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A brief CBT intervention for depersonalisation-derealisation disorder in psychosis: Results from a feasibility randomised controlled trial

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ABSTRACT

Background and objectives: Depersonalisation/derealisation symptoms are prevalent in psychosis patients, are associated with increased impairment, and may maintain psychosis symptoms. We aimed to establish the feasibility and acceptability of a brief, six session therapy protocol adapted from a Cognitive-Behavioural model of Depersonalisation-Derealisation Disorder (DDD) in participants with psychotic symptoms.
Methods: A single-blind, randomised controlled trial was conducted with a treatment-as-usual control condition. Feasibility and acceptability estimates included rates of referral, acceptance, eligibility, consent, satisfaction and improved skills/knowledge to manage depersonalisation.
Results: Twenty-one individuals were recruited to the trial. Results suggest that the intervention was feasible and acceptable to participants and there is some signal of effect on clinical outcomes.
Limitations: There were some challenges in recruitment. Recruitment feasibility estimates from the research register used may not be informative for future trials recruiting directly from teams.
Conclusions: Overall, the results suggest that further investigations would be of interest and recommendations for this are made.

1. Introduction

Depersonalisation/derealisation (DP/DR) are types of dissociation and refer to a sense of unreality and disconnection of aspects of the self (depersonalisation-DP) and/or the external environment (derealisation-DR) (Hunter et al., 2003; Sierra et al., 2005; Simeon, 2004; Spiegel et al., 2013). These experiences can range from brief transient phenomena to chronic distressing symptoms that cause functional impairment, becoming diagnosable as Depersonalisation-Derealisation Disorder (DDD) (Hunter et al., 2017). These experiences may also happen alongside other disorders. For example, a recent review of dissociation in psychosis (Cernis et al., 2022) suggests that two thirds of individuals with non-affective psychosis experience dissociative symptoms (including DP/DR). The authors propose a network model which suggests that dissociation is a likely causal factor of hallucinations and is also implicated in paranoia (Cernis et al., 2022). Interventions that target DP/DR symptoms may therefore positively influence not only DP/DR, but also psychotic symptoms. This is an example of the 'interventionist causal' approach (Freeman et al., 2021), that proposes to improve the efficacy of Cognitive Behavioural Therapy for Psychosis (CBTp) by focusing on specific factors and processes associated with the aetiology and maintenance of psychotic symptoms.

The aim of this study was to focus on DP/DR symptoms as a putative causal factor for the maintenance of psychotic symptoms, test the feasibility and acceptability of an intervention to change DP/DR, and provide preliminary examination of its effect on psychosis symptoms. We evaluated the use of a brief, six session CBT protocol (see Hunter, 2003; 2005; Farrelly et al., 2016) designed to reduce DP/DR symptoms in those presenting to clinical services with positive symptoms of psychosis. We addressed the following research questions:

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- Is it feasible to recruit to and deliver a trial of a brief course (six sessions) of CBT that directly targets DP/DR in those with current psychotic symptoms?
- Is this therapy acceptable to participants?

2. Methodology

All procedures and reported trial parameters were in accordance with the published trial protocol (Farrelly et al., 2016); a summary is provided below. Ethical approval was obtained from NRES Committee London - Camberwell St Giles (reference number 15/LO/0081). The trial is registered on ClinicalTrials.gov (Identifier: NCT02427542).

2.1. Design

A single-blinded (researcher blinded) randomised controlled, feasibility trial with a treatment as usual (TAU) control condition was used. Assessments were conducted at baseline and 10 weeks following randomisation.

2.2. Participants

Participants were adults (aged 18–70), with active delusions and/or hallucinations (i.e., scores greater than zero on either the PSYRATS-Delusions or PSYRATS-Auditory Hallucinations scales (HADDOCK et al., 1999), who met threshold for DDD (i.e., >70 on the Cambridge Depersonalisation Scale (CDS(Sierra & Berrios, 2000),) and gave informed consent. Participants were excluded if they: were currently engaged in psychotherapy; had insufficient English proficiency for CBT; and/or had a primary diagnosis of intellectual disability, head injury, substance misuse or organic cause for psychosis.

