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Predictors and moderators of the response of adults with intellectual disabilities and depression to behavioural activation and guided self-help therapies

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Abstract

Background No previous studies have reported predictors and moderators of outcome of psychological therapies for depression experienced by adults with intellectual disabilities (IDs). We investigated baseline variables as outcome predictors and moderators based on a randomised controlled trial where behavioural activation was compared with guided self-help.

Methods This study was an exploratory secondary data analysis of data collected during a randomised clinical trial. Participants (n = 161) were randomised to behavioural activation or guided self-help and followed up for 12 months. Pre-treatment variables were included if they have previously been shown to be associated with an increased risk of having depression in adults with IDs or have been reported as a potential predictor or moderator of outcome of treatment for depression with psychological therapies. The primary outcome measure, the Glasgow Depression Scale for Adults with Learning Disabilities (GDS-LD), was used as the dependant variable in mixed effects regression analyses testing for predictors and moderators of outcome, with baseline GDS-LD, treatment group, study centre and antidepressant use as fixed effects, and therapist as a random effect.

Results Higher baseline anxiety (mean difference in outcome associated with a 1 point increase in anxiety 0.164, 95% confidence interval [CI] 0.031, 0.297; P = 0.016), lower performance intelligence quotient (IQ) (mean difference in outcome associated with a 1 point increase in IQ 0.145, 95% CI 0.009, 0.280; P = 0.037) and hearing impairment (mean difference

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3.449, 95% CI 0.466, 6.432; $P = 0.024$) were predictors of poorer outcomes, whilst greater severity of depressive symptoms at baseline (mean difference in outcome associated with 1 point increase in depression −0.160, 95% CI −0.806, −0.414; $P < 0.001$), higher expectation of change (mean difference in outcome associated with a 1 point increase in expectation of change −1.013, 95% CI −1.711, −0.314; p 0.005) and greater percentage of therapy sessions attended (mean difference in outcome with 1 point increase in percentage of sessions attended −0.058, 95% CI −0.099, −0.016; $P = 0.007$) were predictors of more positive outcomes for treatment after adjusting for randomised group allocation. The final model included severity of depressive and anxiety symptoms, lower WASI performance IQ subscale, hearing impairment, higher expectation of change and percentage of therapy sessions attended and explained 35.3% of the variance in the total GDS-LD score at 12 months ($R^2 = 0.353$, $F_{4, 128} = 17.24$, $P < 0.001$). There is no evidence that baseline variables had a moderating effect on outcome for treatment with behavioural activation or guided self-help.

Conclusions Our results suggest that baseline variables may be useful predictors of outcomes of psychological therapies for adults with IDs. Further research is required to examine the value of these potential predictors. However, our findings suggest that therapists consider how baseline variables may enable them to tailor their therapeutic approach when using psychological therapies to treat depression experienced by adults with IDs.

Keywords behaviour therapy, intellectual developmental disorder, major depression, randomised clinical trial, self-help techniques

Introduction

Adults with intellectual disabilities (IDs) have higher levels of mental ill-health than the general population, with a point prevalence of 40% in a rigorous UK study (Cooper, Smiley, Morrison, Allan, & Williamson 2007). Depression is the most common type of mental ill-health experienced by adults with IDs. The 2-year incidence of depression of 7.2% in adults with IDs is similar to the general population (Cooper *et al.* 2018). However, the point prevalence of depression in adults with IDs of 3.8% (Cooper, Smiley, Morrison, Williamson, & Allan 2007) is higher than in the prevalence of depression of 2.3% in adults who do not have IDs (McManus *et al.* 2009). The higher prevalence and similar incidence suggest that depression is more enduring in adults with IDs. A lack of evidence-based treatments is one possible reason for a more enduring course of depression in adults with IDs (NICE 2016).

Clinical guidelines recommend psychological therapies as the first-line treatment of depression in adults with mild–moderate IDs (NICE 2016), based on the findings of three randomised controlled trials (RCTs) with a total of 130 participants (McCabe *et al.* 2006: McGillivray *et al.* 2008; Hassiotis *et al.* 2013) and three before-and-after, observational studies with a total of 130 participants (Hartley *et al.* 2015; Lindsay *et al.* 2015; McGillivray & Kershaw 2015). The evidence syntheses that were conducted suggest that psychological therapies are effective in treating depression, but the evidence was rated as very low quality because of the very serious risk of bias and the small number of participants (NICE 2016).

Two clinical trials on the effectiveness of psychological therapies for the management of depression experienced by adults with IDs (Jahoda *et al.* 2017; Cooney *et al.* 2018) have been published because these clinical guidelines (NICE 2016) were developed. The BeatIt RCT recruited 161 participants with mild–moderate IDs. Participants were randomised to treatment with behavioural activation or guided self-help. Both groups experienced clinically significant reductions in depressive symptoms and improvements in quality of life measured with the EQ-5D (Wille *et al.* 2010), at the end of the active therapy (4 months) and at follow-up (12 months). There was no evidence that the two treatments differed in terms of their outcomes (Jahoda *et al.* 2017). Cooney *et al.* (2018) randomised 52 participants with mild IDs and depression and/or anxiety to computerised cognitive behavioural therapy (cCBT) or treatment as usual (TAU). A greater proportion of participants in the cCBT group were in remission, defined as a change from the clinical (13 and above) to non-clinical range (12 and below) from pre- to post-treatment at 3-month follow up, compared with the TAU group. These more recent

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studies (Jahoda *et al*. 2017; Cooney *et al*. 2018) have a lower risk of bias and include a large number of participants (n = 213) relative to the total number of participants in the three RCTs included in the clinical guidelines (n = 130; McCabe *et al*. 2006: McGillivray *et al*. 2008; Hassiotis *et al*. 2013). Therefore, the findings from the two more recent trials (Jahoda *et al*. 2017; Cooney *et al*. 2018) add to the previous evidence in a clinical guideline (NICE 2016) supporting psychological therapies as the first-line treatment of depression in adults with mild–moderate IDs.

