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Clinical outcomes of staff training in Positive Behaviour Support (PBS) to reduce challenging behaviour in adults with intellectual disability: a cluster randomised controlled trial

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Abstract

Background: Staff training in Positive Behaviour Support (PBS) is a widespread treatment approach for challenging behaviour in adults with intellectual disability (ID).

Aims

To evaluate whether such training is clinically effective in reducing challenging behaviour during routine care (Trial registration: NCT01680276).

Method

We carried out a multicentre cluster randomised controlled trial involving 23 community ID services (clusters) in England, randomly allocated to either manual-assisted staff training in PBS (n=11) or to treatment as usual (TAU, n=12). Individual data were collected from 246 adult participants.

Results

No treatment effects were found either for the primary outcome (challenging behaviour over 12 months, adjusted mean difference =-2.14, 95% CI -8.79 to 4.51) or secondary outcomes.

Conclusions

Staff training in PBS, as applied in this study, did not reduce challenging behaviour in addition to TAU. Further research should tackle implementation issues and endeavour to identify other interventions that can reduce challenging behaviour.

Introduction

Challenging behaviour is common in adults with ID, has a reported prevalence of 10-15%[1,2] and often leads to long-term hospitalisation, restrictive care practices and neglect.[3-5] The need for effective treatment options for challenging behaviour is urgent. Positive Behaviour Support (PBS) is recommended in routine care for adults with ID who present with challenging behaviour as it has the greatest evidence base regarding efficacy. PBS is a multicomponent approach focused on reducing challenging behaviour with the use of behavioural techniques and consequently improving quality of life in individuals with ID[6] and other population groups across the lifespan.[7-10] PBS aims to help professionals and family or paid carers have a better understanding of an individual's behaviour, and to apply personalised approaches to the management of that behaviour. It can be implemented in a number of ways, including via a single practitioner;[11-13] via professional teams offering interdisciplinary contributions to the PBS framework;[14,15] and via a system-wide implementation comprising a tiered-model of prevention that covers an entire organisation or geographical area.[16]

The only pilot Randomised Controlled Trial (RCT) of PBS incorporating Applied Behaviour Analysis (ABA) was delivered by a specialist behaviour team in one area in England and it showed promising results by reducing the lethargy and hyperactivity domain scores of the Aberrant Behaviour Checklist-Community (ABC-C).[17,18] A naturalistic 2-year follow-up of the same trial participants showed a continued positive effect of the intervention compared to TAU.[19] Observational studies also showed that training of paid care staff in

PBS reduces challenging behaviour.[20] Evidence indicates that staff competencies are central in treating challenging behaviour, maintaining improvements[21] and reducing reliance on containment and inpatient care.[22,23] To the best of our knowledge, although PBS is considered to be a cornerstone of good quality care internationally, staff in community ID services may have insufficient skills to deliver it. There are multiple staff training programmes in PBS which show increases in knowledge and perceived confidence in managing challenging behaviour.[24] This real-world independent multicentre trial investigated the clinical and cost effectiveness of health staff training in PBS in addition to treatment as usual (TAU) to reduce challenging behaviour in adults with ID in England. The present paper reports the clinical outcomes of the definitive trial. The economic evaluation of the study is in preparation. The main objective was to compare clinical effectiveness of staff training in PBS compared to treatment as usual (TAU) alone over 12 months. Secondary objectives were to examine 1) the impact of training in PBS in the subgroup with Autism Spectrum Disorders (ASD) and 2) the interaction between the intervention, gender, level of ID, presence of mental disorder and challenging behaviour.

Methods

Study design

The study protocol has been described elsewhere.[21] In summary, this was a multicentre single-blind parallel two-arm cluster randomised controlled trial of 23 community ID services in England with active recruitment.

The study received ethical approval by the NRES Committee London-Harrow (reference 12/LO/1378).

