Behavioural activation versus guided self-help for depression in adults with learning disabilities: the BeatIt RCT

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Scientific summary

The BeatIt RCT

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Scientific summary

Background

Depression is at least as common in adults with learning disabilities as it is in the general population, with a point prevalence of ≈5%. Indeed, depression is the most common type of mental ill health experienced by adults with a learning disability. Depression is more enduring in such adults than in the general population, suggesting that it is either a more severe disease or more poorly managed. For example, a study with a British cohort found that adults with a learning disability were four times more likely than adults with no learning disability to meet the criteria for chronic depression over a 28-year period.

In recent years there have been important innovations in the treatment of depression. A number of high-intensity psychosocial interventions are as efficacious as, and longer lasting than, medications in the treatment of non-psychotic depression. This was confirmed in a recent individual patient-level meta-analysis with over 1700 patients treated in randomised controlled trials. In 2016, the National Institute for Health and Care Excellence (NICE) identified that the only available evidence on psychological interventions for depression in people with a learning disability was for cognitive–behavioural therapy (CBT), adapted for people with a learning disability. However, it was of very low quality.

Behavioural activation has been shown to be at least as efficacious as antidepressant medications, and superior or non-inferior to CBT, placebo pills and treatment as usual among people with more severe depression, and to have effects as long lasting as CBT following treatment termination. Behavioural activation is more accessible than CBT for people with learning disabilities as it focuses on behaviour more than on cognition, and is therefore less reliant on expressive and receptive communicative abilities or the ability to grasp abstract concepts. The emphasis is on increasing engagement with potential environmental reinforcers. It is also possible to train non-specialist nurses to deliver behavioural activation.

Objectives

The primary objective was to measure the clinical effectiveness of behavioural activation (BeatIt) for adults with a learning disability and depression, compared with a guided self-help intervention (StepUp), in reducing self-reported depressive symptoms.

The secondary objectives concerned whether or not BeatIt had significantly better outcomes than StepUp in relation to (1) carer-reported depressive symptoms, (2) self-reported anxiety symptoms, (3) carer-reported aggressiveness, (4) improved levels of activity and quality of life (QoL) and (5) an improvement in the carer's relationship with the adult with a learning disability who they supported and a greater confidence in supporting adults with learning disabilities who are depressed.

The trial was supplemented with an economic evaluation to consider the cost-effectiveness of providing the intervention compared with the attention control. There was also a qualitative study to explore the views and experiences of participants and their supporters and therapists, using a framework analysis.

Methods

This was a multicentre, single-blind randomised controlled trial (RCT) of an adapted behavioural activation (BeatIt) compared with an adapted guided self-help intervention (StepUp). To ensure that it would be

possible to recruit participants, there was an initial internal pilot phase in Scotland before opening study sites in England and Wales.

The inclusion criteria for participants were: (1) mild to moderate learning disabilities, (2) aged ≥ 18 years, (3) clinically significant depression as assessed using the Diagnostic Criteria for Psychiatric Disorders for use with Adults with Learning Disabilities (DC-LD), (4) the ability to provide informed consent, (5) sufficient communicative abilities to engage in therapy, (6) having a supporter who could accompany them to therapy sessions and (7) having a carer who could provide information for baseline assessments.

The primary outcome was measured using the Glasgow Depression Scale for people with a Learning Disability (GDS-LD) score at 12 months post randomisation. Secondary outcomes were emotional and interpersonal difficulties (carer ratings of depressive symptoms and aggressiveness, self-report of anxiety symptoms); QoL (including community involvement, domestic and leisure activity and perceived social support); adaptive behaviour; carer self-efficacy and patient–carer relationships; life events; and resource and medication use. The primary and secondary measures were collected at baseline and 4 and 12 months post randomisation. Participants' expectations of therapy were also assessed at baseline. Service use data were collected from carers at 8 months. Participants and supporters taking part in the qualitative study were interviewed after the 4-month follow-up to ensure that they could still recall their experience of therapy. Therapist focus groups took place once all participants had completed therapy.

BeatIt was a 12-session manualised behavioural activation intervention, delivered to participants by therapists alongside a supporter, ordinarily within a 4-month period. The focus was on increasing activity, and involved formulating the participants' difficulties, scheduling activity and addressing barriers to change. The guided self-help intervention, StepUp, was chosen as the attention control because it was deemed comparable to BeatIt in terms of therapist attention, the use of a structured, manualised approach and the presence of a supporter. A series of four booklets concerning depression and factors linked to low mood, such as sleep, provided a focus for the sessions. Both therapies were delivered on an outreach basis.

