



# Cognitive behaviour therapy to prevent harmful compliance with command hallucinations (COMMAND): a randomised controlled trial

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## Summary

**Background** Acting on command hallucinations in psychosis can have serious consequences for the individual and for other people and is a major cause of clinical and public concern. No evidence-based treatments are available to reduce this risk behaviour. We therefore tested our new cognitive therapy to challenge the perceived power of voices to inflict harm on the voice hearer if commands are not followed, thereby reducing the hearer's motivation to comply.

**Methods** In COMMAND, a single-blind, randomised controlled trial, eligible participants from three centres in the UK who had command hallucinations for at least 6 months leading to major episodes of harm to themselves or other people were assigned in a 1:1 ratio to cognitive therapy for command hallucinations + treatment as usual versus just treatment as usual for 9 months. Only the raters were masked to treatment assignment. The primary outcome was harmful compliance. Analysis was by intention to treat. The trial is registered, number ISRCTN62304114.

**Findings** 98 (50%) of 197 participants were assigned to cognitive therapy for command hallucinations + treatment as usual and 99 (50%) to treatment as usual. At 18 months, 39 (46%) of 85 participants in the treatment as usual group fully complied with the voices compared with 22 (28%) of 79 in the cognitive therapy for command hallucinations + treatment as usual group (odds ratio 0.45, 95% CI 0.23–0.88,  $p=0.021$ ). At 9 months the treatment effect was not significant (0.74, 0.40–1.39,  $p=0.353$ ). However, the treatment by follow-up interaction was not significant and the treatment effect common to both follow-up points was 0.57 (0.33–0.98,  $p=0.042$ ).

**Interpretation** This is the first trial to show a clinically meaningful reduction in risk behaviour associated with commanding voices. We will next determine if change in power was the mediator of change. Further more complex trials are needed to identify the most influential components of the treatment in reducing power and compliance.

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## Introduction

Schizophrenia affects 0.8% of the UK population, usually starts in young adults, and, in some cases, leads to persistent disability.<sup>1</sup> Individuals with this illness have a high risk of suicide (8%) and deliberate self-harm and, although the risk is small, they are more likely to perpetrate aggression than are those without schizophrenia.<sup>2</sup> Individuals acting on delusions, including commanding voices, are a cause for concern at societal and political levels because members of the public are at risk of apparently random acts of violence, even when the perpetrators are well supported by services. These concerns are shown in national policy documents—eg, the UK national mental health strategy aims to reduce avoidable harm to self or others.<sup>3</sup>

Although drug and other treatments have improved, nearly 50% of individuals will have treatment-resistant symptoms or symptoms arising from non-adherence to drug regimens.<sup>4,5</sup>

Auditory hallucinations are some of the most prominent and distressing of the treatment-resistant symptoms, and command hallucinations are the most high risk of these.<sup>6</sup> Shawyer and colleagues<sup>6</sup> reported a median

53% prevalence of command hallucinations in adult participants with psychiatric disorders; 48% of these participants said the commands stipulated harmful or dangerous actions, rising to 69% for participants in medium secure units.<sup>7</sup>

However, the link between the presence of command hallucinations and harm to self or others is not straightforward. In the MaCarthur study,<sup>8</sup> no association was reported between the presence of delusions or command hallucinations and violence. Thoughts about violence, however, were a strong predictor of violence 6 months later.

Our cognitive model of voices has clarified that it is not only the level of activity of voices, or indeed their content, that drives affect and behaviour, but also the nature of the relationship with the personified voice.<sup>9–11</sup> We showed that compliance or appeasement behaviour can occur when the hearer believes the voice to have malevolent intent, and crucially to have the power to deliver the threat.<sup>9</sup> These findings have been independently replicated in a forensic population.<sup>12</sup>

This theoretical framework informed the development of a cognitive behaviour therapy: cognitive therapy for

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command hallucinations, which was designed to weaken and challenge beliefs about the power of voices, enabling the individual to break free of the need to comply or appease and thereby reduce harmful compliance behaviour and distress.<sup>13,14</sup> This therapeutic model was developed because of a major gap in the evidence base. Although cognitive behaviour therapy is recommended by the UK's National Institute for Health and Care Excellence<sup>15</sup> to reduce overall symptom severity, the guidance notes that there is insufficient evidence for voice compliance and frequency and inconsistent evidence for any direct effect on delusions.