Although the two clinical trials described earlier show that the evidence is growing for the potential effectiveness of psychological therapies for adults with IDs, not everybody with depression responds in the same way or to the same extent to treatment with psychological therapies. At follow-up 12 months after randomisation, 46.7% of participants in the BeatIt trial still had significant depressive symptoms (Jahoda *et al*. 2018), and there was variation in the extent of change in depression symptoms from baseline to follow-up. At the 3-month follow-up in the cCBT trial, 62.5% of participants were classified as non-responders (Cooney *et al*. 2018). These results are similar to the finding that around 50% of people accessing psychological therapies for depression in clinical services do not respond to treatment (National Health Service, 2016).

Variability in response to psychological therapies has driven forward research to identify factors associated with response to psychological therapies by examining (1) which baseline variables are *predictors* of outcome of treatment with a single type of psychological therapy (Baron & Kenny 1986) and (2) which baseline variables are *moderators* of outcome because they influence the response to one type of psychological therapy compared with a second type of psychological therapy or to TAU/control conditions (Kraemer *et al*. 2002). None of the published RCTs (McCabe *et al*. 2006: McGillivray *et al*. 2008; Hassiotis *et al*. 2013; Cooney *et al*. 2018), or controlled-before-and-after studies (Hartley *et al*. 2015; Lindsay *et al*. 2015; McGillivray & Kershaw 2015), of psychological therapies for adults with IDs and depression have examined predictors or moderators of outcome. Therefore, we have a limited understanding of predictors and moderators of outcome of psychological therapies for the treatment of adults with IDs and depression.

The controlled design, large sample size and treatment with two types of psychological therapies in the BeatIt trial (Jahoda *et al*. 2017) provide an ideal opportunity to examine whether the response of adults with IDs and depression to different psychological therapies is associated with pre-treatment factors. Because there is very little previous research on this topic, this study takes an exploratory approach to examine whether pre-treatment variables are predictors and/or moderators of outcomes experienced by adults with IDs and depression treated with behavioural activation or guided self-help.

Methods

Study design

Predictors and moderators of outcome were examined using data from all 161 participants randomised in a multi-centre single-blind RCT (Jahoda *et al*. 2017) of behavioural activation ('BeatIt') compared with guided self-help ('StepUp'). The primary outcome was the Glasgow Depression Scale (GDS-LD; Cuthill *et al*. 2003) and all outcome measures were collected at baseline, at 4 months post-randomisation (expected to be post-treatment), and at follow up, 12 months after randomisation.

The West of Scotland Research Ethics Committee 3 gave ethical approval for the multi-centre study (NRES: 13/MH97) and the full trial protocol (Jahoda *et al*. 2015), and main outcome study of the trial has been published (Jahoda *et al*. 2017). Individual consent to participate in the research was taken from each participant.

Sample and recruitment

Participants were recruited from specialist health and social care services for adults with IDs in Scotland, England and Wales. Inclusion criteria for the study were (1) mild to moderate IDs, (2) the ability to provide informed consent, (3) being 18 years or older and (4) experiencing clinically significant depression as assessed using the Diagnostic Criteria for Psychiatric Disorders for use with Adults with Learning Disabilities (RCPsych 2001). Participants also needed to have a supporter (e.g. a staff member,

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family member or friend) who could accompany them to therapy sessions. Being actively suicidal, or having difficulties that could prevent two-way interactions with the therapist or retaining information from sessions (e.g. late stage dementia), was the exclusion criteria.

In total, 84 participants were randomised to BeatIt and 77 participants to StepUp. Of these, 64 (76%) BeatIt and 67 (87%) StepUp participants completed the trial. Further details of participant flow through the trial and full results are provided in the final report of the clinical trial (Jahoda *et al.* 2018).

Psychological therapies

BeatIt and StepUp were both delivered by community nurses and allied health professionals with experience of working with people who have IDs. All therapists received 1 to 2 days of training in the delivery of the intervention and were supervised throughout the trial by clinical psychologists. Participants in both treatment arms used accessible resources to aid understanding and engagement in the therapeutic process. Further information and eLearning modules on both interventions are available on the NHS Education for Scotland website (https://www.nes.scot.nhs.uk/education-and-training/by-discipline/psychology/multiprofessional-psychology/learning-disability.aspx).

Behavioural activation (BeatIt)

BeatIt was adapted from the Lejuez *et al.* (2011) behavioural activation intervention to meet the needs of adults with IDs. The manualised intervention was delivered over 12 sessions. BeatIt focusses on increasing participation in activities that lead to positive affective and social experiences. A collaborative approach is used by the therapist to enable the participant and supporter to establish regular purposeful activities and break the negative cycle of avoidance, which contributes to the development and maintenance of depression and low mood.

Guided self-help (StepUp)

StepUp is a manualised intervention that uses a psychoeducational focus to enable participants and supporters to develop new knowledge and skills to deal with common difficulties associated with depression. The intervention is structured around a series of four booklets: (1) depression and factors linked to low mood, (2) sleep, (3) physical activity, and (4) problem solving. The self-help booklets were developed with the assistance of people with IDs associated with a third sector organisation. As most study participants had few, if any, literacy skills, care was taken to ensure that the topics covered, the language used and the format, including the use of case examples, helped to make the booklets comprehensible to individuals with IDs.

Outcomes

The use of the RCT primary outcome is recommended in studies to identify predictors and moderators of outcome (Wallace *et al.* 2013). In the BeatIt trial, the primary outcome measure was the Glasgow Depression Scale (GDS-LD; Cuthill *et al.* 2003) with the primary end-point at 12 months post-randomisation. The change in the GDS = LD score from baseline to 12 months is the outcome used in the predictor and moderator analyses. The GDS-LD is a self-report 20-item scale designed specifically for adults with IDs that asks participants to indicate how often they have experienced particular depressive symptoms over the previous week using a 3-point scale (never/sometimes/always). GDS-LD scores can range from 0 to 40 and higher scores represent more frequent depressive symptoms.

