapted. There was some comment that participant need was not met in some instances with a specific example being given about marked physical health anxieties and associated medication changes or a lack of participant engagement which made meeting need challenging. Therapists were of the view that carer needs were

met, but there were some difficulties caused by different carers attending different sessions. They also thought the adapted materials were acceptable, but additional information or adaptation was needed in some instances. They were positive about the intervention, and some indicated that they would use it again. Randomisation in a future clinical trial was also deemed acceptable, Table S11.

#### *Therapist training*

Therapists were positive about the training they received. They considered it helpful, accommodating, interactive, and well explained, amongst other positive attributes, as reported within Table S12.

#### *Therapist experiences of intervention delivery*

Therapists commented that further adaptation around the length and frequency of sessions was needed at times, and the commitment required by carers was substantial for some. The experience of delivery was positive, inclusive of carer involvement, but having different carers attend different sessions was mentioned as a potential challenge. Intervention facilitators were seen to be the structure of the intervention, use of adapted materials, carer engagement and understanding, supervision, the preference assessment, fidelity assessments, and the research team, amongst others, indicating that key aspects of the intervention were seen as important facilitators by therapists. Some of the barriers were difficulties with implementing relaxation, participant complexity, carer attitudes and commitment, illness, different carers attending different sessions, and having insufficient time. One therapist commented that undertaking 'university-based' research in the NHS is 'exceedingly challenging'. Another commented that qualified clinical psychologists do not typically use evidence-based interventions with people with intellectual disabilities and they had to change their practice to implement the intervention. Therapists also recognised the importance of an independent assessment of fidelity, Table S13.

#### *Therapeutic relationship*

Therapists spoke about the positive relationships that they built with participants and their carers which they perceived as key to the implementation of the intervention. They commented that this was helpful, and specific aspects of the intervention helped to promote a positive therapeutic relationship (e.g., the preference assessment, structure, timing, and length of sessions). One therapist commented that the therapeutic relationship was challenging which affected intervention implementation, Table S14.

#### *Intervention improvements*

Therapists commented that increased flexibility around the number and timing of sessions would be welcomed along with further guidance about additional adaptations to resources. This included an increased focus upon relaxation along with other aspects of the intervention (e.g., inclusion of videos, introducing concepts sooner, increasing clarity about some components). They also spoke about increased contact with the central study team in the future. The majority of the recommendations involved minor revisions to

the manual to help ensure that therapists are empowered to make adaptations that are person-centred. One therapist commented that the intervention was simplistic and did not include cognitive elements; this suggests that an increased focus upon the rationale for this intervention should be included within therapist training as cognitive components were intentionally excluded. Therapists were also asked about additional outcome measures that could be included and made a few suggestions (e.g., carer confidence, self-esteem), Table S15.

## 4 | DISCUSSION

The aim of this study was to model our adapted intervention to determine the acceptability and feasibility for all stakeholders, including those with intellectual disabilities, carers, and therapists, and adjust as required. The intervention was successfully modelled with 28 autistic adults with moderate to severe intellectual disabilities who had anxiety. Findings from Talking Mats<sup>®</sup> interviews with participants, and semi structured interviews with carers and therapists indicated that the intervention was acceptable, and it was feasible to deliver the intervention to autistic adults with moderate to severe intellectual disabilities. Autistic participants and carers were positive about the intervention. Carers indicated that it met their needs as well as the needs of participants while they also detailed positive outcomes as described within the logic model. Therapists were similarly positive, and again focused upon key mechanisms as described within the logic model (e.g., carer engagement, therapeutic relationship, preference assessments, adaptations), Figure S1. However, it must be noted that some carers and therapists reported difficulties with intervention implementation with some individuals due to participant complexity or carer engagement.

Some further adjustments to the intervention were warranted based upon the data captured from stakeholders. These included: (a) strengthening the importance of consistent carer engagement, understanding, and motivation, within the intervention (b) further guidance on the timing, frequency, and number of intervention sessions; (c) further guidance on the creation of person-centred intervention materials to meet participant need; (d) further guidance about teaching relaxation, including consideration as to whether this is necessary when participants find learning and using these skills too difficult; (e) increased guidance about the nature and degree of intervention adaptation to meet need; and (f) formalising arrangements for supervision within the context of a future trial. This would most likely be group-based supervision led by members of the trial team and in addition to local supervision.

We also estimated key parameters including: (1) recruitment rate; (2) protocol adherence; and (3) outcome data to inform the decision as to whether a future clinical trial was feasible in accordance with pre-specified progression criteria, Table 7. The majority were judged 'green', while recruitment was judged as 'red' due to the challenges encountered which were pandemic related. Towards the end of the recruitment period, the accrual rate improved and was judged as 'amber'. The progression criteria focusing upon the acceptability of

**TABLE 7** An evaluation of findings against each of our progression criteria informing the decision as to whether a future clinical trial should be completed.