Service and participant recruitment

The community ID services supporting adults with ID and challenging behaviour (hereinafter referred to as clusters) were recruited through the Clinical Research Networks covering urban and semi-rural/rural areas in England. The number of registered adults with ID in each cluster ranged from 100 to 1000 and services employed a median of 23 full-time equivalent health and/or social care staff (range 4-70). Included were a maximum of 14 participants with ID aged 18 years and over with any level of ID (mild to profound) and challenging behaviour as indicated by a total score of at least 15 on the ABC-C[18] were recruited from each cluster. Excluded were 1) participants with a primary clinical diagnosis of personality disorder or substance misuse as there is no evidence that PBS would be a treatment of choice, participants with a relapse of a pre-existing mental disorder, or where the clinical team decided that a referral to the study would be inappropriate and 2) clusters which had embedded PBS therapists or local specialist behaviour teams. Health and social care professionals in each cluster identified potential participants who were screened for eligibility and expressed interest to meet with researchers prior to cluster allocation. Clinical managers in each cluster were asked, and they agreed, to reduce the routine caseload of the staff who volunteered to train by about 30% in order to allow them sufficient time to deliver enhanced treatment to the trial participants. This was based on an assumption of spending a total of

approximately 12.5 hours on the intervention per participant, excluding travel and paperwork.

Easy read information sheets and consent forms were prepared with assistance from the study service user reference group. Researchers were trained in obtaining informed consent and in the study processes. Where a participant lacked capacity another adult was identified or nominated to act as consultee on their behalf.

Randomisation and masking

The clusters were randomised using an independent Web-based randomisation system (Sealed Envelope) and random permuted blocks on a 1:1 allocation. We stratified the randomisation by calculating the staff:patient ratio for each cluster, creating a binary factor which indicated whether a cluster was below or above the median ratio. The trial manager contacted the sites to inform them of the treatment allocation.

Researchers conducting the study assessments were blind to arm allocation status. Researchers were asked to guess allocation for each participant at each follow up point and to report any incident of unblinding.

Procedures

PBS training

Two health staff (henceforth, referred to as therapists) from a variety of professions, e.g. psychiatrists, psychologists, nurses, occupational therapists, and speech and language therapists, from each cluster volunteered to receive

the training. This included three two-day face-to-face workshops supported by a manual and delivered by an organisation with a track record in training delivery across many clinical settings and a wide consultancy client base. The curriculum consisted of the following topics which are essential elements of the application of PBS in routine care:

a) Functional Behavioural Assessment and formulation skills using the Brief Behavioural Assessment Tool for brief functional analyses

b) Primary Prevention of challenging behaviour

c) Secondary Prevention and Reactive Strategies

d) Periodic Service Review and Problem Solving

- Developing individualised periodic service reviews
- Troubleshooting

PBS is a combination of approaches which are mainly aiming at altering aspects of the environment that may impact on behaviour. These include understanding of the triggers that lead to a behavioural outburst, improvement of communication between the individual and his/her carers, promotion of a person-centred community living and the use of specific techniques to achieve changes in behaviour by encouraging pro-social responses from the individual. Therapists were shown how to 1) fill in behavioural charts, 2) work on developing interventions for each identified behaviour, 3) plan interventions using non-contingent reinforcement, skills teaching and differential reinforcement, 4) take into consideration the impact of other potential triggers such as ill health. Each participant's plan should, therefore, include some of these aspects after a comprehensive assessment and observations. Two cohorts of therapists were trained over a 15-week period and therapists were

expected to have begun work with participants who had completed a baseline assessment after the first workshop. The therapists received a certificate of completion of training. This is an accepted training format deemed appropriate for the study, although variations in duration and content internationally do exist.

Each therapist was allocated one of the four trainers as a mentor for one year and the therapists were responsible for utilising this facility which was aimed at maintaining motivation and enhancing practice skills. However, in order to ensure an increase in uptake, monthly teleconferences and site visits by trainers and study personnel were conducted, together with the therapists being supported by an administrator in completing and submitting trial-related paperwork.

Clinical responsibility remained with the clusters.

Treatment as usual

TAU included any treatment approach that is available to community ID teams within the NHS. Most services in England employ a variety of health and social care professionals and patients have access to behavioural, psychosocial, and pharmacological interventions, e.g. physical health checks, simple behavioural modification, prescribing and monitoring of psychotropic medication. None of those treatments is strongly evidence-based but there is sufficient guidance concerning “what good care looks like”.

All aspects of TAU were also available to the participants in the intervention arm.

