Evaluating the feasibility of a two-session intervention targeting inflated responsibility beliefs in people who experience command hallucinations

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June, 2017

Research submitted in partial fulfilment of the requirements for the degree of Doctor in Clinical Psychology (DClinPsy), Royal Holloway, University of London.

ACKNOWLEDGEMENTS

Many people have helped me throughout this lengthy journey. Firstly, I would like to thank the three Royal Holloway supervisors I had throughout this process, but particularly Professor Andy Macleod, for providing invaluable feedback and much needed laughter in supervision towards the end. A huge thanks to my four incredible therapists - Dr Naomi Glover, Dr Madiha Shaikh, Dr Zarina Abbas and Dr Marianne Rabassa - for your continuous support and enthusiasm right from the start. It wouldn't have been possible without you four!

To Sunil – my best friend and husband (to-be!). You have been there every step of the way, and have been the (lucky) one to listen to my exceedingly boring thesis chat and my moans about tiredness. You have kept me sane! Nola – you were born in the middle of the doctorate, and whenever I see your sweet smile and funny little personality, it has given me such joy and motivation.

Lastly to my parents – your unwavering support and encouragement always keeps me going. Words can't express how much you both mean to me and you are such fantastic parents. I love you both so much.

ABSTRACT

Though an inflated sense of responsibility was initially considered a unique feature of OCD, recent research has identified a potentially transdiagnostic role for responsibility beliefs (RBs) in psychopathology. Studies have found people experiencing command hallucinations to endorse significantly more problematic beliefs about responsibility than either those experiencing non-commanding voices or OCD, and non-clinical controls. As such, it is suggested that novel psychological interventions for voice hearers might benefit from addressing RBs by employing similar techniques to those used in CBT for OCD.

This study evaluates the feasibility and acceptability of a two-session intervention targeting RBs in people who hear command hallucinations. The research questions were: i) is recruitment and retention of participants feasible; ii) are the outcomes measures utilised effective in capturing impact; iii) is the intervention as a whole acceptable to, and suitable in, this client group; iv) is the implementation of this study and intervention feasible with respect to resources; and v) do preliminary participant responses indicate the intervention to be clinically helpful.

This study had three components: *Phase 1* consisted of development of the intervention; *Phase 2* used a Single Case Experimental Design (SCED) for preliminary evaluation of intervention effectiveness across three participants; and *Phase 3* comprised Thematic Analysis (TA) of a focus group with the four participating therapists.

Results show that no firm conclusions could be drawn from the SCED analysis of clinical effectiveness on measures of RBs, voice hearing and general well-being, partly due to small improvements seen in central tendency and trend across baseline.

Equally, evidence suggestive of clinically significant change (CSC) is very limited. However, findings do indicate that the intervention appears safe, with no worsening of symptoms across measures. Results from *Phase 3* identify six overarching themes, and broadly conclude that, in its current format, the intervention is neither feasible nor acceptable.

Overall, this research demonstrates the necessity for substantial adaptations to the intervention and implementation protocol for a future feasibility study in the area. Moreover, further research is clearly required in clarifying the precise role of elevated perceived responsibility in command hallucinations. The implications of these findings and suggestions for future research are discussed.

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CHAPTER 1: INTRODUCTION

1.0 Overview

Recently, a greater understanding of the maintenance factors influential in specific psychotic symptoms, such as auditory hallucinations (in particular command hallucinations) and persecutory delusions, has led to more targeted methods of assessment and treatment (Birchwood et al., 2014; Freeman et al., 2016). These "causal-interventionist", modular interventions were initially developed through feasibility and pilot studies, and have led to a refinement of psychological approaches in psychosis. Cognitive processes such as inflated responsibility beliefs (hereafter RBs) - originally implicated in cognitive models of Obsessive-Compulsive-Disorder (OCD) - have been shown to be relevant in psychosis (Ellett et al., in press.; Luzón, Harrop, & Nolan, 2009), whereby heightened levels of RBs in voice hearers (particularly those experiencing command hallucinations) are associated with increased distress. Given that i) elevated perception of personal responsibility is clearly implicated in the experience of distress associated with - and in the nature of peoples' responding to - commands (Ellett et al., in press), ii) that techniques for targeting RBs are established as effective in CBT for OCD (Salkovskis, 1999) and iii) that interventions for commanding voices in psychosis aim, in part, to reduce compliance (Birchwood et al., 2014), it is reasonable to suggest that future psychological approaches for people experiencing voices may benefit from a specific module targeting RBs.

This chapter will begin by outlining the nature of psychosis, before summarising theoretical accounts of auditory hallucinations and how to treat them psychologically. RBs will be described in relation to OCD and how they are treated, before a discussion of their relevance in auditory hallucinations (specifically command hallucinations).

Advances in psychological treatments for psychosis will be discussed, and in particular, the role of feasibility studies in establishing the potential merits of recent interventions with great specificity. Finally, the current study will then be outlined, with respect to gaps in the literature it intends to address.

1.1 Psychosis

Psychosis is a severe mental health condition – most commonly associated with a "schizophrenia spectrum" diagnosis – that is characterised by positive and negative symptoms. Schizophrenia affects 0.8% of the UK population (Os & Kapur, 2009). Positive symptoms include hallucinations (visual, tactile, olfactory, auditory, and/or gustatory), thought insertion, thought withdrawal, thought broadcast, and/or thought disorder (incoherent speech, flight of ideas and pressure of speech). Voice hearing is the most commonly reported form of auditory hallucination (Mawson, Cohen, & Berry, 2010) and is defined as hearing a voice in the absence of an external stimulus (Woods, Jones, Alderson-Day, Callard, & Fernyhough, 2015). Negative symptoms include apathy, attention impairments and poverty of speech (Morrison, Haddock, & Tarrier, 1995)

Both the symptoms of psychosis, and trajectories for recovery, can vary markedly across individuals. Whereas a proportion of people make good recoveries following a first episode, others are found to experience more chronic and persistent difficulties (NICE, 2014). Pre-morbid, and then prodromal, stages are thought to precipitate the onset of psychosis, during which individuals typically display a reduction in functioning alongside short-lived or attenuated positive symptoms (Fusar-Poli et al., 2012). In some people, this "at-risk mental state for psychosis" (ARMSp) is followed by a 'first-episode'. Psychotic experiences can be precipitated by stress, and

are associated with comorbid mental health problems such as anxiety and depression (Garety, Kuipers, Fowler, Freeman, & Bebbington, 2001).

Symptoms have a significant impact on peoples' social, personal and occupational functioning, and exact a notable societal cost through absence from work and unemployment (both for individuals themselves and for their carers) (Andrew, Knapp, McCrone, Parsonage, & Trachtenberg, 2012). Medication is only partially effective, with up to 40% of clients continuing to experience persistent, distressing positive symptoms (NICE, 2014) alongside distressing side-effects (Gartey, 2003). Relapse rates after initial remission of symptoms are high (Gleeson et al., 2009) and sufferers are thirteen times more likely to take their own lives than individuals in the general population (Palmer, Pankratz, & Bostwick, 2005). There is a substantially increased risk of physical health problems and early mortality (Chang et al., 2011).

1.2 Cognitive Models of Psychosis

The symptoms of psychosis can perhaps best be understood as a confluence of psychological, neurobiological, social and phenomenological levels of explanation. Cognitive models of psychosis (e.g. Meaden et al., 2013; Morrison, 2001) provide a framework for conceptualising the development and maintenance of psychotic symptoms, as well as associated distress and impairment. The testable hypothesises generated by these models have brought about further theoretical and therapeutic advances (Garety et al., 2001). These models have been influential in our understanding of the symptoms of psychosis as reasonable, grounded in experience, and amenable to the processes of formulation and intervention. The best-evidenced psychological therapy in psychosis – Cognitive Behavioural Therapy for Psychosis (CBTp) (NICE, 2014) – is well researched and government recommended (Wykes, Steel, Everitt, &

Tarrier, 2008) and is based on the principles of these frameworks. Yet a recent meta-analysis has shown that CBTp has modest benefits (Jauhar et al., 2014), and the heterogeneity of symptoms under the umbrella of psychosis makes generic approaches difficult to implement. Instead, recent advancements have focused on "causal-interventionist" approaches, targeting the mechanisms implicated by cognitive models (Mehl, Werner, & Lincoln, 2015). As such, we shall now discuss approaches that deal specifically with auditory hallucinations, as this is the focus of the study.

1.3 Understanding voice hearing

Auditory hallucinations (AHs) are one of the most common positive symptoms of psychosis, and are defined as "*a sensory perception that has a compelling sense of reality, but occurs without external stimulation of the sensory organ*" (American Psychiatric Association, 2000). AHs are comprised of a diverse phenomenological experience, the content of which is frequently meaningful to the hearer (Mawson et al., 2010). The most common form of AH is the experience of hearing voices, with research suggesting that approximately 66% of people with psychosis hear voices (Johns & van Os, 2001). Voices can involve multiple and/or single voices; are most likely to be in a person's first language though may be in a different language; occur in the first, second and/or third person; may be known and/or unknown to the voice-hearer; and may offer comments, commands, insults or even encouragement and comfort (Jones, 2010).

The psychological understanding of voice hearing has been influenced by a number of prominent models of auditory hallucinations (for example Chadwick & Birchwood, 1994; Morrison, 1998; Waters, Badcock, Michie, & Maybery, 2006). Chadwick & Birchwood's (1994) model will be the focus of this chapter.

1.3.1 Chadwick & Birchwood (1994) Model

This model suggests that beliefs regarding the intent, power, and identity of voices, as well as the perceived degree of control a person has over the experience, predict depression, distress, and problematic responses to voices (such as compliance) (Chadwick & Birchwood, 1994). The model conceptualises a person's i) beliefs about the voice and ii) relationship with the voice, as a product of broader schemas relating to self and others. The interpersonal dynamic with the voice is therefore grounded in an individual's impression of their wider position in the social world (Birchwood et al., 2004). Certainly, a person's appraisal of their voice (and their authority in relation to it) is found to be influential in relation to distress and response style (Mawson et al., 2010). For example, a systematic review found that when voices were perceived as being characterised by supremacy and malevolence, this was associated with significantly higher levels of distress (Mawson et al., 2010). The heterogeneity of voice hearing experiences makes further delineation helpful and necessary (Larøi & Woodward, 2007). The following section will focus on what is perceived to be the most impairing sub-category of voice hearing – command hallucinations (Shawyer, Mackinnon, Farhall, Trauer, & Copolov, 2003).

1.4 Understanding command hallucinations

Command hallucinations (CHs) - a subset of auditory hallucinations, where the voice commands an individual to engage in a specific action (Mackinnon, Copolov, & Trauer, 2004) - are considered one of the most distressing, high-risk and treatment resistant symptoms of psychosis (Byrne, Birchwood, & Trower, 2006; Shawyer et al., 2003) Between 33-74% of voice hearers have reported a commanding aspect to their voices (Birchwood & Chadwick, 1997). Commands can range from harmless gestures

(for example to turn off the television), to social transgression (such as swearing at someone), to more severe behaviours (such as harming or killing oneself or others) (Trower et al., 2004). Shawyer and colleagues found that 47% of participants experiencing CHs reported their voices to be stipulating dangerous or harmful actions (Shawyer et al., 2003).

Birchwood and Chadwick's (1997) ABC model of auditory hallucinations (an update following on from Chadwick & Birchwood, 1994), has been applied to command hallucinations (Figure 1). Here, it is suggested that when someone hears a voice (A- the activating event), this experience gives rise to a set of idiosyncratic beliefs and appraisals (B) regarding the meaning and purpose of the voice. Influential appraisals are likely to relate to voice dominance, identity, power (omnipotence), and intent (malevolence), and trigger emotional and behavioural consequences (C), many of which – such as avoidance, appeasement, isolation, or compliance - are seen to maintain the problem.

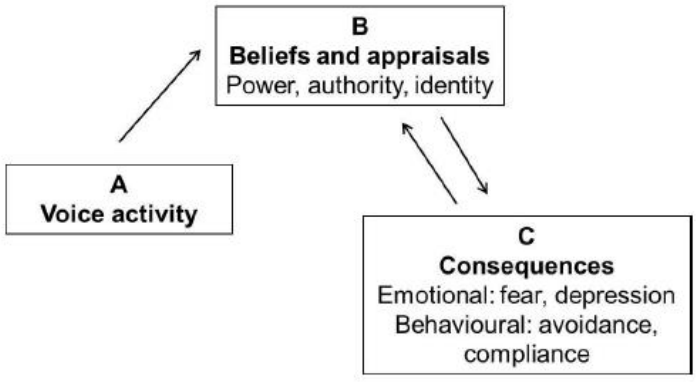


Figure 1: Chadwick and Birchwood (1994), and Birchwood and Chadwick's (1997) ABC model of auditory hallucinations.

This model has established that it is not only voice frequency and content that dictate affect and response, but also the nature of one's relationship with a voice (Chadwick & Birchwood, 1994; Connor & Birchwood, 2013), as people derive meaning from their experience (Close & Garety, 1998). If an individual believes a voice to have malevolent intent, and importantly, the power to deliver its threat, then compliance or appeasement become more likely (Birchwood et al., 2014). When people experience a command to harm another person, compliance is found to be more likely in cases where the hearer credits their voice as having good intentions (a perception of voice benevolence) (Joireman, Anderson, & Strathman, 2003). Accordingly, when the voice is characterised as malevolent, compliance is less frequent (Joireman et al., 2003). Equally, studies have shown that perceptions of the voice's power and authority (Birchwood et al., 2014; Joireman et al., 2003), estimations of elevated social rank (Meaden, Keen, Aston, Barton, & Bucci, 2013) and fear of consequences for disobeying (Barrowcliff & Haddock, 2010), to be predictors of compliance. Of course, compliance itself should be recognised as multifaceted, and appeasement often involves complying with the commanding voice's prescribed action in a symbolic manner, or partially. For instance, a person commanded to harm themselves by cutting may pick at an existing wound instead (Meaden et al., 2013). The work of Chadwick & Birchwood (1994), in addition to the many studies that have been conducted in providing empirical support, allow us to recognise that the distress and impairment associated with commanding voices is more nuanced than can be accounted for by explanations citing form and content alone. Perceptions of power and authority – linked to higher incidences of anxiety and depression (Birchwood et al., 2014) – play a central role in beliefs about voices, and therefore in determining emotional and behavioural responses to the voice

hearing experience. The NICE recommended treatment for voices will now be discussed.

1.5 Researching the impact of CBTp in people who hear voices

CBTp aims primarily to impact the process by which people with psychosis appraise their experience (Meaden et al., 2013). Therapy is tailored to personal recovery goals, and care is taken to foster a therapeutic relationship that is genuinely collaborative and empowering (Johns, Jolley, Keen, & Peters, 2014; Peters et al., 2010). Within CBTp - particularly when focussed on voices - there is an emphasis on sense-making within an interpersonal and developmental framework. The approach seeks to change peoples' relationships with their voices (often pertaining to issues of power and control); address important beliefs about voices; enable flexibility around compliance; and promote meaningful change within the context of valued goals. Behavioural experiments are often designed to test alternative – more adaptive - perspectives and responses (Thomas et al., 2014).

The effectiveness of psychological therapies for voices is most frequently evaluated through examining the overall efficacy of CBTp, which is likely to have been measured as a function of its outcomes with respect to a range of positive symptoms combined. A recent meta-analysis indicated advantages of CBTp over any active control condition (Turner, van der Gaag, Karyotaki, & Cuijpers, 2014). However, there is far less available evidence regarding effects of CBTp on hearing voices, with relatively few trials having explored this phenomenon specifically. This grouping together of outcomes relating to voices and unusual beliefs results in problematic sample heterogeneity (Thomas et al., 2014), particularly where the proportion of time

actively addressing voices in CBTp can be small (Farhall, Freeman, Shawyer, & Trauer, 2009).

Individual trials incorporating voice measures have observed improvements - with the most robust change in depression (Peters et al., 2010) - yet most have been deemed inconclusive due to insufficient power (Thomas et al., 2014). A meta-analysis published in 2014, evidencing (modest) benefits of CBTp on measures of positive symptoms (post-treatment between-group effect sizes ranging from 0.25 to 0.47), also reported a small to moderate significant effect of CBTp on post-treatment voice severity compared to control (Hedge's g = 0.34) (Jauhar et al., 2014). This analysis, however, was limited by the combination of trials conducted in chronic and acute psychosis, and included trials that did not directly target positive symptoms. However, treatment studies specifically targeting voices through CBT-based interventions have demonstrated improvements on several voice related indices (Haddock, Slade, Bentall, Reid, & Faragher, 1998; Thomas, Rossell, Farhall, Shawyer, & Castle, 2011), such as significant improvement post-treatment on a scale that quantifies the severity of delusions and hallucinations (The Psychotic Symptom Rating Scales; Haddock et al., 1999)

The typical RCT design recruits participants experiencing a broad range of unusual experiences, delivers a variable and individualised therapy based on an extensive range of cognitive/and or behavioural principles, and examines outcomes using broad indices of mental health (Thomas et al., 2014). Where the field has been focused primarily on establishing efficacy, with some success, there are relatively limited findings with respect to measuring the supposed mechanisms of change in voice work (for example beliefs about voice omnipotence) (Thomas et al., 2014). The same

can be said in relation to delusions (Freeman, 2011). As such, the task of identifying key mechanisms of therapeutic change remains. It has been argued that when research efforts are focused on single symptoms, interventions – based on theoretical models - can be developed to target the mechanisms that play an important role in maintenance (Garety & Freeman, 2013). Regarding voices, a greater understanding of the maintenance factors implicated in voice-hearers' distress would represent a foundation for novel therapeutic approaches (Birchwood et al., 2014). Emotional disorders have consistently been highlighted as central in the development and maintenance of psychosis, a finding with important treatment implications (Birchwood, 2003).

1.6 Psychosis and Anxiety disorders

Consistently high rates of anxiety are found in people with psychosis, - one study reported that 38% of clients with psychosis present with at least one anxiety disorder (Achim et al., 2011) - and anxiety has an established role in the development and maintenance of psychotic symptoms (Freeman & Garety, 2003). Retrospective and prospective studies have found that in the majority of cases (around 80%), symptoms of anxiety precede the appearance of positive symptoms by up to four weeks (Birchwood et al., 1994; Startup, Freeman, & Garety, 2007). Clients experiencing psychosis who also present with co-morbid anxiety disorders typically demonstrate restricted social and occupational functioning (de Haan, Hoogenboom, Beuk, van Amelsvoort, & Linszen, 2005), more entrenched hopelessness (Lysaker & Whitney, 2009), have an increased risk of suicide (Achim et al., 2011), utilise healthcare services more frequently, and have a poorer prognosis (Schirmbeck & Zink, 2013)

1.6.1 Psychosis and Obsessive Compulsive Disorder (OCD)

Within anxiety disorders, research has shown particularly significant co-morbidity between psychosis and OCD (de Haan et al., 2005). One prevalence study indicated that 15.1% of clients with psychosis were also experiencing OCD (Braga, Mendlowicz, Marrocos, & Figueira, 2005), or 30% co-morbidity for those experiencing Obsessive Compulsive Symptoms (OCS) (Tundo & Necci, 2016). Studies report poorer treatment outcomes when this comorbidity is apparent (Jäger et al., 2008), as well as more treatment resistant psychotic symptoms (Hwang, Yum, Losonczy, Mitchell, & Kwon, 2006).

The first meta-analysis exploring the co-morbidity of OCD and psychosis found presence of OCD in psychosis to be associated with higher global, positive and negative psychotic symptoms (Cunill, Castells, & Simeon, 2009). Despite comorbidity estimates as high as 64% in some studies (Kayahan, Ozturk, Veznedaroglu, & Eraslan, 2005) evidence detailing optimal treatment for this group is almost non-existent, and research on treatment strategies is scarce (Tundo & Necci 2016). These findings suggest that the OCD/OCS comorbidity in people with psychosis is a common and underestimated clinical problem, which substantially impact distress and functional recovery (Schirmbeck & Zink, 2013). Given the established relationship between anxiety and psychosis – both in relation to co-morbidity and conceptualisation – and the particularly striking overlap between OCD and psychosis, there is reason to believe that further investigation of cognitive processes in anxiety disorders may help us to better understand maintenance factors in psychosis. As such, the next section will focus on responsibility beliefs (RBs) in OCD - as a mechanistic factor underpinning formulation and treatment - and then go onto discuss their relevance in psychosis.

1.7 Responsibility beliefs in OCD

The most prominent model of OCD is that of Salkovskis (1985), which suggests that inflated perceptions of responsibility are central to our understanding. This model specifies two levels of responsibility-related cognitions: (1) responsibility appraisals or interpretations pertaining to the potential for harm in specific situations, and (2) responsibility attitudes or assumptions – broader self-implicating beliefs about personal responsibility, commonly associated with feelings of guilt and depression. Responsibility is therefore a complex concept, with scope for misunderstanding (Clark & Purdon, 1993). A specific psychological definition has been proposed, with responsibiliy as:

> "The belief that one has power which is pivotal to bring about or prevent subjectively crucial negative outcomes. These outcomes are perceived as essential to prevent. They may be actual, that is, having consequences in the real world, and/or at a moral level" (Salkovskis et al., 2000)

Whereas this definition does not necessarily imply dysfunction, it is the adopting of inflated responsibility - involving unrealistic and exaggerated perceptions of the causal influence of one's thoughts or actions on events (perceived as "consequences") - that we may identify as maladaptive. This perception is inevitably associated with the notion that a person needs to take preventative or restorative action in the form of ritualistic neutralising behaviours (Salkovskis, 1999). Such beliefs differ from normal, adaptive responsibility beliefs in that they clearly exceed societal expectations of practical and/or moral responsibility. Yet, the terms *responsibility beliefs* and *inflated responsibility* are often used interchangeably in the OCD literature to denote the same concept. Within this thesis, these two concepts are referred to as responsibility beliefs (RBs).

There is established empirical support for the influence of RBs in OCD (Arntz, Voncken, & Goosen, 2007; Salkovskis et al., 2000). RBs, as assessed by the Responsibility Interpretations Questionnaire (RIQ) and Responsibility Attitude Scale (RAS), are found to be significantly elevated in individuals with OCD compared with non-clinical and anxious control participants (Cougle, Lee, & Salkovskis, 2007; Foa, Amir, Bogert, Molnar; Przeworski, 2001; Salkovskis, 2007). It was found that people with OCD report higher levels of responsibility in low and medium-risk scenarios (measured using the Obsessive Compulsive Responsibility Scale) compared with a non-anxious control group and those with social phobia (Foa et al., 2001). There is also considerable support for the role of RBs in literature relating to compulsive checking (Ladouceur, Léger, Rhéaume, & Dubé, 1996)

1.7.1 Intervention for RBs in OCD

CBT for OCD is government recommended (NICE, 2005), and there is substantial evidence to suggest its effectiveness (Radomsky, Shafran, Coughtrey, & Rachman, 2010). The main principles – similar to those in treatment protocols for other anxiety disorders – relate to: helping the client construct and accept a less fearful account of their own narrative; testing alternative explanations and perspectives (for example those that do not implicate them so strongly in terms of responsibility); helping to normalise the experience of intrusive thoughts; and reduction of safety behaviours (often through behavioural experiments), all of which are hypothesised as important mechanisms in the cognitive model (Salkovskis, 1985). Despite clear overlap between various CBT interventions in anxiety, the distinctive characteristic of CBT for OCD is that it seeks to modify clients' inflated perceptions of responsibility in breaking a self-perpetuating cycle (Clark, 2004).

One of the best-established CBT techniques for treating inflated responsibility beliefs in OCD is the *Responsibility Pie Chart* (Salkovskis, 1999). The Responsibility Pie Chart is helpful in gathering information regarding perceptions of responsibility, and aims to modify appraisals of responsibility for feared events. In exploring a particular event, the client is first asked to allocate responsibility to a series of factors outside of themselves (including other people), with the remainder being accounted for personally. This strategy – in drawing the client's attention to a range of sources, and apportioning responsibility in turn - serves to modify a tendency towards overestimation of one's own control. Behavioural experiments (BE) are also frequently utilised in collecting new information and modifying RBs, with the *Responsibility Contract* (Radomsky et al., 2010) a notable example. The Responsibility Contract allows for temporary transfers and suspensions of responsibility, with the client encouraged to trial the process of absolving themselves of responsibility for defined periods, which are then evaluated and interpreted in session. While the belief in - and felt sense of - inflated responsibility is associated with distress and impairment, both these techniques seek to experiment with alleviating this burden in a containing and reasoned way.