Potential predictors and moderators

Pre-treatment variables were included if they have previously been shown to be associated with an increased risk of having depression in adults with or without IDs or have been reported as a potential predictor or moderator of outcome of treatment for depression with psychological therapies. Based on the consensus of the research team about this existing evidence base, the pre-treatment variables included in the analyses were

- gender (Parker *et al.* 2011);
- age (Cuijpers *et al.* 2016);
- IQ (Willner *et al.* 2013);
- adaptive functioning (Willner *et al.* 2013);
- socioeconomic status (Finegan *et al.* 2018);
- level of social support (Lindfors *et al.* 2014);

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- depressive symptoms (Furukawa *et al.* 2017);
- anxiety symptoms (Buckman *et al.* 2021);
- aggression (Dutton & Karakanta 2013);
- epilepsy (Hesdorffer *et al.* 2012);
- visual and hearing impairment (Shoham *et al.* 2019);
- previous psychotherapy (Grenyer *et al.* 2008);
- use of antidepressants (Cuijpers *et al.* 2014);
- use of mood stabilisers (Trivedi *et al.* 2011);
- life events (Bulmash *et al.* 2009);
- expectation of change (Constantino *et al.* 2018); and
- percentage of therapy sessions attended (Cahill *et al.* 2003).

Intelligence quotient (IQ) of participants was measured with the Wechsler Abbreviated Scale of Intelligence (WASI; Wechsler 2011). The WASI provides an estimate of general intellectual ability by testing participants' vocabulary and matrix reasoning skills. We used WASI sub-scale scores on verbal IQ and performance IQ as pre-treatment variables in the predictor and moderator analyses. WASI verbal and performance sub-scale scores can range from 45 to 160, with a higher score representing higher verbal and performance functioning (Wechsler 2011).

Six sub-scales of Part 1 of the Adaptive Behaviour Scale—Residential and Community: Second Edition (ABS-RC2; Nihira *et al.* 1993), assess skills relevant to autonomy and independence (Nihira *et al.* 1993) and were included as a measure of the adaptive behaviour of participants. These sub-scales were (1) Self-Direction (5 items), (2) Responsibility (3 items), (3) Socialisation (7 items), (4) Personal self-sufficiency (18 items), (5) Community self-sufficiency (38 items) and (6) Personal social responsibility (17 items). Responses to items take two forms, either a rating of the highest level of adaptive behaviour exhibited on an item or a checklist of yes/no responses which are summed to form the item score. For some items, the rater picks a single option from the list of behaviours that a person can usually achieve. Because items with three options have a maximum score of three and items with six options have a maximum score of six, there are no fixed ranges for the sub-scales. However, for all the sub-scales, higher score values indicate higher adaptive functioning.

The aggression/destructive behaviour sub-scale of the Behaviour Problems Inventory short form (Rojahn *et al.*, 2012) was completed by carers and used to examine the frequency with which the participants displayed different aggressive behaviours. The Behaviour Problems Inventory short form has 30 items, with a total score range of 0 to 150, with higher scores representative of more frequent behaviour problems.

Self-reported anxiety symptoms were measured using the Glasgow Anxiety Scale-ID for people with IDs (GAS-ID; Mindham & Espie 2003). The GAS-ID scale has 27 items and asks participants to rate symptoms experienced over the previous week using a 3-point scale (never/sometimes/always). A total GAS-ID score can range from 0 to 54, with higher scores representative of more frequent anxiety symptoms.

At baseline, participants were asked whether they experience seizures or have a diagnosis of epilepsy (Yes/No), visual impairment (Yes/No) or hearing impairment (Yes/No). Data were collected on whether participants had previously been treated for depression with psychological therapies (Yes/No), were currently prescribed antidepressants (Yes/No), or were currently prescribed mood stabilisers (lithium, carbamazepine, sodium valproate and lamotrigine; Yes/No).

Participants' expectations of change from treatment with psychological therapy were assessed prior to starting treatment using two questions rated on a 4-point scale. The Therapy Expectation Measure is a reliable and valid measure of treatment expectations of adults with IDs (Kilbane & Jahoda 2011). For this study, participants answered the two questions (1. *My problems will get better when I see the therapist*. 2. *It's going to be hard work to make my problems better*.) from the Therapy Expectation Measure that measure expectation of treatment outcome, using a 4-point scale (0 None, 1 A little, 2 Quite a bit, 3 A big bit). The total score of these two items (item 2 is reverse scored) was combined to give an overall rating of expectation of change, with a range of 0 to 6, with a higher score representing a greater expectation of change.

The carers' perceptions of their ability to provide support to adults with IDs were examined using the Emotional Difficulties Self-Efficacy scale (EDSE; Hastings & Brown 2002). This is a four-item questionnaire that asks carers to rate their confidence in supporting the emotional difficulties of the person

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with IDs. The EDSE total score can range from 4 to 28, with a higher score representing a higher level of self-efficacy (Hastings & Brown 2002).

The self-report version of the Bangor Life Events Schedule for Intellectual Disabilities (Hulbert-Williams *et al*. 2011) was used to record participants' recent life events. This questionnaire recorded yes/no answers to which of a possible 24 important life events that had taken place in participants' lives over the previous 12 months. For each life event experienced in the past 12 months, a participant is invited to rate the impact these events had on their lives on a 3-point Likert scale. The total impact score can range from 0 to 3, with a higher score representing a greater negative impact of the life events experienced.

Statistical analysis

All analyses were carried out using Stata version 14.0.

Descriptive statistics

Means and standard deviations were calculated for baseline continuous variables and frequencies and proportions used to describe categorical baseline data.

Regression analyses

The variables included in the exploratory analyses as potential predictors and moderators were gender, age, verbal IQ, performance IQ, ABS personal self-sufficiency, ABS community self-sufficiency, ABS personal social responsibility, ABS self-direction, ABS responsibility, ABS socialisation, neighbourhood deprivation (the relevant Index of Deprivation for Scotland, Wales and England were used and categorised into quintiles), relationship of carer to participant (family, worker, other), level of support (less than daily support, daily support), baseline depressive symptom severity, baseline anxiety symptoms severity, baseline aggression severity, epilepsy diagnosis (yes/ no), visual impairment (yes/no), hearing impairment (yes/ no), participant expectations of change, previous therapies for depression (yes/ no), use of antidepressants (yes/ no), use of mood stabilisers (yes/no), Bangor Life Events Schedule for Intellectual Disabilities life events negative impact, carer efficacy (EDSE total score), and percentage of therapy sessions attended.