In 5 cases, it was revealed that trial participants lived in accommodation where the provider had offered PBS awareness seminars or employed consultants to advise its care staff on PBS approaches.

The researchers collected participant demographic information (gender, age, ethnicity), level of ID (measured by the Wechsler Abbreviated Scale of Intelligence; WASI) [25] and carer-reported adaptive behaviour (measured by the short version of the Adaptive Behaviour Scale[26]) at baseline. Cause of intellectual disability was recorded if known. Participants were also screened for autism using the autism symptom checklist of the Mini Psychopathology Assessment Scale for Adults with Developmental Disability (Mini PASADD).[27] The postcode of the participant's residence was recorded for linkage with the Index of Multiple Deprivation (IMD), obtained via the UK Data Service Website.

Follow-up assessments were conducted at 6 and 12 months after randomisation with a window of +/- 4 weeks around the due date for each assessment.

Outcomes

The primary outcome was challenging behaviour measured by the total ABC-C score (ABC-C_T) over 12 months.[18] Secondary outcomes were symptoms of mental disorder (Mini PASADD),[27] Community Participation (Guernsey Community Participation and Leisure Activities Scale-GCPLAS),[28] Family Carer Burden (Uplift/Burden Scale)[29] and Family Carer Psychiatric Morbidity-GHQ12.[30] Paid Carer Burden was measured with the Caregiving Difficulty Scale-Intellectual Disability (CDS-ID).[31] Primary and secondary outcome

measures were paid or family carer administered at all three assessment points.

Serious adverse events were defined as events that were life threatening, resulted in death, in hospital admissions/prolongation of hospitalisation and/or in persistent or significant disability or incapacity.

Statistical analysis

The sample size was calculated to detect a difference of 0.45 SD in the primary outcome, ABC-C_T score, measured over 12 months, with 90% power and 5% significance level[21] indicating that a minimum of 19 clusters and 246 participants were required

The analysis plan was developed and discussed with the Trial Management Team and further agreed with the Data Monitoring and Ethics Committee and the Trial Steering Committee which also oversaw the conduct of the study.

Primary outcome

For the ABC-C_T score, a three-level random effects regression model adjusting for baseline ABC-C_T score, time period, staff:patient ratio and effects of clustering by services and repeated measures within participants was used. This random effects model provides valid inferences under the assumption that data are missing at random (MAR). The normality assumptions of the residuals were investigated using residual plots. The primary analysis was performed by two statisticians separately to ensure its accuracy.

Pre-specified patient characteristics that were not balanced across the arms, and that were potentially related to the primary outcome, were adjusted for in a supportive analysis.

Secondary outcomes

Similar analyses were conducted for the secondary outcomes using linear or logistic models, as appropriate for the type of outcome.

Exploratory multivariate analyses

These examined the effect of staff training in PBS on standardised ABC-C_T domains using a three-level multivariate linear regression model where the standardised domains were considered simultaneously within a multivariate framework, allowing the estimation of intervention effects for multiple outcomes.

Subgroup analyses

We explored the treatment effect by gender, age groups (categorised into quartiles), level of ID, ethnicity, autism spectrum disorder, and presence of mental disorder.

Sensitivity analyses

The model used included two random effects at the service level, one for each arm.[32] The primary analysis model included the predictors of missingness as covariates with a 'Baseline Observation Carried Forward' analysis to include participants with missing values of the ABC-C_T score.

All statistical tests and confidence intervals are 2-sided. Statistical analysis was performed using STATA software version 14. All analyses were by intention-to-treat (ITT). Results from all supportive analyses are exploratory and presented as estimates with confidence intervals.

Fidelity assessment

An independent reviewer assessed all treatment documentation submitted by the therapists including functional assessment, observational data, PBS plan, and Goodness-of-Fit checklist using the Behaviour Intervention Plan Quality Evaluation Scoring Guide II (BIP-QE II). The tool is designed to evaluate the quality of behaviour intervention planning. Plans are classified as weak, underdeveloped, good or superior.