1.8 Responsibility Beliefs in Psychosis

Though inflated responsibility was initially considered a unique feature of OCD, more recent research –including an influential meta-analysis (Pozza & Dèttore, 2014) - has identified the potential role of RBs more widely, providing an emerging rationale for recognising inflated responsibility as a transdiagnostic factor in psychopathology (Tolin, Worhunsky, & Maltby, 2006). As discussed previously, anxiety is commonly linked to the experience of psychosis (in particular voice hearing)

and as such investgiating the role of inflated responsibility in psychosis is warranted. RBs are commonly measured using the Obsessive Beliefs Questionnaire (OBQ-44), which was developed by the Obsessive-Compulsive Cognitions Working Group (OCCWG, 2003). This tool was designed to measure beliefs considered crucial in the development and maintenance of OCD, and has three subscales: (1) Responsibility/ Threat Estimation, (2) Perfectionism/Certainty, and (3) Importance/Control of thoughts.

The first study to employ the OBQ-44 in people with psychosis used the measure to explore metacognitive beliefs (Linney & Peters, 2007). This study investigated two groups of people with psychosis (those with thought inference and those without). The two groups did not differ on any of the OBQ-44 subscales. However, as RBs were not the focus of the Linney and Peters (2007) study, it is unclear whether people with psychosis had elevated levels of RBs in comparison to people with OCD or non-clinical controls.

The second study to use this measure attempted to understand more specifically the role of RBs in psychosis. RBs were investigated in two groups of people with psychosis (acute and stable) and a non-clinical control group (Luzón et al., 2009) . The two groups with psychosis reported significantly higher levels of RBs than non-clinical controls (as measured by the OBQ-44 Responsibility/Threat estimation subscale). There were also significant differences between the two psychosis groups, with the acute group scoring significantly higher on the OBQ-44. The psychosis groups were also shown to score significantly higher than OCD samples. The authors concluded that these findings should be taken to indicate that inflated perceptions of responsibility represent a vulnerability factor in the development of psychosis. However, there were

significant limitations to this study. One limitation is that participants were grouped according to the current status of their condition (e.g. acute or stable psychosis versus non-clinical controls), in contrast to the causal-interventionist strategy of conceptualising symptom specific models (e.g. command hallucinations). A second limitation is that potential confounding variables were not controlled for (such as depression, anxiety and obsessive-compulsive symptoms). Given the established comorbidity of psychosis and anxiety disorders generally, it is possible that the inflated responsibility beliefs reported by Luzón et al (2009) are in part attributable to the presence of other disorders. A third limitation is that responsibility and threat beliefs are conflated in this study, with both being measured using a single subscale of the OBQ-44. It is known that malevolent or omnipotent voices typically impact threat perception (Chadwick & Birchwood, 1995), and therefore we should expect elevated OBQ-44 scores in this group even where this is not attributable to responsibility. A forth limitation is that the study compared data only to previously published OCD findings, while a final issue is the authors' conclusion that inflated perceptions of responsibility represent a vulnerability to the development of psychosis, where this is not substantiated by the results.

RBs have been explored in people with persecutory delusions (Pugh, Luzon & Ellett, in submission). Thirty participants with persecutory delusions were recruited into this study (split across inpatient and outpatient services). Two main methodologies were implemented. First a semi-structured interview was used to explore participants' ideas regarding who they believed was responsible for the harm that they felt was occurring to them. This methodology aimed to explore the content of RBs and their relation to the phenomenology of persecutory delusions. Secondly, the

Responsibility/Threat Estimation Subscale from the OBQ-44 was employed to explore whether RBs are inflated in people with persecutory beliefs. Quantitative data on RBs was compared to that from a non-clinical control group and with published data from patients with OCD and anxiety disorders. Rectifying one of the limitations from the Luzón et al., (2009) study, the responsibility and threat items were analysed separately. The semi-structured interview showed all but one participant attributed some responsibility to their perceived persecutors, only eleven attributed *sole* responsibility to persecutors. One third attributed some responsibility to themselves. People with persecutory delusions were found to score significantly higher than the non-clinical group on both responsibility and threat estimation items of the OBQ-44. People with persecutory delusions also scored higher on the responsibility and threat estimation items when compared with both the anxiety disorders group and the OCD group. This data extends the Luzón et al., (2009) study by taking a symptom-based approach to the research question, and by analysing threat and responsibility scores separately. Overall, the data suggests that RBs are prominent features of the cognitive profile of people with persecutory delusions (Pugh et al., in submission). However, there are several limitations to the study and the small sample size means results should be interpreted with caution. The authors used existing data sets to compare RBs in different clinical groups, meaning that confounding variables may have been influential. In the non-clinical control group, a diagnostic screening tool would ensure a more rigorous screening procedure, and finally, due to the cross-sectional nature of the design no conclusions regarding causality can be drawn.

Following on from this study and the Luzón et al., (2009) study, RBs have also been further explored in people who hear voices (Ellett et al., in press). An emerging

hypothesis is that heightened perceptions of responsibility may be of particular relevance for individuals who experience command hallucinations. Owing to the degree to which compliance with commanding voices may entail harm to self or others, it is suggested that the endorsement of a heightened sense of responsibility for *preventing* harm is likely to be an important determinant of distress (Ellett et al., in press). This paper has made three unique contributions to the research field: i) validated measures were used to understand the impact of command hallucinations on levels of anxiety and depression; ii) the relationship between command hallucinations and beliefs about voice's omnipotence and intent was explored using the established Beliefs About Voices Questionnaire-Revised (BAVQ-R); iii) the differential impact of RBs in command versus non-command groups have never previously been evaluated.

Data was presented from 151 participants with a schizophrenia-spectrum diagnosis, who were experiencing current auditory hallucinations, either with (n=77) or without (n=74) commands. Findings showed that the experience of hearing voices commanding harm to self or others was associated with higher levels of anxiety and depression (Ellett et al., in press). Notably, mean scores on a validated questionnaire measuring RBs (the RIQ) were significantly higher in the commanding voices group, compared not only with the non-commanding voices group, but also with OCD participants (Salkovskis et al., 2000). Elevated sense of responsibility was also strongly associated with distress. An emerging hypothesis is that the more an individual feels personally responsible for *preventing* harm, the more distressing it is to experience voices that *command* harm (Ellett et al., in press). Although this is the largest study to date investigating RBs – and while findings support the hypothesis that RBs are influential trans diagnostically (Ellett et al., in press; Luzón et al., 2009; Tolin et al.,

2006) - there are a number of limitations to consider. For instance, although specific inferences can be drawn regarding the cognitive, affective and symptomatic profile of command hallucinations (Ellett et al., in press), causal inferences cannot be established. It would have been interesting to measure delusions as the presence and/or intensity of their delusions could have impacted on the subjective appraisals of responsibility and distress. A strength of this research is that although individuals with command hallucinations are typically difficult to recruit (Birchwood et al., 2014), the study was adequately powered to detect group differences.

These studies suggest that future psychological interventions for voice hearers might benefit from focussing on RBs, potentially through similar psychological techniques to those used in OCD. It has been suggested that targeted approaches may yield changes in both compliance and distress (Birchwood et al., 2014). In working towards novel treatment strategies for voice hearers, Abbas et al., (2012) (as part of the wider Ellett et al., in press, study) piloted a technique that is commonly used to target RBs in OCD (The Responsibility Pie Chart). In this study, the command hallucination group were interviewed regarding their RBs - and specifically in relation to *compliance* with voices - using an adapted version of the pie chart technique, which was found to be an acceptable and useful tool in this group. Research that has linked particular psychological processes with individual psychotic symptoms has previously led to the development of new interventions to target these processes specifically. This "causal interventionist" strategy in relation to mechanisms such as power, sleep and worry has led to improvements in psychotic symptoms and importantly a reduction in distress (Birchwood et al., 2014; Freeman et al., 2016).

1.9 Causal interventionism as a treatment advance

The work of Freeman and colleagues (Freeman et al., 2016) has been fundamental in developing more targeted therapeutic approaches, and much of this work has been in the context of delusional beliefs. Freeman's approach has been to: i) study single symptoms of psychosis; ii) establish a theoretical model, and iii) develop treatments to address mechanisms implicated by the model (Freeman et al., 2016). In building an intervention, one putative causal factor is taken at a time, manipulated, and the effect on the symptom examined. This approach is called 'causal-interventionism". The research team have focussed particularly on the factors maintaining persecutory delusions. Brief, manualised, modular interventions have been developed – each addressing a causal factor identified in the cognitive model of persecutory delusions - with the ultimate aim of developing a combined treatment (Freeman et al., 2016). Each module (targeting worry, self-beliefs, anomalous experiences, sleep, reasoning, safety-seeking behaviours) - separately evaluated at different phases of development, from feasibility studies, to piloting, and eventually efficacy trials - has been deemed to merit inclusion into the full treatment study (Freeman et al., 2016). For example, in order to explore the implication that the treatment of worry in individuals with persecutory delusions may also lessen paranoia, a small pilot study was conducted. The study found that a reduction in worry was associated with a reduction in paranoia (Foster, Startup, Potts, & Freeman, 2010). Leading on from this pilot study, a RCT was conducted. The 'Worry Intervention Trial' has demonstrated the most significant effects of all the modules that have been evaluated, with both worry ($p<0.001$) and persecutory delusions ($p=0.005$) significantly reduced after six sessions (Freeman, Dunn, et al., 2015)

The important implication here is that by impacting an underlying mechanism (e.g. worry), improvements can be observed in relation to a common, distressing, and traditionally persistent positive symptom of psychosis. A larger RCT (Freeman et al., 2015) - grounded in this pilot and others - showed reductions in overall psychiatric symptoms and significant increases in psychological well-being. Similarly, there is good evidence to suggest that brief reasoning interventions impact both reasoning processes and paranoia in clients with persecutory delusions (Garety et al., 2015). This work led to the 'Thinking Well' brief reasoning intervention (Waller et al., 2015), which was found to bring about a reduction in delusion conviction compared with standard care. Finally, a trial to enhance positive self-beliefs in order to limit the effects of negative self-beliefs also showed significant reductions in delusions and improvements in psychological well-being (Freeman et al., 2014). A combination of these approaches and others, 'The Feeling Safe Study', is comprised of all of the modules described above. A feasibility study using case series methodology was successful, and suggested significant clinical benefits (Freeman, et al., 2016). An RCT to establish efficacy is currently underway.

While the work of Freeman et al (2016) has mainly targeted cognitive and emotional factors implicated in the development and maintenance of persecutory delusions, research elsewhere has sought to do the same in relation to voices. In accordance with the theoretical frameworks described earlier (Chadwick & Birchwood, 1994; Morrison, 2001) specific interventions for voices have targeted interpersonal and social variables (Paulik, 2012). The COMMAND study was developed based on these theoretical developments and designed to impact beliefs about the power of voices. The approach seeks to reduce an individual's need to appease or comply with the voice, and

in doing so, reduce compliance behaviour, distress and risk behaviour (Birchwood et al., 2014). The approach was first tested in a proof-of-principle study, where compliance, perceived power of the voice, delusion distress and depression were all reduced (Trower et al., 2004). Following the pilot study, a major RCT was conducted, finding there was also a reduction in rate of compliance compared with treatment as usual, which made this the first major RCT to show a clinically meaningful reduction in risk behaviour (Birchwood et al., 2014). The COMMAND study has potentially been the most informative so far in furthering psychological interventions to target voices, as it illustrates the benefits of developing specific models and combines a specific therapeutic process with measurement of a targeted outcome.

Alongside COMMAND, it is notable that therapy approaches developed for voices have been mainly been derived from extensions of therapies developed for mood difficulties (Thomas et al., 2014). Contemporary interventions – including CBTp - have been used to promote greater resilience in the context of critical voices. CoMeT (which standards for competitive memory training) involves strengthening positive memories (incompatible with critical voice content) through rehearsal that incorporates imagery (Steel et al., 2015). An RCT found reductions in levels of depression, which were mediated by changes in voice acceptance and perceived voice power (Steel et al., 2015). There has also been a recent wave of new therapy approach for voices. Evidence is building for the benefit of mindfulness-based interventions (MBIs) in psychosis (Chadwick, 2014), while Person Based Cognitive Therapy (PBCT) targets three sources of distress: 'symptomatic meaning' of beliefs about voices/persecutory delusions; self-defeating responses to psychotic symptoms; and core beliefs that define the self as negative (Chadwick, 2006). Pilot studies have shown that group MBIs have had

beneficial clinical effects (Chadwick, Hughes, Russell, Russell, & Dagnan, 2009) and the first group-PBCT RCT in voice hearers (participants either receiving group PBCT or treatment as usual) showed significant differences in voice-related distress, perceived controllability of voices, and recovery (Chadwick et al., 2016).

Despite the clear benefits associated with developing a range of empirically supported approaches, this variety of methods does have implications for how therapies are conceptualised and presented. While some interventions are presented as distinct therapeutic modalities (e.g. MBI/ COMMAND), they also prioritise methods and principles that are endorsed by CBTp, and fit under its broad umbrella. In any case, it is clear that the continued identification of key mechanisms, and the development of interventions based on them – in the mould of COMMAND and the various modular approaches described for delusions – represents a promising way forward.

Although no randomized control trials (RCTs) have investigated the efficacy of CBT for OCD techniques in people with psychosis co-morbid with OCD, case reports and case series have identified important intervention principles (Schirmbeck & Zink, 2013). The first systematic review on the subject found that CBT does appear i) safe (that is, it does not worsen psychotic symptoms), ii) acceptable (with discontinuation rates similar to those reported for OCD treatment without psychosis), and iii) effective (with equitable symptom reduction to that found in interventions for OCD alone) (Tundo & Necci, 2016). Although these early stage outcomes should be interpreted with caution, promising preliminary findings are encouraging with respect to the potential for safety, tolerability and efficacy to be better established in CBT for OCD intervention strategies in psychosis.

1.10 Feasibility Studies

Ellett et al. (in press) furthered our understanding of the psychological impact of both command and non-command hallucinations. In highlighting RBs as influential the study supports efforts to develop novel, modular psychological interventions for voices (Birchwood et al., 2014; Ellett et al., in press). As research into RBs in psychosis remains in its infancy, feasibility studies are required to determine whether an emerging intervention should be recommended for further testing through a pilot study.

In accordance with the Medical Research Council (MRC) framework for the development and evaluation of RCTs for complex interventions (MRC 2008), feasibility studies are an essential step in the development and testing. Evaluations are often undermined by problems of compliance, delivery, acceptability, recruitment and retention, and smaller than expected effect sizes that might have been predicted by feasibility and pilot studies (Eldridge, Ashby, Feder, Rudnicka, & Ukoumunne, 2004). It is important to recognise the difference between feasibility and pilot studies, as the terms are often used interchangeably. The British National Institute for Health Research's (NIHR) Evaluation, Trials and Studies Coordination Centre (NIHR, 2012) makes a clear distinction. A feasibility study focuses on conducting research to examine whether the study can be done (e.g. asking the key question - can it work?), whereas pilot studies are smaller versions of the main study used to test whether the components of the main study can all work together (NIHR, 2012) (see Figure 2). Feasibility studies therefore, are formative, adaptive and iterative, as is appropriate in novel interventions, and focus on the process of developing and implementing an intervention resulting in preliminary examination of the responses to the intervention by participants (Bowen et al., 2009).

Feasibility studies are suitable when there are few, or no other, previously published studies or existing data sets using the specific intervention techniques investigated (Bowen et al., 2009). They enable researchers to assess whether or not ideas and findings can be shaped to be relevant and sustainable, and may illustrate what elements of methodology or protocol require modification. Ultimately, they help determine whether an intervention should be recommended for efficacy testing (Bowen et al., 2009).

Although large-scale efficacy trials are the gold-standard in establishing interventions, their taking place in controlled conditions, with expert therapists, can represent a limitation to dissemination and generalisability (Green & Glasgow, 2006). Considering current economic constraints, clinicians are calling for more studies to test the suitability of interventions for real-world settings (Bowen et al., 2009; Green & Glasgow 2006). As such, feasibility studies should reflect the realities of practice settings, making it essential that clinicians are meaningfully involved in the design and execution of feasibility research. (Bowen et al., 2009).

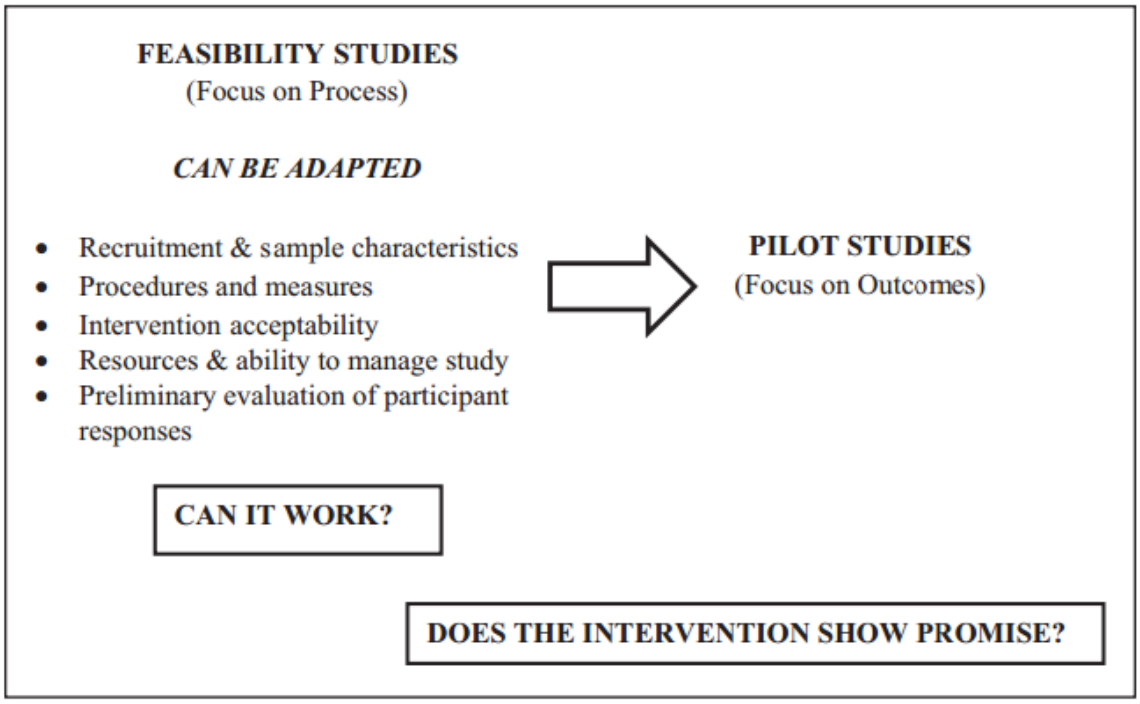


Figure 2: Distinctive Features of a Feasibility Study (Orsmond & Cohn, 2015).

1.11 Current Study

Evidence is in its very preliminary stages and the study is very speculative, due to the literature being sparse. It may be premature to carry out this study, yet initial indications from the literature are promising. Given that i) elevated perception of personal responsibility is clearly implicated in the experience of, distress associated with, and responses to hearing commanding voices (Ellett et al., in press), ii) that techniques for targeting RBs are established as effective in CBT for OCD (Radomsky et al., 2010; Salkovskis et al., 1999), and iii) that interventions for commanding voices in psychosis aim, in part, to reduce compliance (Birchwood et al., 2014), it is reasonable to suggest that future psychological approaches for people experiencing voices may benefit from a specific module targeting RBs. Guidance regarding the development and evaluation of psychological treatments indicates the appropriateness of conducting a

feasibility study (Medical Research Council, 2008). A treatment module was developed to test the feasibility of targeting RBs in voice hearers, and study conducted and evaluated using the recommendations published by Orsmond and Cohn (2015). Orsmond & Cohn (2015) have conceptualized their interpretation of the distinctive features of a feasibility study. Their recommendations suggest that the main objectives of feasibility studies should centre around: (a) evaluation of recruitment capability and resulting sample characteristics (b) evaluation and refinement of data collection procedures and outcome measures, (c) evaluation of the acceptability and suitability of the intervention and study procedures, (d) evaluation of the resources and ability to manage and implement the study and intervention, and (e) preliminary evaluation of participant responses to intervention.

The study had 5 research questions:

1) Is recruitment and retention of participants for this intervention feasible?
2) Are the outcomes measures employed effective in capturing the impact of this intervention?
3) Are the study procedures and the intervention acceptable and suitable for participants?
4) Is the implementation of this study and intervention feasible with respect to management and resources?
5) Is the intervention useful and effective as shown by preliminary evaluation of participant responses?

To answer the research questions, a mixed-methods approach was used, due to the potential for this design to yield more meaningful feasibility results (Bowen et al., 2009).

The following feasibility study was conducted over three phases.

Phase 1 comprised the development of a two-session intervention and accompanying therapist manual. Although the work is manualised, the therapy remains pragmatic and can be adapted to the individual and their changing needs.

Phase 2 explored the preliminary evaluation of participant responses to the intervention, based on three service users who undertook additional sessions as a component of their on-going therapy. A Single Case Experimental Design (SCED) was used, and this phase also evaluated recruitment capability and retention.

Phase 3 explored recruitment capability and retention, suitability of outcome measures, acceptability and suitability of the intervention, evaluation of resources and ability to manage and implement the study. Thematic Analysis examined perspectives via a focus group attended by professionals involved in the intervention.

Following the feasibility study – and based on its findings - the researchers identified strategies to address the noted challenges, and to revise components of the intervention where necessary.

CHAPTER 2: PHASE 1

2.0 Overview

The aim of the intervention was to employ CBT techniques established as effective for tackling RBs in OCD – with appropriate modifications - to treat heightened perceptions of responsibility in clients who hear voices.

The manual (see Appendix A) was informed by:

i) Empirically validated CBT treatment protocols for both OCD and Psychosis (Hagen, Turkington & Berge, 2010; Wilhelm & Steketee, 2006; Wright et al., 2014)

ii) Extensive consultation (with Clinical Psychologists working in a National and Specialist OCD Service and a Consultant Psychiatrist in EIS)

iii) The research team's own clinical experience working in psychosis services

The manual was designed to meet the idiosyncratic needs of individual clients, and therefore permitted flexibility based on clinical judgment. The central aims were to examine the feasibility and acceptability of this approach, and to determine whether outcomes suggest that this brief RBs module – as an adjunct to CBTp – may be useful in targeting distress.

This chapter will first discuss the timing of the intervention during CBTp, the overall structure of the manual, and the adapted cognitive and behavioural strategies from the OCD literature. Amendments to existing approaches for working with RBs were made either following consultation with experts, consultation with a service-user, or as requirements for attaining ethical approval.

2.1 Timing of the intervention during CBTp

It was decided that the RBs intervention would be offered at approximately the midpoint of a client's CBTp, and/or after a minimum of six sessions. This was intended to ensure that clinician and client are afforded adequate time to establish an effective working relationship beforehand, meaning that suitability was more easily assessed and any potential risk issues known, and also allowed for some preparatory work relating to the client's voice(s) to have been completed. In the first six sessions of CBTp (focused on distressing voice hearing), the work would typically have comprised: psychoeducation and normalisation around unusual experiences; assessment of voices; initial formulation of the impact of the voices, particularly in relation to perceived power and control, responses and emotional and behavioural reactions; and exploration of coping strategies. Of course, as a feasibility study, one of aspects of acceptability this research intends to evaluate is the appropriateness of the timing for this additional module.

2.2 Manual Structure

The manual was separated into four parts. Please refer to Appendix A. The first gave an overview of the study and the therapists' role in the intervention. The second part outlined the agenda for the two sessions, which the therapists would share with participants. The third part gave written examples of all the strategies that could be used in the study, with some strategies involving a script for the therapist to use in the sessions. The fourth part consisted of blank worksheets corresponding to the strategies.

The techniques used were both cognitive and behavioural. Cognitive interventions and behavioural experiments represent core, indispensable elements of treatment for both OCD (Moorey, 2010; Veale, 2007) and psychosis (Hagen et al.,

2010; Wright et al., 2014). Strategies in this intervention are all commonly used within CBT for many disorders (psychoeducation, formulation, behavioural experiments and the continuum technique), though two techniques (the Responsibility Pie Chart and Responsibility Contract) were originally used for treatment in OCD and have since been adapted for other client groups. The particular adaptations made for this group are detailed below:

2.2.1 Cognitive Strategies

Psychoeducation and Formulation

In any psychological intervention, it is crucial that clients have a meaningful understanding of their difficulties and what may be maintaining them. Formulation can also serve as a map that informs the client and therapist about the client's past, present and future. The vicious flower formulation is commonly used in anxiety disorders (Moorey, 2010) and frequently in OCD (Challacombe, Oldfield, & Salkovskis, 2011) It is a simple way of conceptualizing a problem, which encourages a focus on the maintenance cycles prolonging and exacerbating difficulty. Accordingly, a vicious flower formulation was used to conceptualise clients' inflated sense of responsibility and the impact that these beliefs have on well-being, functioning and their voices. As the concept of inflated responsibility can be difficult to understand, a psychoeducation and information sheet was developed in helping people to understand the nature of RBs. Together, the psychoeducation material and vicious flower formulation represent a foundation for the specific techniques utilised; with the intervention subsequently framed as method of plucking the flower's petals to undermine the power and influence of unhelpful beliefs themselves.