2.3. Procedure

Research and clinic registers were screened for participants who reported active symptoms of psychosis; these potential participants had provided consent when joining the register for researchers to contact them. Referrals were also sought from local clinicians, who obtained potential participants' permission for the researcher to contact them. Potential participants were sent a letter of invitation, followed by a phone call. Potential participants were screened, provided informed consent and allocated to the intervention with TAU or TAU only control group, using an online randomisation program with randomly permuted block sizes to ensure equal allocation. TAU typically involved contact with a care coordinator and/or psychiatrist, with medication. A blinded follow-up assessment occurred ten weeks after randomisation with a different researcher (MA).

2.3.1. Intervention

The intervention involved six sessions of Cognitive Behavioural Therapy (CBT) focusing on symptoms of, and distress associated with, DP/DR. Session content was based on the protocol developed for DDD (Hunter et al., 2003, 2005) and modified for delivery in the context of psychosis. Individual formulations made links between positive symptoms of psychosis, anxiety and depersonalisation/derealisation, but the focus was on DP/DR symptoms specifically, with the rationale that a reduction in depersonalisation would, in turn, lead to an improvement in psychosis symptoms. The intervention aimed to: reduce distress through psychoeducation and normalisation (where appropriate); develop a shared formulation of current and past triggers as well as maintenance cycles; and introduce strategies that targeted cognitive, behavioural and emotional factors involved in DDD (see Box 1). The intervention components listed did not necessarily map on to individual sessions, rather sessions covered factors determined by the individual formulation of the participant. The intervention was delivered by the first author (a clinical psychologist in training) under the clinical supervision of the author of CBT model for DDD (ECMH). Supervision was weekly and covered the process and delivery of the intervention and problem solving any impasses. During the intervention period, competence in CBT and fidelity to the DPD protocol were assessed by ECMH using audio recordings of sessions.

2.4. Data collection

Demographic and relevant clinical data were collected at baseline. Feasibility of trial recruitment was assessed by monitoring rates of referral, contact with potential participants, acceptance of screening offer, eligibility and consent. Feasibility of delivering the intervention was assessed by monitoring number of sessions attended, completion of homework tasks, and number of weeks taken to complete therapy. Therapist competence and fidelity were assessed by ECMH using a random selection of 10% of intervention session audio recordings using a standardised CBT adherence measure (Blackburn et al., 2001) and a specifically designed fidelity measure for DDD protocol. Feasibility of data collection was assessed by: rate of data attrition; weeks to obtain outcome data; and number of blinding breaks.

Acceptability of the intervention was monitored by participant ratings on a five-point Likert scale on: expectations of progress, satisfaction, gained new knowledge/skills and open-ended questions about the most helpful/unhelpful aspects of the intervention.

Psychopathology data were collected at baseline and follow-up using the following (see (Farrelly et al., 2016) for full description):

- Cambridge Depersonalisation Scale (CDS; Sierra & Berrios, 2000).
- The Psychotic Symptom Rating Scales (PSYRATS; HADDOCK et al., 1999)
- Beck Depression Inventory (BDI; BECK, 1961)
- Beck Anxiety Inventory (BAI; Beck et al., 1988).
- Post-traumatic Diagnosis Scale (PDS, Foa et al., 1997).
- Structured clinical interview for DSM-IV dissociative disorders (SCID-D)(Steinberg, 1997).

2.5. Analysis

As this was a feasibility study a priori power calculations were not conducted (Arain et al., 2010). Instead, we aimed to recruit sufficient participants (n = 30) to provide reasonable estimates of study parameters according to good practice recommendations for feasibility/pilot studies (Julious, 2005; Lancaster et al., 2004), and based on estimates to screen and recruit participants in the time available for the study. A prior, unpublished study (Emma Davies, unpublished thesis) recruiting from the same pools suggested that approximately 50% of participants reporting DP/DR in psychosis also met criteria for DPD. Assuming 50% of those screened would meet the eligibility criteria, we anticipated needing to screen 60 participants to obtain our target sample.

Continuous clinical data and sample characteristics were described using mean and standard deviations (SD). Frequencies and proportions were used to analyse categorical variables. Effect sizes (Cohen's d) and confidence intervals were calculated for within-group pre-post scores. Differences in between-group change were calculated as follows: mean pre-post change in treatment minus the mean pre-post change in the control group, divided by the pooled pre-test standard deviation (Morris, 2007).

Feasibility of trial procedures, therapist adherence and acceptability of therapy were assessed using proportions and estimated 95% confidence intervals (CIs).

