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Guided self-help cognitive-behaviour Intervention for VoicEs (GiVE): Results from a pilot randomised controlled trial in a transdiagnostic sample

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ABSTRACT

Background: Few patients have access to cognitive behaviour therapy for psychosis (CBTp) even though at least 16 sessions of CBTp is recommended in treatment guidelines. Briefer CBTp could improve access as the same number of therapists could see more patients. In addition, focusing on single psychotic symptoms, such as auditory hallucinations ('voices'), rather than on psychosis more broadly, may yield greater benefits.
Method: This pilot RCT recruited 28 participants (with a range of diagnoses) from NHS mental health services who were distressed by hearing voices. The study compared an 8-session guided self-help CBT intervention for distressing voices with a wait-list control. Data were collected at baseline and at 12 weeks with post-therapy assessments conducted blind to allocation. Voice-impact was the pre-determined primary outcome. Secondary outcomes were depression, anxiety, wellbeing and recovery. Mechanism measures were self-esteem, beliefs about self, beliefs about voices and voice-relating.
Results: Recruitment and retention was feasible with low study (3.6%) and therapy (14.3%) dropout. There were large, statistically significant between-group effects on the primary outcome of voice-impact ($d = 1.78$; 95% CIs: 0.86–2.70), which exceeded the minimum clinically important difference. Large, statistically significant effects were found on a number of secondary and mechanism measures.
Conclusions: Large effects on the pre-determined primary outcome of voice-impact are encouraging, and criteria for progressing to a definitive trial are met. Significant between-group effects on measures of self-esteem, negative beliefs about self and beliefs about voice omnipotence are consistent with these being mechanisms of change and this requires testing in a future trial.

1. Introduction

The National Institute for Health and Care Excellence (NICE, 2014) recommends everyone with a psychosis diagnosis should be offered at least 16 sessions of cognitive behaviour therapy (CBT). In practice, the dissemination of CBT for psychosis (CBTp) is extremely poor. Fewer than 10% of patients are offered CBTp in the UK (Schizophrenia Commission, 2012) – with lack of resources the most frequently cited barrier to implementation (Ince et al., 2015). This is a global issue, with half of people with psychosis worldwide not receiving any intervention (World Health Organisation (WHO), 2014). Because funding for mental health services is unlikely to increase in the coming years, we must consider ways to increase access that use only the resources currently available.

The Improving Access to Psychological Therapies (IAPT) initiative in England has substantially improved access to CBT for people with depression and anxiety by offering briefer, guided, self-help forms of CBT within a stepped care approach (Clark, 2011). This could be a way forward for CBTp too: The results from recent meta-analyses show that brief CBTp (<16 sessions) leads to significant benefits (Hazell et al., 2016b; Naeem et al., 2016). Concurrently, this field is moving towards a symptom-specific approach (Birchwood and Trower, 2006), whereby CBTp targets a specific symptom, such as delusions or distressing voices, rather than psychosis more broadly. By combining these two areas of research, we have developed a brief, guided self-help CBT intervention for distressing voices (CBTv). In line with the CBTv model (Birchwood and Chadwick, 1997), the aim of this intervention is to reduce the negative impact of voices, rather than reduce or change voice characteristics.

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The present study reports findings from a pilot randomised controlled trial (RCT) of guided self-help CBTv compared to a wait-list control for mental health service users distressed by voices, irrespective of diagnosis (Hazell et al., 2016a). This study aims to: (1) determine whether findings justify a definitive trial of the intervention, (2) establish the effect size on voice-impact (primary outcome) for use in future study sample calculations, and (3) assess the feasibility and acceptability of the intervention and study design.

2. Method

2.1. Trial design

This trial is a pragmatic, single-blind, external pilot RCT comparing guided self-help CBTv to a wait-list control using 1:1 allocation ratio (Fig. 1). Both groups received usual mental health care throughout the study. The study protocol was published before recruitment ended (Hazell et al., 2016a).