Responsibility Pie Chart

The Responsibility Pie Chart is a common technique in OCD (Salkovskis, 1999; van Oppen & Arntz, 1994) used to shift the perceived degree of personal responsibility for a catastrophic event by facilitating a more helpful dialogue that incorporates alternative explanations. In OCD, the therapist elicits all possible contributory factors, with the client then allocating a proportion of the "pie" to each. The client's own personal causal contribution is inserted last, after careful consideration of other sources of responsibility (Wilhelm & Steketee, 2006). The technique can help challenge negative automatic thoughts associated with over-responsibility and self-blame, and allows the client to develop a more realistic and adaptive view of responsibility (Veale, 2009). A similar approach is commonly used in psychosis - primarily in generating alternative explanations in the context of distressing persecutory delusions (Wright et al., 2014) – and can also be helpful where schematic beliefs relate to unhelpful conclusions drawn from past events (Meaden, et al., 2013). For example, this technique was used in the COMMAND Trial, where clients' inflated sense of responsibility was found to be influential in self-blame when bad things happened, an appraisal that is subsequently reinforced by critical voices (Meaden et al., 2013). The Responsibility Pie Chart was used to challenge the clients' sense of responsibility, and was reported to help people to achieve a degree of freedom from the voices' criticisms and reduce perceived voice power and self-blame. Therefore, the Responsibility Pie Chart has been demonstrated to be clinically helpful and acceptable with this client group.

Although the Responsibility Pie Chart is commonly used in the context of both persecutory delusions and voices (via indirect links to clients' inflated responsibility), it has been adapted for the purposes of this research to focus specifically on a particular

RB and its relations with a person's commands. By completing a Responsibility Pie Chart, a client's assumptions and beliefs around their responsibility and voices will be challenged and it will help them to develop alternative assumptions that do not generate distressing emotions.

Continuum Technique

This technique is commonly used to address black and white thinking (Wilhelm & Steketee, 2006) in clients with OCD. This technique was included given that thinking in black and white (extreme) terms can lead to equally extreme emotional and behavioural responses (Wilhelm & Steketee, 2006). Beliefs such as "either I am responsible for causing harm or I am not" can therefore be influential and problematic. However, by conceptualising these two possibilities as ends of a continuum – and recognising the considerable middle ground - clients can be helped to appreciate the difficulties associated with both positions, encouraging the absolute rule to be reconfigured. This technique was adapted to reduce black and white thinking and introduce flexibility of thought regarding responsibility. Ultimately it aims to support the client in considering what constitutes responsibility, and has needed little adaptation from its use in OCD.

2.2.2 Behavioural Strategies

Behavioural tasks are an equally important component of CBT. The rationale for encouraging a person to engage in behavioural experiments is to help them experience an alternative outcome to that suggested by the established or existing appraisal. As such, this process facilitates recognition of the distinction between thoughts and facts, in that the experience undermines a previous prediction (Lopatka & Rachman, 1995; Morrison, Renton, Dunn, Williams & Bentall, 2003). Behavioural

experiments often consist of reality testing procedures, and a common version of this in CBT for OCD is the Responsibility Contract.

Responsibility Contract

Within OCD, the therapist and client together draw up two contracts, which facilitate temporary transfers of responsibility to the therapist. That is, the therapist accepts responsibility for the feared outcome during an allocated time-period. Previous research demonstrates that in the absence of such contracts, where instead only verbal transfers of responsibility are agreed, clients find the transfer of responsibility more difficult (Lopatka & Rachman, 1995). Therefore, it has been deemed necessary to prepare written contracts covering the short periods of experimentation (Radomsky et al., 2010), as a method of challenging the underlying belief. This technique, to the researcher's knowledge, has never been used with clients with psychosis. However, due to its frequency of use in CBT for OCD, it was felt necessary to add a contract to the manual. The researcher was interested in better understanding how clients with command hallucinations find the concept of transferring responsibility, and in exploring whether this technique can be meaningfully adapted. It is important that some psychoeducation around what the term "responsibility belief" means had already been completed with clients, so that the term RBs are not confused with responsibility for actions.

Alternative Behavioural Experiments

In CBTp, clients commonly underestimate their own agency and control in making behavioural decisions in the context of voices perceived as omnipotent and powerful (Chadwick & Birchwood, 1994), for fear that non-compliance will have

harmful consequences (Meaden et al., 2013) A common element of CBTp therefore involves the devising of behavioural experiments to examine these predicted consequences, in order to investigate the underlying belief. Fears in OCD often focus in the present and thus can be easily tested using a behavioural experiment. However, after consultation with Clinical Psychologists working in psychosis, feared consequences are often conceptualised far into the future (e.g. "I will die of cancer if I don't do what the voices tell me to do"). This makes observed outcomes difficult to measure. It was discussed that experimentation around perceptions of personal responsibility itself may be an effective adaptation. That is, addressing the degree to which clients believe they can influence positive or negative occurrences in the world, and in doing so impacting the distress associated with an elevated sense of personal responsibility. Therefore, it was hypothesised that a reduction in elevated responsibility in this client group could also be achieved through development of a behavioural experiment targeting the general and wide-reaching belief "I can cause things to happen", be the event positive or negative.

Two behavioural experiments relating to the experience of hearing voices were devised. First, the therapist agrees with the client that the voices' comments and commands would be ignored for a defined period of time. Pre and post outcomes are measured in relation to: degree of conviction in the voices' power and control, rate of compliance, and distress. The second involves the therapist agreeing either positive (e.g. "winning the lottery") or negative (e.g. "house getting burgled") outcomes with the client and experimenting to determine the client's influence over these outcomes. Ratings of perceived responsibility would be taken. This experiment could potentially be set as a homework task and take place out of session.

2.3 Feedback from the Research Ethics Committee (REC) and therapist consultation

The original application was rejected for ethical approval. Following feedback from the REC, the researcher consulted a Consultant Clinical Psychologist who is the Lead Clinician for a highly specialised OCD/BDD service; two Consultant Psychiatrists; a service user with personal experience of psychosis, and the participating therapists. The original manual was developed based on literature, and subsequently the manual was modified to account for feedback from the REC, who recommended adaptations to the behavioural techniques. The final version of the manual specifies that any transfer of responsibility will apply only to a particular feared catastrophe, over which it is obvious that neither client nor clinician could possibly exert any control: for instance, natural disasters or the end of the world.

2.4 Service User (SU) Consultation

A SU was consulted in relation to the protocol, the manual (particularly regarding the cognitive and behavioural techniques), and the REC opinion. The SU was chosen due to their experience of receiving CBTp and their having established diagnoses of both psychosis and OCD. Their CBTp therapist – who was one of the participating clinical psychologists- believed that heightened levels of perceived responsibility drove the SU's compliance with command hallucinations. Both the therapist and SU recognised perceived responsibility as causing substantial distress. The SU reviewed the manual alongside the researcher. The SU described having previously used a Responsibility Pie Chart as part of their CBTp work on modifying persecutory delusions, and reported having found the exercise very helpful, specifically in providing a visual representation of their minimal or non-existent individual

responsibility in certain contexts. Although the SU had not used the continuum technique, they felt that it would likely be beneficial with respect to their own elevated responsibility, and important given the commonality of "black and white thinking". Overall, the SU believed the strategies to be similar to ones they had previously used in CBTp, and that the focus on responsibility beliefs would be a highly beneficial method of tackling associated distress.

2.5 Training the therapists

Following subsequent receipt of ethical approval and recruitment of NHS teams to participate, training on the administration of the treatment protocol (according to the manual) was provided prior to the start of the intervention. Four clinicians took part in the training: two from Early Intervention for Psychosis Services and two from Specialist Psychosis Services. All were Senior Clinical Psychologists and had been qualified for over three years. Senior Clinical Psychologists trained in the delivery of this two-session module will be referred to as "therapists" for the remainder of this thesis. Training was delivered by the researcher (RM), alongside a Senior Clinical Psychologist working in the specialist OCD service and who had previously consulted on the manual. Training consisted of discussion of the protocol; role-playing the therapeutic techniques described above; and watching videos illustrating administration of the Responsibility Contract (Radomsky et al., 2010). The difficulties of two clients currently working with the therapists involved were discussed in relation to the protocol. Both clients heard voices (one person experiencing command hallucinations and another non-command), and reported a heightened sense of responsibility. To aid training, scripted examples were provided when introducing the concepts to clients. As such, the training included a worked example of each cognitive and behavioural

technique planned, intended for therapists to refer to during the intervention. It was intended that group supervision would occur with the OCD expert at least once, during the study.

CHAPTER 3: METHODOLOGY AND RESULTS FOR SCED (PHASE 2)

3.0 Overview and Ethics

This chapter is in two parts. The methodology is detailed first, followed by a description of retention and recruitment rates, and then preliminary analysis of outcome data. A London NHS Research Ethics Committee initially did not give ethical approval. Following subsequent resubmission, ethical approval was obtained from: a London NHS Research Committee (London-Camberwell St Giles); the Health Research Authority; two Research and Development Offices of London Foundation Trusts; a Psychosis Clinical Academic Group; and the Psychology Department Ethics Committee at Royal Holloway, University of London (Appendix B).

3.1 Methodology

3.1.1 Participants

Five participants consented to take part in this research. Three completed the study, with two participants dropping out (see Table 1 for individual participant information). Figure 4 in the results section details the reasons for drop out. Participants had never had any previous therapy targeting RBs (as reported by their responsible clinician and therapist)

Inclusion criteria for the study included:

1. Adults aged between 18 and 65 years old.
2. Ability to read and write English, and capacity to give informed consent.
3. Experience of active positive symptoms of psychosis (current voice hearing).
4. A heightened degree of perceived responsibility.

Exclusion criteria for the study included:

1. Risk of harm to self or others.
2. Established intellectual disability.
3. Presence of organic brain disease or brain injury.
4. A primary diagnosis of Post-Traumatic Stress Disorder (PTSD) or Personality Disorder (PD)

Table 1: Participant Information

Participant	Gender	Age	Ethnicity	Diagnosis	Length of Illness	On antipsychotic medication/any changes during therapy	Hospitalisation	How many sessions of CBTp before intervention	How many sessions of CBTp between Follow Up 1 and Follow up 2 / Focus of sessions	Any significant life events during intervention
1	F	25	White British	Psychosis	>5 years	Yes/ No changes	1 (5 years ago)	9	3 CBTp Focussed on BA- what she can do independently and how not to feel commands	No
2	M	18	Asian	First Episode Psychosis	1 year	Yes/ No changes	No	6	3 CBTp Focussed on BA 1 Family Intervention	No
3	F	46	Afro Caribbean	First Episode Psychosis	1.5 years	Yes/ No changes	No	6	1 CBTp Focussed on building coping strategies for voices and revisiting Responsibility Pie Chart at clients request	Yes – immigration status and sister diagnosed with breast cancer

The decision not to include a psychosis diagnosis as part of the inclusion criteria was taken for several reasons: i) to allow for a wider range of participants to be involved, as those in Early Intervention Services do not routinely receive a diagnosis on acceptance to the team; and ii) to mirror, as closely as possible, those seeking treatment for voice hearing across services in general. As a feasibility study, it was important to assess how feasible and acceptable the intervention was deemed across a variety of services, with differing levels of provision.

3.1.2 Recruitment

Sample size considerations were based on previous literature. The median number of cases used in SCEDs is three (Smith, 2012), although research demonstrates that three cases will only yield statistical power of 0.8 and adequate power is achieved with seven cases. As this was essentially a feasibility study, sample size criteria was not as strict as it would be for an outcome study. Although the researcher aimed to recruit seven people (in order to generalize the findings as far as possible), only three completed. Participants were recruited through four services - two Early Intervention Services (EIS) for Psychosis, and two Specialist Psychosis Services - across two NHS trusts. Four Senior Clinical Psychologists trained in the manual supported this recruitment, three from EIS and one from a Specialist Psychosis Service.

3.1.3 Design

An ABA design with a three-week baseline, two-week intervention, and two-week follow-up was utilised to evaluate changes in RBs. Replication across three participants - in different settings, with varying RBs and experiences of voice hearing – allowed for greater generalisability of any indications regarding feasibility. There are two difficulties associated with using a SCED within naturalistic treatment settings: i)

isolating the desired treatment component and ii) acquiring a stable baseline for people who are already in therapy. A period of at least six weeks since the start of a person's therapy was specified before the RBs intervention was facilitated, meaning both that the therapeutic relationship and stable baseline could be established. This method of collecting baseline data avoids the ethical and practical difficulties associated with interrupting routine treatment for a longer period of time. It allows the measurement of changes attributable to the RBs intervention, even in the context of potential improvement prior to this point through CBTp. The Visual Analogue Scales (VASs) related specifically to participants' responsibility beliefs around their voice hearing to isolate a target for the SCED.

3.1.4 Measures

Please see Appendix C.

Psychotic Symptom Rating Scales (PSYRATS) (Haddock, McCarron, Tarrier, & Faragher, 1999)

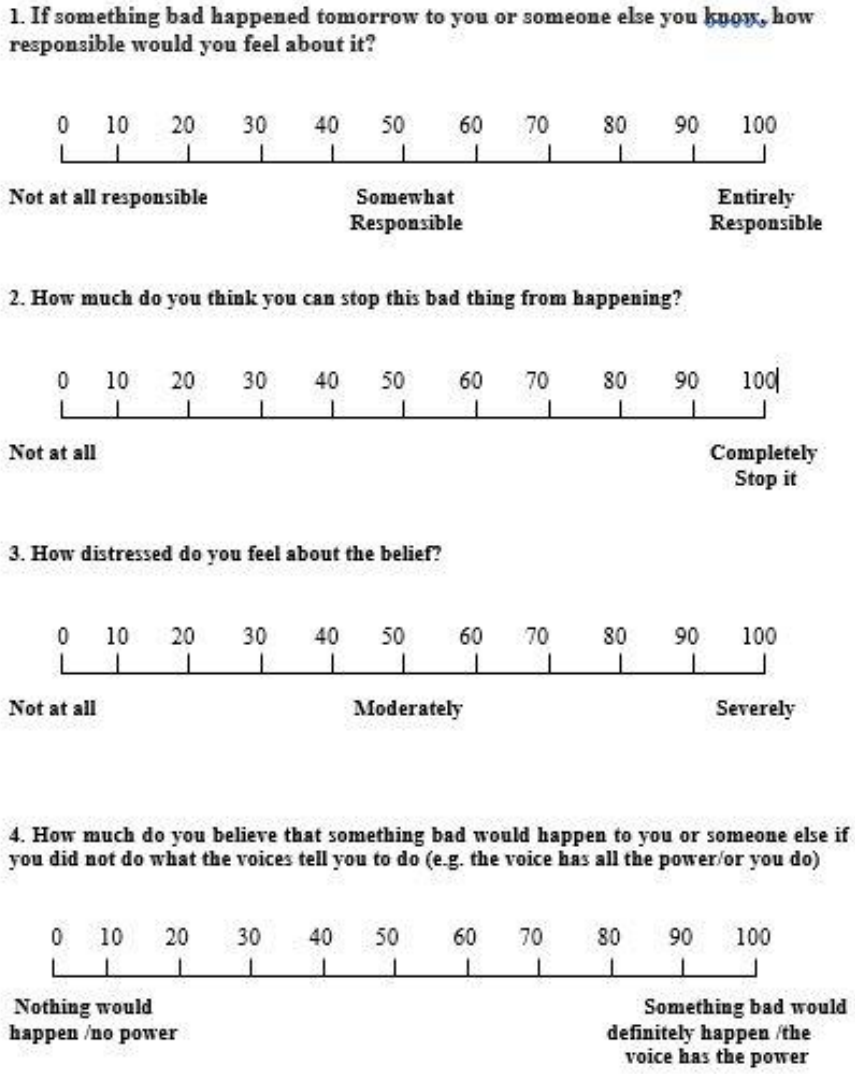
The PSYRATS are semi-structured interviews designed to assess the subjective characteristics of hallucinations and delusions. The auditory hallucinations subscale (PSYRATS-AH) is an 11-item semi-structured interview assessing subjective characteristics of auditory hallucinations experienced over the preceding week. The scale includes items for: voice duration, controllability, frequently, location, and loudness; as well as intensity of associated distress, severity, beliefs about voice origin, amount and degree of negative content, and disruption caused. All 11 items are rated on a five-point severity scale (0-4), by clinicians. The PSYRATS delusions subscale has six items: duration, frequency of preoccupation, intensity of distress, amount of distressing content, conviction and disruption. PSYRATs has good reliability and

validity, both in people experiencing a first episode of psychosis (Drake, Haddock, Tarrier, Bentall, & Lewis, 2007) and people suffering from chronic schizophrenia (Haddock et al., 1999). The largest study to date examining RBs and voice hearing (Ellett et al., in press) found Cronbach's alpha to be acceptable for the scale as a whole (Cronbach's alpha = 0.76).

Visual Analogue Scales (VASs)

VASs were administered throughout the course of Phase 2. VASs are generally considered one of the simplest and most effective ways of measuring subjective experience (McCormack, Horne, & Sheather, 1988) and have been shown to be reliable and valid (Ahearn, 1997). The measure is straightforward, sensitive to small changes in individual experience, and can be used to follow therapy processes over time (Morley,2015; Tennant et al., 2007). The VASs were utilised in assessing four factors relating to participants' views around RBs generally, as well as regarding beliefs about their own responsibility with respect to their voice hearing. Participants provided ratings by placing a cross on a horizontal scale and giving a percentage.

The questions are as follows:



Warwick–Edinburgh Mental Wellbeing Scale (WEMWBS, Tennant et al., 2007)

The WEMWBS is a measure of general psychological well-being. Fourteen positively phrased items are rated from 1 (none of the time) to 5 (all of the time). The authors report good internal consistency, test–retest reliability, content and criterion validity for mixed groups including those with psychosis (Clarke et al., 2011; Tennant et al., 2007). Cronbach's alpha for the scale lies between 0.87 and 0.91, and one-week test-retest reliability at r=0.83 (Clarke et al. 2011; Tennant et al. 2007). The WEMWBS

has been shown to be acceptable and feasible when used on a weekly basis with first episode psychosis client groups and those with more chronic psychosis (Jolley et al., 2015). The scale is common element of routine evaluation in the teams recruited from, and was administered at each assessment point.

Responsibility Interpretations Questionnaire (RIQ) (Salkovskis et al., 2000)

The RIQ assesses beliefs relating to specific interpretations of intrusive thoughts about harm. Participants were asked to rate the extent to which they endorsed 16 responsibility-related statements, as experienced over the past two weeks in relation to the content of their auditory hallucination(s) and inflated RBs. Items are rated on a scale of 0 (I did not believe this idea at all) to 100 (I was completely convinced this idea was true). Internal consistency of the RIQ has been shown to range from good to excellent (Cronbach's alpha 0.86-0.93) (Salkovskis et al., 2000), as was observed in a study using the measure with this client group (0.93) (Ellett et al., in press).

Hospital Anxiety and Depression Scale (HADs) (Zigmond & Snaith, 1983)

The HADS is a 14-item self-report measure of depression and anxiety symptoms (both seven items). Participants rate each symptom on a scale from 0-3, based on experiences over the past week. The HADs has good internal consistency (alpha coefficients of 0.83 and 0.84 for the depression and anxiety subscales respectively) (Dagnan, Chadwick, & Trower, 2000) and has been frequently used in this client group (Ellett et al., in press)

Obsessive Compulsive Inventory (OCI) (Foa, Kozak, Salkovskis, Coles, & Amir, 1998)

The OCI was used as a measure of OCD to see if any of the participants rated highly (although the measure is not diagnostic), which the therapists completed. The OCI consists of 42 items making up seven subscales: washing, checking, doubting, ordering, obsessing (i.e. having obsessional thoughts), hoarding, and mental neutralising. Each item is rated on a five-point scale of symptom distress. A total score of 42 or more suggests the presence of OCD (total score can reach 168). The OCI has high internal consistency (range .86 to .95) (Foa et al., 1998).

It is thought that there are common risk factors for developing psychosis and OCD, therefore if someone has psychosis than they might have some of the risk factors for OCD as well (and vice versa) and they are more likely to have traits of each other. As with complex presentations it might be difficult to clearly diagnose either psychosis or OCD, therefore it is understandable that OCI scores are elevated in this population.

Semi Structured Feasibility Interview

This brief semi-structured interview was devised to assess the feasibility and acceptability of the intervention, as evaluated by those who participated. Open-ended questions are intended to facilitate discussion, with prompts used where appropriate to encourage detail and richness. The questions can be seen below:

i) Did you find the intervention helpful? What was / was not helpful?

ii) What techniques were useful/ not useful?

iii) Do you feel less responsible following the intervention? Yes/No – why?

iv) Did you comply less to your voices?

v) What would you change about the intervention?

vi) Would you recommend it to someone else in your position? If yes/no – why?

Demographics and Clinical Characteristics Questionnaire

The following information was recorded for all participants: age, gender, ethnicity, marital status, highest level of education, employment status, previous or current diagnosis of OCD, previous or current diagnosis of any other mental health difficulty, length of illness (both OCD and any other diagnosis), duration of voice hearing, length of current episode, medication, any previous admissions, any previous psychological therapy, number of CBTp sessions before RBs intervention, and the content of those sessions.

Screening Questions

Clinicians were provided with four screening questions:

i) Do you sometimes fear something bad will happen to you/someone else/the world? If so, who would be responsible for that bad thing happening?

ii) Do you sometimes feel the urge to do things to keep you/others safe?

iii) If you were not able or decide not to comply with your voices, and something bad would happen as a result who would be to blame? How responsible would you feel? 0-10.

iv) Are you ever troubled by distressing feelings of guilt? If yes, do you feel guilty when you don't do what the voices tell you to do?

3.1.5 Procedure

Initial screening consisted of four questions and consideration of the inclusion/exclusion criteria, for clients either on a waitlist for CBTp or on the current caseload of a participating therapist. Due to the research timescale, and to mitigate

against risk, the majority of clients invited to take part had already recently begun therapy. Clients were required to be considered suitable for the study by both their therapist and responsible clinician. If deemed suitable, potential participants were introduced to the study by their therapist, and if interested in further information were given a Participant Information Sheet (PIS) and a consent form (please see the Appendix B). At this point, people were given at least 24 hours to make a decision, and were also offered the opportunity to speak with either their therapist, or the researcher (RM). Once consent was established, the participants continued with CBTp. Figure 3 shows details for the process of data collection, which began three weeks prior to the first RBs intervention session (baseline assessments). Due to time constraints, an Assistant Psychologist – trained by RM in administering the measures, and supervised by a therapist (who was also their clinical supervisor) - collected one participant's data.

At each assessment, participants were reminded that they were not obliged to answer any questions they did not wish to, and of their right to withdraw from the study at any time. Participants were assured that withdrawal from the study would not affect their clinical care in any way. All participants were given an identifying number, which was used on all study materials to ensure confidentiality and anonymity throughout.

Following the completion of three baseline assessments, and on visual inspection by RM that baselines were stable, therapists facilitated the two session RBs intervention according to the manual. Each session lasted for 60 minutes. As adaptation is an important feature of feasibility studies, establishing fidelity to demonstrate that the intervention procedures or protocols were implemented as intended most likely occurs in the pilot stage. However, as a feasibility study it was important to explore what techniques were helpful or unhelpful. Therefore, to ensure as naturalistic and

idiosyncratic a process as possible - while also maintaining standardisation and fidelity to the manual - therapists were required to complete the psychoeducation worksheet/formulation and *at least* one Responsibility Pie Chart and one form of behavioural experiment over the two sessions. Assessment measures during the two intervention sessions were administered by the therapists. On completion of the RBs intervention, the researcher (and Assistant Psychologist) conducted an ending assessment the following week, after which CBTp was recommenced. The researcher then administered a follow up assessment with each participant to conclude their participation in the study, which occurred within four weeks since the end assessment. Participants were paid £15 for their involvement, a figure deemed acceptable and appropriate by the Royal Holloway Ethics Committee. It was made clear in the PIS (and when meeting with potential participants), that payment was not considered a benefit of taking part, and nor was it intended to offset any potential risks they may encounter. Participants were debriefed following study completion in June 2017.

