Positive behaviour support training for staff for treating challenging behaviour in people with intellectual disabilities: a cluster RCT

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Scientific summary

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Background

People with intellectual disability (ID) present with significant impairments in cognitive, social and practical skills. Between 10% and 15% of adults with ID also present with challenging behaviour, with aggression being the most common type. Challenging behaviour is associated with long-term hospitalisation (often out-of-area), restrictive care practices and neglect, as well as increased service use and prescription of antipsychotic medication. The existing literature on pharmacological and psychosocial interventions is limited to observational studies and single-site randomised controlled trials (RCTs) that focus on short-term outcomes and are therefore vulnerable to significant bias.

Despite the dearth of interventions for adults with ID and challenging behaviour, there is substantial evidence for the efficacy of a psychosocial intervention, Positive Behaviour Support (PBS). PBS is a multicomponent approach that is focused on reducing challenging behaviour and improving quality of life in people with ID as well as other populations. It focuses on identifying and understanding the individual's behaviour and the context in which the behaviour occurs in order to provide a personalised PBS plan for each individual. A pilot study of a specialist team delivering PBS including applied behavioural analysis reported a significant reduction in challenging behaviour at 6 and 24 months. Moreover, longitudinal findings from observational studies have shown that training paid care staff in PBS can reduce challenging behaviour.

Although the efficacy of PBS appeared to be supported by a number of small-scale studies, a definitive trial of its effectiveness in pragmatic conditions was warranted.

Objectives

Primary objective

Examine the clinical effectiveness of staff training in PBS on carer-reported ratings of challenging behaviour over 12 months as measured by Aberrant Behaviour Checklist – Community total score (ABC-C_T) in community-dwelling adults with ID.

Secondary objectives

1. Examine the cost-effectiveness of staff training in PBS.
2. Examine the impact of the intervention on the prescription of psychotropic medication, paid carer and family carer burden, service user mental status as well as participation in community-based activities over 12 months when compared with treatment as usual (TAU) alone.
3. Measure the influence on the primary outcome of level of ID, adaptive behaviour scores, mental health status and autism spectrum disorder (ASD) status.
4. Carry out an exploratory analysis of the impact of the intervention on all measures in a subsample of participants with an ASD over 12 months.
5. Understand factors that promote and hinder the successful training of staff and the delivery of PBS within community ID services.

Design

This study was a multicentre, single-blind, two-arm, parallel-cluster RCT with active recruitment. It evaluated the clinical outcomes of adults with challenging behaviour and ID who are treated by staff who have received manual-assisted face-to-face staff training in PBS. The unit of randomisation was the community ID service using an independent web-based randomisation system (Sealed Envelope Ltd, London, UK) and random permuted blocks on a 1 : 1 allocation stratified by a staff-to-patient ratio for each cluster.

Sample size

In order to have 90% power and a 5% level of significance to detect a difference of 0.45 standard deviations in ABC-C_T measured over 12 months between treatment arms, we estimated that we needed to recruit a minimum of 19 clusters and 246 participants. It was assumed that there would be no treatment by time period interaction over 12 months, as supported by a previous pilot study. Sample size calculations included an attrition rate of 10% over the 12-month period.

Setting

We recruited 23 community ID services through the Clinical Research Networks, covering urban, semi-rural and rural areas in England. All of the participating services support adults with ID who display challenging behaviour.

The inclusion criteria for services were (1) a willingness to participate in the study, (2) availability of at least two staff members willing to train in PBS and (3) written agreement by the service manager to participate in the study. We excluded services that had already received training in PBS and were delivering it to their patients.

Participants

Adults with ID and challenging behaviour were recruited through participating community ID services. The inclusion criteria were (1) eligibility to receive care from an ID service, (2) age $\geq$ 18 years, (3) mild to severe ID and (4) an ABC-C_T of $\geq$ 15 at the initial screening. We excluded (1) participants with a primary clinical diagnosis of personality disorder or substance misuse, as there is no evidence to support PBS as intervention for such disorders; (2) participants experiencing a relapse of a pre-existing mental disorder; and (3) participants whose clinical team decided that a referral to the study would be inappropriate.