2.2. Participants

Participants were recruited between September 2015 and January 2016. All participants were accessing NHS mental health services in the South of England. We recruited 28 participants (14 per arm – in line with pilot RCT guidelines (Julious, 2005)) who met the following inclusion criteria: (1) aged 18 years or older; (2) currently distressed by hearing voices, quantified by a score of at least 3 on either item 5 ('how much do the voices interfere with your daily activities?'), 6 ('how distressing are the voices that you hear?'), or 7 ('how bad do the voices make you feel about yourself?') on the Hamilton Program for Schizophrenic Voices Questionnaire (HPSVQ) (Van Lieshout and Goldberg, 2007); (3) heard voices for the previous 12 months;

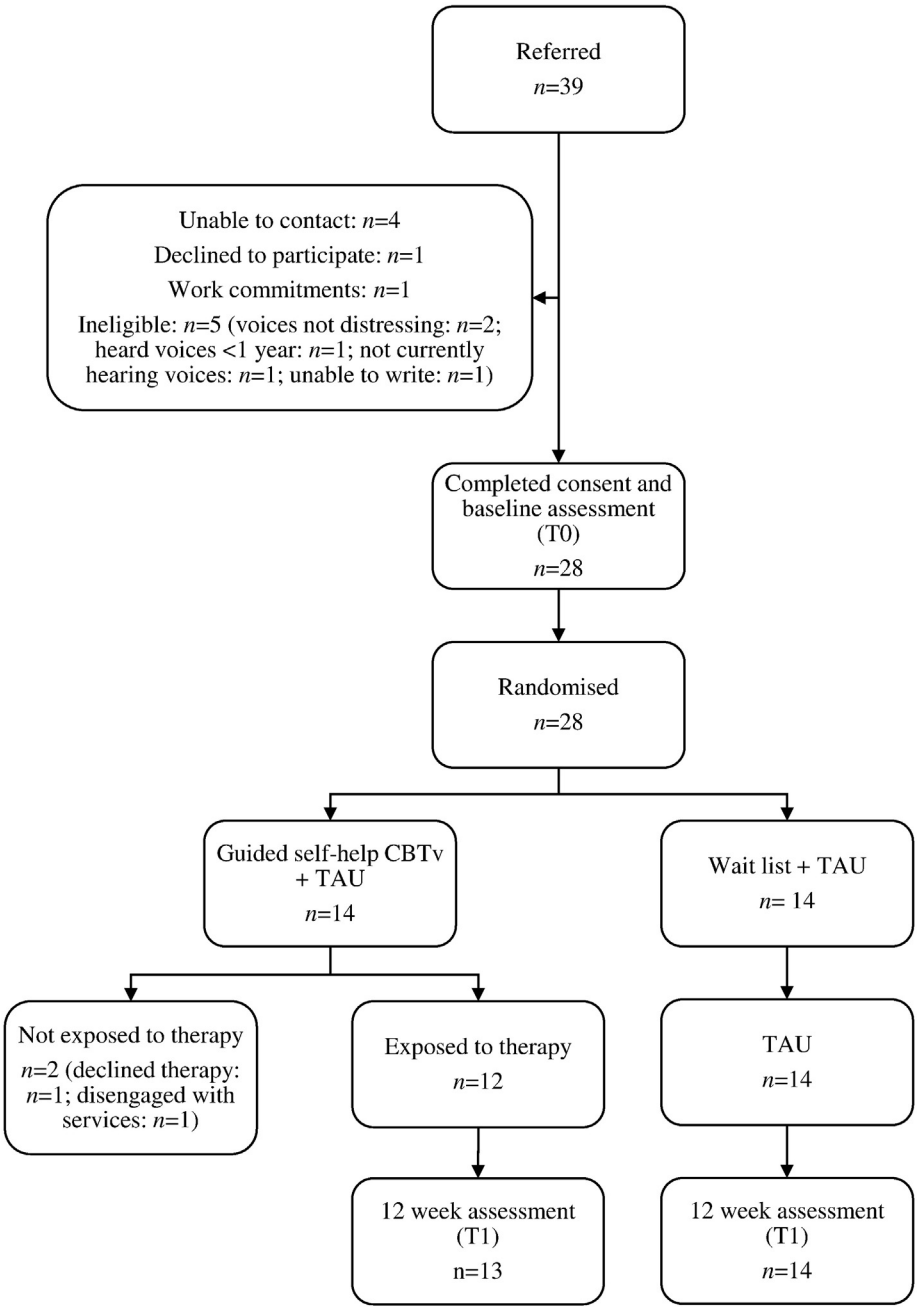

Fig. 1. Trial CONSORT diagram. *Note*: TAU = treatment as usual; CBTv = cognitive behaviour therapy for voices.