Continuous variables were grand-mean centred prior to use in the analyses (Aiken *et al*. 2001). This was carried out by subtracting the grand-mean of a variable from each of its individual values. All regression models also included baseline GDS-LD, treatment group, study centre and antidepressant use as fixed effects, and therapist as a random effect.

R^2 is reported to represent the proportion of the variance in the outcome at 12 months represented by the multivariable regression models.

Predictor regression analyses. If there is a significant relation between an independent variable and the outcome variable, the independent variable could be said to be a predictor of the outcome. Exploratory analyses used mixed effects regression methods to examine pre-treatment demographic and clinical variables as potential predictors of outcome as measured using the GDS-LD at 12 months.

Each baseline variable was included separately in a univariate regression analysis to identify potential predictors of outcome. For continuous variables, the regression coefficient represents the mean change in outcome for every one point increase in the predictor variable. Predictors from the initial univariate regression models with $P < 0.10$ were taken forward to a multivariable model. A backward stepwise approach, using automated commands in R, was then used to sequentially remove any individual variables that were no longer significant ($P < 0.05$) in the multivariable model of predictors of outcome at 12 months.

Moderator regression analyses. A moderator in an RCT is a baseline variable that has an interactive effect with treatment on outcome. Moderation is considered to have occurred when a significant moderator × treatment interaction indicates that the treatment worked differently for various levels of the moderator. Two-way interaction terms (variable × treatment) are calculated, and if the variable × treatment interaction is significant, this suggests that treatment effect difference varies according to the level of the moderating variable. For example, treatment A might be more effective than treatment B for females, but not for males.

Each baseline variable was included separately in a univariate regression analysis to identify potential moderators of outcome. In our analyses, we first

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examined whether there was an interaction between each potential moderator and treatment (BeatIt vs. StepUp). For continuous variables, using age as an example, the output of the regression analysis shows the treatment effect difference for an individual with mean age, plus an interaction term, representing the additional treatment effect difference for every one-year increase in age. For categorical variables, mean differences in GDS-LD comparing BeatIt and StepUp are provided for each category. For example, mean differences in GDS-LD at 12 months are provided for males randomised to BeatIt and StepUp, and separately for females randomised to BeatIt and StepUp. The overall interaction effect for treatment × gender is then calculated using a likelihood ratio test and the significance (*P* value) of the interaction reported.

Moderators from the initial univariate regression models with $P < 0.10$ were taken forward to a multivariable model. A backward stepwise approach, using automated commands in R, was then used to sequentially remove any individual variables that were no longer significant ($P < 0.05$) in the multivariable model of moderators of outcome at 12 months.

Results

The clinical and demographic characteristics of the sample are presented in Table 1.

Predictors of treatment outcome

Seven variables had a *P* value less than 0.1 and were carried forward from the univariate analysis (Table 2) to the final multivariable model examining predictors of outcome at 12 months: baseline depression symptoms, performance IQ, baseline anxiety symptoms, hearing impairment, expectation of change and percentage of therapy sessions attended.

Using backwards stepwise elimination, ABS personal self-sufficiency dropped out from the first model, leaving six baseline variables with a significant association with outcome on the GDS-LD at 12 months (Table 3). The final model shown in Table 3 explained 35.3% of the variance in the total GDS-LD score at 12 months ($R^2 = 0.353$, $F_{4, 128} = 17.24$, $P < 0.001$).

Increased severity of depressive symptoms at baseline predicted better outcome on the GDS-LD at 12 months. In contrast, greater severity of anxiety symptoms at baseline was a predictor of poorer outcome on the GDS-LD at 12 months. A lower score on the WASI performance IQ subscale and the presence of hearing impairment at baseline both predicted a poorer outcome on the GDS-LD, at 12 months. Participants with a higher expectation of change of baseline had a better outcome at 12 months. The percentage of therapy sessions attended had a positive relationship with outcome on the GDS-LD at 12 months.

Moderators of treatment outcome

The results of the initial moderator analysis using GDS-LD as the outcome at 12 months are shown in Table 4. All the variables in Table 4 were included in the univariate moderator analysis to examine for an interaction of the individual variable with treatment (BeatIt vs. StepUp). The only evidence of moderating effects identified in this initial univariate analysis was that individuals with higher carer self-efficacy at baseline and individuals with higher levels of expectation of change at baseline showed greater benefit when randomised to Step-Up instead of Beat-It. Since the *P* values were below the cut-off of $P < 0.1$, the variables self-efficacy and expectation of change were taken forward to the multivariable model. However, neither of these interaction effects were retained in the final model. Therefore, this study did not identify any variables that can be used to guide decision making about when to offer Step-Up or BeatIt as first-line treatment for depression experienced by adults with IDs.