Results

Recruitment took place from 2 June 2013 to 24 November 2014. Originally, 28 clusters agreed to take part but 5 dropped out prior to allocation. From the remaining 23 clusters, 11 were allocated to the intervention and TAU arm and 12 to the TAU alone arm. In the 11 intervention clusters, twenty-one therapists were trained in total. Of the 382 potential participants that were screened, 246 (64%) consented to take part. One participant was erroneously consented as s/he did not meet the ABC-C inclusion threshold, and therefore was excluded from the analysis. The median number of participants recruited per cluster was 13 (IQR 6 – 14) (CONSORT flow diagram shown in Fig. 1).

[Figure 1 near here]

215 (87%) and 225 (92%) participants completed the 6- and 12-month follow-up, respectively. There was no difference in attrition between the arms (7% in the intervention and 9% in the TAU arms, respectively). Table 1 shows the baseline demographic and clinical characteristics of the participants.

[Table 1 near here]

At baseline the mean ABC-C_T score in the intervention arm was 61·8 (SD 27·7) compared to 68·5 (SD 29·0) in the TAU arm. In the intervention arm, ABC-C_T reduced to 55·5 (SD 32·5) at 6 months and to 54·0 (SD 32·1) at 12 months. The respective scores in the TAU arm were 60·6 (SD 32·6) at 6 months and 59·2 (SD 28·8) at 12 months.

The primary model used 439 ABC-C_T score measurements from 233 participants over the two follow-up time points. The intervention was not statistically significant compared with TAU in terms of ABC-C_T score (adjusted mean diff -2.4; 95% CI: -8.7, 4.5; p = 0.528). Details are shown in Table 2 and Supplementary Fig. 1.

[Table 2 near here]

The intracluster correlation coefficient (ICC) for the ABC-C_T score at the service level was 0.021 (95% CI 0.001, 0.286) and for the repeated measures within participants it was 0.625 (95% CI 0.542, 0.702).

None of the subgroup analyses showed a significant effect with treatment; estimates of the intervention effect on subgroups are shown in Fig. 2.

[Figure 2 near here]

A series of analyses undertaken as follows adjusting for: 1) area deprivation, 2) participant or carer respondent, 3) unbalanced baseline characteristics (ethnicity and participant's cohabitant); 4) percentage of participants within each cluster who had at least one element of the intervention; 5) a model including two random effects; 6) imputing missing values with 'Baseline Observation Carried Forward'; all showed non-significant results with differences in ABC-C_T score between arms ranging from -3.4 to -0·8. None of

the participant baseline data predicted missing data and, therefore, no further analyses were conducted (Supplementary Table, ST, 1).

Multivariate analysis examined the effect of the intervention on the individual domains of the ABC-C. The inappropriate speech domain was not included in the multivariate model as it had low correlations (ρ=0·300, 0·094, 0·175, 0·360) with the (i) irritability, agitation, crying; (ii) lethargy, social withdrawal; (iii) stereotypic behaviour; and (iv) hyperactivity, non-compliance domains respectively. The intervention had no significant effect on all four domains (ST1).

Regarding the secondary outcomes, there were no differences between the arms for mental illhealth or frequency of community activities over 12 months. In total, 69 family carers were included in the study, 19 in the intervention arm and 50 in the TAU arm. The majority (n=59, 86%) were female with a median age of 54 years (IQR 48-59). Due to the small numbers in the intervention arm, only descriptive analyses were undertaken. One hundred and seventy-five (175) paid carers took part in the study, 89 in the intervention arm and 86 in the TAU arm. Two thirds (n=108, 67%) were female with median age of 41 years (IQR 32-53). Over the 12 months, 86 (49%) of the paid carers changed (49 in the TAU arm and 37 in the intervention arm, respectively) and therefore, no further analyses were carried out (ST2).

Psychotropic medication

Sixty-three percent (63%) of participants in the intervention arm and 65% in the control arm were receiving antipsychotic medication by the end of the study. The respective proportions of other psychotropic applications were 72% and 76%, respectively. The proportions of participants on antipsychotics and

other psychotropic medications remained stable across the two arms over the study duration.

Serious adverse events

Twenty-nine (29) participants experienced 45 serious adverse events unrelated to the intervention, mainly hospitalisations for a variety of physical ailments and one death. Twenty-six (26) of the serious adverse events occurred in the intervention arm and 19 in the TAU arm.