3. Results

Twenty-two participants were eligible and 21 consented to participate; see CONSORT in Fig. 1. Sample demographics are shown in Table 1.

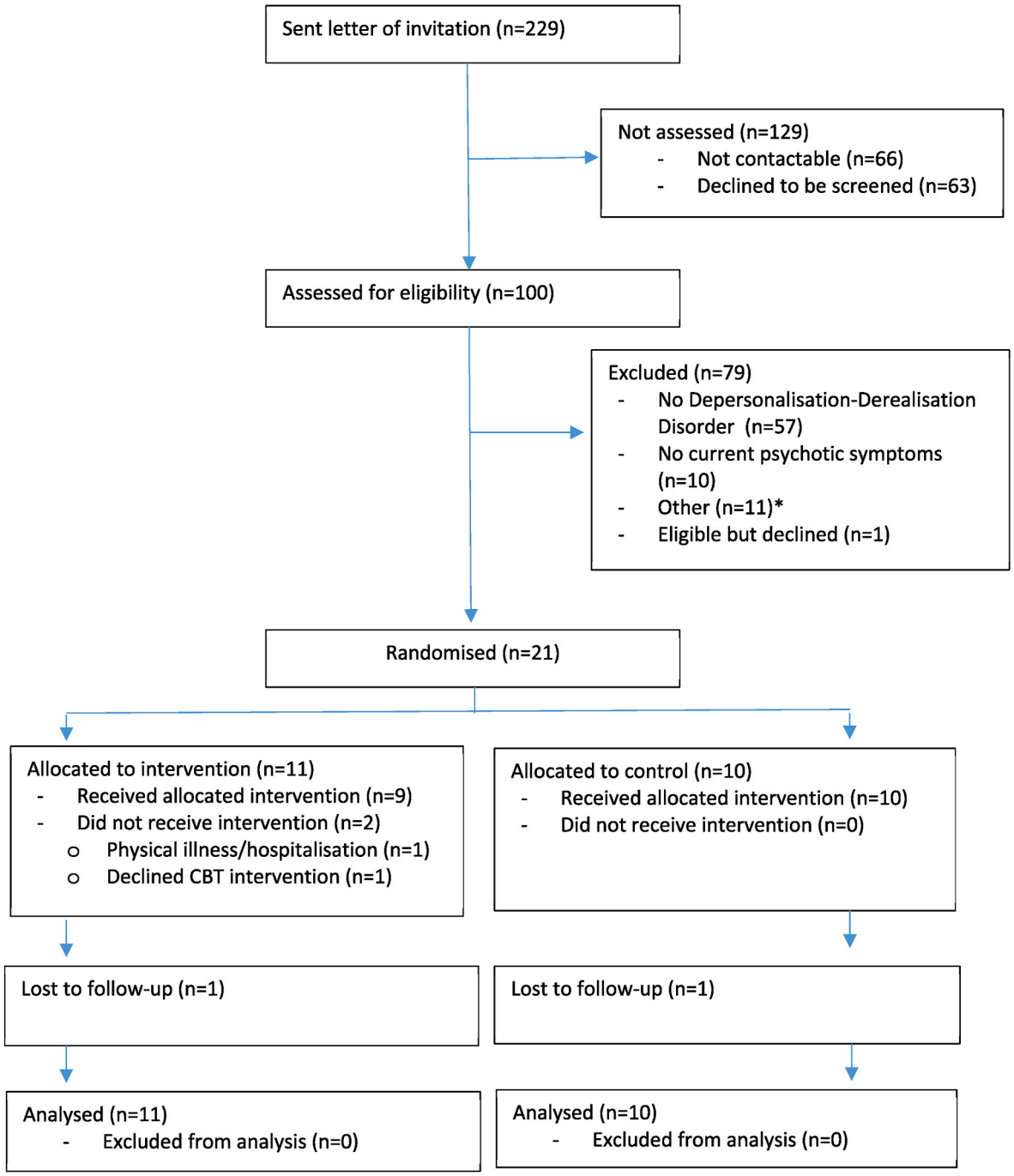

Fig. 1. CONSORT diagram
Notes:
*Other category includes – unable to consent (n = 6), currently engaging in therapy (n = 3), needing an interpreter (n = 1), unable to speak (laryngectomy) (n = 1).

