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.

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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; Naem et al., 2016). Concurrently, this field is moving towards a symptom-specific approach (Birchwood and Trower, 2006), whereby CBT 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.
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;
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