Thirteen participants (3 in the intervention arm and 10 in the TAU arm) moved from their original address to a new home due to either closures of previous accommodation or changes in the participants' needs.

Fidelity of intervention and implementation

Eight (8) of the 26 trained therapists left the study due to long-term illness, maternity leave, sabbatical or job changes. Out of a possible 108 intervention reports, 33 included all elements, i.e. functional assessment, observational data, PBS plan, and Goodness-of-Fit checklist. Forty-seven included 1-3 elements and for 28 participants there was no submitted paperwork due to the person being not seen, participant's refusal to work with the therapist, not presenting with challenging behaviour at the time of contact, therapist citing lack of time to take on work relating to the study, and a PBS plan having been devised by external providers. The PBS plans included the following domains: "welcome to my PBS plan", "Understanding my behaviours", "Days that I like", "Primary prevention", "Secondary prevention", "Reactive strategies", "Evaluation and review" setting the time frame for plan review usually within 4-6 months.

The available PBS plans were rated as weak by the independent assessor. Weak plans though may lead to change in the identified behaviour but lack several of the following: a functional analysis, a range of interventions, modelling new approaches, specifying environmental changes that maintain behaviour. Over a 30-month period, the study administrator made weekly to two-weekly phone calls to the therapists, each intervention site was visited twice, and 22 teleconferences were convened which were attended by 0-4 therapists and local investigators in addition to trainers and administrators/other study personnel. The therapists rated the training and mentoring arrangements highly but several reported organisational difficulties, e.g. with obtaining overtime pay for study-related work, dissatisfaction with study-related amount of work in addition to overall caseload, participant not having challenging behaviour or high turnover of paid carers which impeded implementation of plans.

Other aspects

There were six cases of unmasking researchers to the participant's trial arm allocation; another researcher collected data from those sites. Researchers predicted the arm allocation of 123 (59%) and 126 (56%) participants at 6 and 12 months, respectively, which were not better than chance.

Discussion

The cluster RCT evaluated the clinical outcomes of training health professionals, who are specialists in working with adults with ID, in PBS to reduce challenging behaviour. It did not detect significant reductions in carer-reported challenging behaviour in the intervention plus TAU arm compared to

TAU arm alone over 12 months. Secondary outcomes were also similar between the two arms over 12 months including the proportion of participants on psychotropic medication. Given the high statistical power, the findings suggest that community ID services staff training in PBS, as delivered in this study, was no more effective than TAU in reducing challenging behaviour.

Strengths and limitations

The study has several strengths, including recruitment of the required number of participants, testing a single primary outcome, achievement of low attrition rate and an *a priori* analysis plan, which are indicators of a reduced risk of bias. The ICC for the primary outcome is smaller than that which was originally assumed. In order to guard against the tendency of the impact of training to dissipate over time, we set up long-term mentoring and peer support[33] as discussed previously. Adjusting for differences in participant characteristics at baseline in the main analysis had no bearing on study outcomes.

The study also has limitations, including the less than optimal delivery of the intervention. Thirty percent (33/108) of participants received all elements of the PBS approach as specified in the training and 43.5% received only partial input, mainly initial observations. Although not all services were able to manage a reduction in the therapist caseloads, some staff also found the amount of time spent on study-related work to be too onerous. This may be a reflection of the realities of implementing PBS within community ID services without additional resources, such as specific posts for accredited behavioural therapists.

It could be argued that gradual adoption of PBS-based care in some of the clusters in the TAU arm over the study duration may have reduced any differential between the trial arms. However, we explicitly excluded teams that employed PBS specialists or specialist teams which was supplemented by a survey of the clusters prior to the study commencing which explored pre-existing behavioural approaches, training, and resources in each cluster. The previous pilot trial[17] examined a specialist team which included highly motivated and trained behavioural specialists. Therefore, the short duration of training in this study may have been less than optimal in generating confidence in the therapists to deliver a highly complex intervention. Further, as therapists found that some participants did not present with challenging behaviour at the time of contact, hence the therapists did not initiate any of the intervention procedures. This may be accounted for by the course of challenging behaviour which has a remitting-relapsing nature.