3.1. Recruitment

Over a period of 10 months (between April 2015 and January 2016), an attempt was made to contact 229 individuals to offer them the opportunity to participate in the trial. At the end of the recruitment period, 21 (9.2% of those contacted) individuals had consented.

3.2. Feasibility estimates of recruitment (rate of referrals, contact, acceptance and eligibility)

Of the 229 attempted contacts, 24 individuals were referrals from clinicians in the local mental health trust, making the proportion of referred participants 10.5% (95% CI: 7.1–15.1). Of these referrals: 22 were contacted (91.7% (95% CI: 74.2–97.7)), 18 accepted the offer of screening (75.0% (95% CI: 55.1–88.0)); 10 referrals were eligible (41.7% (95% CI 24.7–61.2)); and 9 consented (37.5%, (95% CI 21.2–57.3)).

The remaining 205 individuals approached were found from research registers (i.e., they had given their permission for researchers to approach them). The contact rate was 79.5% (95%CI: 73.3–84.8). Of those who were contacted, 63 (38.7% (95% CI 31-1-46.5)) declined the offer to be screened. Reasons for declining screening were: not wanting to participate in research generally (n = 16); not having the time, including concerns that the research was too much of a commitment in

Table 1
Demographic characteristics of the sample at baseline.

		Intervention (n = 11)	Control (n = 10)	Total (n = 21)
Gender (n, %)	Male	9, 81.8	6, 60.0	15, 71.4
	Female	2, 18.2	4, 40.0	6, 28.6
Age (mean, sd)		42.6 (14.0)	38.2 (12.1)	40.5 (13.0)
Ethnicity (n,%)	White British	7, 63.6	4, 40.0	11, 52.4
	Black/Black British	1, 9.1	3, 30.0	4, 19.1
	Asian/Asian British	1, 9.1	1, 10.0	2, 9.5
	White European/ White Other	1, 9.1	1, 10.0	2, 9.5
	Mixed	1, 9.1	1, 10.0	2, 9.5
Marital status (n, %)	Married/Civil partnership	1, 9.1	1, 10.0	2, 9.5
	Co-habiting	1, 9.1	2, 20.0	3, 14.3
	Divorced	2, 18.2	0, 0	2, 9.5
	Single	7, 63.6	7, 70.0	14, 66.7
Level of education (n,%)	No qualifications	3, 27.3	1, 10.0	4, 19.1
	GCSEs/level 2	3, 27.3	5, 50.0	8, 38.1
	A-Levels	2, 18.5	2, 20.0	4, 19.1
	Diploma or higher	3, 27.3	2, 20.2	5, 23.8
Clinical diagnosis (n,%)	Schizophrenia	8, 72.7	8, 80.0	16, 76.2
	Bipolar	2, 18.2	0, 0	2, 9.5
	Depression with psychotic symptoms	1, 9.1	2, 20.0	3, 14.3
Age at first: (mean, sd)	DP/DR symptoms	18.3 (12.8)	21.0 (11.8)	19.5 (13.1)
	Psychosis symptoms	24.2 (10.3)	25.7 (9.9)	24.8 (121)
	Contact with mental health services	26.2 (11.0)	27.2 (9.7)	26.6 (10.2)
Duration (years) of: (mean, sd)	DP/DR symptoms	24.4 (17.7)	17.2 (14.1)	20.9 (16.1)
	Psychosis symptoms	18.5 (15.2)	13.5 (10.2)	16.1 (13.0)
Previous psychological therapy (n,%)	Yes	11, 100	9, 90.0	20, 95.2
	No	0, 0	1, 10.0	1, 4.8

terms of number of sessions (n = 14); being too unwell (n = 5); not interested (no further reason given) (n = 28); and not enough remuneration offered for the assessments (n = 1). In this context, 100 individuals from research register who were contacted, agreed to be screened for the trial making the acceptance of screening rate of 61.3% (95% CI: 53.4–68.9).

The number of these individuals meeting the eligibility criteria was lower than expected. Of the 100 individuals who agreed to be screened,12 (12%, 95%CI 6.4–20.0) met the eligibility criteria. Expressed as a percentage of register participants approached, this is 5.8% (95% CI 3.1–10.0) The most common reason for not meeting eligibility criteria was having no current depersonalisation phenomena or not meeting clinical threshold on the CDS (n = 57, 57%).