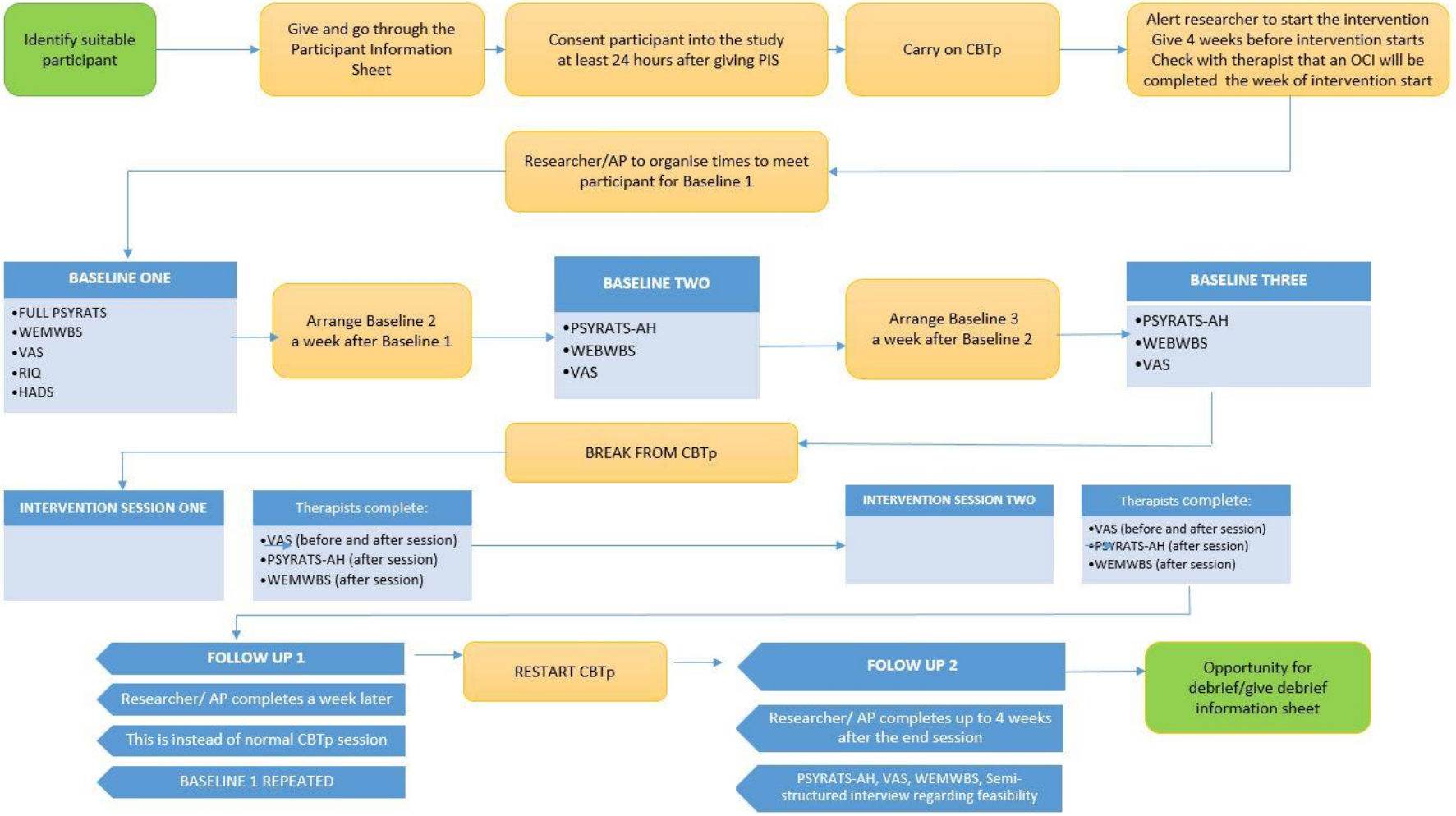


Figure 3: Procedure Flowchart

3.2 Results Overview

The results for this chapter consist of two sections: i) evaluating the recruitment capability and retention within London NHS trusts, and ii) SCED analysis and Reliable Change (RC) and Clinically Significant Change (CSC) calculations. Specifically the SCED analysis section will begin with the analysis plan and methods for SCED and Reliable Change/Clinically Significant Change. A case description will follow, reporting each participant's current psychiatric symptoms and RB. The results will report on the techniques completed in CBTp sessions, particularly those taking place during the baseline assessments and the follow up phase. Visual analysis of the VAS subscales, PSYRATS-AH and WEMWBS will be presented individually for each client. RC and CSC analysis will be presented in relation to the HADS, PSYRATS, RIQ and WEMWBS, for all three participants.

3.2.1 Evaluating recruitment capability and retention

The researcher contacted 20 teams to inform them about the project, either by email or through telephone contact with the lead psychologist (as shown in Figure 4). The researcher offered to attend a team meeting to present the study and speak about suitable participants. Of the teams that did respond, two EISs stated that although they had suitable participants, they were currently inundated with research requests so could not be involved. In other EISs, many clinical psychologists were undertaking the CBTp Postgraduate Diploma, and suitable clients could not be seen for both research and clinical training purposes. Three CMHTs were currently under-going restructuring and therefore were not accepting research requests. All other teams either did not have suitable clients on their current caseloads or did not reply to the researcher. In total, four of the teams contacted were interested in the study and the researcher presented

the study to three teams. The teams recruited included two EIS and two specialist psychosis services. Originally Six Clinical Psychologists consented to be therapists in the study.

Seventeen potential participants were either screened from the therapists' current caseloads, or from the services' waiting lists. Participants met the exclusion criteria for the following reasons: primary diagnosis of PTSD and/or Personality Disorder; RBs that were associated with persecutory delusions and not voice hearing; risk issues evident during screening; and insufficient English language abilities. On the basis of these criteria ten potential participants were screened out.

The seven people deemed suitable for the study were taken through the PIS by the researcher. At this stage, one participant opted out of the study feeling that there were too many assessments to complete. During this time, one participant's psychotic symptoms increased due to increased drug use, to the point where their responsible clinician considered their involvement inappropriate.

Five out of seventeen potential screened participants consented into the study. Two of these participants dropped out during the baseline assessments. In one case this was due to language abilities, and in the other the participant disengaged from the service after completing five baseline assessments. Ultimately, of seventeen screened potential participants, three completed the study.

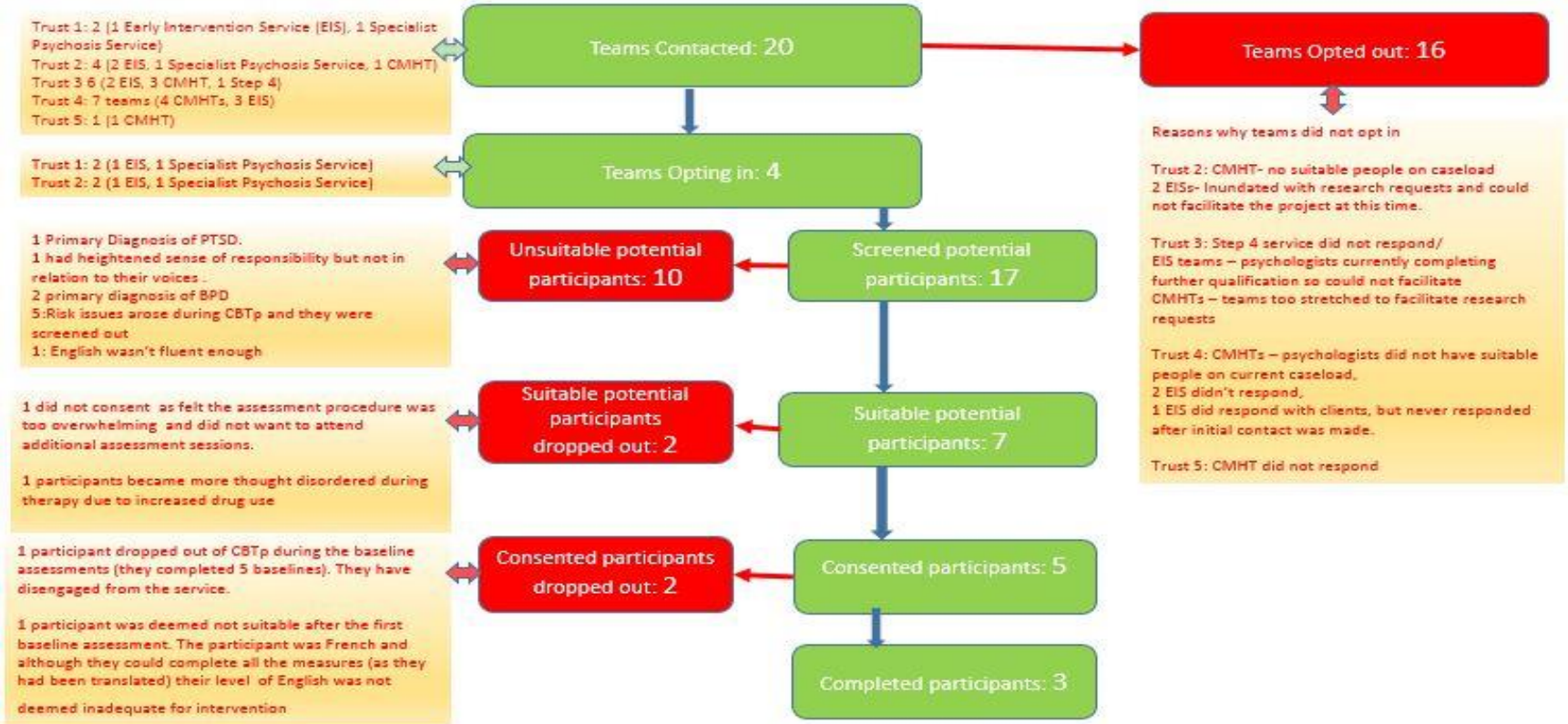


Figure 4: Recruitment Flowchart

3.2.2 Analysis Plan for SCED

Visual Analysis

Graphical analysis of case series data was conducted according to guidance provided by Morley and Adams (1991), Kratochwill and Levin (2010), and Morley (2015) for clear graphical presentation of single case data in clinical psychology research. The analytic approach was informed by the data, in particular the small number of data points per phase. The three phases in this study were baseline, intervention and follow-up. Morley and Adams (1991) suggest that three indices of data should be used in visual analysis: central tendency, trend in central tendency and variability.

First baseline stability was assessed so that intervention effects could be examined. The central tendency, trend in central tendency, and variability within each phase was then assessed. Observed patterns across phases were compared to explore any pattern change. There exists a debate in the literature regarding whether visual analysis of graphs in SCEDs is sufficient (Barlow, Nock & Herson, 2009; Morley, 2015), and whether statistical analysis is necessary (Kazdin, 2007; Shadish, 2014). However, due to associated threats to validity and the small sample size, conventional parametric statistics are deemed inappropriate (Shadish, Rindskopf, Hedges, & Sullivan, 2013).

Baseline stability

The basic premise for using repeated measures is that clinical change will be self-evident following the introduction of a therapeutic intervention. The degree to which change is perceptible depends on the magnitude of therapeutic impact and the

nature of the pre-intervention baseline. Firm conclusions regarding therapeutic impact can only be drawn when a stable baseline has been obtained. Baseline stability can be assumed when 80% of the phase data falls within a 20% range of the median (Jacobson & Truax, 1991; Spriggs & Gast, 2010). Due to a small number of data points available in the sample, a conservative approach to measuring baseline stability was used. Stability was assumed only when all phase data points fell within a 20% range of the median. Across the three participants, baseline stability was assumed and visual analysis of the data was conducted.

Determining Central Tendency, Trend in Central Tendency and Variability

Table 2 describes some of the key methods for calculating central tendency, trend in central tendency and variability, and explains the terms used in this section.

Table 2: Explanation of key terms within graphical analysis

KEY TERM	EXPLANATION
MEDIAN	Number in the middle of the data when data was rank ordered. If there is an even number of data points, then the median is estimated by calculating the average of the two middle two data points.
RUNNING MEDIAN OF 2 (RM2)	Average of successive sets of two data points throughout the phase. This method is considered most appropriate for 'n < 5' case series designs where 'n' is the number of data points per phase (Morley, 2015)
TRENDED RANGE (TR)	Lines connecting the highest and lowest values in each half of the phase

Central tendency, trend of central tendency and variability were calculated for the VASs, PSYRATS-AH and WEMWBS. Various methods were used to calculate these parameters, depending on phase length (Morley, 2015). Table 3 summarises the calculations used, and the style of graphical presentation. Change in phase is indicated by a vertical line. The baseline phase ends after Measurement 3, and the intervention

phase after Measurement 7. The follow up phase was complete following Measurement 9. Each graph will illustrate a participant's raw score over time on the VASs, PSYRATS-AH and WEMWBS. Lines of central tendency and trend in central tendency will be superimposed. Variability graphs for all participants are shown in Appendix E.

Table 3: Calculations used for central tendency and trend

Measures of Central Tendency – Dashed Line		
Phase Length	Method Used	Represented Graphically by
1	Data points only (no line)	Round dots
2-5	Median	Dashed line
Trend in Phase Data – Dotted Line		
Phase Length	Method Used	Represented Graphically by
1-2	Data points only (no line)	Round dots
3+	Running Mean of 2 (RM2)	Dotted line
Variability within Phases – Solid Lines		
Phase Length	Method Used	Represented Graphically by
1-2	Data points only (no line)	Diamond shaped dots
3+	Trended Range	Solid black lines

3.2.3 Analysis plan for Reliable Change and Clinically Statistic Change

RC and CSC was conducted to answer two questions:

1. Is an individual's change reliable, that is, is the magnitude of the observed change in excess of what can be explained by errors of measurement? RC is achieved when a change in score is larger than the likely variation posed by a measure (Evans, Margison, & Barkham, 1998).

2. Has treatment led to a change substantial enough for this to be considered important? That is, is it clinically significant?

Reliable Change Index (RCI) Analysis

Jacobson and Traux's (1991) formula (see below) for calculating reliable change indexes (*RCI*) was used to calculate *RCIs* for the current study's standardised measures.

$$RCI = \frac{M^1 - M^2}{SE_{diff}}$$

Generally, RC refers to a magnitude of observed change that is more than can be explained by measurement error alone. Within the formula, M1 () refers to outcome scores before the intervention, and M2 refers to scores post-intervention. The *standard error of difference (SEdiff*) was calculated as $\sqrt{2} \times SEM2$ where *SEM* refers to the *standard error of measurement*. SEM is calculated as $SD \times \sqrt{(1-r)}$ where *r* refers to the reliability of the measure being used. The current study used Cronbach's alphas (α) as measures of internal reliability. The Cronbach's alpha figures reported in the methodology section were used as measures of reliability.

CSC Analysis

CSC is change that has resulted in the person's classification moving from the "dysfunctional" group to a score typically observed in the "normal" population (Jacobson & Truax, 1991). Jacobson and Truax (1991) suggest several criteria for calculating clinical change. An externally valid criterion can also be employed. If an

externally determined cut-off score is not used, then a criterion based on statistical criteria can be implemented. These are Criterion A, B and C. Criterion "A" was used to determine CSC where normative data from a non-clinical population were not available (Morley, 2015). This is defined as post-treatment or follow-up scores falling outside of the range of the clinical population, and being at least two standard deviations above or below baseline scores of a clinical sample (Jacobson & Traux, 1991). Criterion "B" was used to determine CSC where normative data from a non-clinical population were available. This is defined as post-treatment or follow-up scores falling within 1.96 standard deviations of the mean of the non-clinical population mean (Jacobson & Traux, 1991). Criterion "B" was used as opposed to criterion "C" as clinical and non-clinical norms did not overlap.

In order to calculate the RC and CSC, the Leeds Reliable Change Indicator was used (Morley & Dowzer 2014). Reference data was used to calculate RCIs and CSC for the WEWMBS, HADs, RIQ and PSYRATS delusions subscale. Clinical and non clinical reference data for use in calculating RCI and CSC was obtained from various sources relating to the WEMWBS, HADs, RIQ and PSYRATS (HADS; Spinhoven et al., 1997; RIQ; Salkovskis et al., 2000 PSYRATS; Jolley et al., 2015 and WEMWBS; Schrank et al., 2016)

For the WEMWBS, HADs anxiety, HADS depression and RIQ, Criterion B was used, and calculations yielded clinical cut-off scores of 50.8, 12.15, 9.80 and 50.05 respectively. These scores (or above) therefore indicate clinically significant improvement. As no population norms were available for the PSYRATS delusions subscale, Criterion A was used and a clinical cut-off score of 8.5 or above indicated clinically significant improvement on this measure.

3.2.4 Participant 1 (P1)

Case Description

P1 had been under the care of a specialist psychosis service for three years, with a diagnosis of Treatment Resistant Psychosis with mixed personality traits. She heard one main commanding voice almost continuously throughout each day, which was believed to be 'non-human' and caused by other people. The commanding voice was always derogatory, and instructed her to harm herself. Where she did not comply with these instructions, the voice told her that it would harm her family. P1 complied with the voice consistently and self-harmed on a weekly basis. P1 had an unusual belief that she was in the wrong body, which caused marked distress. Although she had no formal diagnosis of OCD, P1 scored highly on the OCI (110), indicating the presence of OCD. She scored particularly highly on the checking and obsession scale. Please see the mean scores for P1 in Appendix E.

P1 took part in 40 sessions of CBT between 2014-2015 (the focus of these sessions was unclear). Prior to the start of the intervention, P1 had nine sessions of CBTp. These initial sessions had focussed on developing a shared formulation, establishing coping strategies for the voices, starting to explore her beliefs about the voices, and discussing alternatives to self-harm. Behavioural activation had helped P1 to explore what she could do 'despite' her voices, which had previously been an obstacle to leaving the house.

> P1 had the RB: "If I don't do what the voices tell me what to do (self-harm/not take medication), bad things will happen to me and my friends and it will be my fault'

During Session 1, the therapist went through the psychoeducation sheet, which led onto completing a Responsibility Pie Chart together. A behavioural experiment (BE) homework task was devised, with Session 2 a review of this experiment. A second Responsibility Pie Chart was completed, and the implications of both the cognitive and behavioural techniques were tentatively linked back to a wider formulation. As such, fidelity to the manual was achieved.

Visual Analysis of P1

VAS scales, WEMWBS, and PSYRATS-AH total score are graphically displayed in Figures 5-10 respectively.

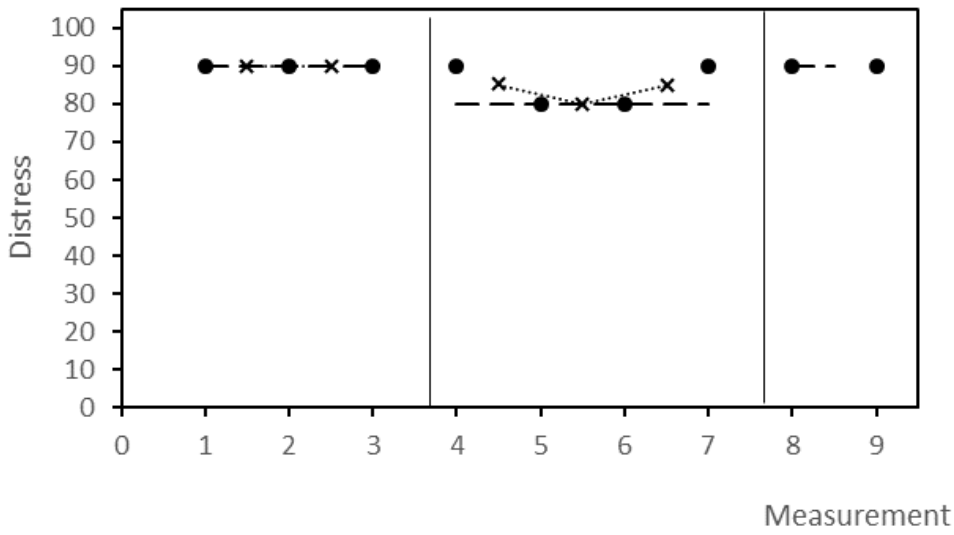


Figure 5: P1 Distress VAS: raw data (●), central tendency (----) and trend (--x--)

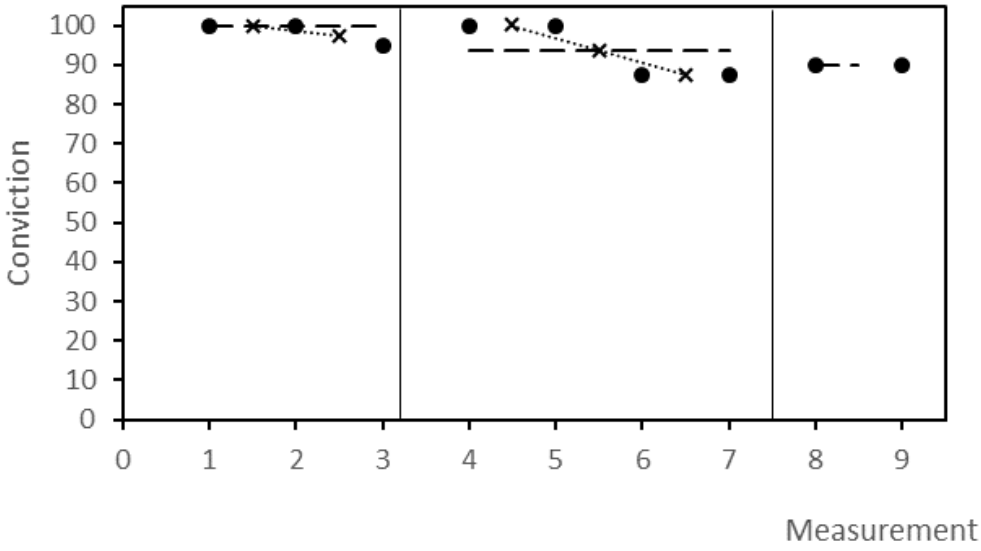


Figure 6: P1 Conviction VAS: raw data (●), central tendency (----) and trend (--x--)

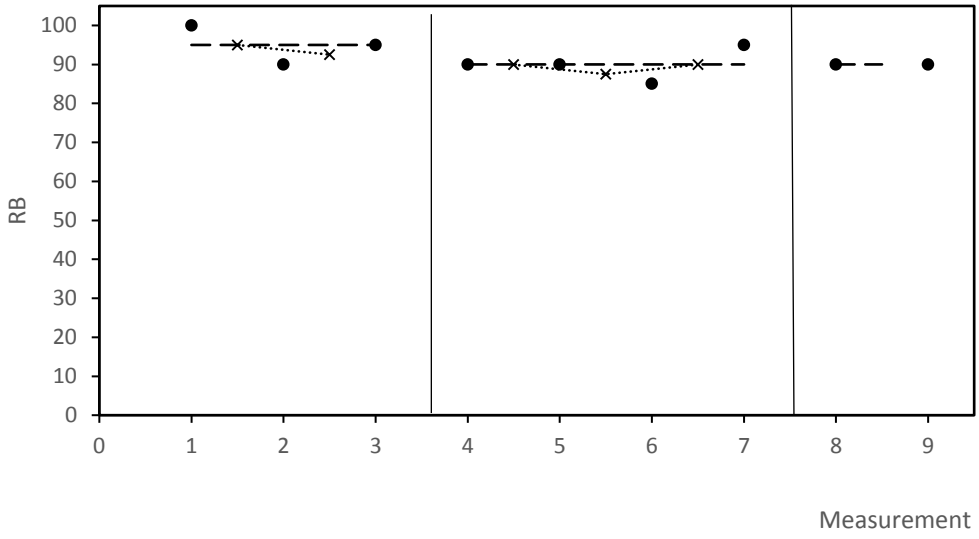


Figure 7: P1 RB VAS: raw data (●) central tendency (----) and trend (--x--)

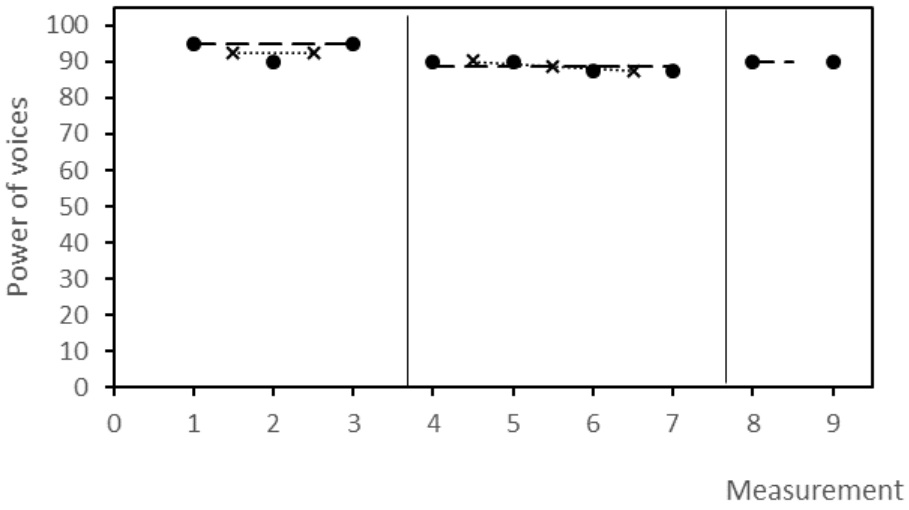


Figure 8: P1 Power of voices VAS: raw data (●), central tendency (----) and trend (--x--)