Comparisons with existing literature

To the best of our knowledge, MacDonald and McGill[34] conducted the only systematic review to date on outcomes of training staff in PBS. The authors concluded that the training of paid care staff increases their competence in managing challenging behaviour, reduces the use of restrictive practices and reliance on other professional support but does not improve participant quality of life. However, none of the included studies used a randomised or quasi-randomised design and follow up was limited to 6 months. Therefore, previously reported significant effects of staff training in PBS on challenging behaviour are likely to be due to study bias.[35] The present study did not

measure staff skills or knowledge, hence any improvements in those aspects as a consequence of training in PBS were not captured.[36,37] Therapists may have been less confident in carrying out functional analysis, which is an important element of behavioural approaches; however, multilevel analysis of n=1 experimental studies showed that functional analysis does not moderate the relationship between an intervention and its impact on challenging behaviour, consequently such an omission is unlikely to have significantly impacted participant outcomes.[34]

McClean and Grey[38] carried out a 26-month follow up of a 5-year rolling training in PBS of paid carers. They found that no specific components of PBS plans were associated with reductions in challenging behaviour. Therefore, even though the plans in this study were rated as weak, they may have had little influence on overall improvements in behaviour. An issue remains, though, as to what are the specific ingredients that would provide added benefit to routine clinical care, given the resource-intensive task of drawing up plans and their subsequent application over time. Other researchers have begun to investigate mindfulness based PBS training to reduce restrictive practices, improve staff job satisfaction and reduce challenging behaviour in care homes.[39]

As is evident by the examination of the median scores on the primary outcome, there was a reduction in challenging behaviour for the majority of participants in both arms. Offering training in PBS beyond what is already available within community ID services does not provide added benefits in reducing challenging behaviour, use of psychotropic medication, or community engagement. Future studies, drawing from psychotherapy

research in mental health[40] should investigate the relative role of setting, participant, therapist and organisational characteristics which underlie any treatment effects found. Finally, identification and evaluation of other treatment approaches are long overdue.

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Trial Collaborators

Participating services

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Fig. 1 CONSORT flow diagram.

