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Relating Therapy for distressing auditory hallucinations: A pilot randomized controlled trial

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ABSTRACT

Auditory hallucinations (AH) are a common and distressing experience and patients report distress reduction to be a priority. Relating Therapy adopts a symptom-specific and mechanism focused approach to the reduction of AH distress. We conducted this single-blind, pragmatic, parallel groups, superiority pilot RCT within a single mental health centre in the UK. Patients (18+ years) with persistent and distressing AH, irrespective of diagnosis were randomly allocated to receive either Relating Therapy and Treatment-as-usual (RT) or Treatment as-usual alone (TAU). Assessment of outcome was completed pre-randomisation (T0), 16 weeks post-randomisation (T1) and 36 weeks post-randomisation (T2). The primary outcome was the 5-item Distress scale of the Psychotic Symptoms Rating Scale - Auditory Hallucinations (PSYRATS-AHRS) at T1. We randomly assigned 29 patients to receive RT ($n = 14$) or TAU ($n = 15$). Twenty-five patients (86%) provided complete datasets. Compared with TAU, RT led to reductions in AH distress in the large effect size range across T1 and T2. Our findings suggest that Relating Therapy might be effective for reducing AH distress. A larger, suitably powered phase 3 study is needed to provide a precise estimate of the effects of Relating Therapy for AH distress.

1. Introduction

Auditory hallucinations (AH) are reported by the majority of patients with Schizophrenia Spectrum Disorder (Thomas et al., 2007) and are also common in other psychiatric disorders (Sommer et al., 2012). This symptom can have a devastating effect on patients' lives due to high levels of distress (Birchwood and Chadwick, 1997), depression (Birchwood et al., 2004) and an increased risk of suicide (Kjelby et al., 2015). Patients with persistent AH report the reduction of distress to be a priority for treatment (Greenwood et al., 2010; Meddings and Perkins, 2002).

NICE recommend antipsychotic medication and Cognitive Behaviour Therapy for Psychosis (CBTp) for the treatment of 'positive' symptoms of schizophrenia, including AH (National Collaborating Centre for Mental Health, 2014). Despite evidence for its benefits, antipsychotic medication is often not fully effective, and 40–50% of patients are non-adherent (Lacro et al., 2002). CBTp has evidence from 12 meta-analyses that suggest small to moderate effects (ranging from Hedges g = 0.09 to 0.49 depending on trials included and outcomes examined). However, CBTp as a broad approach has not consistently reduced AH distress (Mawson et al., 2010).

To better target AH outcomes, a symptom-specific approach that focuses on key processes hypothesized to be associated with adaptation to persisting AH is needed (Thomas et al., 2014). Such an approach has been used successfully with paranoid delusions (Freeman et al., 2015) and has resulted in larger effect sizes than broader CBT approaches (Mehl et al., 2015). For AH, a large and methodologically robust trial of Cognitive Therapy for Command hallucinations (CTCH) has successfully utilized a symptom-specific and mechanism-focused approach to reduce the targeted outcome of behavioural compliance with command hallucinations (Birchwood et al., 2014). However, this study reported no reduction in AH distress. Avatar Therapy (Leff et al., 2013) and Competitive Memory Training (COMET) (Van Der Gaag et al., 2012) are also psychological therapies that have specifically focused upon AH. Whilst they have reported encouraging findings from pilot studies, neither has targeted or reported specific outcomes for AH distress.

We have drawn upon Birtchnell's Relating Theory (Birtchnell, 2001) and Birchwood's interpersonal CBT model of AH (Birchwood et al., 2004) to develop Relating Therapy (RT) as a symptom-specific therapy that targets interpersonal relating as a mechanism associated with AH distress. An evolving literature has explored AH within relational frameworks and patients have been found to have subordinating and

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intrusive relationships with their AH (Hayward et al., 2011). These relationships are associated with distress (Sorrell et al., 2010), share similarities with patient's relationships with people within their social environments (Birchwood et al., 2004; Hayward, 2003), and are often maintained by the submissive (Hayward et al., 2008) and/or aggressive (Thomas et al., 2009) responses of the patient. Relating Therapy has been developed to modify the 'negative relating' of the patient through the teaching of assertiveness skills. An initial case series found Relating Therapy to be intuitive and acceptable to patients and therapists (Hayward and Fuller, 2010; Hayward et al., 2009).

Within this pilot RCT we sought to generate a descriptive summary of the primary and secondary outcomes to provide robust estimates of variability to inform calculations for a subsequent fully powered phase 3 trial. We also explored differences in outcomes between groups and changes over time.

2. Experimental methods

2.1. Study design

This was a pilot study for conducting a single-blind, pragmatic, parallel groups, superiority RCT comparing Relating Therapy plus treatment as usual (hereafter referred to as RT) with treatment as usual alone (hereafter referred to as TAU). Eligible participants were recruited from one mental health centre in Sussex, UK. Recruitment began in June 2013 and was completed in February 2015. Follow-up assessments began in April 2014 and were completed in November 2015. Assessments were completed pre-randomisation (T0), 16-weeks post-randomisation (T1) and 36-weeks post-randomisation (T2). The published research protocol was followed throughout the study (Hayward et al., 2014).