(4) currently receiving care from NHS mental health services; (5) not currently receiving psychological therapy and not having plans to do so; (6) able to read and write in English.

Exclusion criteria were: (1) primary diagnosis of substance misuse; (2) an organic illness causing voices. With the exception of these criteria, participants were not excluded on the basis of diagnosis. This decision was firstly a response to a number of studies that have found non-significant differences in the experience of hearing voices between those with and without a psychosis diagnosis (e.g. Hepworth et al., 2013; Toh et al., 2015); and secondly a reaction to calls for interventions targeting distressing voices that can be offered transdiagnostically (Thomas et al., 2014).

Diagnosis was confirmed by the most recent psychiatrist clinic letter; all diagnoses were made in line with ICD-10 criteria (World Health Organisation (WHO), 1992). Two participants (7.1%) (one per arm) were not taking psychiatric medication at the time of the baseline assessment; both had previously taken antipsychotic medication; 21 (75.0%) participants were prescribed at least one antipsychotic medication. See Table 1 and Fig. 1 for further recruitment and participant information.

2.3. Intervention and control arms

2.3.1. Guided self-help CBTv

Participants randomised to the intervention arm were offered up to eight, hour-long sessions of guided self-help CBTv, over a maximum of 12 weeks. The intervention was based on the 'Overcoming Distressing Voices' CBT self-help book (Hayward et al., 2012), and an accompanying workbook created for this trial. All participants received a therapy pack that included the self-help book, workbook, a carers' information leaflet, and information about a local Hearing Voices Network group. The therapy protocol and pack were developed in partnership with people who hear voices.

Each session was linked to a specific chapter within the Overcoming Distressing Voices book (Hayward et al., 2012), and the intervention was divided into five modules: (1) Coping – exploring ways to manage voices; (2) Me – targeting negative beliefs about the self; (3) My Voices - targeting unhelpful beliefs about voices; (4) My Relationships – improving assertiveness in difficult relationships; and (5) Looking to the Future – making plans to continue the use of new skills. Modules 2, 3 and 4 were each offered over two sessions (six sessions in total), and modules 1 and 5 were each one session long.

All of the trial therapists were clinical psychologists with extensive CBTp experience; additional training on guided self-help CBTv was provided by authors. All of the trial therapists were offered monthly group supervision.

2.3.2. Wait list control

All participants (both arms) received their usual treatment throughout the study. The control group was assigned to a wait list for CBTv which ended when they had completed the 12 week (T1) assessment.

2.4. Outcome measures

All outcome measures were collected at baseline (T0), and post-intervention (12 weeks post-randomisation, T1). Assessments were conducted at the participants' local mental health facility; where participants had mobility issues, home visits were offered. The voice-impact subscale on the Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ) (Van Lieshout and Goldberg, 2007) was the primary outcome (Hazell et al., 2016a). This subscale, confirmed through factor analysis, has 4 items (Kim et al., 2010). Scores on the self-report HPSVQ (Van Lieshout and Goldberg, 2007) correlate highly (all $r > 0.8$) (Kim et al., 2010) with scores on the widely used, clinician-administered PSYRATS auditory hallucination (AH) scale (Haddock et al., 1999). The secondary outcome measures were: (1) the Choice of Outcome In Cbt for psychosEs (CHOICE) questionnaire severity subscale (Greenwood et al., 2010): a measure of service-user defined recovery, including two items where participants identify their personal goals; (2) the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983); (3) the Short Warwick-Edinburgh Mental Well-being Scale (SWEMBS) (Tennant et al., 2007); (4) the Rosenberg Self-Esteem Scale (RSES) (Rosenberg, 1965).