Results

In total, 161 participants were randomised, 84 to BeatIt and 77 to StepUp. Participant retention was good, with 141 participants completing the trial. The majority of participants were recruited through specialist learning disability, community health and social care services, with a small number recruited from Improving Access to Psychological Therapies services.

The baseline data suggested that participants had severe/enduring difficulties, with 66% of those allocated to StepUp and 63% of those allocated to BeatIt prescribed antidepressants. In addition, 18% of participants allocated to StepUp and 20% allocated to BeatIt had received prior psychological therapy and participants had extensive contacts with psychology, psychiatry and community nursing.

There was good adherence, with participants in the BeatIt arm attending an average of 9.9 sessions and those in the StepUp arm attending an average of 7.1 sessions. Moreover, therapists from both arms of the trial were rated strongly for non-specific components such as warmth and empathy, and delivered the therapy with excellent fidelity to the manuals.

Primary outcome

Both groups improved during the trial, but there were no statistically significant group differences in the effects of StepUp and BeatIt on depression scores (measured using the GDS-LD) at the 12-month primary outcome point.

Secondary outcomes

There were within-group reductions in both arms of the study on depression scores (measured using the GDS-LD) at 12 months (–4.20 points for BeatIt and –4.46 points for StepUp). The reductions occurred between baseline and the 4-month follow-up, immediately following the end of therapy, and there were no changes between the 4-month and 12-month follow-ups. Other psychological outcomes followed a similar pattern of results to the primary outcome. For carer-reported depression in the participants, self-reported anxiety and carer-reported aggressive behaviour, there were no treatment group differences. Within-group analyses showed reductions in carer-reported depression and self-reported anxiety from baseline to both 4 and 12 months post randomisation, associated primarily with reductions from baseline to 4 months that were maintained through to follow-up. Similar findings for carer-reported aggression showed a reduction from baseline to 4 months, but for the BeatIt group only.

In terms of QoL outcomes, there was increased participation in domestic and leisure activities in the BeatIt group at 12-month follow-up compared with the StepUp group. Although self-reported health-related QoL [measured using the EuroQol-5 Dimensions – youth version (EQ-5D-Y)] followed a similar pattern of within-group analysis findings (improvements compared with baseline in both treatment groups). Adaptive behaviour skills showed no treatment group differences at 12 months.

Carers' sense of self-efficacy in supporting adults with a learning disability and depression increased within both treatment groups from baseline, but again there were no treatment group differences at either 4 or 12 months' follow-up.

Given the lack of differences between the BeatIt and StepUp groups at the primary end point (12-month follow-up), it is not surprising that there was also no economic evidence to suggest that BeatIt may be more cost-effective than StepUp. No differences in resource use were found at 12 months. Overall, the vast majority of the support costs for participants in both treatment groups were not related to the treatments themselves; intervention costs were approximately 4–6.5% of the total support costs.

Exploratory analyses of predictors and potential moderators of outcomes suggested that the two treatments worked equally across a variety of participant characteristics. Notably, intelligence quotient (IQ) scores were unrelated to outcome. One interesting finding was that the participants' positive expectation of change at the outset predicted a better outcome.

Results of the qualitative research with participants, supporters and therapists were almost without exception in concert with the quantitative findings. In particular, both treatments were perceived as active interventions and both treatments were valued in terms of their structure, content and perceived effect/outcomes. The qualitative data from supporters did offer additional insight in relation to the putative impact on carer–participant relationships. Supporters reported understanding more about the person and/or their depression following either treatment and reported more positive relationships with participants following either treatment.

Implications for practice

Primary and secondary outcomes, economic data and qualitative results all clearly demonstrate that there was no consistent evidence that BeatIt was more effective than StepUp. The improvement seen with both BeatIt and StepUp may mean that they are effective, but in the absence of an inactive control, this cannot be determined.

There is an absence of accessible psychosocial interventions for adults with learning disabilities who are depressed. This research was unable to determine if these two interventions could fill that gap.

Implications for future research

This study has shown that the intervention is acceptable and practical in routine settings. A further evaluation of BeatIt against an inactive control would be needed to assess its clinical effectiveness.

Trial registration

This trial is registered as ISRCTN09753005.

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