With one exception, all of those who were eligible (from referrals and register) for the study agreed to participate, making a consent rate of 95.5% (95% CI: 78.2–99.2). The one individual who was eligible but declined participation (a referral) was put on a waiting list for a specialist clinic and decided it was preferable to wait for this support rather than engage in brief therapy as part of the trial.

In summary, overall the rates of contact (71.2%) and acceptance of screening (61.3%) were acceptable, but the overall 22% rate of eligibility was much lower than the expected 50%, this was particularly so in the research register. In this context, the overall recruitment rate and number was lower than projected.

3.3. Delivery of the intervention

Eleven participants were randomised to receive the intervention and nine (81.8%, 95% CI: 52.3–94.8) completed the intervention, a 'drop-out' rate of 18.2% (95% CI: 5.1–47.7). Of those who did not complete, one attended two sessions before declining further sessions, citing a difficulty with the CBT approach; one individual attended one session before declining further sessions due to high levels of anxiety regarding leaving the home (home visits were also declined). For the nine participants who completed the intervention, the six sessions were delivered over an average of 8.3 weeks (maximum allowed was 10).

Homework tasks were given at the end of each session and completion was noted at the beginning of the next session. Five participants completed all homework tasks, giving 100% completion amongst 55.5% (95% CI: 26.7–81.1). The average completion was 4, giving an overall homework completion rate of 80% (95% CI: 37.5–96.4).

The average item rating on the CBT adherence measure was 5.2/6, an adherence rate of 86.4% (95% CI: 82.2–89.6). The average item rating on the DPRD fidelity tool was 5.1/6, a fidelity rate of 85.9% (95% CI: 81.7–91.8).

3.4. Components of the intervention delivered

There were six potential topic areas (see Box 1 in Supplementary Materials) and an average of four topic areas were covered over the course of the six sessions. Two participants received all six components of the intervention. All nine participants received the psychoeducation and formulation, emotional focus and the review/relapse prevention components. The least frequent area covered was cognitive (n = 3), followed by behavioural focus (n = 5).

3.5. Acceptability of the intervention

At follow-up interview, participants were asked about their expectations for progress at the beginning of therapy. Five reported that they had expected to make 'no progress' and the remaining four reported that they had expected to make a 'little progress'. Regarding actual progress made, seven participants reported that they made 'a lot' or 'a little' progress, and two participants thought they had made 'no progress'.

Eight participants reported they were 'very satisfied' or 'satisfied' with therapy, and one reported they were 'indifferent'. All participants reported that the therapist understood their problems 'very well'. There were high levels of confidence in the therapist with eight participants stating they could trust the therapist 'a lot' and one participant reporting 'a little'. Homework tasks were rated as 'very helpful' by seven participants and 'slightly helpful' by two participants.

The majority of the recipients (n = 7) of the intervention either 'agreed' or 'strongly agreed' that they had gained new knowledge and skills about their DP/DR and 6 either agreed or strongly agreed they had more control over DP/DR.

In terms of the most helpful aspects of the intervention, there were a range of responses and some participants stated more than one aspect, including: learning about maintenance cycles and triggers (n = 3); coping strategies to manage mood and worry about the depersonalisation (n = 5); and the relationship with the therapist (n = 3). One participant said the therapy was not long enough to determine the most helpful aspects.

Participants were also asked about the least helpful aspects of the intervention. Responses included: nothing unhelpful (n = 4); and six sessions not being long enough (n = 4). Interestingly, three participants reported that six sessions felt about right to address depersonalisation, however, all three wanted to continue engaging in therapy to address further issues including self-esteem and trauma.

3.6. Feasibility estimates of data collection

Follow-up assessments were attended by 19 of the 21 participants: 90.4% (95% CI: 71.1–97.4). There was equal attrition between the two groups. Follow-up interviews were conducted on average 11.6 weeks after randomisation (range 9.3–16.9). There were two incidences of unblinding of the research assistant (10.5%, 95% CI: 1.3–33.1) follow-up interviews conducted, in both cases the participant unblinded the research assistant.

3.7. Clinical outcome data

Summary descriptive statistics for clinical outcomes are shown in Table 2. Two-thirds of the intervention group no longer met criteria for DDD at follow-up, compared to 33% in the control group.