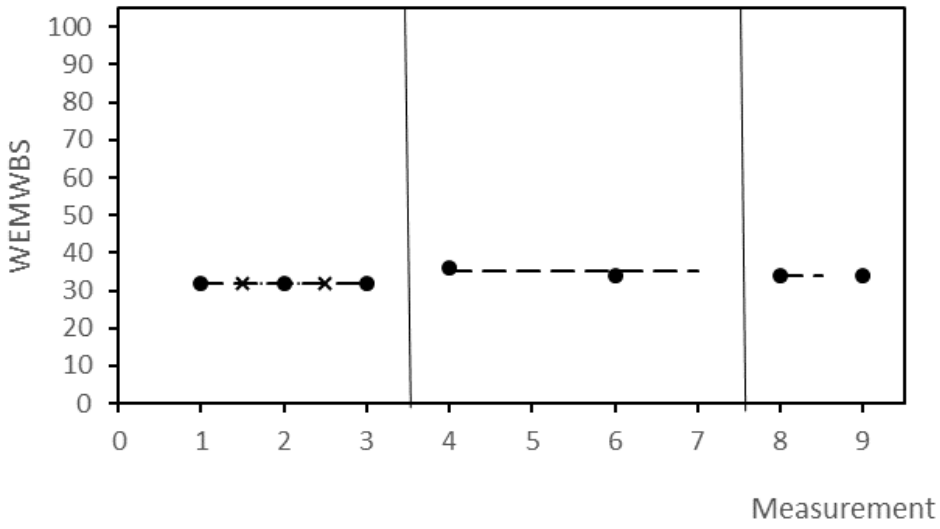


Figure 9: P1 WEMWBS total: raw data (●), central tendency (----) and trend (--x--)

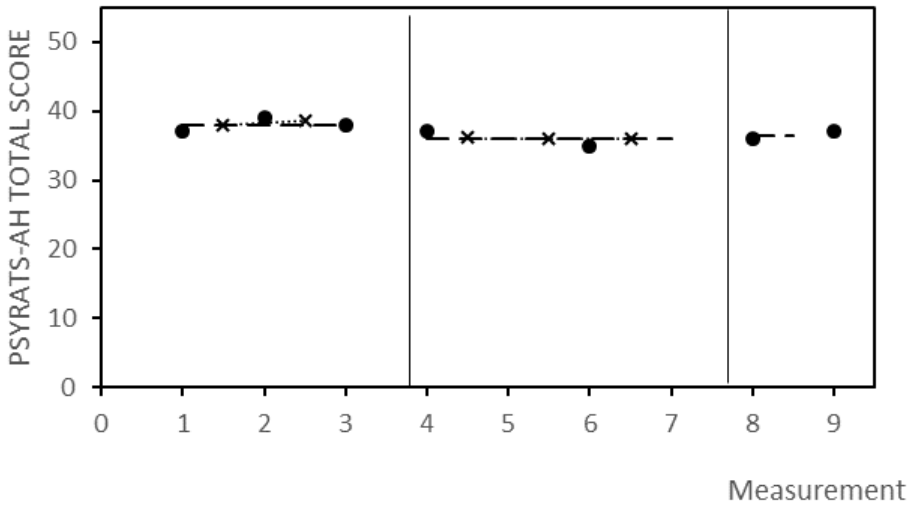


Figure 10: P1 PSYRATS-AH Score: raw data (●) central tendency (----) and trend (--x--)

Examining baseline trends for P1 on a factor-by-factor basis, there is a slight downward trend for conviction and RB, with a slightly upward trend in PSYRATS-AH (see Figures 6, 7, 10). There were small but clear decreases in central tendency from baseline across intervention for distress, conviction in belief, RB, power of voices, and PSYRATS-AH. The small reduction seen in conviction may be attributable to the slight decreasing trend observed during the baseline phase. Regarding conviction, P1's endorsing of the RB was unchanged over the course of intervention Session 1, though there was a clear decrease in conviction at the start of Session 2. This may be tentatively attributable to a behavioural experiment conducted in the week between Sessions 1 and 2. Across all the measures displayed graphically (apart from distress), P1's raw scores at the beginning of Session 2 represent a reduction compared with the end of Session 1.

Central tendency also changed in the correct direction for WEMWBS total score, with P1 reporting an improved score in the intervention phase compared with the baseline phase. The trend in central tendency for distress showed a pattern whereby

scores decreased from the start to the end of Session 1, and was unchanged at the start of the Session 2, potentially demonstrating a lasting effect between sessions. However, the trend increased by the end of Session 2. A similar trend is apparent with respect to the RB, though to a lesser extent.

Comparison of scores between the intervention and follow up phases shows that central tendency for belief conviction continued to reduce (see Figure 6). There was no change in central tendency between intervention and follow up phase for RB, power of voices, WEMWBS and PSYRATS-AH (Figures 7,8, 9 and 10 respectively). Regarding distress, central tendency increased between intervention and follow up, indicating a worsening. There were no substantial degrees of variability across any of the measures displayed graphically (as shown in Appendix E), and the slight trend towards improvement in conviction and RB should be interpreted with caution given that a trend in this direction was also apparent during baseline.

3.2.5 Participant 2 (P2)

Case Description

P2 had been under the care of an EIS since July 2016, and first began experiencing symptoms of psychosis in April 2016. P2 heard two commanding voices a few times per week, which last for several minutes at a time and were believed to be externally caused. The voices were derogatory and commanded self-harm. Compliance was frequent, to '*make them go away*'. P2 did not report any distressing beliefs, and had no formal diagnosis or indication of OCD, scoring a total of five on the OCI.

P2 had never received psychological therapy previous to starting therapy. Prior to participating in the study, P2 had engaged in six sessions of CBTp. These sessions

focussed on trust and rapport building, alongside the development of a tentative formulation. Psychoeducation around emotional regulation techniques to manage self-harm behaviour was completed, as well as behavioural activation in targeting mood. The Maastricht Hearing Voices Interview (Escher, Hage & Romme, 2000) was conducted in parallel with baseline assessments, in order to increase knowledge and awareness of the voice hearing experience.

> P2 had a RB of: "If I don't listen to the voices and do what they say, then they will give me a headache (and then I might do something to harm myself to cope with this)"

During Session 1, the therapist briefly went over the psychoeducation worksheet, completed a Responsibility Pie Chart, and conducted a brief in-session behavioural experiment. P2 was asked to complete a Responsibility Pie Chart for homework. During Session 2, the therapist revisited these techniques and employed the continuum technique. Fidelity to the manual was therefore achieved. P2 stopped hearing voices between the first and second intervention session.

Visual Analysis of P2

VAS scales, WEMWBS and PSYRATS-AH total scores are graphically displayed in Figures 11-16 respectively.

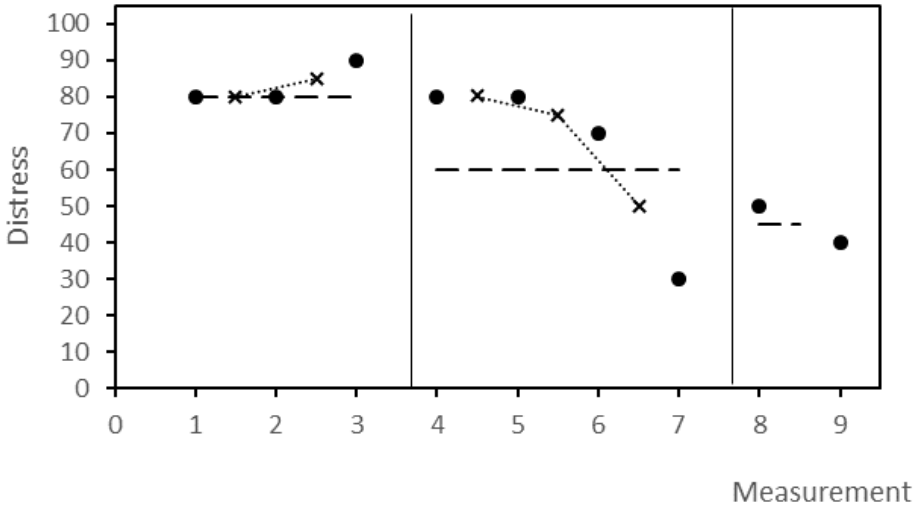


Figure 11: P2 Distress VAS: raw data (●), central tendency (----) and trend (--x--)

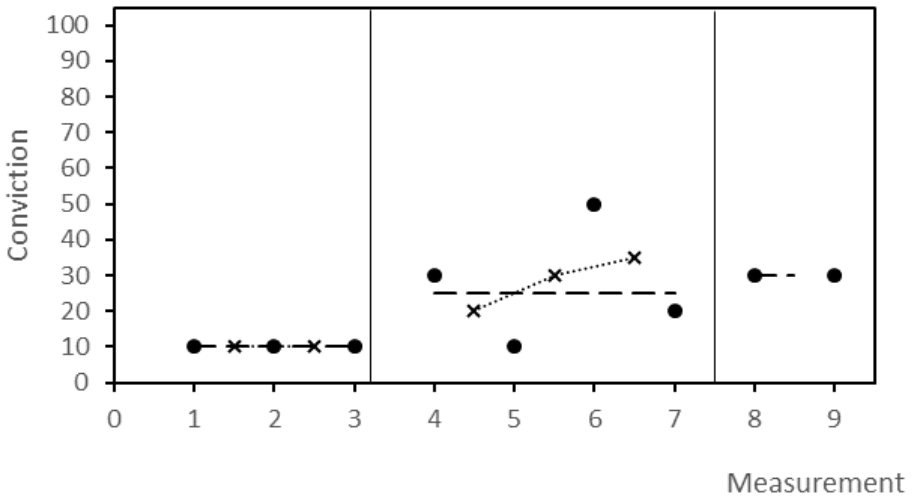


Figure 12: P2 Conviction VAS: raw data (●), central tendency (----) and trend (--x--)

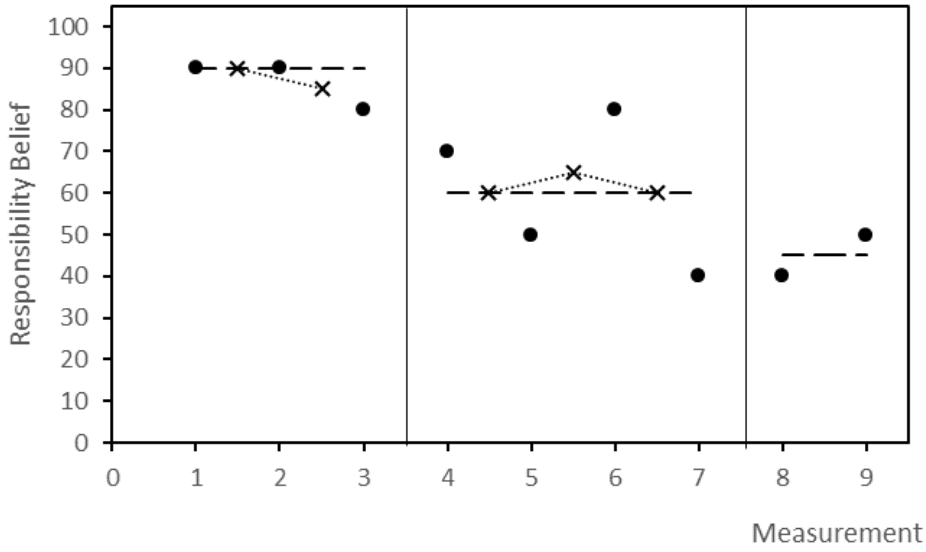


Figure 13: P2 RB VAS: raw data (●), central tendency (----) and trend (--x--)

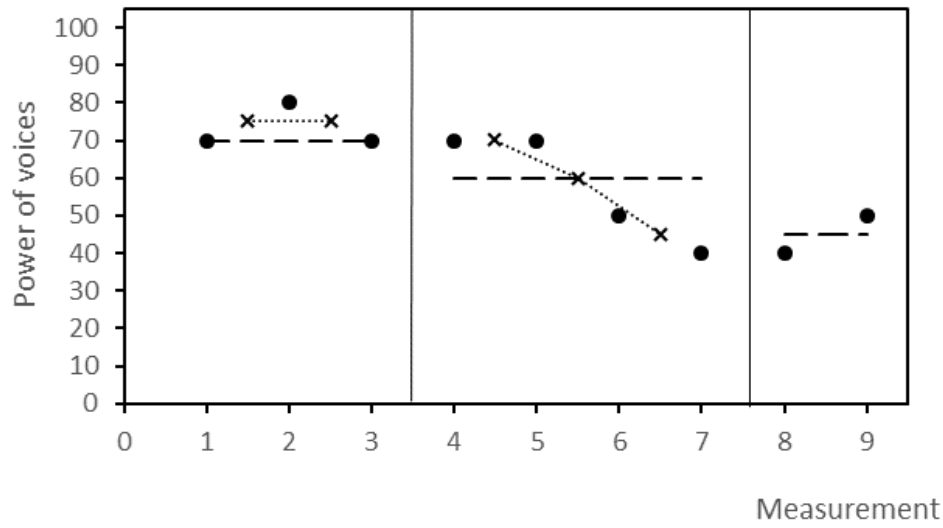


Figure 14: P2 Power of Voices VAS: raw data (●), central tendency (----) and trend (--x--)

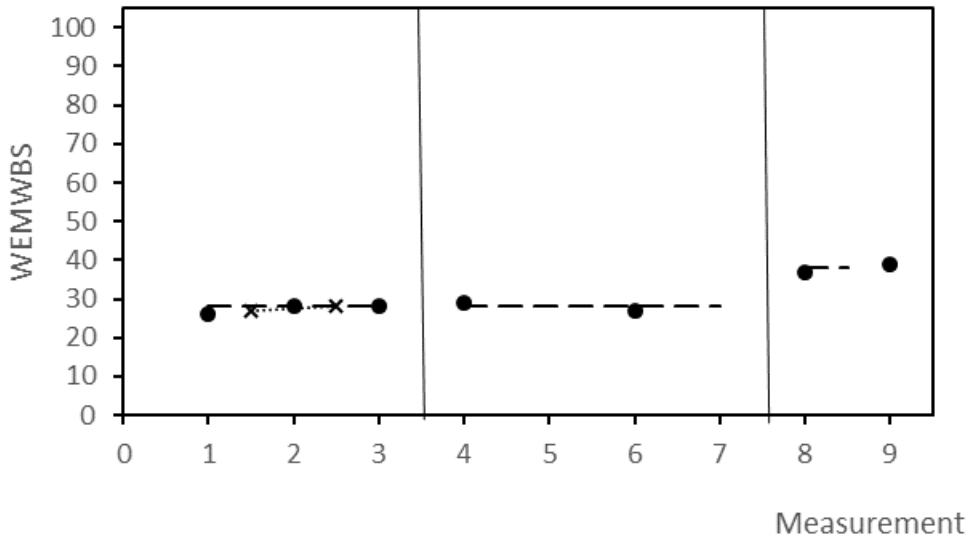


Figure 15: P2 WEMWBS Total Score: raw data (●), central tendency (----) and trend (--x--)

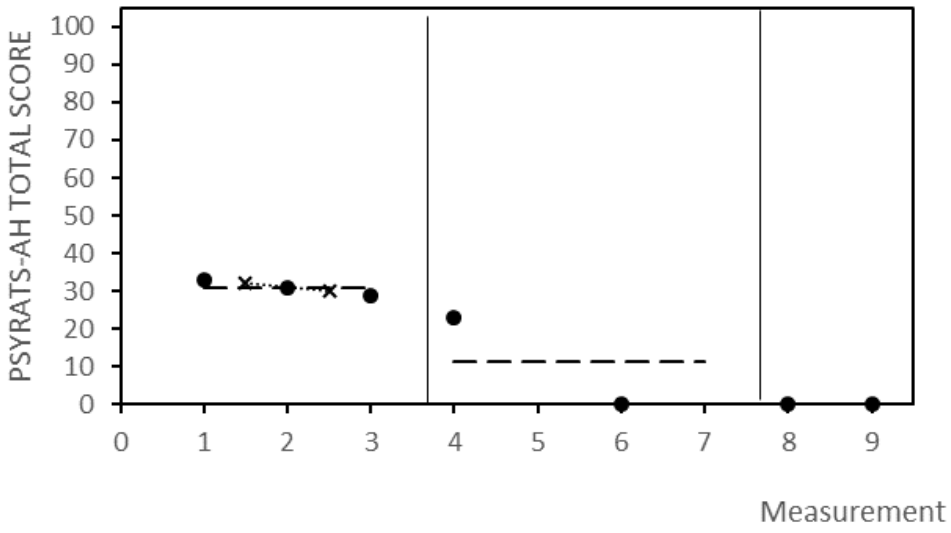


Figure 16: P2 PSYRATS-AH Score: raw data (●) central tendency (----) and trend (--x--)

Examining baselines in Figures 11-16, there are stable trends for conviction and power of voices, and a slight increasing trend for WEMWBS total score and distress. This sufficient consistency – with little or no trend - allows comparison with a new

pattern following the intervention phase. Two measures (RB and PSYRATS-AH) had downward trends over baseline (PSYRATS-AH was very slight).

Regarding distress, a clear reduction in central tendency from baseline to intervention was observed (see Figure 11). This reduced further in the follow-up phase. There was a clear downward trend during the intervention phase. Reduction in central tendency may have occurred as a result of a reversal in trend, from an increasing baseline trend to a decreasing intervention trend. However, distress did appear to reduce following the intervention phase. However, variability was shown during the intervention phase (Figure 30; Appendix E) which limits the conclusions that can be drawn regarding reduction in distress.

An increase in central tendency between the baseline and intervention phases for belief conviction are shown in Figure 12. An increasing trend in the intervention phase can also be seen. This indicates that P2's level of perceived responsibility increased during the intervention. A pattern of variability was observed over the intervention phase, as shown in the Appendix E, Figure 31, whereby scores decreased notably from the start to the end of a session, followed by a subsequent increase by the beginning of the next session, and then again a decrease by the session's completion. This variability limits the confidence with which conclusions can be drawn.

Figure 13 illustrates a downward trend in perceived responsibility over the baseline phase. There is a decrease in central tendency from baseline to intervention, though this reduction could be attributable to improvement already observable during baseline. The pattern of variability described above with respect to belief conviction was also apparent in relation to perceived responsibility over the intervention phase (see Figure 32; Appendix E), again meaning that results should be interpreted with

caution. Central tendency continued to decrease in the follow up phase, showing a large decrease in perceived responsibility when compared with baseline. The decreasing trend over baseline again limits the conclusions drawn.

With respect to beliefs about power of the voices and personal sense of responsibility, there was a clear reduction in central tendency from the baseline phase to the intervention phase, and a further reduction at follow-up. Within the intervention phase, there was a clear downward trend. Between Sessions 1 and 2, P2 stopped hearing the commanding voice, which might partially explain decreases in both perceived voice power and personal sense of responsibility.

There was no change in central tendency for WEMWBS from the baseline to intervention, followed by a slight improvement during follow-up (see Figure 15). This suggests that P2's general well-being remained stable over the intervention, but then improved between intervention and first follow-up. P2 did not receive any CBTp during this period, meaning that the small increase in well-being may be attributable to the intervention. There was a decrease in central tendency from the baseline phase to the intervention phase for the PSYRATS-AH.

3.2.6 Participant 3 (P3)

Case Description

P3 had been under the care of an EI service since August 2016, and first began experiencing positive symptoms of psychosis in January 2016. P3 heard two commanding voices daily, lasting for hours at a time, and which she believed to be spirits. The voices were always derogatory and told her that people were out to get her. Non-compliance came with the threat of harm to herself and her family. P3 always

complied, and engaged various in safety seeking behaviours such as checking repeatedly that the door was locked and that no-one was outside. P3 had a persecutory belief that people were looking at her strangely, and this experience was associated with her voice hearing. Although she had no formal diagnosis of OCD, P3 scored highly on the OCI (121) – particularly on the checking and obsession scale - indicating the presence of OCD. Please see her mean scores in Appendix E.

P3 had received no psychological therapy before their current course of CBTp, and prior to study participation she had completed six sessions. Initial sessions focussed on trust, rapport building, and the sharing of a tentative formulation. Sessions 3-6 were centred around exploring and developing responses to the voices, evaluating the accuracy and legitimacy of what the voices say, and the use of written coping and validation statements to build confidence and assertiveness in relation to the voice. These sessions ran alongside the baseline assessments. P3 experienced significant negative life events during the study. Her leave to remain in the country had been uncertain throughout participation, while between Baseline 3 and Session 1 her sister was diagnosed with breast cancer.

> P3 had a RB of: "If I don't listen to and do what the voices say, then the people might come in my room and kill me or somehow harm my family, and it will be my fault."

In Session 1, the therapist went through the psychoeducation sheet and began to show P3 the Responsibility Pie Chart, which she was asked to complete for homework. In the second session, the Responsibility Pie Chart was reviewed and a second Responsibility Pie Chart was completed for consolidation, meaning that the therapist did not have time to complete a behavioural experiment. The therapist felt that with this

particular client – particularly given the external stressors evident - greater clarification and repetition was required to ensure the Responsibility Pie Chart was fully understood and executed meaningfully. As such, fidelity to the manual was not achieved.

Visual Analysis of P3

VAS scales, WEMWBS and PSYRATS-AH total score are graphically displayed in Figures 17-22 respectively.