We tested the model in a proof-of-principle trial<sup>16</sup> in a group at high risk of compliance with commands because of recent (<9 months) harmful compliance or appeasement. This operational definition of risk was associated with a 39% rate of recurrence of harmful compliance within 12 months in the control group; in people receiving the therapy, the rate of compliance dropped to 14%, equivalent to an effect size of 1.1. This drop was accompanied by a reduction in the perceived power of the voice; there was a reduction in delusional distress and depression, but this was not maintained at 12 months' follow-up. Crucially, as expected, no change was noted in the frequency or intensity of voices, but only in the (power) relation with them. The results of a similar trial by Shawyer and colleagues<sup>17</sup> of a different therapy based on acceptance of voices by "cultivating the capacity to just notice voices and associated thoughts rather than believe and act on them" showed no effect on compliance or other outcomes. However, this study had a low base rate of compliance.

The aim in the COMMAND trial was to assess the acceptability, effectiveness, and cost-effectiveness of cognitive therapy for command hallucinations. The primary hypothesis was that in participants with command hallucinations who have recently acted on the voices and are therefore at high risk of doing so again cognitive therapy for command hallucinations would increase resistance and thereby reduce the level of further harmful compliance behaviour and the associated risk. Secondary hypotheses were that the perceived power of the persecuting voice would be reduced, which would act as the mediator of change in compliance; there would be no changes in the frequency or topography of voices; and cognitive therapy for command hallucinations would reduce delusional distress and depression.

## Methods

### Study design

This was a single-blind, prospective, pragmatic randomised controlled trial for the comparison of cognitive therapy for command hallucinations + treatment as usual with treatment as usual alone.<sup>18</sup> Eligible participants were recruited for the trial from three UK centres in Birmingham (which included a site

in Leicester), London, and Manchester. Recruitment to the trial began in February, 2008, and was completed in July, 2010. Follow-up assessments began in November, 2008, and were completed in January, 2012. Treatment was for 9 months and follow-up was at 9 months and 18 months after randomisation.

The West Midlands Research Ethics Committee (number 06/MRE07/71) provided ethics approval for the study.

Participants were eligible if they met the following criteria: had International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10), schizophrenia, schizoaffective (F20, 22, 23, 25, 28, 29), or mood disorders (F32),<sup>19</sup> and were under the care of a clinical team; were aged 16 years and older; had a history of harmful command hallucinations for at least 6 months with recent (<9 months) history of harm to self or others, or major social transgressions as a result of the commands (full or incomplete compliance); or had harmful command hallucinations whereby the individual was distressed and appeasing the powerful voice.

Exclusion criteria were organic impairment or primary diagnosis of addictive disorder or insufficient command of English.

Eligible participants were identified by clinical studies officers from the UK Mental Health Research Network who reviewed electronic case records for history of auditory hallucinations and evidence of risky, aggressive, and violent behaviour. Trained researchers did a screening interview with each participant to confirm eligibility for the trial. After the screening interview, eligible participants were invited to take part and asked to provide informed consent. Once written informed consent had been obtained, the researchers administered a battery of assessments and on completion participants were randomly allocated either to the cognitive therapy for command hallucinations + treatment as usual group or to the treatment as usual only group.

### Randomisation and masking

Participants were randomly assigned to the cognitive therapy command hallucinations + treatment as usual group or the treatment as usual only group in a 1:1 ratio using an allocation sequence generated with OpenCDMS.<sup>25</sup> and were stratified by the centre with permuted blocks with a randomly varying block size after stratification by centre. OpenCDMS then sent an email notification of the allocation to the therapists and trial manager. After randomisation, an email notification about group allocation was sent to the trial manager, trial administrator, and therapists. An email notification confirming that the participant had been randomly assigned to treatment (with no information about group allocation) was sent to the centre research assistant. The trial administrator then sent a letter to the participant and the care coordinator informing them about the outcome of the randomisation. Thus, the results of the

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