The measures of proposed mechanisms of action were: (1) the Brief Core Schema Scale (BCSS) self-scale (Fowler et al., 2006): a measure of participants' positive and negative beliefs about themselves; (2) the

Table 1
Baseline participant demographics. *Note*: TAU = treatment as usual; employment status 'Other' includes student, homemaker, retired and carer; psychosis spectrum disorder includes schizophrenia, paranoid schizophrenia, schizoaffective disorder, psychosis not otherwise specified and first episode psychosis; mood disorder includes depression, depression with psychotic features and bipolar disorder; diagnosis 'Other' includes posttraumatic stress disorder (PTSD) and dissociative identity disorder (DID).

Variable		Guided self-help CBTv + TAU ($n = 14$)	Wait list + TAU ($n = 14$)	Total ($n = 28$)
Age *M(SD)*		39.07(10.16)	45.93(13.49)	42.50(12.23)
Gender *n*(%)	Male	4(28.60)	7(50.00)	11(39.30)
	Female	9(64.30)	7(50.00)	16(57.10)
	Other	1(7.10)	0(0.00)	1(3.60)
Employment status *n*(%)	Employed	3(21.40)	4(28.60)	7(25.00)
	Unemployed	10(71.40)	5(35.70)	15(53.60)
	Other	1(7.10)	4(28.60)	5(17.90)
Marital status *n*(%)	Single	6(42.90)	7(50.00)	13(46.40)
	Married/civil partnership	1(7.10)	3(21.40)	4(14.30)
	Cohabiting	2(14.30)	0(0.00)	2(7.10)
	Separated/divorced	5(35.70)	2(14.30)	7(25.00)
	Widowed	0(0.00)	2(14.30)	2(7.10)
Country of birth *n*(%)	England	13(92.90)	10(71.40)	23(82.10)
	Other	1(7.10)	4(28.60)	5(17.90)
Ethnicity *n*(%)	White (British)	13(92.90)	12(85.70)	25(89.30)
	White (Other)	1(7.10)	2(14.30)	3(10.70)
Level of education *n*(%)	Left school before 16	7(50.00)	4(28.60)	11(39.30)
	Left school at 16	2(14.30)	3(21.40)	5(17.90)
	Left school at 17/18	3(21.40)	4(28.60)	7(25.00)
	Completed/completing college course	1(7.10)	1(7.10)	2(7.10)
	Completed/completing university course	1(7.10)	2(14.30)	3(10.70)
Age of voice onset *M(SD)*		28.50(14.22)	23.71(17.76)	26.11(15.97)
Diagnosis *n*(%)	Psychosis spectrum diagnosis	5(35.71)	8(57.14)	13(46.43)
	Borderline personality disorder	5(35.71)	3(21.43)	8(28.57)
	Mood disorder	1(7.15)	3(21.43)	4(14.29)
	Other	3(21.43)	0(0.00)	3(10.71)

Persons Relating to Others Questionnaire short version (PROQ3) (Birtchnell et al., 2013): a measure of social relating patterns; (3) the Voice and You (VAY) (Hayward et al., 2008): a measure of voice relating patterns; (4) the Beliefs about Voices Questionnaire – revised (BAVQ-R) (Chadwick et al., 2000): a measure of participants' positive and negative beliefs about their voices; (5) HPSVQ phenomenology subscale (Van Lieshout and Goldberg, 2007): a measure of voice phenomenology. Participants in the intervention arm were also asked to complete a patient experience questionnaire based on the IAPT service experience questionnaire (Clarke, 2011).

2.5. Randomisation and masking

Participants completed the T0 assessments and were then randomised to either receive guided self-help CBTv or join the wait-list by an independent statistician blind to participant details. Participants were randomised using a 1:1 ratio with random permuted block randomisation using block sizes of two, four, and six. The T1 assessments were completed by a research assistant who was blind to the participants' group allocation. Blinding was broken once part-way through a T1 assessment.

2.6. Statistical analyses

All of the analyses were conducted in line with the trial data analysis plan (Hazell et al., 2016a) using STATA version 13. The recruitment and consent rates have been reported in line with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

All of the standardised effect sizes were coded so that a positive effect size favours the intervention group over the control group. The between group effect sizes are interpreted in line with Cohen's (Cohen, 1960) criteria (i.e. small ≥ 0.2, medium ≥ 0.5, and a large effect ≥ 0.8). The minimum clinically important difference (MCID) on the primary outcome was 2 points difference. Missing data on individual outcome items were treated as missing completely at random. Missing items were imputed using simple mean imputation.