Discussion

This is the first study to explore potential predictors and moderators of outcome of psychological therapies for adults with IDs and depression. With respect to potential prognostic predictors of outcome, more severe baseline depressive symptoms, greater expectation of change and higher percentage of therapy sessions attended predicted better outcomes at 12 months. Lower performance IQ, hearing impairment and greater severity of anxiety symptoms at baseline were all associated with poorer outcomes at 12 months. We did not identify any evidence that individual participant characteristics at baseline act as

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Table 1 Demographic and clinical characteristics of participants at baseline

	Beat It (*n* = 84)	Step Up (*n* = 77)
Sex		
Male	38 (45.2%)	38 (49.4%)
Female	46 (54.8%)	39 (50.6%)
Mean age in years (standard deviation)	40.3 (11.7)	40.1 (12.0)
Ethnicity (data missing for 1 participant in each treatment arm)		
White	81 (97.6%)	75 (98.7%)
Other	2 (2.4%)	1 (1.3%)
Marital status (data missing for two participants in the StepUp arm)		
Married/cohabitating	5 (6.0%)	7 (9.3%)
Separated/divorced/widowed	6 (7.2%)	1 (1.3%)
Single	73 (86.9%)	67 (89.3%)
Support with living		
Less than daily support	25 (29.8%)	24 (31.2%)
Daily support (contact at some point 7 days/week)	59 (70.2%)	53 (68.8%)
Relationship of carer to participant (family, worker, other)		
Other	25 (29.8%)	23 (29.9%)
Family carer	24 (28.6%)	22 (28.6%)
Paid carer	35 (41.7%)	32 (41.6%)
Mean deprivation decile (standard deviation)	4.5 (2.6)	3·8 (2·1)
Mean IQ		
Verbal (standard deviation)	58.87 (8.67)	63.14 (10.15)
Performance (standard deviation)	57.84 (9.18)	58.45 (8.11)
Full scale (standard deviation)	55.44 (8.02)	58.34 (8.38)
Mean ABS sub-scale score		
Personal self sufficiency (1 pt)	48.63 (8.5)	50.79 (11.5)
Community self sufficiency (1 pt)	51.81 (7.7)	54.48 (7.2)
Personal social responsibility (1 pt)	24.25 (9.8)	21.68 (8.8)
Self-direction (standard deviation)	15·38 (5·41)	14·60 (5·49)
Responsibility (standard deviation)	8·27 (1·77)	7·62 (2·10)
Socialisation (standard deviation)	20·92 (3·55)	20·75 (3·12)
Mean GDS-LD (standard deviation)	16·60 (7·91)	16·90 (6·73)
Mean GAS-ID (standard deviation)	25·05 (11·15)	24·71 (11·00)
Mean BPS-IDD (standard deviation)	1·96 (2·74)	2·10 (3·61)
Epilepsy		
Epilepsy diagnosis	15 (17.9%)	21 (27.3%)
No epilepsy diagnosis	69 (82.1%)	56 (72.7%)
Vision		
Visual impairment	55 (65.5%)	45 (58.4%)
No visual impairment	29 (34.5%)	32 (41.6%)
Hearing		
Hearing impairment	20 (23.8%)	8 (10.4%)
No hearing impairment	64 (76.2%)	69 (89.6%)
Mobility		
Mobility problems	19 (22.6%)	20 (26.0%)
No mobility problems	65 (77.4%)	57 (74.0%)
Previous therapies for depression		
Yes	17 (20.2%)	4 (18.2%)
No	67 (79.8%)	63 (81.8%)
Prescribed antidepressants		
Yes	53 (63.1%)	51 (66.2%)
No	31 (36.9%)	26 (33.8%)
Prescribed mood stabilisers		

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Table 1. *(Continued)*

	Beat It (*n* = 84)	Step Up (*n* = 77)
Yes	11 (13.1%)	15 (19.5%)
No	73 (86.9%)	62 (80.5%)
Mean BLESID life events negative impact score (standard deviation)	2·04 (2·35)	1.79 (2.03)
Mean expectation of change (standard deviation)	3.05 (1.5)	3.1 (1.6)
Mean carer efficacy EDSE total core (standard deviation)	20·73 (4.98)	21·04 (4.68)
Mean percentage of therapy sessions attended (standard deviation)	82.6 (26.9)	88.2 (26.4)

Table 2 Predictors of outcome (GDS-LD score) at 12-month follow up

	Total GDS-LD score at 12-month follow up		
Predictor	**Mean difference**	**95% CI**	***P* value**
Gender (male vs. female)	1.545	(−0.708, 3.798)	0.176
Age	−0.051	(−0.149, 0.047)	0.299
Verbal IQ (1 pt)	0.040	(−0.082, 0.162)	0.513
Performance IQ (1 pt)	0.129	(−0.017, 0.275)	0.083
ABS personal self sufficiency (1 pt)	0.208	(0.019, 0.397)	0.032
ABS community self sufficiency (1 pt)	0.012	(−0.129, 0.153)	0.869
ABS personal social responsibility (1 pt)	−0.064	(−0.250, 0.121)	0.491
ABS self-direction (1 pt)	−0.058	(−0.269, 0.153)	0.586
ABS responsibility (1 pt)	−0.313	(−0.883, 0.256)	0.276
ABS socialisation (1 pt)	−0.086	(−0.419, 0.247)	0.608
Neighbourhood deprivation (SIMD quintile)	−0.087	(−0.560, 0.386)	0.715
Relationship of carer to participant (family, worker, other)			
Other	REF	REF	REF
Family member	1.112	(−1.883, 4.108)	0.461
Paid carer	−1.235	(−3.919, 1.449)	0.361
Level of support (daily support vs. less than daily support)	−1.327	(−3.767, 1.113)	0.281
Baseline depression symptoms (GDS total score 1 pt)	−0.386	(−0.545, −0.228)	<0.001
Baseline anxiety symptoms (GAS total score 1 pt)	0.126	(−0.011, 0.263)	0.072
Aggression (BPI-IDD)	0.127	(−0.215, 0.470)	0.461
Epilepsy diagnosis (yes/no)	0.763	(−1.952, 3.477)	0.577
Visual impairment (yes/no)	0.365	(−2.122, 2.852)	0.771
Hearing impairment (yes/no)	2.784	(−0.387, 5.955)	0.084
Previous therapies for depression (yes/no)	0.720	(−2.084, 3.525)	0.610
Use of antidepressants (yes/no)	0.906	(−1.512, 3.323)	0.457
Use of mood stabilisers (yes/no)	−1.853	(−4.844, 1.137)	0.220
BLESID life events negative impact	−0.127	(−0.915, 0.661)	0.748
Expectation of change	−0.974	(−1.708, −0.241)	0.010
Carer efficacy in supporting depression (EDSE total score)	−0.040	(−0.295, 0.215)	0.754
Percentage of therapy sessions attended	−0.045	(−0.088, −0.002)	0.038

Baseline GDS-LD, treatment group, study centre and antidepressant used as fixed effects, and therapist as a random effect. Continuous variables were grand-mean centred prior to use in the analyses.