The Surrey Research Ethics Committee (number 12/LO/2045) provided NHS ethics approval for the study.

2.2. Participants

Participants were eligible for the study if they met the following inclusion criteria: aged 18 years or older; currently receiving specialist mental health care; hearing distressing AH for at least one year (irrespective of diagnosis); scoring 3 or 4 (rated on a 0–4 scale) on either the intensity of distress item or the amount of distress item on the Psychotic Symptoms Rating Scale - Auditory Hallucinations Scale (PSYRATS-AHRS) (Haddock et al., 1999) at the time of consent. Exclusion criteria were: AH with an organic cause; a primary diagnosis of substance misuse; and currently receiving psychological therapy for distressing AH.

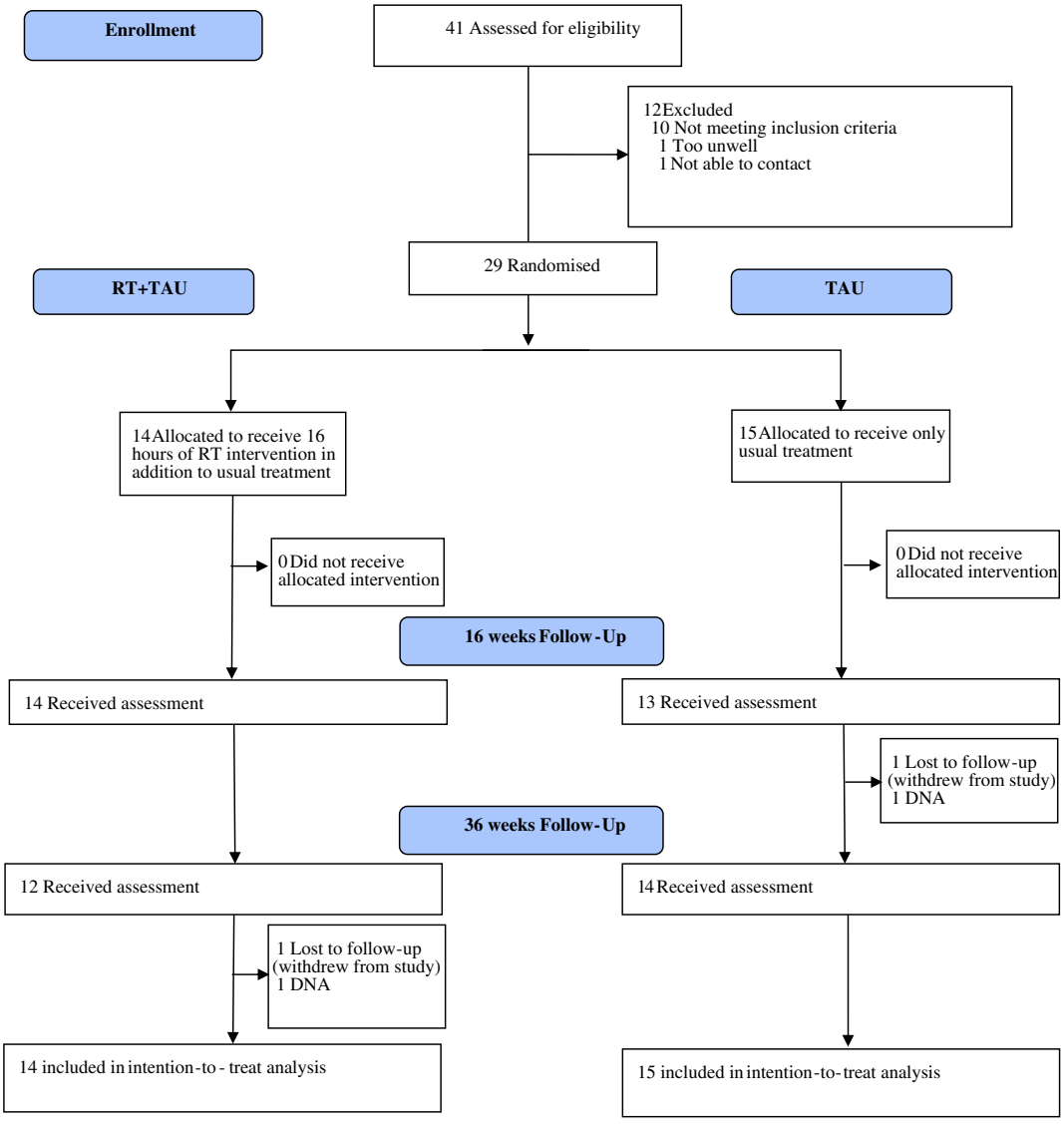

Fig. 1. CONSORT.

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