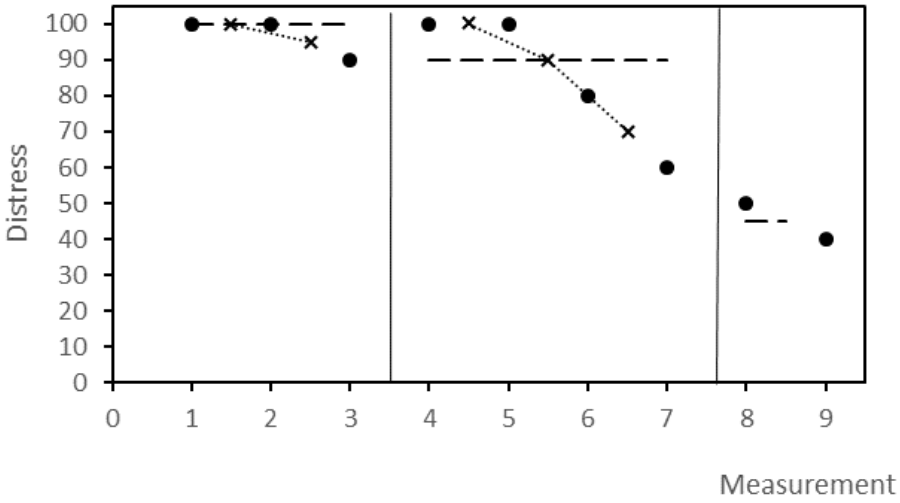


Figure 17: P3 Distress VAS: raw data (●), central tendency (----) and trend (--x--)

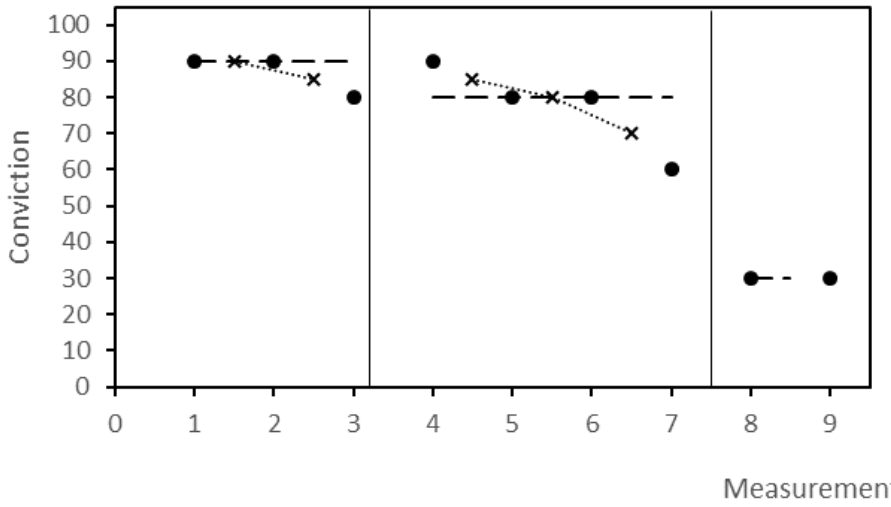


Figure 18: P3 Conviction VAS: raw data (●), central tendency (----) and trend (--x--)

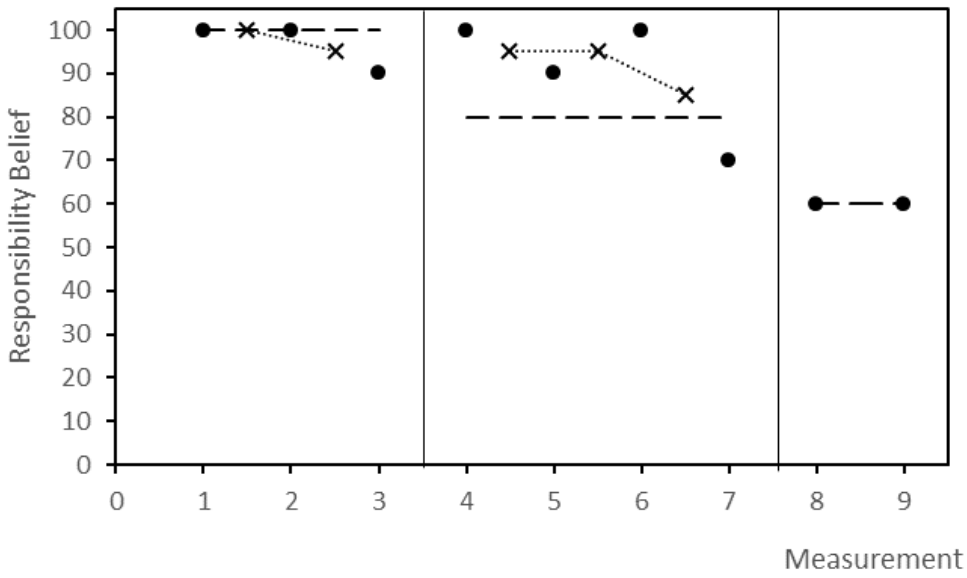


Figure 19: P3 RB VAS: raw data (●) central tendency (---) and trend (--x--)

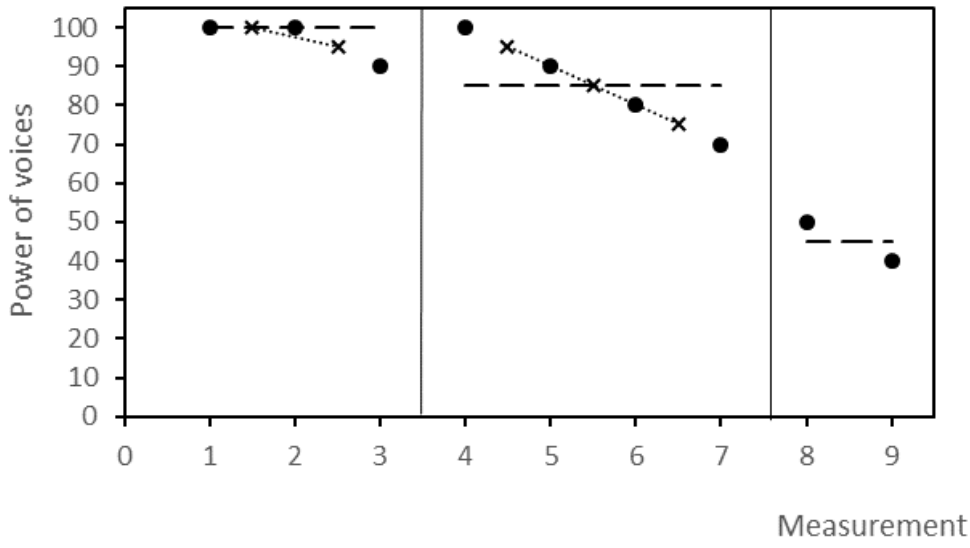


Figure 20: P3 Power of voices VAS: raw data (●), central tendency (---) and trend (--x--)

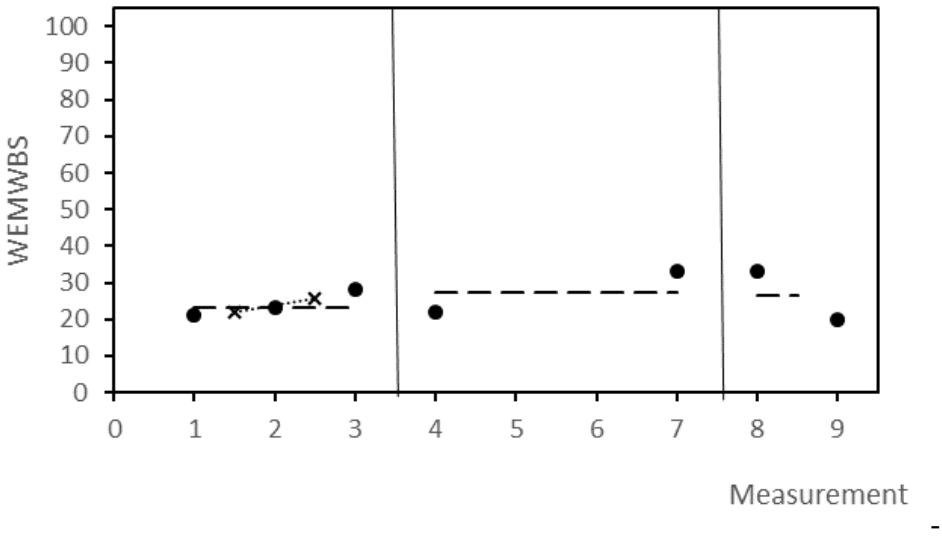


Figure 21: P3 WEMWBS total score: raw data (●), central tendency (---) and trend (--x--)

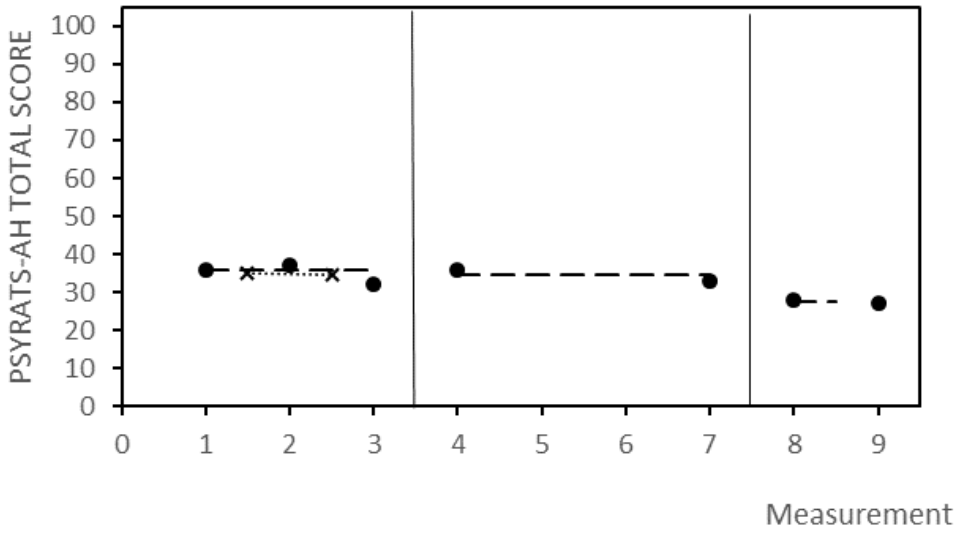


Figure 22: P3 PSYRATS-AH Total Score: raw data (●), central tendency (----) trend (--x--)

Unstable baseline trends are problematic for all measures, apart from the PSYRATS. The VAS baseline trends all decrease, while the WEMWBS baseline trend shows a slight increase, indicating improvement in well-being over baseline. A clear reduction in WEMWBS scores is evident over Baseline 2 and 3, during which time P3's CBTp sessions were focussing on strategies for coping with and challenging her voices. Given that the first two baseline points are stable, this therapeutic work may account the change to some extent.

A clear reduction in central tendency is evident from the baseline to the intervention, and is maintained at follow-up for all measures apart from the PSYRATS. However, these results should be interpreted with caution given that the reduction in central tendency may be a product of the decreasing trend already apparent at baseline. Although the trend decreases in the intervention phase, raw scores at the start of the intervention Session 1 are higher (or for the WEMWBS, Figure 21, lower). This corresponds with a life event occurring between the end of baseline and the beginning

of the intervention, which seemed to significantly impact well-being and beliefs around responsibility. The trend observed across these measures steadily decreased as the intervention progressed, suggesting that the intervention may have been successful. However due to the decrease in trend over baseline, it is not possible to draw firm conclusions regarding lasting change.

There was a very slight reduction in central tendency for the PSYRATS-AH (Figure 22) from the baseline to the intervention phase, maintained at follow-up. Variability of responses was not an issue in this instance, and as such we might speculate that the intervention has potentially been successful in slightly reducing P3's voices, given that the line of central tendency at the intervention phase is at a lower value than at the baseline phase.

3.2.7 Summary of patterns across participants

Due to the small number of participants and variability in scores for some participants, these patterns are suggested tentatively. For all participants, slight improvements were observed from the baseline phase to the intervention phase on all VAS measures (apart from P2 on the conviction VAS). There were no areas of symptom worsening from baseline to intervention. For measures of well-being and voice hearing, participants either improved from baseline through intervention and then follow-up, or their scores were unchanged.

3.2.8 Reliable Change and Clinically Significant Change

RC and CSC were calculated using an average of the three baseline scores and the first follow-up score to determine whether change had occurred from pre-intervention to post-intervention. CBTp was recommenced following the first follow-

up, meaning that scores from the second follow-up were not used. Table 4 evidences RC and CSC for all participants across the HADs, PSYRATS, WEMWBS and RIQ.

P1 did not demonstrate any CSC or RC on the HADs, PSYRATS or WEMWBS. P2 showed RC in the direction of functionality on the WEMWBS at post-intervention, though the score did not reach threshold for CSC. On the PSYRATS-AH, P2's scores indicate clinically significant improvement from pre-intervention to post-intervention. For P3, RC was evident on all measures apart from PSYRATS-Delusions, while CSC is apparent with respect to the HADs Anxiety subscale. All participants reached threshold for reliable improvement on the RIQ (the only measure showing this). Participants 2 and 3 showed clinically significant improvement, that is, statistically reliable change whereby their scores drop below cut off.

Table 4: RC and CSC Results

Measure	Participant	Pre-test score	Post-test Score	Change Score	Reliable Change	Clinically Significant Change
HADs (Depression)	1	12	10	2	No	NA
	2	12	11	1	No	NA
	3	20	10	10	Yes	No
HADS (Anxiety)	1	18	17	1	No	NA
	2	11	8	3	No	NA
	3	21	10	11	Yes	Yes
PSYRATS-DELUSIONS	1	18	15	3	No	NA
	2	5	0	3	No	NA
	3	22	11	11	No	NA
PSYRATS-AUDITORY HALLUCINATIONS	1	38	36	2	No	NA
	2	31	0	31	Yes	Yes

	3	35	28	7	Yes	No
WEMWBS	1	32	34	2	No	NA
	2	27	37	10	Yes	No
	3	23	33	10	Yes	No
RIQ	1	73	56	17	Yes	No
	2	64	0	64	Yes	Yes
	3	91	49	42	Yes	Yes

HADS (Depression) Cut-off score (b) = 9.8, HADS (Anxiety) Cut-off score (b) = 12.15

PSYRATS-Delusions Cut-off score (a) = 8.54, PSYRATS- Auditory Hallucinations Cut-off score (a) = 6.22, WEMWBS Cut-off score (b) = 50.8, RIQ Cut-off score (b) = 50

CHAPTER 4: THEMATIC ANALYSIS (PHASE 3)

4.0 Overview

This chapter will first describe the methodology used, followed by the analysis plan and finally displaying the results of the Thematic Analysis.

4.1 Methodology

4.1.1Participants

The focus group was attended by four therapists who had consented Phase 2 participants into the study, and the Assistant Psychologist who had administered the assessment of one participant. All participants were female and worked across the trusts who had opted into the study. The therapists were all Senior Clinical Psychologists and had at least three years' experience working with the client group. The Assistant Psychologist had approximately eighteen months' experience working with this client group.

4.1.2 Design

Phase 3 utilized a qualitative design with data gathered from a single semi-structured focus group, conducted at a central Royal Holloway location. Data pertaining to the research aims was collected using a semi-structured interview (Appendix D), with questions developed in collaboration with an internal supervisor.

4.1.3Procedure

The semi-structured interview invited open ended responses, was based on objectives set out by Orsmond & Cohn (2015), and took place over two hours. Of particular interest was the evaluation of: feasibility of recruitment; data collection procedures; suitability of outcome measures; acceptability and suitability of the intervention and study procedures; management and implementation of the

intervention; and preliminary indications regarding participant responses to the intervention.

The interview comprised five core questions:

1. How did you find recruitment?
2. How did you find the procedure of the study? What did you think of the outcome measures?
3. What did you think of the manual?
4. How do you think the team found the study?
5. What do you think the participants thought of the study?

These questions were supplemented by reflection, probes and prompts as appropriate, and was facilitated by RM. The interviewing stance was one of curiosity and flexibility in the face of disclosure; intended to encourage participants to fully explore their experiences without feeling too constrained by the wider structure and schedule. The focus group was audio-recorded and transcribed verbatim by the researcher, with data then interpreted using Thematic Analysis.

4.1.4 Results Analysis

While there are a range of available qualitative analytical methods of varying complexity, an elemental process shared among all is that of 'thematising meanings' (Holloway & Todres, 2003). The process of thematic coding is also recognised as a method in its own right (Braun & Clarke, 2006). Thematic Analysis of the interview transcript utilised Braun and Clarke's (2006) six-stage method, with data then indexed using NVivo (version 11) software. The analytical process is described in discreet stages for clarity (below), though within the current study analysis moved fluidly

between stages until a comprehensive thematic framework was established (Braun & Clark, 2006). In keeping with guidelines on defining a theme, the themes identified from the current data set are grounded in quantifiable measures (such as frequency), but are included based on a capacity to *"capture something important in relation to the overall research question"* (Braun & Clarke, 2006). Both the Braun & Clarke (2003) 15-point quality checklist for Thematic Analysis, and the well-established criteria described by Elliott, Fischer & Rennie (1999), were adhered to throughout this process. Please see Appendix D for the 15-point quality check as outlined by Braun and Clark (2006).

For readers to comprehend and consider alternative interpretations of the data, authors of qualitative research need specify their theoretical orientations, interests and personal assumptions (Elliott, Fischer, & Rennie, 1999). The researcher (RM) is a female Clinical Psychology Doctorate Student at Royal Holloway, University of London, who has previous experience in conducting and transcribing semi-structured interviews within staff groups. As the researcher developed the manual, they had an inevitable and committed interest in the usefulness of the intervention, which will have impacted the analytic process. The analytic process was theoretically-driven, meaning that the researcher was reading for interesting patterns and meanings specifically related to intervention acceptability and feasibility. The analysis was semantic; that is, it did not seek to theorise with regards to underlying ideologies or conceptualisations.

4.1.4.1 Braun & Clarke (2006) Six Stage Model for Thematic Analysis

Phase 1: Familiarising yourself with the data

RM conducted, recorded and transcribed the focus group verbatim, a process that allows the researcher to immerse themselves in the data (Smith, 2012). The transcript was reviewed several times, until such time that a thorough and comprehensive overview of the data was achieved.

Phase 2: Generating Initial Codes

This phase marks the beginning of clustering data into meaningful groups. However, these initial codes differed from the eventual themes as - in keeping with the recommendations of Braun & Clarke (2006) – no attempt at interpretative analysis was made. Codes at this stage were manually generated, and were essentially "data driven"; that is, drawn from participants' own choice of words. They were coded using 'N Vivo' software. Once a comprehensive list of codes had been collated, all relevant text extracts were grouped accordingly. Codes were checked against the original transcribed interview – and against each other - to ensure that the list represented a coherent and comprehensive account (Braun & Clarke, 2006). This process resulted in a comprehensive list of 52 different codes. Codes included "*small pool of participants*" and "*the need for this study*" and "*mechanism of change*". An example of the code "*small pool of participants*" and its corresponding extracts can be seen in Appendix D.

Phase 3: Searching for Themes

Excerpts underneath each code were thoroughly examined for differences. In accordance with Braun & Clarke's (2006) guidelines, the list of codes was then refined by collapsing, subdividing, and rewording codes into principal themes. Each theme

goes beyond simply describing or paraphrasing its contents, and is intended instead to represent an appraisal or interpretation of the meaning within. As such, the wording of labels for themes is no longer tied to participants' own language but is a product both the original data and the researcher's interpretation (Braun & Clarke, 2006). Given a lack of research in this area, an inductive approach to recognizing themes was adopted, whereby themes are identified at a latent level (Braun & Clarke, 2006).

Phase 4: Reviewing Themes

At this stage, the researcher ensured that all themes – as well as their corresponding extracts - were consistent, coherent and distinctive (Braun & Clarke, 2006). This phase is intended to be highly fluid, with themes further reworded, collapsed or subdivided in improving the extent to which they adequately represent the range of meaning within the data set. Data extracts were moved between themes when the researcher felt an alternative theme better encompassed their meaning. On completion of this stage an initial thematic framework was produced.

Phase 5: Defining and Naming Themes

With a thematic framework devised, the researcher produced a table containing the initial list of themes, with selected extracts from the transcript and a description of what the theme represents. In defining and detailing the themes in this way the essence of each is increasingly established, the overall narrative or "story" about the data was further conceptualised (Braun & Clarke, 2006). This analysis yielded six overarching themes relating to the feasibility and acceptability of the intervention (see Table 5).

Phase 6: Producing the Report

A final thematic framework was produced. As the analysis was theoretically driven – with the data pertaining to specific result questions – some themes are more descriptive in nature.

4.2 Results

This analysis was conducted according to the six-phase procedure outlined above by Braun & Clarke (2006), and adhered to the 15-point checklist of criteria that the authors propose (please see Appendix D). In keeping with criteria for the practice of good qualitative analysis, each theme is described and subsequent subthemes are grounded in a minimum of two examples (Elliott, Fischer & Rennie, 1999). In the Thematic Analysis literature, there is a discussion about how best to report the prevalence of individual themes, and even regarding whether to do so at all (Braun & Clarke, 2006). While certain researchers feel that reporting prevalence demonstrates that the theme truly existed in the dataset, Braun and Clarke (2006) note that frequent occurrence of a theme is not necessarily an indication of its importance. Rather, the inclusion of a theme should be based on its centrality to the person's own account. The analysis here applies this broader account of value and importance in that the researcher has decided upon what constitutes a theme, but at the same time seeks to convey prevalence by reporting on themes that were particularly common, by using such terms as "the majority of participants" (Meehan, Vermeer, & Windsor, 2000), or "infrequently articulated by participants".

The analysis yielded six overarching themes relating to the feasibility and acceptability of the intervention (see Table 5). As the analysis was theoretically driven – with the data pertaining to specific research questions - some themes are more descriptive in nature. The six themes and their corresponding subthemes will now be

described and illustrated using extracts from the interview transcripts. The participants that were recruited for Phase 2 are referred to throughout as 'clients'.

Table 5: Themes and sub-themes of the Thematic Analysis

THEME	SUB-THEME
Understanding barriers to recruitment	Lack of time for recruitment with a small pool of potential participants
	Psychological readiness for therapy
	Service buy-in to the study
Understanding mechanisms of change	Responsibility as a mediator of change
	Capturing change in inflated RBs
Developing a shared understanding of responsibility	Facilitating client understanding
	Client socialisation to the model
	Time
Effectively impacting responsibility	Visually representing responsibility
	Difficulties adapting behavioural techniques to psychosis
	The influential role of behavioural experiments
Barriers to implementation	Burden to clients
	Burden to team
Therapist confidence and familiarity	Therapist understanding
	The need for supervision

4.2.1 Understanding barriers to recruitment

All participants talked about barriers to recruitment, and the discussion began to establish possible explanations for a small sample size. Within this general theme,

the following three sub-themes were identified: lack of time for recruitment with a small pool of potential participants, psychological readiness for therapy and buy-in to the study.

Lack of time for recruitment with a small pool of potential participants

There were several key areas that presented obstacles to recruitment. Most prominent was the time available for study recruitment, coupled with the already small pool of suitable clients. All participants felt that with a longer timescale, recruitment of a larger number of suitable clients may be possible.

> "If you had the luxury of time, then you would be able to get the handful of people that this applies to quite well" (Participant 3)

There was also a consensus that the recruitment period – much of which was over Christmas - fell at an inconvenient time. However, even accounting for time constraints, all participants felt that the pool of potential participants would always be small, given fairly strict inclusion criteria.

> "So I just think that you have to be realistic that in psychosis services, those that hear voices and particularly those that hear commands, is a really small proportion of what we are actually getting through and what actually makes their way to psychology services" (Participant 1)

Another barrier was the availability of Clinical Psychologists within teams to assist with screening potential participants and implementing the intervention. It was acknowledged a good degree of expertise and experience was required of participating therapists.

> "you need to have a certain level of skill and competency in CBTp and then be able to implement the responsibility intervention. At that time, we didn't have a therapist that would have had the level of experience and could help screen" (Participant 5).

Even when suitable therapists were available, there were inevitably competing service demands and clinicians seeking similar clients to complete a Postgraduate Diploma in CBTp. Many voice hearers within EI services were recruited for this training course. As such, a combination of factors – including recruitment time, therapist expertise and availability, competing service demands, and small pool of suitable clients - made recruitment for this study difficult.

Psychological Readiness for Therapy

This subtheme identified that even when a person was suitable for the study in terms of their presentation, they may not have been psychologically ready for therapy. In screening potential clients, all participants found that many people who were currently symptomatic were too unwell to engage in therapy:

> "So quite often they are having commands, but they are still at the stage of confusion, and not understanding that they were unwell" (Participant 3)

In some cases, participants also felt that even if clients had insight into the nature of their experiences, there would be associated distress. Participants felt that engaging in a meaningful piece of psychological work at that time would be difficult for certain clients, and recruitment rates were impacted as a result.

> "If they are still hearing command hallucinations, then there is a lot more distress and a lot more chaos to their life, and they might not be ready for psychology, and therefore definitely not research." (Participant 1)

Participants also raised the issue of socio-economic factors and practical issues in peoples' lives as barriers to engaging in regular, structured therapy sessions.

> "We tried to assess several people with commands for this, but then there were always other issues – e.g. child protection issues, or housing problems or trauma, and then you just know that they won't be suitable for the study" (Participant 2)

This sub-theme highlights concerns about clients' readiness for therapy, and the obstacles to consistent engagement in psychological therapy presented by distressing symptoms and practical issues.

Service buy-in to the study

This sub-theme illustrates participants' feeling that their services had not had not "bought into" the research study. Participants recalled frequently reminding the MDT, yet finding that teams were not forthcoming with suitable clients.

> "We were kind of saying to people "have they got commands?" without the team coming to us to say "I've got this person with commands" – it didn't seem to be in people's minds as much" (Participant 2)

One perspective was that this may reflect a lack of incentive for teams, while another view was that teams did not have a good grasp of what the study entailed.

> "Our team are quite characteristic of many teams I think, if they can see an actual benefit for them or the client, they will send people to it. If they can't see that then they just won't do it or remember to send people" (Participant 3)

In counteracting this, participants advocated for a presentation as a helpful way to raise the study's profile within teams:

> "I think the presentation you came and did in the psychosis pathway was actually really helpful and something like that for our team [EI], could have maybe, get the team to buy into it a bit more." (Participant 3).

4.2.2 Understanding mechanisms of change:

All participants recognised inflated RBs as a potential mediator in reducing clients' compliance with their voices. However, participants also agreed that the precise mechanism here was difficult to understand, and that there is an apparent gap in the literature. All stressed that the Visual Analogue Scale (VAS) was not able to capture this potential mediating effect. Two sub-themes emerged from this data: Responsibility as a mediator of change and capturing change in inflated responsibility beliefs.

<u>Responsibility as a mediator of change</u>

All participants agreed that inflated sense of responsibility might mediate change in levels of compliance with commanding voices, which was in turn considered likely to be influential regarding distress. However, these hypothesises were very tentative.