It was not the purpose of this study to test for statistical differences between or within the groups; however effect sizes were calculated to aid future power calculations. Several patterns can be noted. The mean total score on the CDS in the intervention group reduced at follow-up (d = 0.57) and while mean scores in the control group increased, the CI crosses zero, suggesting no reliable change. A similar pattern was shown in the PSYRATS-AH scale (mean scores reduced in the intervention group (d = 1.05)). Small to moderate effect sizes were found when comparing the change scores between groups, however the confidence intervals in all comparisons crossed zero and are therefore to be interpreted with caution.

4. Discussion

We describe the feasibility and acceptability of a brief, six-session intervention for DDD in the context of psychotic symptoms. To our knowledge, this is the first such trial. The findings suggest that it is both feasible in terms of recruitment and delivery and is highly acceptable to participants.

Feasibility rates of contact and acceptance (of screening) were acceptable or within expected ranges, however the rate of eligibility was much lower than expected. The two sources of participants had markedly different eligibility rates. The eligibility rate from referrals was close to our estimate of 50% based on a previous study. However, rates of eligibility within participants sourced from a research register was significantly lower. Further awareness amongst clinicians of the prevalence of service users with psychosis who met the diagnostic threshold for DDD would also assist in future studies with respect to recruitment. The number of referrals was low in this study, in part, due to clinicians' lack of awareness of DP/DR symptoms and their impact for consumers with psychosis. It may also be of interest in future studies to not rely on diagnostic thresholds for DDD, but rather use the prevalence of symptoms and distress for eligibility criteria. This may improve feasibility of recruitment as recent studies show that two thirds of individuals with psychosis experience DP/DR symptoms (Cernis et al., 2022).

The estimated eligibility rate of 50% was based on a previous study in the same local area that used a self-report measure to determine if diagnostic threshold for DDD was met in consumers with active psychotic symptoms. In the current study, a clinical interview was used to establish if the threshold was met. This more rigorous methodology found an overall eligibility rate of 22% of those screened. This led to a smaller sample, some minor differences in intervention groups and large confidence intervals in feasibility and acceptability estimates creating difficulty in estimating parameters for future trials. Previous studies have used self-report measures of DP/DR and some authors (Gonzales-Torres et al., 2010; Schafer, Aderhold, Freyberger, & Spitzer, 2008) have suggested that individuals who are experiencing psychotic symptoms may have difficulty understanding the questions regarding DP/DR symptoms. This study administered the CDS as part of a clinical interview and it is possible that this rigorous methodology provides a closer estimate of the prevalence of DDD in psychosis. Nevertheless, with one in five participants in this study meeting threshold for DDD, we suggest that clinicians consider the routine assessment of depersonalisation/derealisation in those with psychosis.

There was a high level of interest in the intervention amongst those meeting criteria and overall, the intervention was highly acceptable to participants. While it was not the purpose of the study to measure treatment response or effect size, the summary data were promising. Most individuals receiving the intervention (66%) no longer met threshold for DPRD at follow-up, compared to 33% in the control group. We observed that those who remained above diagnostic threshold at

Table 2
Summary of clinical data in the two groups at baseline and follow-up.

	Control				Intervention				Effect size for group differences in change score	
	Baseline (n = 10)	Follow-up (n = 9)			Baseline (n = 11)	Follow-up (n = 10)				
	Mean (SD)	Mean (SD)	Mean Change (SD)	Effect size (change) d (95% CI)	Mean (SD)	Mean (SD)	Mean Change (SD)	Effect size (change) d (95% CI)	Mean difference (pooled SD)	d (95% CI)
CDS total	98.3 (24.5)	108.2 (65.2)	+9.9 (45.1)	0.22 (−0.11, 0.55)	108.8 (39.3)	89.2 (52.6)	- 19.6 (34.7)	0.56 (0.07, 1.05)	−29.5 (40.0)	−0.74 (−0.21, 1.69)
PSYRATS-AH	25.0 (13.7)	24.7 (11.9)	- 0.3 (9.5)	0.03 (−0.43, 0.49)	24.4 (14.5)	17.5 (16.5)	- 6.9 (6.5)	1.06 (0.53, 1.59)	−6.6 (8.1)	−0.82 (−0.13, 1.77)
PSYRATS-D	11.1 (9.8)	7.6 (8.3)	−3.5 (4.8)	−0.72 (−1.19, −0.25)	15.3 (5.9)	12.0 (7.8)	- 3.3 (6.1)	−0.54 (−1.11, 0.03)	0.2 (5.6)	0.04 (−0.87, 0.95)
BAI	28.2 (12.5)	28.4 (13.8)	+0.2 (9.4)	0.02 (−0.43, 0.47)	37.5 (10.7)	29.4 (18.5)	- 8.1 (15.9)	−0.51 (−1.15, 0.13)	−8.3 (13.3)	−0.63 (−1.57, 0.31)
BDI	31.6 (14.9)	32.3 (15.6)	+0.7 (10.8)	0.06 (−0.39, 0.51)	35.5 (11.5)	29.1 (19.6)	- 6.4 (12.5)	−0.51 (−0.95, −0.07)	−7.1 (11.7)	−0.61 (−1.55, 0.33)
PDS distress	22.6 (16.8)	23.7 (12.7)	+1.1 (14.7)	0.07 (−0.54, 0.68)	24.4 (13.8)	31.0 (10.5)	+6.6 (17.9)	0.37 (−0.46, 1.2)	5.5 (16.5)	0.33 (−0.59, 1.25)