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Table 3 Multivariate model of predictors of outcome (GDS-LD score) at 12-month follow up using variables with $P < 0.1$ from the univariate model

	Total GDS-LD at 12-month follow up		
Predictor	**Mean difference**	**95% CI**	***P* value**
Baseline depression symptoms (GDS total score 1 pt)	−0.610	(−0.806, −0.414)	<0.001
Performance IQ (1 pt)	0.145	(0.009, 0.280)	0.037
Baseline anxiety symptoms (GAS total score 1 pt)	0.164	(0.031, 0.297)	0.016
Hearing impairment (yes/no)	3.449	(0.466, 6.432)	0.024
Expectation of change	−1.013	(−1.711, −0.314)	0.005
Percentage of therapy sessions attended	−0.058	(−0.099, −0.016)	0.007

Baseline GDS-LD, treatment group, study centre and antidepressant used as fixed effects, and therapist as a random effect. Continuous variables were grand-mean centred prior to use in the analyses. $R^2 = 0.353$, $F_{4, 128} = 17.24$, $P < 0.000$. Variables not retained in the final model: (1) ABS personal self sufficiency.

moderators of outcome. Therefore, none of the baseline variables included in this study can inform whether BeatIt or StepUp should be offered as the first-line treatment for adults with IDs and depression with different characteristics.

Predictors of 12-month outcome measured with the Glasgow Depression Scale for Adults with Learning Disabilities

Increased baseline severity of depressive symptoms was a predictor of greater reduction of depressive symptoms at 12 months. This is the first time that this has been reported in a study examining prognostic predictors of psychological therapies for adults with IDs and depression. However, this effect is commonly reported in studies examining the efficacy of psychological therapies for depression in adults who do not have IDs. It could be that participants with higher scores at baseline have greater scope for improvement in symptoms or the difference may be attributable to a regression to the mean effect. Nonetheless, this finding provides some evidence for therapeutic optimism and, in keeping with recent individual patient data meta-analyses, suggests that psychological therapies (and also antidepressants) are equally effective for individuals with more severe depression (Weitz *et al.* 2015; Furukawa *et al.* 2017).

This is the first study to report that high baseline anxiety symptoms are a predictor of poorer outcome in adults with IDs and depression receiving psychological therapies. However, high levels of anxiety symptoms at baseline have been found to predict a poor response to psychological therapies for depression in adults who do not have IDs (Buckman *et al.* 2021). Although depressive and anxiety symptoms often coexist (Jacobson & Newman 2017), this has not been extensively reported in adults with IDs. BeatIt does include strategies to tackle avoidance, which is commonly found in anxiety, and also adopts a formulation based approach, which provided an opportunity to address other anxiety symptoms which were barriers to engaging in activity. However, the moderator analyses did not find that BeatIt was more effective (compared with StepUp) for participants with higher anxiety symptoms at baseline. There may be a need to consider adding more specific treatment components for anxiety symptoms as core elements of psychological therapies for depression with adults with IDs. For example, social anxiety symptoms have been found to have a particularly strong predictive effect on outcomes of psychological therapies for adults with depression who do not have IDs (Assmann *et al.* 2018). There may be value in adding sections on coexisting anxiety to BeatIt and StepUp that challenge safety behaviours or reduce self-focused attention in participants with social anxiety symptoms. However, further research is required to increase our understanding of co-existing depression and anxiety in adults with IDs (Melville *et al.* 2016).

This is the first study to examine IQ and outcome of psychological therapies for depression. We found that a lower score on the WASI performance IQ sub-scale predicted poorer outcome at 12 months,

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Table 4 Moderators of outcome (GDS-LD score) at 12-month follow up

		GDS-LD total score at 12-month follow up			
Predictor		**Mean difference**	**9%% CI**	***P* value**	***P* value for the overall interaction**
Gender (Trt × gender)	Female	1.228	(−2.020, 4.477)	0.453	0.343
	Male	−0.926	(−4.096, 2.244)	0.561	
Age (1 year; Trt × age)		0.151	(−0.040, 0.342)	0.119	
Verbal IQ (1 pt; Trt × verbal IQ)		−0.112	(−0.357, 0.134)	0.367	
Performance IQ (1 pt; Trt × performance IQ)		0.093	(−0.189, 0.374)	0.513	
ABS personal self sufficiency (1 pt; Trt × personal self-sufficiency)		0.181	(−0.200, 0.561)	0.346	
ABS community self sufficiency (1 pt; Trt × community self-sufficiency)		0.039	(−0.243, 0.321)	0.782	
ABS personal social responsibility (1 pt; Trt × social responsibility)		−0.029	(−0.411, 0.354)	0.882	
ABS self-direction (1 pt; Trt × self-direction)		0.071	(−0.353, 0.496)	0.738	
ABS responsibility (1 pt; Trt × responsibility)		−0.100	(−1.259, 1.058)	0.863	
ABS socialisation (1 pt; Trt × socialisation)		−0.008	(−0.674, 0.658)	0.982	
Neighbourhood deprivation (SIMD 1 quintile; Trt × Deprivation)		0.114	(−0.861, 1.090)	0.816	
Relationship of carer to participant (Trt × Relationship)					
Other		2.236	(−1.777, 6.249)	0.270	0.351
Family member		−2.037	(−6.580, 2.507)	0.374	
Paid carer		−0.106	(−3.738, 3.525)	0.953	
Level of support (Trt*Support)	daily support	0.919	(−1.959, 3.798)	0.526	0.450
	less than daily support	−0.987	(−5.234, 3.261)	0.644	
Baseline depression symptoms (GDS total score 1 pt; Trt × depression)		0.022	(−0.299, 0.343)	0.893	
Baseline anxiety symptoms (GAS total score 1 pt; Trt × anxiety)		0.044	(−0.160, 0.248)	0.670	
Aggression (BPI-IDD total score 1 pt; Trt × aggression)		−0.024	(−0.744, 0.697)	0.948	
Epilepsy diagnosis (Trt × Epilepsy)	Yes	−2.021	(−6.844, 2.803)	0.406	0.254
	No	1.075	(−1.702, 3.851)	0.442	
Visual impairment (Trt × Visual impairment)	Yes	−0.062	(−3.060, 2.935)	0.967	0.756
	No	0.680	(−3.238, 4.599)	0.730	
Hearing impairment (Trt × Visual impairment)	Yes	4.229	(−2.120, 10.578)	0.188	0.136
	No	−0.877	(−3.499, 1.745)	0.506	
Previous therapies for depression (Trt × previous therapies)	Yes	1.352	(−3.697, 6.400)	0.594	0.610
	No	−0.082	(−2.797, 2.633)	0.952	
Use of antidepressants (Trt × antidepressant use)	Yes	0.460	(−2.527, 3.447)	0.759	0.817
	No	−0.096	(−4.020, 3.828)	0.961	
Use of mood stabilisers (Trt × mood stabiliser use)	Yes	0.636	(−4.868, 6.140)	0.818	0.825
	No	−0.025	(−2.618, 2.568)	0.984	
BLESID life events (1 pt; Trt × negative impact)		−0.209	(−1.648, 1.231)	0.773	
Expectation of change		1.227	(−0.190, 2.643)	0.088	
Carer efficacy (1 pt, Trt × EDSE total score)		0.561	(0.071, 1.052)	0.026	