> "for others there is a massive inflated response for causing harm and we don't know how much that impacts their compliance, but I guess we are wondering if this does play a role in maintaining distress" (Participant 5)

Participants felt further research was required to explore mechanisms of change, and to establish whether inflated RBs are indeed a driver of compliance. Everyone felt that this was a vital piece of research, due to compliance to voices being an influential risk factor.

> "We need to know more about this because of the risk that complying to command hallucination poses" (Participant 5)

> "There isn't a network analysis about compliance, and there is no real understanding about the various factors that influence compliance – we think that responsibility is one aspect on the influence of compliance" (Participant 3)

This subtheme suggests that although inflated RBs are regarded a potential mediator of change, there is a lack of knowledge around what impacts compliance and distress.

Capturing change in perceived responsibility

This second sub-theme relates to experiences of administering the VAS, which was intended to capture change in RBs. Participants discussed some of the difficulties with this concept and measure, and suggested potential solutions. Participants discussed the potential for the VAS to track changes in behaviours (such as safety behaviours or valued actions), given its apparent unsuitability for measuring change in RBs.

> "I guess the focus of these questions were more about that overall feelings of responsibility but actually, would it be much better to focus more on their behavioural responses, e.g. in terms of compliance and day to day, quality of life – has this improved?" (Participant 1)

Other participants stressed that while it remains important to include questions on RBs, the VAS in its current format appears inadequate for these purposes.

> "The VAS is difficult to understand. I wonder if there is something about rating it 0-100 that sounds massive. I wonder if scale should be 0-10". (Participant 5)

All participants agreed that the VAS was generally difficult to understand, and potentially led clients to respond without fully understanding the question

> "I was not quite clear what was being asked, and then it just felt that the client was going in with 100%, yep 90%, I am responsible, who is responsible – me. I'm not sure how helpful

> that was at all really, or what that was capturing" (Participant 4)

4.2.3 Developing a shared understanding of responsibility

This theme explored participants' experiences of certain techniques from the manual, particularly in relation to their usefulness in developing a shared understanding. Three sub-themes were identified: Facilitating client understanding, client socialisation to the model and time.

Facilitating client understanding

Within this sub-theme, participants expressed the importance of facilitating understanding of the main concepts involved, and describing how this work links to a wider formulation. All participants commented on the usefulness of the psychoeducation worksheet in this respect and how it was validating:

> "She found that very normalising – "ah ok, it isn't just me that feels like that"" (Participant 1)

All participants agreed that to facilitate client understanding it was essential to link this specific psychoeducation – and the subsequent techniques employed - back to the wider formulation. Difficulties were discussed in relation to cases where this process was problematic.

> "Yes we always do it verbally, but I think we needed something to make it more explicit of why you are doing it, and how it fits into the bigger picture" (Participant 1)

Although a vicious flower template formulation was included in the manual, participants felt that this was perhaps too simplistic to account for the complexity of experiences within psychosis as well as the specifics of OCD.

> "The vicious flower didn't capture the whole picture that we are describing" (Participant 1)

Participants felt that a longitudinal formulation, in addition to referencing other evidence-based models, would be appropriate in facilitating shared understanding and setting up this specific piece of work.

> "So you can do this piece of work on responsibility, but then you then feed it back into the wider formulation, in some sort of visual way, a version of the Garety/Chadwick model" (Participant 1)

Overall, participants felt that the thoughtful and collaborative use of formulation should be considered a central aspect of this type of intervention for responsibility.

> "So when you do these sessions, you can pin it onto the formulation and the whole thing makes sense more." (Participant 3)

<u>Client socialisation to the model</u>

Within this sub-theme participants felt that clients were not sufficiently socialised to the CBT model, and therefore had little understanding of the rationale behind the cognitive and behavioural techniques utilised. Participants felt that clients may not have had the 'basic' level of understanding required to meaningfully implement the techniques.

> "Just getting them to a stage where as a baseline, they have 'XYZ', and they may have 'ABCD' as well, but we are after the 'XYZ' as a basic skill set" (Participant 2)

Specific techniques, such as the continuum technique, were difficult to implement, given that no work on cognitive distortions had been completed at this point.

> "…the continuum technique touches on black and white thinking, but if you haven't done work on cognitive biases, sometimes it can be harder to introduce something like that" (Participant 1)

Participants began to devise a list of 'pre-requisites' they thought would facilitate socialisation to the model, and which would represent a good foundation for the intervention.

> "I wonder if we were to do it again, you need to have covered, rather than it being time led and X amount of sessions completed, could you in fact have a criteria that you need to have covered: so you need to have introduced them to cognitive biases, you need to have shared a formulation so you can link the work back, completed a behavioural experiment in order to explain the rationale being them, that sort of stuff. This then helps to get everyone at the same baseline before they start the intervention, barring individual therapeutic differences." (Participant 2)

Time

This sub-theme explored participants' views on the intervention comprising two sessions. All participants felt that although two sessions might have been an appropriate length of time to focus on RBs for clients with OCD, it was inappropriate for this client group.

> "I think in OCD, doing a pie chart and then setting up a behavioural experiment, then that fits quite well in the time, but with psychosis, you need the time to set it up" (Participant 1)
>
> "That requires a lot more for trust building and thinking 'why are we doing this" (Participant 5)

Participants felt that the length of the intervention inhibited both client understanding and socialisation to the RB intervention. One participant struggled to get through the

material in two sessions and felt that a much longer time was required to facilitate understanding, accounting both for the complexity of the content and potential cognitive deficits.

> "We didn't get very far at all, we probably needed 4-6 sessions to get through all the material and to make sense of it. This also depends on the client and you might be having shorter sessions as they can't concentrate" (Participant 5)

Although other participants managed to complete both a cognitive and behavioural technique in the two sessions, they wondered whether it had been psychologically meaningful for the client, and was unsure about the person's understanding of key concepts.

> "She was going to do a experiment, and then we were going to evaluate this - but I think it was too brief to do anything more meaningful than that" (Participant 1)

Participants also felt that while during the normal course of CBTp techniques are informed by a formulation and the individual's goals, in this case, they did not have the time to ground the techniques in this way. As such participants wondered whether techniques that may appear useful in the session might actually lead to little lasting cognitive or behavioural change.

> "So stand alone, in the session, it felt helpful and she was quite engaged with doing the pie chart and she reflected afterwards that was interesting, but to retain it and make any difference to her beliefs and/or behaviours in a lasting way, I'm not so sure those two sessions would cut it" (Participant 1)

Participants' experiences in this theme explored areas in which the intervention was thought to be lacking, particularly in relation to the task of facilitating understanding of

RBs. It is clear that clients would have benefitted from a more comprehensive CBT skill-set, in order for them to fully understand the intervention rationale. While the work needed to be linked back to wider formulation, time available was a significant obstacle to this.

4.2.4 Effectively impacting responsibility

A key objective of this feasibility study was to determine what parts of the manual were effective in targeting responsibility. Three sub-themes were identified from the data, these being: Visually representing responsibility, difficulties adapting behavioural techniques to psychosis, and the influential role of behavioural experiments

Visually representing responsibility

All participants agreed that the Responsibility Pie Chart was a powerful technique when working with this client group, feeling that its visual representation of responsibility made the material particularly accessible and meaningful. All participants agreed that they would use this technique again during CBTp, but that it needs to relate back to a wider formulation:

> "The pie chart can be used in conjunction with other techniques that you do over the course of therapy, but needs to be fed back" (Participant 5)

As discussed in the subtheme '*Clients socialisation to the model'* (Theme 3), participants felt that clients struggled to comprehend the continuum technique due to unfamiliarity with this way of working. Participants also felt that reliance upon verbal explanations rather than visual representations may have been problematic.

> "I think it would have been better to make the continuum more visual and reduce the words around it, I think visual techniques work better with this client group" (Participant 5)

Overall, participants felt that the Responsibility Pie Chart was a successful cognitive technique in reducing inflated RBs, in large part due to its visual nature.

Difficulties with adapting behavioural techniques for psychosis

Overall, it appears that participants considered behavioural techniques more difficult to adapt for clients with psychosis. None of the participants felt that the Responsibility Contract was suitable in this client group, and highlighted: i) the problem of testing delayed outcomes and ii) the power of clients' voices, as important considerations. All participants acknowledged the merits of the Responsibility Contract in people with OCD, while discussing its limitations.

> "I think the difficulty with the contract, I remember thinking – for some of my clients, either in the past, or the person in the trial, the feared consequence is a delayed feared consequence. So it doesn't work for this – as transferring responsibility onto me, you won't find out until he is 90" (Participant 2)

Participants also doubted if their clients would truly understand the Responsibility Contract as it felt very abstract to the participants, and so they felt that the client may struggle meta-cognitively as evidenced by the below extract:

> "We know cognitively people with psychosis might struggle with abstract thinking, so think the outcome measure and Responsibility Contract is cognitive demanding for psychosis population." (Participant 5)

Therefore, this sub-theme clearly states that the Responsibility Contract was not an appropriate technique to use with clients with psychosis.

The influential role of behavioural experiments

Although the Responsibility Contract was not considered an appropriate behavioural technique, all participants agreed that, as in any CBTp, it is important to implement both cognitive and behavioural strategies. Participants felt that other behavioural experiments in the manual helped clients to conceptualise and test out influential beliefs.

> "The other ones in the manual are helpful. When I talked about have they ever done [what the voices are telling them to do] he was able to tell me positive things that didn't come true – so that was helpful in order for us to think about what they do say and what comes true/doesn't and his level of responsibility around those things happening… (Participant 3)

In working with behavioural experiments, all participants emphasised the importance of a therapeutic relationship characterised by trust and the time to adequately establish the rationale. Although two participants did complete a behavioural experiment in the two sessions, all agreed that time was an influential limiting factor.

> "I think it was a bit tricky to try and find something that linked over to the next session, to do as a behavioural experiment. Just in two sessions." (Participant 1)

This sub-theme indicates that although behavioural experiments are an important part of CBTp, it was not feasible to complete them in a meaningful way in two sessions. Overall, this theme illustrates that certain techniques are perceived to be more effective than others in targeting RBs. While the Responsibility Pie Chart benefitted from its capacity to represent the central concept visually, the Responsibility Contract was considered unsuitable.

4.2.5 Barriers to Implementation

A key objective for this feasibility study was exploring potential barriers to implementation within services. Two sub-themes emerged from the data: burden to clients and burden to team.

Burden to Clients

Participants had contrasting views on whether the protocol was burdensome for clients. Some participants felt that the number of assessments was acceptable, and that coordinating these with routine appointments was helpful.

> "I didn't get that feeling [of burden] from clients because when they came in, they usually had another appointment" (Participant 4)

However, other participants considered there to be too many assessments, which were felt to impact both recruitment of potential participants and the validity of findings.

> "My client, you know, he disengaged slightly in the beginning. He agreed, and then refused. That was partly because the additional appointments that he would need to come for" (Participant 3)

On occasions participants tried to reduce the burden of additional appointments by cutting short their therapy sessions.

> "We tried to do so I had a half hour session and then the researcher goes to see him for the rest of it, so it doesn't feel like such a burden" (Participant 3)

However, one participant explored how limiting CBTp sessions in this way this could feasibly have implications for the client's understanding of the techniques used, and crucially the person's recovery more broadly.

> "I guess that is a risk with that many baselines that it does impact the engagement and maybe with therapy more long term" (Participant 2)

Participants discussed possible explanations as to why clients may not have wanted to engage with the assessments and intervention. A lack of understanding of the therapy and its intended benefits was suggested here.

> "I maybe there just needs to be enough, kind of, explanation before, so that they can really see that this is helpful to them, before then asking them to do the extra three [initial assessment] sessions" (Participant 1)

Participants disagreed as to whether the assessments should be considered burdensome for clients. This sub-theme illustrates how participants tried to problem-solve some potential issues (e.g. co-ordinating assessments with other appointments), but that there continue to be important considerations in this regard, which impacts on recruitment and engagement.

<u>Burden to team</u>

All participants agreed that from a service point of view, implementation of this intervention requires the support of an Assistant Psychologist (AP) or Research Assistant, in screening potential participants, promoting the study among care-coordinators, and completing assessments:

> "I would have found it much more burdensome without the AP" (Participant 3)

Participants also discussed the involvement of other MDT members, in the screening and assessment processes. Participants agreed on the importance of involving psychiatrists in screening to identify clients who have reported command hallucinations

during medical review, again with the support of an Assistant Psychologist. The possibility of involving care-coordinators in completing measures was also raised, a suggestion that relates to a sub-theme of Theme One: *buy into the study*.

> I wonder about more team buying in, going back to what we were talking about before, for example if we got the care-coordinator to see the client for a session after, that might have been more of a function for it, rather than just doing research, but then would involve a lot of co-ordination from the team, but then if the team was brought into it as well… (Participant 2)

This theme again indicates barriers to implementation, which relates back to previous themes and the importance of team "buy in".

4.2.6 Therapist Confidence and Familiarity

This theme describes participants' lack of confidence and familiarity with the study, and implications for recruitment and implementation. Two sub-themes emerged from the data: therapist understanding and the need for supervision.

Therapist Understanding

All participants described a relative lack of confidence – which may have impacted results - particularly around administering the VAS.

> "I was unsure about what I was supposed to be asking, and with the measures, not feeling quite 100% sure about you were doing" (Participant 1)

One participant expressed confusion regarding their client's specific responsibility belief.

> "I was thinking 'I'm not sure if I fully got this' – there were two ways where you could have framed his responsibility

> belief – I'm not sure which one I should be working on here" (Participant 2)

Participants also expressed the idea that their own lack of confidence with certain techniques should be a caveat for judgements and perspectives relating to the suitability of the techniques themselves.

> "Not sure if it is that not all of these techniques that are used in OCD are applicable to psychosis, or is it something about therapist competence and confident and needs to have further thought about how to adapt this to psychosis." (Participant 5)

Most participants suggested that more frequent meetings with the research team might have been helpful in building their own understanding, in turn potentially facilitating implementation.

> "I think there is something about our buy in as well – I feel that we now, after today and talking about it, I have more of a sense of the actual intervention, before, when we had the training / meetings – I'm not sure I had a good handle on it" (Participant 2)

Some participants felt that their own lack of understanding may also have hindered the recruitment process.

> "Now, if we could iron out the issues and make it more applicable to the client group, I think I would feel more comfortable selecting people and looking out for the right people" (Participant 3).

<u>The need for supervision</u>

The complexity of both the study and the client group meant all participants agreed that specialist supervision – or a balance of external and peer supervision -

during the intervention would have been beneficial in terms of implementation and recruitment.

> "Because of the complexity of psychosis the therapists did need guidance. During the intervention, if we had supervision we had more time to feed back and think about the protocol with more of a 'caseload' lens on, and what we know now and have it works, then would have been good – it's all learning isn't it." (Participant 3)

Three participants working within the same trust described the helpfulness of being able to engage in peer-supervision.

> "We had a chat about it for quite a while, so maybe some sort of group supervision would be really useful" (Participant 2)

However, one participant working in a different trust – and who felt comfortable with the study rationale - spoke about how external supervision around practical aspects would have been helpful.

> "Because of researching this for my doctorate, I was in a good position to be assessing and thinking who would suitable for this, but would have been nice to chat to someone else about some of my problems with implementing, like how to fit all that in the first session…" (Participant 5).

These extracts illustrate the need for on-going supervision – relating to practical and theoretical issues - in conducting a feasibility study.

4.2.7 Summary

The themes and sub-themes of the Thematic Analysis illustrate some significant barriers to recruitment, with time and the small potential pool of suitable clients as key factors. Therapist and team "buy in" to the study was a recurrent theme, with participants identifying the need for further training and support. Regarding the

intervention, participants discussed the appropriateness and acceptability of assessment measures and therapeutic techniques. While some – such as the Responsibility Pie Chart were considered helpful and effective, others require adaptation for use within this client group. The brevity of the intervention, and the complexity of concepts around responsibility, meant that while it was felt that clients would have benefitted from prior knowledge of cognitive-behavioural ways of working, therapists equally would have felt supported by more targeted supervision. Both these issues relate to participants' agreement on the importance of relating this work to a wider formulation, which though possible in a shorter time with OCD, was a difficult for participants implementing similar techniques in psychosis. Finally, participants pointed towards areas for future research, particularly around therapeutic mechanisms and capturing change.

CHAPTER 5: DISCUSSION

5.0 Overview

This section summarises the answers to the five research questions, and identifies strategies to address the noted challenges and/or revise components of the intervention where necessary. Strengths and limitations of the study are further discussed, followed by suggestions for future research. The clinical implications of the research are stated, and final conclusions follow.

5.1 Is recruitment and retention of participants for this intervention feasible?

Individuals with command hallucinations are notoriously difficult to recruit (Birchwood et al., 2014). There is also the added complexity of recruiting participants with RBs. It was felt that many teams needed to be approached to obtain sufficient numbers, to account for a relatively small pool of suitable participants and attrition. Although a large number of teams were contacted (twenty), only four opted in. The majority of teams considered themselves to be too stretched to facilitate research, which emphasises the pressure services are under in the current NHS climate. Many therapists were undergoing NHS England recommended further training at the time of recruitment, which again affected the availability of suitable clients for a research study. However, these factors relate to a particular set of present circumstances, and do not necessarily imply that recruitment would not be possible in the future. Regarding retention, two people dropped out during the assessment phase. One was due to language difficulties, and one disengaged from the service. The client that disengaged from the service was under the care of an EIS. Young adults are at high risk for disengaging from mental health services (Lal & Malla, 2015). It is stated that for the client group, service engagement is a complex and dynamic phenomenon that changes

in relation to stage of treatment, patient needs and developmental factors (Lal & Malla, 2015). We do not know if this client disengaged due to their engagement in the study, or if it was due to other circumstances. However, in order to conduct further research, a larger number of potential participants will be required to account for those who may disengage.

It was clear that expectations regarding the number of participants it was feasible to recruit for this study were unrealistic in the authors available timeframe, given that even where a client's presenting problems may suggest suitability they may not be psychologically ready for therapy. Therapists felt that many clients who were currently symptomatic, and who in theory would benefit from the intervention, were not possible to recruit for the study at that particular time. It was felt that the research team could potentially have had a stronger presence in the services, with the intention of keeping recruitment on the team's agenda. It would have been useful for the researcher to present the study to each of the potential teams involved, to raise awareness and increase understanding.

For the recruitment process to be feasible in subsequent studies, a longer recruitment period and a stronger presence within teams is required. The involvement of other members of an MDT - such as care-coordinators - in identifying potential participants would also represent an improvement to the strategy. In addition, therapists felt that having a psychiatrist more directly involved would have been beneficial, given that people experiencing command hallucinations on referral would routinely have a medical assessment in the early stages of their time with the EIS. Therefore, a combination of factors meant that recruitment was a challenge. In order to achieve the

requisite recruitment rates for a pilot or efficacy study, these challenges would need to be addressed.

5.2 Are the outcomes measures employed effective in capturing the impact of this intervention?

To answer this research question, the feasibility study aimed to evaluate the appropriateness of the outcome measures for the client group. The selection of outcome measures for an intervention study is challenging (Coster, 2013). Often, researchers select measures purely based on these having been used in relation to similar interventions or populations previously (Orsmond & Cohn, 2015). New measures may need to be developed alongside new interventions, and where this is the case they must be in alignment with the underlying theoretical perspective and hypothesised mechanisms of change pertaining to that intervention. Where a trial is not observed to be effective, it may be that the chosen outcome measure was not adequately sensitive, or congruent with the conceptual casual model (Orsmond & Cohn, 2015).

Standardised measures:

The most problematic standardised measure for participants to complete independently was the RIQ. Although the RIQ had previously been used in this population (Ellett et al., in press), participants in this research were found to have difficulty comprehending how the measure related to their inflated RB. After two participants struggled to complete the full measure, it was agreed that the conviction subscale alone would be used for subsequent participants, and at the post-intervention stage. A hallmark of feasibility studies is that procedures can be adapted as necessary during the process, to achieve the most promising results (Orsmond & Cohn, 2015). Following the adaption, participants demonstrated a greater understanding of the

measure, and this appeared to improve the validity of their responses. For instance, participants tended initially to rate all questions the same, but were later able to respond more meaningfully.

Regarding the remaining standardised measures, all were found to be useful in capturing change relating to participants' psychotic symptoms, OCD symptoms and general well-being. In hindsight, it would have been useful to administer the OCI before and after the intervention to determine whether levels of OCD had reduced. A formalised measure of client satisfaction should also have been employed in evaluating acceptability. This is discussed in the limitations section.

Un-standardised measure

Therapists in Phase 3 felt that the VASs were not sensitive to all areas of change. They proposed that failure to demonstrate a reduction in inflated RBs might have been attributable to the measure's inability to adequately capture emotional and behavioural impact, rather than the nature of the intervention itself as ineffective. Therapists reported a discrepancy between VAS responses and participants' qualitative feedback, which was indicative clients were better able to cope with inflated perceived responsibility and more able to pursue behavioural goals. The VASs were not able to reflect such outcomes. CBTp typically aims to reduce the distress associated with psychotic experiences and help clients work towards what they deem important, rather than attempting to reduce the frequency of those experiences per se (Morrison & Barratt, 2010). Accordingly, future studies in the area would benefit from the inclusion of a VAS scale evaluating behavioural change, such as: '*Am I able to take action consistent with my goals in life?'* Other important areas of investigation would relate to a potential reduction in safety behaviours, rates of compliance with commanding

voices, and the extent to which these outcomes are associated with inflated responsibility, distress and behavioural change.

Due to differences in presentation and symptomatology between OCD and psychosis, both the qualitative and quantitative results indicate that further work is required in identifying appropriate outcome measures for a potential pilot study, particularly with respect to the appropriateness of OCD measures in a psychosis population. Piloting all selected measures prior to undertaking this feasibility study would have been advantageous in overcoming some of the challenges encountered. The modifications described – as well as a period of field-testing - above would aid the development of measures effective in capturing the various ways in which targeting RBs may be influential.

5.3 Are the study procedures and the intervention acceptable and suitable for participants?

Acceptability and feasibility of the intervention was assessed via qualitative findings from Phase 3, and through participants' responses to a post-intervention semi-structured interview from Phase 2.

Assessments

Therapists had contrasting views on whether the length and number of assessments was acceptable for participants, with some feeling that the frequency of assessments required in SCED methodology may have impacted recruitment and attrition. It is well established that people with psychosis commonly suffer with difficulties in attention and concentration (Barch & Sheffield, 2014) which may be a factor in issues relating to recruitment and retention in this group. Therapists attempted

to ease the burden of assessment by cutting short their corresponding CBTp session, though such impact on routine care comes with a risk of impacting the usefulness of therapy, and is therefore not recommended for future studies. Although SCED methodology was employed to mitigate against risk, and was embedded within CBTp, this study has demonstrated no adverse effects, with no drop-outs during the intervention phase. For any potential future pilot studies, measures could be completed pre-intervention (all outcome measures), during the intervention (VAS measure, PSYRATS and WEMWBS), and at follow-up (repeat pre-intervention assessment). This would significantly reduce the number of assessments required.

Intervention Length

Consistent feedback - both from therapists and participants – indicated that the two-week intervention protocol was too short for participants to understand the rationale, fully utilise the techniques, and see any meaningful change. The study protocol was influenced by advances in the use of causal interventionism as a clinical and research strategy, and particularly by the pioneering work of Daniel Freeman (Freeman et al., 2016). In previous examples of this approach, each of the modules developed - for targeting constructs such as self-confidence, worry and sleep - were 6-8 sessions in length (Freeman et al., 2014, Freeman al., 2015; Freeman et al., 2015). This allowed time for techniques to be appropriately introduced, utilised and consolidated, and for the work to be linked back to the client's formulation and therapy goals. The shorter duration of this intervention meant that these processes were not possible in full, and future studies should allow for more time. In the absence of formal, on-going evaluation of acceptability and suitability, the intervention length was not adapted in real time to better meet participants' needs. This is a clear limitation.

Although researchers have discussed the adaptability of feasibility studies, which are able to proceed iteratively (Hagen, Biondo, Brasher, & Stiles, 2011) ethical challenges and time constraints make the implementation of this principle difficult.

Intervention Techniques

The psychoeducation worksheet, Responsibility Pie Chart, and adapted behavioural experiments appeared to be acceptable and feasible for use in this client group. The formulation in its current format and the Responsibility Contract were deemed to be unhelpful.

The psychoeducation worksheet was felt to be a helpful resource. Given that the focus of treatment in CBT is helping the client to adopt and test an alternative, less threatening explanation of their problems, most therapy techniques involve at least some aspect of reappraisal. A key component of this work is normalising clients' experiences, and in the case of OCD this is particularly true in relation to intrusions (Salkovskis, 1999). It is therefore unsurprising that participants found the worksheet helpful. Participant 3 for instance found that the psychoeducation material resonated with her experiences and *"made me feel that I was not alone"*.