Professionals at each participating ID service identified potential participants who were screened for eligibility prior to randomisation of the clusters.

Interventions

Manual-assisted face-to-face training in PBS was provided to therapists from the community ID services that were randomised to the intervention arm. The training was conducted by expert trainers over a total of 6 days, delivered in three 2-day workshops over the course of 15 weeks. It covered the use of functional behavioural assessment, primary prevention, secondary prevention and reactive strategies, as well as periodic service review and problem-solving. Post-training mentoring was offered to staff therapists for at least 1 year. Several meetings took place with service managers and therapists in order to ensure that they were 'buying in' to the study and to ensure the ongoing support of the therapists. The TAU arm continued with their existing treatment approaches.

Main outcome measures

The primary outcome was the challenging behaviour of participants as measured by the ABC-C_T. Secondary outcomes were (1) symptoms of mental disorder (Mini Psychiatric Assessment Schedules for Adults with Developmental Disabilities), (2) community participation (Guernsey Community Participation and Leisure Activities Scale), (3) family carer burden (Uplift/Burden Scale), (4) family carer psychiatric morbidity (General Health Questionnaire) and (5) paid-carer burden (Caregiving Difficulty Scale – Intellectual Disability). The EuroQol-5 Dimensions Youth was conducted to calculate quality-adjusted life-years (QALYs) and a modified version of the Client Service Receipt Inventory (CSRI) for people with ID was administered to collect information on the costs of care. Primary and secondary outcome measures were paid carer- or family carer-administered at all three assessment time points. In addition, we collected demographic information, level of ID (as measured by the Wechsler Abbreviated Scale of Intelligence) and carer-reported adaptive behaviour (as measured by the short version of the Adaptive Behaviour Scale) at baseline. Furthermore, the use and/or change of all medications and serious adverse events (SAEs) were recorded for the duration of the trial.

Process evaluation

The aim of the process evaluation was to explore service users', carers', therapists' and managers' views of both the intervention and the training components by means of individual semistructured qualitative interviews. It also explored reasons that may have had an impact on implementation in a clinical setting and the overall reach and dose of the intervention. An independent quality assessment of behaviour plans was conducted using the Behaviour Intervention Plan Quality Evaluation Scoring Guide II.

Results

A total of 246 participants were recruited from 23 teams, of whom 109 were treated by 1 out of 11 teams in the intervention arm and 137 were treated by 1 out of 12 teams in the control arm. One participant who did not meet the inclusion threshold on the ABC-C_T was erroneously consented and was therefore excluded from the analysis.

We found no significant difference in challenging behaviour between the intervention and control arms [mean difference –2.14, 95% confidence interval (CI) –8.79 to 4.51; $p = 0.528$]. The intracluster correlation coefficient (ICC) for the ABC-C_T at the service level was 0.021 (95% CI 0.001 to 0.286). The ICC for the repeated measures within participants was 0.625 (95% CI 0.542 to 0.702).

The sensitivity analyses adjusting for (1) area deprivation, (2) the nature of the respondent, (3) unbalanced baseline characteristics, (4) the percentage of PBS plans written, (5) a model including two random effects and (6) imputing missing values with 'Baseline Observation Carried Forward' all gave similar results, with differences in ABC-C_T between arms ranging from –3.45 to –0.81. Multivariate analysis examining the effect of training staff in PBS on the individual domains of the ABC-C_T (excluding the inappropriate speech domain because of low correlations) showed that the intervention had a similar effect on all four domains, varying from a standardised difference of –0.016 (95% CI –0.22 to 0.19) for the lethargy, social withdrawal domain to –0.050 (95% CI –0.25 to 0.14) for the stereotypic behaviour domain between the two arms.

No treatment effects were found for any of the secondary outcomes including the autism subgroup analysis.