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Table 4. *(Continued)*

Predictor	GDS-LD total score at 12-month follow up			
	Mean difference	9%% CI	*P* value	*P* value for the overall interaction
Percentage of therapy sessions attended (1 pt; Trt × Percentage of possible treatment sessions attended)	0.012	(−0.072, 0.096)	0.777	

Baseline GDS-LD, treatment group, study centre and antidepressant used as fixed effects, and therapist as a random effect. Continuous variables were grand-mean centred prior to use in the analyses.

regardless of treatment, but there was no relationship between verbal IQ and outcome at 12 months. Previous research on anger experienced by adults with IDs found that verbal IQ (Willner *et al.* 2002; Rose *et al.* 2005) and higher full-scale IQ both predicted better outcomes for CBT in individuals with anger (Willner *et al.* 2013). Our results suggest that the research team have successfully developed two interventions that are accessible to adults with IDs and minimal verbal reasoning skills. However, whilst the use of visual and other communication strategies can support verbal understanding and reasoning, BeatIt and StepUp both require non-verbal processing of in-session therapeutic processes, such as the relationship with the therapist and supporter. There are also several components of BeatIt that are dependent on non-verbal reasoning, such as goal setting and problem solving. Performance IQ has been found to be an important component of successful problem solving. Both BeatIt and StepUp include content on problem solving because problem solving therapy is known to be an effective treatment for depression in adults who do not have IDs. Therefore, it could be that the participants with higher performance IQ were more able to make better use of the problem-solving components of BeatIt and StepUp. Where an individual's performance IQ is impacting on problem solving, one potential solution could be for supporters to play a more active role in facilitating problem-solving. While little consideration has been given to non-verbal reasoning (Lindsay *et al.* 2013), there has been a plethora of research focussed on adapting approaches to verbal communication when working with adults with IDs (Chinn 2017), and using this evidence, was successful in supporting participants with lower verbal IQ in this study. However, our findings suggest that research is required to examine the effectiveness of strategies to support the non-verbal reasoning of participants with lower performance IQ in psychological therapies.

Our finding that, regardless of treatment allocation, individuals with a hearing impairment had a poorer outcome at 12 months on the GDS-LD is particularly important because adults with IDs are at high risk of hearing impairments (Evenhuis *et al.* 2001). The effect of hearing impairment on outcome may be due to problems that individuals with IDs and hearing impairment have in engaging with the process of psychological therapies, lack of success in adapting treatment for this impairment or lack of therapist awareness about the sensory impairments of those they were treating. BeatIt and StepUp both use visual communication strategies where possible, but they are still heavily dependent on verbal communication between the participant, therapist and supporter. Hearing impairment may be impacting on in-session learning and may even impact on the therapeutic relationship that participants develop with the therapist. Because a large number of adults with IDs have undiagnosed hearing impairments (Hild *et al.* 2008), this flags up the importance of therapists being aware of hidden disabilities that can impact on the therapeutic process. Practical adaptations to therapies that could positively impact on the engagement of participants with IDs and hearing impairments include use of additional visual communication strategies, such as Talking Mats (Murphy & Boa 2012), and frequent checking that the

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participant has heard, understood and retained any information that has been discussed during the therapy session.

This study replicates the finding in the general psychological therapies literature that participants' expectation of change has been consistently found to have a significant, direct relationship with the outcome of psychological therapies (Constantino *et al.* 2018). Studies have shown that it is possible for therapists to influence expectation of change at baseline and potentially improve outcomes (Constantino *et al.* 2012). Therefore, our finding suggests that therapists working with individuals with IDs and depression should explore expectation of change as part of the initial assessment process (Dagnan *et al.* 2013) and consider using strategies that can foster expectation of change (McClintock *et al.* 2017).

The relationship between the number of sessions of psychological therapy and outcome is often described in terms of a dose–response effect. In this study, we found that the percentage of sessions attended was a significant predictor of outcome at 12 months. The only other clinical trial of psychological therapies for adults with IDs to report this finding was a RCT of a group-based, anger management programme (Wilner *et al.* 2013). The dose–response effect reported in studies of psychological therapies for adults who do not have IDs (Robinson *et al.* 2020) is often described as non-linear, with optimum numbers of sessions somewhat dependent on the type of therapy. However, in this paper, and the Willner *et al.* (2013) study, treatments are time limited and have a clear beginning, middle and end with unique elements of the treatment being introduced in each phase. Thus, attending as many of the manualised sessions as possible is important. Because many adults with IDs will experience financial, transport and other barriers to attending therapy sessions, the dose–response relationship reported here emphasises the importance of making sessions accessible and offering flexible timetabling of appointments, where possible. In this study, therapy was delivered to the participants on an outreach basis.