2.7. Ethics and research governance

Ethical approval was granted by the North West – Lancaster Research Ethics Committee (REC) (ref: 15/NW/0575). The trial was sponsored by the University of Sussex, and registered with the International Standard Randomised Controlled Trial Registry (ISRCTN77762753). In line with Medical Research Council (MRC) (Medical Research Council (MRC), 1998) the study was monitored by a Trial Steering Committee with an independent Chair, independent expert and lived experience member.

2.8. Adverse events

Seven adverse events were reported during the course of the study: five were hospital admissions (two for physical health, and three for mental health), one report of suicidal intent, and one disengagement from services. None of the adverse events were deemed to be related to the study. All participants in the intervention arm who were admitted to hospital chose to continue with the intervention when they were discharged.

3. Results

3.1. Recruitment, retention and adherence

Of the 39 study referrals, 28 (71.8%) consented and were randomised (Table 1). Only one participant (3.6%) did not provide data at both time points (Fig. 1). Participants were deemed to have been exposed to the intervention if they attended at least four out of the eight intervention sessions. Two participants randomised to the intervention arm did not begin therapy (Fig. 1). Of the 12 participants who began the intervention, 1 participant attended four sessions (8.3%), 3 participants (25.0%) attended seven sessions, and 8 participants (66.7%) attended all eight sessions.

3.2. Primary outcome

There was a large, statistically significant between-group effect in favour of the intervention group ($d = 1.78$, 95% CI 0.86, 2.70) on the HPSVQ voice-impact subscale (Table 2). The difference between pre-post change scores (4.05) exceeds the MCID of 2.

3.3. Secondary outcomes

All between-group effect sizes for secondary outcomes favoured guided self-help CBTv over the wait-list condition. There were large, statistically significant between-group effects ($d > 0.8$) on service-user defined recovery (CHOICE), anxiety (HADS anxiety), and wellbeing (SWEMBS) (Table 2). Effects on depression (HADS) were small and non-significant ($d = 0.27$).

3.4. Mechanism outcomes

All between-group effect sizes for mechanism outcomes favoured guided self-help CBTv over the wait-list condition. There were large, statistically significant between-group effects ($d > 0.8$) for negative beliefs about self (BCSS), beliefs about voice omnipotence (BAVQ-R) and self-esteem (RSES) (Table 2). Effects on remaining mechanism measures were small to medium and non-significant (Table 2).

3.5. Patient experience

Of the 12 intervention participants, 11 (91.7%) reported they were 'very satisfied' with the therapy, and 'very satisfied' with their therapist. One participant (8.3%) reported they were 'dissatisfied' with the therapy and 'neutral' about their therapist. When asked about the overall experience of the therapy, 9 participants reported they were 'very satisfied' (75.0%), 2 participants were 'satisfied' (16.7%), and 1 participant was 'neutral' (8.3%).

Table 3 shows the results of the patient experience questionnaire. Most participants reported benefit across all of the items. The areas where participants most frequently reported no improvement were the management and reduction of medication ('Not at all/Somewhat': $n = 5$; 41.7%), and physical health ('Not at all/Somewhat': $n = 6$; 50.0%). Conversely, the areas where participants most frequently reported largest improvements were their mental health and wellbeing ('Very much so/Quite a lot': $n = 6$; 50.0%), and their ability to engage in meaningful activities ('Very much so': $n = 7$; 58.3%). All participants (100%) said they would recommend guided self-help CBTv to a friend or family member who was hearing distressing voices.

4. Discussion

4.1. Summary of results

This study aimed to: (1) determine whether findings justified a definitive trial of the guided self-help CBTv intervention, (2) establish the effect size on voice-impact (primary outcome) for use in future study sample calculations, and (3) assess the feasibility and acceptability of the intervention and study design.