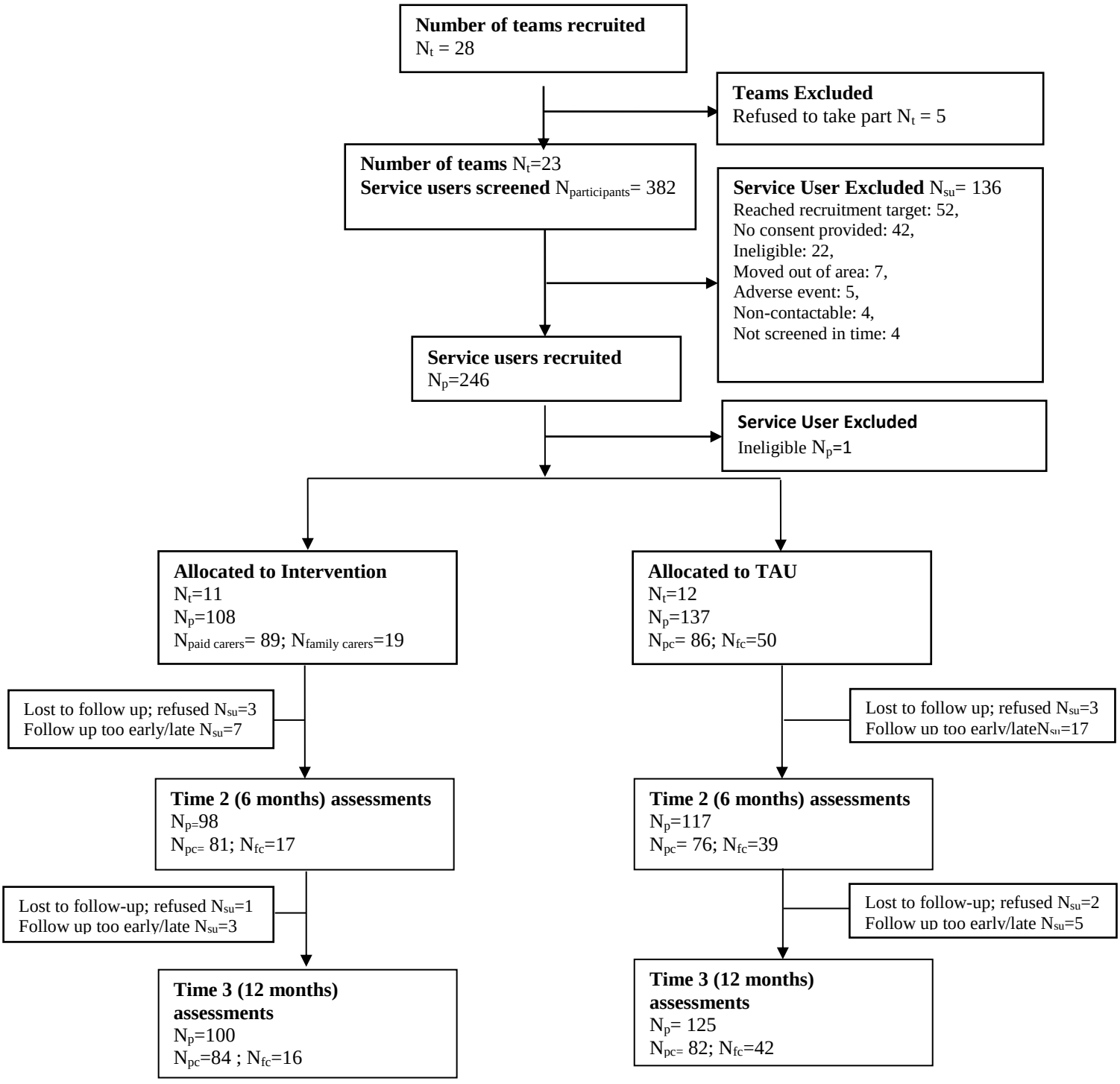


Table 1 Baseline participant characteristics

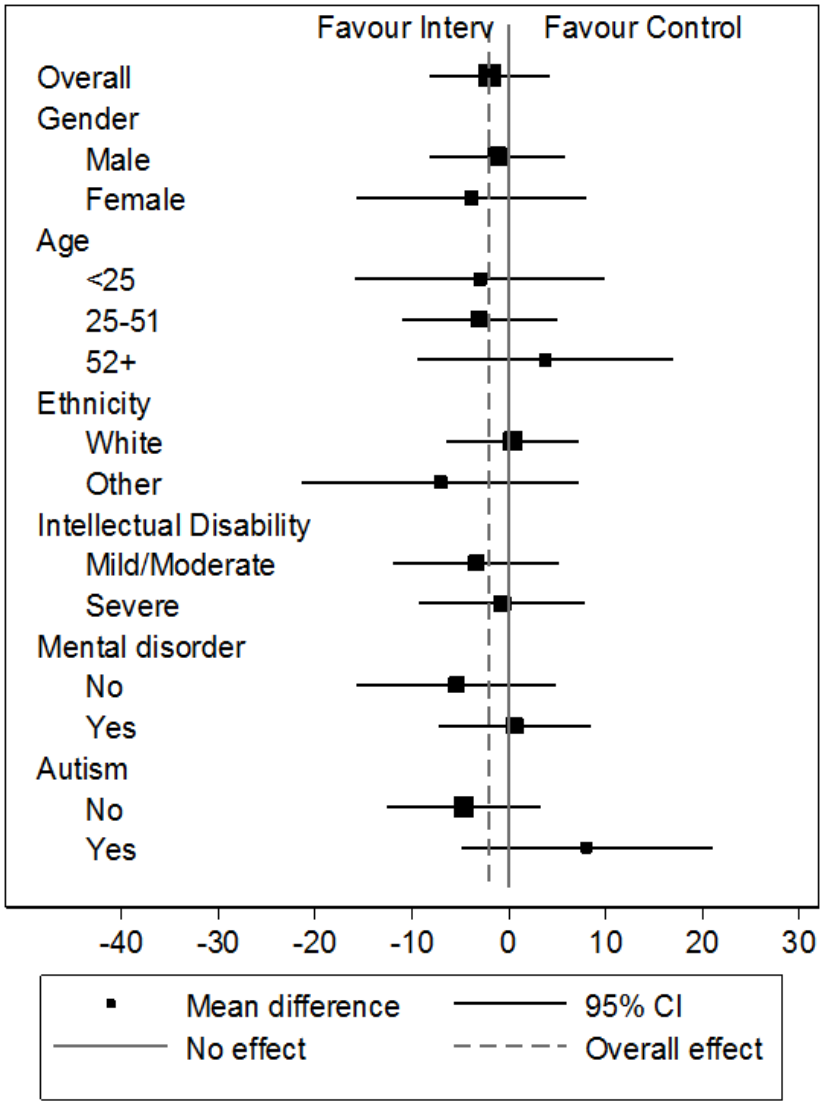
N (%)	Total (n=245)	TAU (n=137)	PBS (n= 108)
Demographics			
Age, years *(Median, IQR)*	37 (25-51)	33 (24 – 51)	42 (27 - 50)
Gender, Male	157 (64)	90 (66)	67 (62)
Ethnic origin, White	176 (72)	95 (69)	81 (75)
Service-reported level of ID			
Mild	41 (17)	17 (12)	24 (22)
Moderate	77 (31)	46 (34)	30 (28)
Severe	127 (52)	73 (53)	54 (50)
ABS (median, IQR)	48 (29,68)	42 (25,64)	55 (35,73)
WASI, Full scale IQ 4 (n=95)	44 (40,52)	43 (40,50)	46 (41,53)
Current accommodation			
Residential	105 (43)	52 (38)	53 (49)
Supported living	69 (28)	36 (27)	33 (30)
Family home	64 (26)	47 (34)	17 (16)
Own flat/house	7 (2)	2 (1)	5 (5)
Clinical			
ABC (median, IQR)			
Total score	64 (44,86)	68.5 (47,87.5)	60 (43,80)
Irritability	20 (13,29)	21.5 (15,29)	18 (11,26)
Lethargy	12 (7,21)	13 (6.5,21)	12 (7,21)
Stereotypy	5 (2,10)	5.5 (2,10)	4 (2,9)
Hyperactivity	20 (12,26)	21 (13,28)	18 (11,24)
Inappropriate speech	4 (1,8)	4 (1,8)	5 (1,8)
Medications			
Any medications	220 (90)	124 (91)	96 (89)
Antipsychotics	165 (67)	91 (66)	74 (69)
Other psychotropic	180 (73)	96 (70)	84 (78)
Mini-PASADD			
Common mental disorder	117 (49)	61 (46)	56 (52)
Severe mental illness	47 (20)	27 (20)	20 (19)
Autistic spectrum	50 (21)	31 (23)	19 (18)
Physical health problems	180 (74)	107 (80)	73 (68)
Mobility* (n=180)	64 (36)	38 (36)	26 (36)
Sensory	43 (24)	29 (27)	14 (19)
Epilepsy	67 (37)	42 (39)	25 (34)
Incontinence	78 (43)	46 (43)	32 (44)
Other	103 (57)	63 (59)	40 (55)

*Of those with physical health problems, the number of people with the named problem.

Table 2 ABC-C_T score over 12 months

Time	Arm	*N*	*Mean*	*SD*	*Median*	*IQR*
Baseline	TAU	136	68.5	29.0	68.5	47 – 87.5
	PBS	107	61·8	27·7	60	43 – 80
6 months	TAU	116	60.6	32.6	54	37 - 81
	PBS	98	55·0	32·5	50.5	30 – 75
12 months	TAU	125	59.2	28.8	55	42 – 75
	PBS	100	54·0	32·1	49	32 – 73

Fig. 2 Subgroup analysis.



Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	No changes were made
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10-11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	No changes were made
Sample size	7a	How sample size was determined	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	None planned
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7 and also 17
	11b	If relevant, description of the similarity of interventions	7-9 and in discussion
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11-12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	12

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	13 and table 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	30 in CONSORT diagram
Recruitment	14a	Dates defining the periods of recruitment and follow-up	13
	14b	Why the trial ended or was stopped	Not applicable
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	31
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	30, 32 (primary outcome)
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	32, 34, 35
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	14, table 2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	32, 34,35 and ST 1
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	16
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	18-19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19-21
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	21
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	Ref 21
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

CONSORT 2010 checklist of information to include when reporting a randomised trial*

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.