Moderators of 12-month outcome measured with the Glasgow Depression Scale for Adults with Learning Disabilities

Our finding that no significant moderators were retained in the multivariable model on the GDS-LD suggests that none of the factors so far examined explain differential response to the BeatIt and StepUp treatments. This is an important finding in the context that baseline expectation of change was a significant predictor of outcome. Therapists are able to discuss BeatIt and StepUp as viable treatment options with participants and offer whichever treatment the participant believes is most likely to support them to manage their depressive symptoms.

Study strengths and limitations

The recruitment of a relatively large sample and the collection of developmental, social, psychological and physical health variables are significant strengths of this study. We followed the best practice guidelines for statistical methods to examine predictors and moderators of outcome from psychological therapies.

We want to emphasise that this is an exploratory study to generate rather than test hypotheses. The study methods were constrained by the requirements of the main study examining the effectiveness of BeatIt and StepUp. Because the primary focus was on the RCT, this impacted on the resources available to complete the predictor and moderator analyses and the availability of variables that could be examined as potential predictors or moderators of outcome. We did not have a TAU group in this study, so we were not able to decisively demonstrate that either treatment was effective. Inclusion of TAU group in future studies may allow the identification of moderators of treatment effects of psychological therapies in general, which we were unable to identify in the design used in this RCT. Future studies should be powered appropriately and use best practice methods to refine personalised approaches to the management of depression (Huibers *et al.* 2021) experienced by adults with IDs.

The list of variables included in the analyses was based on existing evidence and the consensus of the research team. However, this is by no means exhaustive, and the analyses were limited by the variables measured in the research and also by the fact that the study was not powered to detect moderation effects. Thus, future studies should consider including novel variables that may influence outcome and include proactive design and measurement to examine predictors and moderators of outcome. Of particular interest would be variables examining the

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therapeutic alliance or psychological variables, such as self-efficacy.

Research to identify personalised approaches that aim to improve outcomes for people with depression is blooming. We hope that this exploratory work will inform future studies that focus on the heterogeneity of outcomes for adults with IDs and depression. More specifically, minimal research has been carried out examining potential predictors of outcome of psychological therapies in adults with IDs. Therefore, rather than examine predictors of outcome separately for BeatIt and StepUp, we feel it is more relevant to identify potential predictors that health and social care practitioners can make use of as part of the process to tailor psychological therapies to the needs of adults with IDs, more broadly. However, this broad approach generates guidance for practitioners rather than evidence that can be automatically generalised to all therapies and researchers should consider examining predictors of specific relevance to individual therapeutic approaches in the future.

Implications for clinical practice

Co-existing anxiety was an independent predictor of outcome in people diagnosed with depression. This highlights the importance for clinicians to complete a comprehensive assessment of all symptoms of mental ill-health, regardless of what the most prominent category of symptoms are. For example, in one study of co-morbid depressive and anxiety diagnoses, 78.5% of participants with depressive disorder met criteria for the diagnoses of additional mental ill-health (Kessler *et al*. 2003). This will allow service users and clinicians to discuss treatment options and priorities for co-existing conditions and help to improve clinical outcomes.

The finding that several baseline variables influenced the outcome of treatment with BeatIt and StepUp reinforces the potential value of a personalised approach to the management of mental ill-health experienced by adults with IDs. Many psychological therapies provide the flexibility for clinicians to personalise their approach to the functioning and needs of individuals. To personalise psychological therapies, clinicians should complete a detailed assessment and formulation. We have highlighted potential ways to tailor psychological therapies to the needs of individuals with anxiety symptoms, lower performance IQ, hearing impairments and low expectation of change above. We encourage therapists to use their experience and creativity to personalise the treatment of depression, in the context of a clear therapeutic approach. Interestingly, the BeatIt and StepUp therapists in the study felt that developing a strong grasp of the interventions gave them the confidence and know how to adapt their approach to meet the particular needs of the individuals they worked with (Smith *et al*. 2021).

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Author contributions

Melville: Conceptualisation, Methodology, Funding Acquisition, Writing- Original Draft Preparation. **Hatton:** Conceptualisation, Methodology, Funding Acquisition, Writing- Reviewing and Editing. **Beer:** Methodology, Writing- Reviewing and Editing. **Hastings:** Conceptualisation, Methodology, Funding Acquisition, Writing- Reviewing and Editing. **Cooper:** Conceptualisation, Funding Acquisition, Writing- Reviewing and Editing. **McMeekin:** Writing- Reviewing and Editing. **Dagnan:** Conceptualisation, Methodology, Funding Acquisition, Writing- Reviewing and Editing. **Appleton:** Project Administration, Data Curation, Writing- Reviewing and Editing. **Scott:** Investigation, Writing- Reviewing and Editing. **Fulton:** Investigation, Data Curation, Writing- Reviewing and Editing. **Jones:** Conceptualisation, Funding Acquisition, Writing- Reviewing and Editing. **McConnachie:** Conceptualisation, Methodology, Funding Acquisition, Formal Analysis, Writing- Reviewing and Editing. **Zhang:** Methodology, Funding Acquisition, Formal Analysis, Writing- Reviewing and Editing. **Knight:** Investigation, Writing- Reviewing and Editing. **Knowles:** Investigation, Writing- Reviewing and Editing. **Williams:** Conceptualisation, Funding Acquisition, Writing- Reviewing and Editing. **Briggs:** Conceptualisation, Funding Acquisition, Writing-

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Reviewing and Editing. **Jahoda:** Conceptualisation, Methodology, Funding Acquisition, Supervision, Writing- Original Draft Preparation.

Conflict of interest

AJ, CM, RH, CH, S-AC, DD, AM, RJ, CW, and AB all report receiving grant funding from the National Institute for Health Research during the course of the study. All other authors declare no competing interests.

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Data availability statement

The data are not publicly available due to privacy or ethical restrictions.

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