We found a large, statistically significant between-group effect on the pre-determined primary outcome of voice-impact, as well as on a range of secondary outcomes (anxiety, wellbeing, and recovery), and mechanisms (self-esteem, beliefs about self, and beliefs about voices). Furthermore, the small therapy (14.3%) and study (3.6%) attrition

Table 2
Primary and secondary outcomes at T0 (baseline) and T1 (12 weeks post randomisation). *Note*: HPSVQ = Hamilton Program for Schizophrenic Voices Questionnaire; CHOICE = Choice of Outcome In Cbt for psychosEs; HADS = Hospital Anxiety and Depression Scale; SWEMBS = Short Warwick-Edinburgh Mental Well-being Scale; RSES = Rosenberg Self-Esteem Scale; BCSS = Brief Core Schema Scale; PROQ3 = Persons Relating to Others Questionnaire short version; VAY = Voice and You; BAVQ-R = Beliefs about Voices Questionnaire – the revised edition; * = $p < 0.05$ and 95% CIs do not cross zero; *B* = unstandardised effect; *d* = standardised effect; 95% CI for *d* calculated using the standard deviation for Cohen's *d* (Cohen, 1960).

	T0		T1		*B* (*SE*; 95% CI)	*d* (95% CI)
	Guided self-help CBTv + TAU ($n = 14$)	Wait list control group + TAU ($n = 14$)	Guided self-help CBTv + TAU ($n = 13$)	Wait list control group + TAU ($n = 14$)		
	M(SD)	*M(SD)*	*M(SD)*	*M(SD)*		
Primary outcome						
HPSVQ (voice-impact)	13.14(1.96)	11.21(2.08)	9.31(4.27)	11.43(2.77)	−3.93 (1.31; −6.65, −1.22)	1.78* (0.86, 2.70)
Secondary outcomes						
CHOICE	3.37(1.80)	3.52(1.68)	5.68(1.78)	3.29(1.97)	2.39 (0.59; 1.17, 3.61)	1.40* (0.54, 2.26)
CHOICE (goals only)	5.07(4.70)	4.93(3.85)	12.38(4.13)	5.71(4.76)	6.47 (1.65; 3.07, 9.88)	1.54* (0.66, 2.42)
HADS depression	10.42(3.70)	11.58(3.05)	10.32(2.85)	11.92(2.60)	−0.92 (0.89; −2.77, 0.92)	0.27 (−0.50, 1.04)
HADS anxiety	12.17(2.96)	11.08(3.26)	9.06(2.34)	11.58(2.84)	−2.91 (0.90; −4.77, −1.05)	0.94* (0.13, 1.75)
SWEMBS	17.71(4.36)	18.36(4.07)	21.69(5.01)	17.93(5.50)	3.97 (1.69; 0.47, 7.46)	0.95* (0.14, 1.76)
HPSVQ phenomenology	14.14(2.68)	14.93(2.73)	12.85(2.73)	14.21(3.09)	−0.87 (0.92; −2.78, 1.04)	0.32 (−0.45, 1.09)
HPSVQ total	27.29(3.93)	26.14(3.66)	22.15(6.50)	25.64(4.89)	−4.51 (1.83; −8.29, −0.73)	1.20* (0.36, 2.04)
Mechanism outcomes						
RSES	10.07(6.23)	10.79(4.42)	15.07(5.37)	10.71(5.37)	4.41 (1.75; 0.79, 8.03)	0.83* (0.03, 1.63)
BCSS (negative self)	12.50(5.64)	9.36(5.00)	5.15(5.76)	9.64(5.06)	−6.21 (1.68; −9.67, −2.75)	1.13* (0.30, 1.96)
BCSS (positive self)	4.14(5.16)	6.79(5.71)	8.08(4.99)	7.36(6.55)	2.41 (1.72; −1.14, 5.97)	0.44 (−0.34, 1.22)
PROQ3	60.64(17.19)	48.86(12.56)	49.38(15.96)	51.14(15.63)	−9.27 (4.85; −19.27, 0.74)	0.58 (−0.21, 1.37)
VAY voice dominance	18.14(2.74)	14.50(6.20)	17.23(3.35)	15.50(4.31)	−0.46 (1.00; −2.53, 1.61)	0.09 (−0.68, 0.86)
VAY voice intrusiveness	9.36(4.38)	9.86(3.88)	10.69(3.79)	10.57(3.23)	0.27 (1.28; −2.38, 2.92)	0.07 (−0.70, 0.84)
VAY hearer dependence	9.93(4.81)	5.50(3.65)	5.31(3.97)	6.00(4.40)	−2.65 (1.63; −6.02, 0.71)	0.56 (−0.22, 1.34)
VAY hearer distance	14.64(3.61)	14.43(4.62)	13.92(3.69)	14.71(3.91)	−1.07 (1.46; −4.08, 1.94)	0.26 (−0.51, 1.03)
BAVQ malevolence	13.29(4.39)	10.43(5.32)	10.62(4.54)	11.14(4.64)	−2.24 (1.31; −4.95, 0.46)	0.45 (−0.33, 1.23)
BAVQ benevolence	1.64(2.37)	2.86(3.74)	0.62(1.50)	1.71(3.22)	−0.58 (0.82; −2.26, 1.11)	0.18 (−0.59, 0.95)
BAVQ omnipotence	13.57(3.72)	11.86(3.30)	10.15(4.18)	12.43(3.61)	−3.11 (1.34; −5.87; −0.36)	0.88* (0.07, 1.69)
BAVQ resistance (feelings)	10.50(1.79)	8.50(3.25)	8.62(3.40)	9.14(2.25)	−1.08 (1.16; −3.48, 1.32)	0.39 (−0.39, 1.17)
BAVQ resistance (behaviour)	10.14(4.15)	11.50(3.35)	11.69(2.25)	12.64(2.59)	−0.66 (0.87; −2.47, 1.14)	0.18 (−0.59, 0.95)
BAVQ engagement (feelings)	0.64(1.34)	1.57(2.41)	0.15(0.38)	0.79(1.72)	−0.31 (0.42; −1.17, 0.55)	0.16 (−0.61, 0.93)
BAVQ engagement (behaviour)	1.86(2.57)	2.38(1.85)	1.23(1.42)	1.64(1.95)	−0.49 (0.68; −1.90, 0.92)	0.22 (−0.55, 0.99)