Twenty-nine participants experienced 45 SAEs (intervention arm, $n = 19$; control arm, $n = 26$) relating to physical health problems, with some of these participants requiring hospital admission. Two participants were admitted to hospital for exacerbation of challenging behaviour during the study.

Findings from the health economic evaluation revealed that the mean cost per participant in the intervention arm was £396 for training and £1201 for delivery of the intervention. Over 12 months, there was a difference in QALYs of 0.076 in favour of PBS (95% CI 0.011 to 0.140 QALYs). There is a 60% chance that the intervention is cost-effective compared with TAU from a health and social care cost perspective at the threshold of £20,000 per QALY gained.

The process evaluation of the intervention revealed that 24 out of 108 data sets were complete, 47 were incomplete and in 37 cases there were no data. Sixty-three participants were seen by staff, who spent an average of 27.57 hours on each case (range 1–138 hours). A total of 61 data sets were sent to an independent reviewer to assess procedural integrity. The 33 available PBS plans were considered to be insufficient to have an impact on behaviour. The participants who were interviewed reported an increased knowledge of PBS and of service users' needs, increased therapist and support self-agency, and improved participant support. The most commonly reported challenges in delivering the intervention were managing PBS paperwork, therapist time constraints and paid carer turnover.

Long-term follow-up

The purpose of the long-term follow-up was to examine whether the clinical effectiveness and cost-effectiveness of staff training in PBS of treating challenging behaviour was sustained or improved over a mean 36-month follow-up. No formal power calculation was performed.

A total of 184 participants (75%) were seen (intervention arm, $n = 79$; control arm, $n = 105$). The findings were similar in that the reduction of challenging behaviour was not significantly different between the arms as it reduced over time in both arms (mean ABC-C_T difference –3.70, 95% CI –9.25 to 1.85; $p = 0.191$).

Adjusting for baseline differences, the mean incremental health and social care cost of staff training in PBS compared with TAU is £501 (95% CI –£1274 to £270). The initial finding of a gain in QALYs (PBS minus TAU) was not sustained (0.160 QALYs gained, 95% CI –0.034 to 0.355 QALYs gained).

Conclusions

To our knowledge, this study is the first independent, multicentre, pragmatic RCT of manual-assisted staff training in PBS for treating adults with ID and challenging behaviour. There was a non-significant difference in challenging behaviour between the two arms over 12 months, suggesting that staff training in PBS in our study was no more effective than TAU in reducing challenging behaviour. This result persists at 36 months. Although there was evidence for staff training in PBS being cost-effective as a result of improvements in quality of life, significant improvements were not sustained at 36 months.

Implications for health care

Taking together our main study and long-term follow-up findings, we argue that staff training in PBS at scale is not associated with significant benefits (i.e. a reduction in challenging behaviour or family and paid carer outcomes). It is possible that a failure to fully implement the intervention within the pragmatic conditions of the study may have hindered the realisation of any impact of the intervention. Furthermore, the improvement in health-related quality-of-life findings were not maintained longer term; therefore, we need to be cautious about interpretation given the lack of clinical effectiveness.

Therapists, parents, staff and service managers gave a positive account of the impact of the training, but there were many challenges for therapists and managers in incorporating the specialised elements, for example observations, plans and periodic service reviews, in routine care. Moreover, reporting of psychotropic medication remained stable in both study arms, suggesting that the intervention does not target a reduction or change in the use of psychotropic medication specifically. Although a greater

awareness of PBS has been achieved, overmedication and inpatient numbers stubbornly remain problems as intractable today as they were when the study began.

Recommendations for research

A number of priorities have emerged as requiring further investigation:

- clarity about the PBS components that are most likely to be effective
- mechanisms of action for PBS within different domains such as the family home, care environments, inpatient units, etc.
- service models that are most likely to facilitate delivery
- patient-reported outcomes of interest.

Trial registration

This study is registered as NCT01680276.

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