Abbreviations: AH: auditory hallucinations; BAI: Beck Anxiety Inventory; BDI: Beck Depression Inventory; CI: confidence interval; D: delusions; d: cohen's d; CDS: Cambridge Depersonalisation Scale; IQR: interquartile range; PDS: Post-traumatic Diagnostic Scale; PSYRATS: Psychotic Symptom Rating Scale; SD: standard deviation.

follow-up often had a delusional interpretation of the depersonalisation/derealisation symptoms. Such individuals may represent a more severe subgroup that require more intensive therapy.

There was also a reduction in auditory hallucinations, in the intervention, but not the control group, a finding which may provide some support for the hypothesised link between DP/DR and auditory hallucinations. Further, the indication from participants that their first experience of DP/DR preceded their psychotic experiences, often by several years, provides additional support for this theory.

5. Limitations

The lower than expected eligibility rate resulted in not meeting the original recruitment target of 30 (Farrelly et al., 2016). The smaller sample size also resulted in the intervention and control groups having different characteristics at baseline. Recruitment in most cases came from research registers in the local NHS trust. While all participants were still involved with local mental health teams, it is possible that individuals who agree to participate in research differ from others in community mental health teams (e.g., a higher proportion of participants had received previous psychological therapy, compared to rates of psychological treatment in the local trust at approximately 10–30%). Furthermore, the lower than expected eligibility rate, particularly within the research register meant that far more service users were approached than initially estimated and the estimates provided may not be useful to those recruiting directly from teams. These factors make it difficult to clearly establish feasibility of recruitment for further research.

6. Recommendations for future investigations

The current study findings suggest further investigations in this area would be of interest to service users and feasible to deliver, however, further work is required to establish feasibility for recruitment. In particular, awareness raising about the prevalence of DP/DR amongst clinical staff may raise the rates of referrals. Secondly, investigations of using presence of DP/DR symptoms versus those who meet diagnostic thresholds as eligibility criteria may further improve the feasibility of recruitment. Once established, an appropriately powered pilot feasibility trial would be an appropriate next step, with the following recommendations:

1. A longer follow-up period is required to determine if there are sustained effects of the intervention.
2. It may be necessary to extend the intervention beyond six sessions, particularly for those with no prior experience of therapy and/or those with a delusional belief about their DDD, since these groups are likely to take longer to respond to therapy.
3. An active comparator will be required to isolate the specific impact of this protocol.

7. Conclusions

We provide the first account of delivering a brief CBT intervention for DDD in people with current psychotic symptoms. The intervention was feasible to deliver and acceptable to participants. There were some challenges in recruitment, however, there are some signals of positive clinical outcomes though further, appropriately powered analyses are required. overall, the data suggest this is a promising area for further investigation.

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CRediT authorship contribution statement

Simone Farrelly: Writing – review & editing, Writing – original draft, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Emmanuelle Peters:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Matilda Azis:** Project administration, Methodology. **Anthony S. David:** Writing – review & editing, Supervision, Conceptualization. **Elaine C.M. Hunter:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Conceptualization.

Declaration of competing interest

The authors declare no conflict of interest.

Data availability

Data will be made available on request.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jbtep.2023.101911.

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