rates suggest the study design and intervention were acceptable – this is supported by the positive patient experience questionnaire findings. However, this was a pilot RCT not designed to draw definitive conclusions and findings should be considered in this light.

4.2. Primary outcome

The large effect on voice-impact is in contrast with the majority of CBTp trials which have found minimal effects on measures of voice-related impact (Haddock et al., 2009; Morrison et al., 2014; Valmaggia et al., 2005); despite the cognitive model of voices identifying this as the goal of CBT (Chadwick and Birchwood, 1994). It is possible that symptom-focused CBTp (as in the present study) leads to larger effects on voice-impact. However, these previous studies were in psychosis samples, and differences in effect size may be attributable to the transdiagnostic sample in the current study. Further research is needed to establish whether diagnosis is a moderator of CBTp outcomes.

4.3. Secondary outcomes

Large, statistically significant between-group effects on anxiety, wellbeing, and recovery suggest benefits of the intervention could extend beyond the primary outcome of voice-impact. Effects on depression were small and non-significant but in favour of the intervention group.

Table 3
Results from the patient experience questionnaire. *Note*: N/A = not applicable.

	Not at all/somewhat *n*(%)	Moderately so *n*(%)	Very much so/quite a lot *n*(%)	N/A *n*(%)
The therapy I received has				
Improved your mental health and wellbeing	2(16.7)	4(33.3)	6(50.0)	0(0)
Reduced the need for support from your GP	2(16.7)	1(8.3)	6(50.0)	3(25.0)
Helped you to better manage or reduce your medication	5(41.7)	1(8.3)	5(41.7)	1(8.3)
Helped to promote improvements in your physical health	6(50.0)	3(25.0)	3(25.0)	0(0)
Helped you to engage with community activities	3(25.0)	6(50.0)	3(25.0)	0(0)
Helped you to improve relationships with others	2(16.7)	4(33.3)	6(50.0)	0(0)
Helped to improve the amount of sick time that you take from work	2(16.7)	1(8.3)	0(0)	9(75.0)
Helped you to improve your ability to engage in meaningful activities	1(8.3)	4(33.3)	7(58.3)	0(0)

The between-group effect on the measure of voices characteristics (e.g. frequency, duration, volume) was small. This finding is in line with the aim of CBTv, whereby the goal of therapy is not to reduce voices, but to reduce the negative impact associated with the experience (Chadwick and Birchwood, 1994).