Progression criterion	Progress	Number	Explanation
Recruitment: accrual rate is at least 3 patients per site per month on average	Red	Site 1: Initial 7-month rate: .29; final 3-month rate: 2.00 Site 2: Initial 7-month rate: .29; final 3-month rate: 1.5 Site 3: Initial 3-month rate: 1.33; final 3-month rate: 2.33 Site 4: 1 participant Solent: last site to join the study and recruited 3 in less than 1 month	Recruitment was unduly affected by the pandemic. The accrual rate increased over time. Overall accrual rate collapsing across sites within the final 3 months was 6.33 per month. The average final 3-month site accrual rate was 2.21, which is 'amber'. Target rate achieved by last site to join the study.
Attrition rate is 30% or lower	Green	14%	Attrition appeared not to be related to the intervention or research processes.
Fidelity ratings indicate therapist adherence to the intervention of at least 70%	Green	88.23%-99.54%	-
At least 70% of carers and clinicians report that the intervention and consent procedures were acceptable	Green	86% of carers considered the consent procedures acceptable. 88% of carers considered the intervention acceptable to meet need or considered the therapist responded to need. 100% of therapists considered the intervention was suitable or described benefits.	It was noted that the Mental Capacity Act provisions lengthened the time taken to enrol a participant.
Participants received an average of 70% or more intervention sessions	Green	80%	-
At least 70% of participants and carers complete outcome data at each time point	Green	100%	-
At least 75% of items within each outcome measure for each participant are complete	Green	97.62%-100%	-
At least 70% of carers judge our outcome measures to be acceptable	Amber	Carers completed all the outcome measures. Rates of missing data were low. The majority were of the view that they were acceptable. However, some expressed some concerns about some of the questions.	Carers completed all the outcome measures. Rates of missing data were low. Their view was that some of the items within and across questionnaires seemed repetitive or they had difficulty answering. Some of this was likely associated with testing several measures within a feasibility study; this can be easily re-visited prior to a larger study.

outcome measures was also classed as 'amber'. The reason for this was some carers reported that they found some of the items repetitive or had difficulties answering. This could be considered further within a future larger study. An independent study steering committee recommended that a future trial was feasible, and the recommendation was that a pilot trial with randomisation incorporating progression criteria towards a definitive randomised trial was an appropriate next step.

#### 4.1 | Strengths and weaknesses

There were several key strengths associated with this feasibility study which include working with the IAG to collaboratively adapt the intervention, refine the logic model, fidelity checklist, and therapist

training, and choose outcome measures. It is also a strength that within this study the intervention was modelled to determine its acceptability and generate data to enable further refinements. It is also a key strength that those with moderate to severe intellectual disabilities were included, as this group is often excluded from research about the effectiveness of psychological therapies for mental health problems (Tapp et al., 2023; Vereenoghe et al., 2018; Vereenoghe & Langdon, 2013). Another clear strength was the recruitment of sufficient participants to estimate parameters during a global pandemic. However, there are also some weaknesses which includes the completion of this project during the pandemic which resulted in parameter estimates (e.g., accrual rate) that may be inaccurate. It should also be noted that our sample size was small, but this was appropriate for this type of study, as the research team focused upon modelling the intervention. Further, some NHS staff

commented that the study should have been open to all adults with moderate to severe intellectual disabilities who had an anxiety disorder, including those with and without autism. This should be considered within a future trial. It is also the case that randomisation was not used in the current study, but carers and therapists were asked about this within the semi-structured interviews. Another weakness was that candidate outcome measures were all proxy-rated instruments; the reason for this is that it is not possible for many adults with moderate to severe learning disabilities to complete self-report outcome measures. While this could be considered a weakness, it is the case that the chosen candidate outcome measures are standardised and have good psychometric properties. Outcome measures that are not self-report could also be considered further in future (e.g., physiological measures) studies. Finally, we did not include those with moderate to severe intellectual disabilities within our IAG; while it would have been possible to include those with mild intellectual disabilities, we had concerns that they may be unable to advocate for those with moderate to severe intellectual disabilities and judged the inclusion of both carers and therapists as appropriate. Instead, we opted to capture the views of those with moderate to severe intellectual disabilities after they had taken part in the intervention ensuring their voice was included. In conclusion, the intervention should now be revised before proceeding to complete a pilot trial followed by a definitive clinical trial to generate evidence about intervention efficacy.

## AUTHOR CONTRIBUTIONS

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## CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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## SUPPORTING INFORMATION

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