4.4. Mechanism measures

There were large, statistically significant effects on self-esteem, negative beliefs about self and voice omnipotence. Believing a voice is omnipotent is strongly associated with greater levels of voice distress (Hacker et al., 2008), it is therefore plausible that changes in these proposed mechanisms may be in part mediating effects on clinical outcomes. This hypothesis should be explored in future research.

Effects on other mechanism measures - positive beliefs about self, voice malevolence and relating measures consistently favoured the intervention group, but were in the small or medium range, and non-significant, which could indicate that guided self-help CBTv has limited impact on these variables. In particular, the modest, non-significant effects on the relating subscales could be because two sessions with a relating focus is insufficient to promote substantial changes in negative relating; indeed, Relating Therapy is typically delivered over 16 sessions (Hayward et al., 2017). The role these proposed mechanisms of change play in mediating effects on voice-impact now requires testing within a definitive trial of guided self-help CBTv.

4.5. Recruitment, retention and acceptability

Study recruitment, retention, therapy adherence rates, and patient experience results suggest the study design and intervention were acceptable. The study dropout rates were smaller than those reported in meta-analyses of CBTp. For example, our study dropout rate was 3.6%, compared to 14.5% (Wykes et al., 2007) and 5.5% (Hazell et al., 2016b). It is also encouraging that if participants completed the first session of therapy then they all continued with therapy to the point of exposure (4 sessions).

4.6. Limitations

As the present study is a pilot RCT, the sample size is intentionally small, which explains the wide confidence intervals. Findings should therefore be interpreted in light of this. Also, the use of a wait-list control group means we were unable to control for non-specific therapeutic effects. A definitive trial, with an active control group, that has sufficient statistical power is now needed to fully test the effectiveness of this intervention.

Recruitment for this study was transdiagnostic. Due to the small sample size we were unable to investigate whether psychiatric diagnosis moderated outcomes. The cognitive model of voices can be applied to those who hear voices in the context of psychosis and non-psychosis diagnoses (Waters et al., 2012). However the experience, impact and treatment implications of hearing voices in people with non-psychosis diagnoses requires further research attention (Waters et al., 2014). A larger trial will allow us to determine whether outcomes are moderated by diagnosis.

The primary outcome measure (HPSVQ) has not, as yet, been widely used in clinical trials. Scores on the self-report HPSVQ correlate highly (all $r > 0.8$) with scores on the well-established clinician-administered PSYRATS-AH (Kim et al., 2010). However, the psychometric study by Kim et al. (2010) was in a Korean sample and further validation of the HPSVQ is now required.

The long-term aim of guided self-help CBTv is to help increase access to CBT for people distressed by hearing voices. Our intervention requires 50% of the contact time (8 sessions) recommended by NICE (16+ sessions), meaning twice as many patients could be seen without increasing resources. Moreover, given the lack of trained CBTp therapists (Ince et al., 2015; Mueser and Noordsy, 2005), frontline staff (i.e. mental health nurses) could be trained to deliver the intervention in order to further increase access. CBTp may be effective when delivered by non-accredited therapists (Turkington et al., 2014; Waller et al., 2013). Further research is needed to identify whether guided self-help CBTv would be acceptable, feasible, and effective when delivered by frontline practitioners.

4.7. Clinical implications

Because the present study is a pilot RCT, we do not recommend that guided self-help CBTv be offered in routine practice at this time. However, findings are promising and support the continued investigation of guided self-help CBTv within a definitive trial.

4.8. Research implications

There are a number of potential future research ideas. Our current research priority is to explore the effects of guided self-help CBTv delivered by therapists and frontline mental health practitioners as part of a definitive trial; with mediation analysis to test potential mechanisms, and moderation analysis to explore the impact of psychiatric diagnosis on outcomes.

4.9. Conclusions

Guided self-help CBTv was associated with a large and statistically significant between-group effect size on voice-impact. Low study and intervention drop-out rates, with high participant satisfaction, suggest our intervention is acceptable. Guided self-help CBTv warrants further investigation.

Conflicts of interest

Two of the authors of this paper (CS and MH) are authors of the self-help book tested in the study. No other conflicts of interest are declared.

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