The Responsibility Pie Chart was considered the most effective therapeutic technique. Therapists and participants alike found the visual representation of responsibility particularly accessible and meaningful. Participant 1 stated: "*there's a part of me that's questioning it more now because of the pie chart and because I saw it written down".* The experience of Participant 2 was similar: *"listing all the reasons made me feel less responsible"*. The Responsibility Pie Chart visually represents the principle of shared responsibility and illustrates varied sources of

responsibility proportionally. There may be neurobiological explanations as to why visual techniques are helpful to people with auditory hallucinations. It is thought that people who experience auditory hallucinations demonstrate an over-activity in the primary and/or secondary auditory cortices in the superior temporal gyrus, and altered connectivity with language processing areas in the inferior frontal cortex (Allen, Larøi, McGuire, & Aleman, 2008). The implication here is that this represents a more challenging context for verbal information to be processed, for which the Responsibility Pie Chart may be a suitable solution. This is in keeping with previous research suggesting the usefulness of this technique in people experiencing command hallucinations (Ellett et al., in press), and indicates its value either as a component of CBTp or as part of a stand-alone intervention targeting RBs.

CBT involves the interweaving of cognitive techniques and behavioural experiments (Salkovskis, 1999). Behavioural experiments promote greater cognitive, affective, and behavioural change compared with cognitive techniques alone, which lack an experiential component (Bennett–Levy 2003; Taylor & Reeder, 2015). Within anxiety disorders, behavioural experiments are intended to facilitate the disconfirmation of feared predictions and the development of new beliefs (Bennett-Levy et al., 2003; Salkovskis, 1991). Participants and therapists alike found the responsibility belief behavioural experiments helpful in the process of gathering alterative evidence and exploring the value of new perspectives on commands. Participant 1 stated that the behavioural experiment, though distressing, helped her to question the power and authority of voices: *"the voices want the bathroom door closed, but I left it open and nothing bad happened. I found it initially really stressful not to close the door but then it was really helpful, as I learnt that the voices weren't telling*

the truth, and actually, was I the one responsible anyway?". Given the central role of behavioural experiments in CBTp – particularly in discovering new information, consolidating learning, and feeding implications back into an existing formulation – future studies targeting RBs should prioritise this element of the work and ensure that the requisite time is made available.

Responsibility Contracts are commonly used in OCD (Radomsky et al., 2010), with the aim to facilitate a transfer of responsibility and therefore impacting the client's own perceived sense of responsibility. No therapist used this technique because all believed it to be unsuitable for the client group, particularly given that many clients feared consequences were far into the future, making testing difficult. Therapists also felt that participants would struggle with the metacognitive aspect, in that perceptions of voice power would make it impossible to surrender or apportion responsibility. Two of the participants endorsed paranoid beliefs that made these principles especially difficult to implement. For these reasons the Responsibility Contract was not considered suitable and is not recommended for use in future studies.

The vicious flower template is commonly used in OCD to help formulate a client's difficulties (Taylor & Reeder, 2015). Therapists felt that for this client group the formulation was too simplistic to account for both the complexity of psychotic experiences present and the specifics of OCD. All therapists felt that the work would be better linked back to their wider idiosyncratic formulation (e.g. Garety et al., 2001; Morrison, 2001), as is typically developed during CBTp. However, were this a stand-alone module, therapists felt that the Chadwick and Birchwood model (1997) would be appropriate in facilitating shared understanding, laying a foundation for this specific piece of work, and as a context to relate the implications of the work back to.

Requirements for future studies: pre-requisites before intervention

The number of therapy sessions completed before the RB intervention, as well as the content of those sessions, differed among participants. Overall, therapists felt that certain techniques (such as the continuum and responsibility belief behavioural experiments) were difficult to implement due to a lack of understanding for their rationale, meaning that the premise of these strategies could appear confusing for clients. Participant 2 from Phase 2 said: *"I didn't get ranking your responsibility. I didn't get the whole thing of you as a responsible person and putting yourself on a line, then connecting that with your voices, what does that even mean?"*

Therapists did not feel that clients were adequately socialised to the CBT model. As part of the inclusion criteria, participants were required to have had at least six sessions, including some work focussed on voices. However, the variable nature of an assessment and engagement period in CBTp meant that some clients will have covered relatively little material by session six, and where paranoia or engagement difficulties are factors to consider, direct work relating to voices may be in its fledgling stage, if established at all. As such, future studies in the area would benefit from a recruitment period stretching to mid-point in a person's CBTp, an amendment to this protocol that would lend itself well to a modular intervention. Therapists agreed on the following two therapeutic criteria as pre-requisites for a subsequent study: i) the development and sharing of a formulation, as a context for the RBs intervention; ii) completion of basic cognitive work (such as understanding cognitive biases) and a behavioural experiment (so that the rationale for and utility of behavioural experiments is understood).In summary, two sessions did not represent an appropriate length of time for clients to

develop a sufficient 'base level' of CBTp understanding, which in turn is required for the implementation of specific therapeutic techniques.

5.4 Is the implementation of this study and intervention feasible with respect to management and resources?

The current NHS climate – characterised by stretched resources - presents challenges for the implementation of novel research studies. Though more studies evaluating the suitability of interventions in real-world settings are advocated (Green & Glasgow, 2006), the methodology employed requires numerous assessments and the support of an Assistant Psychologist or Research Assistant. Future studies should therefore be conducted at sites where this additional resource is available. In addition to the requirement for experienced therapists who are familiar with the client group, supervision is an important consideration. Due to staffing constraints, specialist supervision was not provided for this intervention. Supervision facilitates reflection and learning regarding one's practice (Meaden et al., 2013), and therapists in Phase 2 highlighted how helpful supervision would have been as a resource in providing further training, assisting with adapting the intervention as appropriate, and in problem solving recruitment challenges.

The supervision arrangements in place for the COMMAND trial (Birchwood et al., 2014) are recommended. In that study, a system of individual weekly supervision was available, as well as multicentre group supervision on a fortnightly basis, and case problem solving facilitated by leading experts in the field (Meaden et al., 2013). While this level of resource is unattainable in the majority of settings, provision for group supervision with an expert in OCD would be highly beneficial for future studies.

5.5 Is the intervention useful and effective as shown by preliminary evaluation of participant responses?

Although evaluation of intervention outcomes is more the domain of a pilot study, researchers undertaking feasibility work are able to make tentative, preliminary evaluations of participant outcomes and responses, in order to determine the utility of proceeding further (Osmond & Cohen, 2015). This was achieved through visual analysis of the data, computation of the RCI/CSC, and qualitatively in a semi-structured interview format.

Visual analysis suggests small improvements from the baseline to the end of the intervention phase, and there were no areas of symptom worsening over this period. Between intervention and follow up, participants' scores either remained the same, or slightly improved (except for Participant 1's distress score and Participant 2's conviction score). These results should be interpreted tentatively given a decreasing trend (meaning improvement in scores) already apparent over baseline for certain participants (particularly Participant 3), making it difficult to draw firm conclusions regarding the impact of intervention. Few clinically significant changes were seen across the measures, suggestive that the intervention did not have the desired impact. The biggest improvement in reliable change and clinically significant change was on the RIQ, where all participants reached threshold for reliable improvement, and two participants showed clinically significant change. These outcomes map directly on to the study aims.

Qualitatively, participants reported finding the intervention helpful. Like the therapists, all participants identified the Responsibility Pie Chart as the most effective technique, due to its capacity to conceptualise responsibility visually. Despite their

continuing to experience a heightened sense of responsibility, Participant 2 described how the Responsibility Pie Chart helped her apportion responsibility more adaptively: *"Listing to all the reasons made me feel less responsible because it showed that I had a reason and it wasn't entirely my fault"*. Participant 3 found that the psychoeducation material resonated with her and *"made me feel that I was not alone"*. Participant 1 stated that the behavioural experiment (defying the voice by keeping a bathroom door closed), though distressing, helped her to question the power and authority of voices more generally.

5.6 Links to existing approaches in working with voices

The Chadwick and Birchwood model (1997) identifies how in the context of voice activity, one's appraisal of the experience - in relation to its power, authority and identity – is influential in bringing about emotional and behavioural consequences. Although, as discussed, a great deal of further research is required in establishing the precise role of RBs as an aspect of this conceptualisation, the literature to date (Dattilio, Edwards, & Fishman, 2010; Luzón et al., 2009; Ellett et al., in press), including the present study, is suggestive that responsibility may in the future be an important consideration – alongside power, authority and identity – for CBTp therapists seeking to impact the way in which a person's voice hearing experience is perceived and interpreted. If this is to be the case, then our initial findings highlight the possibility of the Responsibility Pie Chart coming to represent a helpful therapeutic technique, both in illustrating this principle and in addressing the problematic implications of heightened responsibility.

5.7 Study Strengths

A strength of this study was that it utilised a mixed methods approach, meaning that both quantitative and qualitative perspectives were explored in answering questions relating to feasibility. Whilst the majority of existing treatment studies have focussed on effectiveness, an intervention with low acceptability will inevitably face challenges in adherence and uptake. Mixed methods allow for triangulation of evidence that accounts for the perspectives of clients, clinicians and services more widely in evaluating a treatment program, and this approach is commensurate with a growing recognition of the importance of service user involvement in shaping the nature of services (Health and Social Care Act, 2008). The wider value of mixed methodology in evaluating feasibility is increasingly recognised. Although RCTs are considered the 'gold standard' in treatment effectiveness, case study designs and qualitative approaches offer the ecological validity and richness of contextual information that RCTs cannot (Dattilio, Edwards & Fishman, 2010). It is proposed that evaluation of psychotherapeutic treatments should always employ mixed method designs, comprising systematic case studies and qualitative exploration (Dattilio et al., 2010). SCED methodology allows for detailed and systematic investigation of change due to an intervention. Given the paucity of knowledge relating to RBs in command hallucinations, SCEDs offer a useful opportunity to explore these beliefs in depth, as their influence unfolds across the treatment process. A further strength of the current study was that all participants contributed the minimum number of baseline data points constituting a phase, as well as two data points at follow-up.

Treatment fidelity

While the flexibility for adaptation is an important characteristic of feasibility studies, and although the task of establishing fidelity is most likely undertaken at the pilot stage, attempts were made within the protocol to attain treatment fidelity, to better ascertain what is achievable in real world settings. For example, consent to audio-record sessions was requested, with the initial intention that two independent assessors would rate the tapes for protocol adherence. Where this was not possible, therapists agreed to complete both a Responsibility Pie Chart and a behavioural experiment; these two components conceptualised as core elements of fidelity across therapists and participants. While an OCD expert provided training in the manual to all participating therapists, initial plans for this expert to provide on-going specialist supervision could not be realised.

Group of participants

A further strength of this study was that participants - and therapists - were a fairly heterogeneous group (see Table 1). There was a range of cultural backgrounds, ages and durations of psychosis. Participants also varied with respect to the amount of treatment received prior to commencing CBTp, and the number of CBTp sessions undertaken previous to the RBs intervention. Equally, specific decisions around implementation – such as that to include participants who did not have a psychosis diagnosis (which accounts for many voice hearers in EI services) – contribute to the external validity of this research. Finally, the sessions were delivered by different therapists and within differing clinical settings.

5.8 Study Limitations

The strengths of a small sample, mixed methods design must also be weighed against the disadvantages of this approach.

Sampling

Due to a small sample size, the generalisability of findings is very limited. This research cannot be interpreted as pertaining to all individuals experiencing command hallucinations, and can only describe acceptability and feasibility in relation to the individual participants involved, across Phases 2 and 3. A lack of power means that any interpretations should be made with caution.

It is also important to note the selection bias inherent in exploring the acceptability of an intervention purely through the perspectives of people who have elected to complete the sessions. Low participant numbers, despite sample heterogeneity, compounds this issue. Similarly, given that the qualitative perspectives described in Phase 2 are likely to be skewed towards the positive - these having been contributed by clients who chose to complete the process - a useful follow-up study would be to interview clients who withdrew. One of the Phase 2 participants who dropped out was French, and spoke English as a second language. Whilst their level of English was deemed sufficient (and did not require the use of an interpreter), it is a general principle that therapeutic work is most effective when undertaken in the client's first language a factor that in this case may have impacted upon engagement.

Fidelity

Treatment fidelity is thought as both a strength and weakness in this study. As this was a feasibility study, it was hoped that the fidelity findings would inform feasibility. During Phase 2, fidelity was not formally assessed, given that participants did not consent to sessions being audio-recorded. This is a common finding in clients who experience psychosis (Birchwood et al., 2014). However, fidelity was measured as a result of therapists noting the techniques employed, and their rationale for these decisions. Although the sessions undertaken by Participant 3 did not achieve fidelity (no behavioural experiment was completed), the current study reflects the type of therapy received during routine care, whereby clinical judgement was not influenced by study participation. Finally, although these considerations are worthwhile, the task of establishing fidelity most traditionally occurs in the pilot stage (Orsmond & Cohn, 2015). For future studies – a brief measure designed specifically to capture fidelity to the RB manual could also be developed, which could be modelled from a well-established CBT adherence measure (such as the Cognitive Therapy Scale-Revised).

During Phase 3, the same researcher who developed the manual also carried out the process of Thematic Analysis. As such, their perspectives and philosophical positions are inevitably an influence and should be considered in interpreting findings. Future research would benefit from consultation with both service-users and an independent coder in the development of themes. Thematic Analysis commonly utilises independent coding as a quality check. The intention in most cases is not simply to demonstrate reliability, but rather to assist the researcher in thinking critically about the thematic structure in development, and the coding decisions that have been made. This process can help to identify where the researcher's assumptions and expectations may

have led them to overlook material that could enrich interpretation, and as such it represents a method of facilitating reflexivity (King & Horrocks, 2010; Wampold, Imel, & Miller, 2009)

Embedding in CBTp

As a novel treatment, and to safeguard against risk, the intervention was embedded within CBTp. There continues to be the possibility that a person's previous CBTp input acts as a confounding variable and influences responses. Participant 3 showed a clear improvement following the intervention, yet a trend towards improvement was already observable during baseline, making the later change more difficult to confidently attribute. Given that CBTp targets distress relating to voices, and seeks to establish effective coping strategies, the impact of the RBs intervention is not easily disentangled from the context of CBTp within which it took place.

Therapeutic Relationship

It can be a challenge to discriminate between treatment effects and factors such as therapeutic alliance, therapist skill, and the credibility of a therapy in the eyes of the client (Wampold, Imel, & Miller, 2009). Alliance has been shown to account for as much as 30% of therapeutic outcome (Norcross, 2000) and factors such as empathy and warmth are found to correlate more highly with outcome than specific intervention techniques (Lambert & Barley, 2001). It is possible that any change observed in the current study was influenced by therapeutic alliance, though no measure was utilised.

Measures

As previously discussed, therapists in Phase 3 felt that achieving belief change in relation to responsibility might be very difficult to achieve within two sessions,

particularly considering the complex presenting problems of participating clients. However, a change in behavioural response was thought far more likely. Therefore, VASs measuring behavioural change - for example relating to compliance - would have been more appropriate. It is hoped, following adaptations, that this measure could try and explore mechanisms of change.

OCI

The OCI was used in this study to establish either the presence or absence of OCD However, future studies may choose to administer the OCI at two time points (pre and post intervention), to explore change overall and relating to the subscales individually.

Importance of client feedback

Both the SCED results in Phase 2, and therapists' results in Phase 3 aimed to evaluate whether the intervention was useful and effective as shown by the preliminary evaluation of participant responses. However, the samples of respondents in Phase 3 (the therapists) were not the most appropriate means of exploring this research question. Interviewing the clients individually and analysing their responses using Thematic Analysis would have represented a more meaningful way of evaluating participant response and addressing the main questions of this feasibility study.

Although participants were asked for qualitative feedback following the intervention using a semi-structured interview, a formal measure of satisfaction may have been helpful in evaluating feasibility and acceptability. Participants were aware that the researcher developed the manual, and this may have led to some bias in responding. An adapted version of the Client Satisfaction Questionnaire (CSQ-8,

(Larsen, Attkisson, Hargreaves, & Nguyen, 1979) could have been employed in evaluating acceptability for these purposes.

PSYRATS Total Score

The auditory hallucination scale includes eleven items and gives a total score, which was used as a primary outcome. This is a clear limitation of the study. The total score sums a series of only modestly inter-correlated scales and introduces noise from variables that are not targeted in therapy (such as voice frequency and location) (Thomas et al., 2014). Whilst the PSYRATS scales provide a total cumulative score for each symptom, the multidimensional nature of the symptoms suggest that the total score should not be presented alone. The use of a total score for the PSYRATS results in the loss of interesting analyses in relation to symptom dimensions (Steel et al., 2007). In the context of a psychosocial intervention for psychosis it has been proposed that only the emotional items of the PSYRATS should be used as outcomes.

Factor analysis has yielded three independent factors for the auditory hallucinations scale: emotional characteristics, physical characteristics and cognitive interpretation (Haddock et al., 1999). However, the PSYRATS factor subscales have not been consistently used. This may be due to the previous inconsistency in reports of symptom dimensions, and the small sample size used by Haddock et al. (1999).

Given that emotional characteristics (such as emotional distress) is routinely the primary target for psychological interventions, this research would have benefitted from analysing key single items from the PSYRATS that are of more relevance

psychologically, such as distress, controllability of voices, and disruption to life caused by voices.

Large recent trials (such as Birchwood et al., 2014) analysed both the total score of the PSYRATS-AH subscale, but also pertinent single key items (e.g. distress and amount of negative content). In the most recent trial by Daniel Freeman (Freeman et al., 2016), the primary outcome measure was conviction in the persecutory delusion (using a 0 to 100 % scale), assessed using the conviction item within the Psychotic Symptoms Rating Scale-Delusions scale. Therefore, even where researchers wish to present PSYRATS data as a total score, authors should also make reference to the key single items relevant to a particular study (Steel et al., 2007).

Prematurity of a feasibility study

Research into RBs in psychosis is still in its infancy. Although an inflated sense of personal responsibility is hypothesised both as distressing, and as a potential mediator in compliance with voices, there is a possibility that this feasibility study has been conducted prematurely, without key mechanisms having been fully established.

5.9 Future Research

The present study is in keeping with a growing body of evidence suggesting that RBs play a transdiagnostic role (Tolin et al., 2006, Luzón et al., 2009). That is, they may be characteristic of psychopathology in general - as well as underlying or contributing to symptoms such as command hallucinations - rather than being associated solely with a specific disorder. Feasibility studies are used to determine whether an intervention is appropriate for further testing; in other words, they enable researchers to assess whether ideas and findings can be shaped to be relevant and

sustainable (Osmond & Cohen, 2015). In the current format – with no amendments - this intervention would *not be* suitable for further testing.

It is thought that inflated RBs may be a potential mediator in reducing clients' compliance with their voices (Ellett et al., in press), yet the precise role of RBs in command hallucinations remains relatively poorly understood, and further research is needed in clarifying this formulation (as mentioned in the limitations section). Further understanding is also required with regards to which connecting and influencing constructs are most influential in terms of distress and impairment for clients who experience commands. It may be that RBs are the construct that may be the most influential in bringing about distress, yet they may not. Significant further research is likely to be required in determining the degree to which RBs represent an important mechanism in clients' presenting problems, and to delineate the nature of this influence.

It is possible that an inflated sense of responsibility might mediate changes in levels of compliance with commanding voices, which might impact distress. It also might impact the power of the voices. The COMMAND therapeutic model seeks to help clients challenge existing beliefs about the power of voices, subsequently enabling voice hearers resist commands with important implications for levels of harmful behaviours and ultimately distress (Birchwood et al., 2014). Despite this being an evidenced hypothesis, and although command hallucinations are one of the most prominent and distressing treatment resistant symptoms (Shawyer et al., 2003), the full range of mechanisms by which it may occurs remain slightly unclear.

There is also the question of whether heightened responsibility is a trait vulnerability factor for command hallucinations, which previous research has prematurely highlighted (Luzón et al., 2009). For example, do people with commands

already have maladaptive RBs, or do inflated RBs arise as a consequence of hearing commanding voices and other contextual factors. A both/and - rather than either/or - perspective is perhaps merited, whereby people with CHs may already experience an elevated perceived responsibility, which is subsequently triggered and maintained through the processes of their voice hearing. It is also important to state that heightened responsibility may also not be a trait vulnerability factor. In any case, future research in this area would benefit from building on existing literature pertaining to pathways into responsibility beliefs (Salkovskis et al, 1999).

Five primary pathways to the development of problematic responsibility beliefs have been proposed (Salkovskis et al., 1999), which include: (1) heightened responsibility as a child; (2) rigid and extreme codes of conduct as a child; (3) overprotective and critical parenting; (4) incidents in which one's actions or inactions caused a serious misfortune; and (5) incidents which appear to bring about harm but are actually coincidental. The Pathways to Inflated Responsibility Beliefs Scale (PIRBS) is a self-report measure of childhood experiences, devised by Salkovskis et al., (1999). These factors are hypothesised to be influential in the development of beliefs about responsibility (Coles & Schofield, 2008) and have been used to explore pathways to responsibility in OCD (Smári, Thornorsteinsdóttir, Magnúsdóttir, Smári, & Olason, 2010). Future research could explore the validity and reliability of this measure in people who experience auditory hallucinations, in the hope of more clearly determining the origins of heightened responsibility in psychosis, and with potential implications for cognitive-behavioural interventions.

Although future research is required to clarify the role of RBs in psychosis, this study has shown that there is a subsection of individuals with psychosis where a focus

on RBs in merited and this work is not currently a regular component of CBTp. This research is intended to add to the existing small evidence base, and leaves two possible routes for how to proceed in meeting the needs of clients who do present with heightened perceived responsibility:

1. To employ established techniques like the Responsibility Pie Chart within CBTp, to target RBs in the hope of reducing distress and compliance.
2. To further develop this protocol and intervention, in part by making all the necessary amendments discussed, and to further test its feasibility.

Both routes need further thought and have clinical implications.

5.10 Clinical Implications

While interpretation of the results here should remain tentative, it is possible to some suggestions for clinical practice. Evidenced psychological therapy for people with psychosis is CBTp, the prominence of which is based on a series of meta-analyses. CBTp is reported to be moderately effective in reducing the severity of positive psychotic symptoms (Wykes et al., 2008). However, results from trials of CBTp do not consistently report significant improvements in voice-related distress (Wykes et al., 2008). Indeed, the largest systematic review indicated substantial heterogeneity (Jauhar et al., 2014). It has been argued that future trials in CBTp should move away from the conventional goal of reducing psychotic symptoms, and focus more wholeheartedly on the principle aim of CBT: that is, impacting affect and behaviour (Birchwood et al., 2014). The COMMAND trial has led the way for utilising this approach in auditory hallucinations, and might be considered a model for the next generation of intervention trials in psychosis (Birchwood et al., 2014).

The present study contributes to an understanding of the impact of command hallucinations, and is in keeping with a modern causal-interventionist approach to developing psychological interventions that target distressing voice hearing through key cognitions and constructs (Birchwood et al., 2014). Studies suggest that targeting underlying processes, rather than symptoms, is more beneficial (Kuipers et al., 2006) The results suggest that although the module is not feasible in its current format, following the adaptations described above it has the potential to be a helpful and accessible psychological treatment for this client group. The goal of increasingly understanding the processes by which commanding voices promote compliance and lead to distress and impairment is an important one, given that even the best evidenced psychological (and pharmacological) treatments are only partially effective, and were RBs to be established as influential, therapeutic strategies addressing them could either be integrated into CBTp, delivered as a stand-alone intervention, or undertaken in combination with other modular approaches such as those targeting compliance (e.g. Birchwood et al., 2014). Even if further feasibility studies are not conducted, clinicians have stated that the adapted Responsibility Pie Chart is a helpful and well-received technique that they will look to incorporate into on-going therapy.

5.11 Conclusions

This research has addressed the main objectives of a feasibility study, and has concluded that a pilot study should not be conducted at this stage, due to the substantial adaptations required. Before another feasibility study in the area is merited, further research is required in delineating the concept of inflated responsibility, which is not yet established as a causal mechanism in the impact of voice hearing. The nature of this research as a feasibility study, and the challenges to implementation described, mean

that our findings cannot greatly contribute to any theoretical advancement in understanding the intersection of voice hearing and perceived responsibility. However, considering that i) research into voice hearing and responsibility is at a very early stage (with some promising findings published), ii) causal interventionism has been shown to be an effective strategy, and iii) providing that the recommended adaptations to this study were made, the pursuit of clinical approaches to target responsibility in this group remains a clinically important aim.

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APPENDIX A - Manual

Version 1: 11.05.2016

CBTp MANUAL:

Targeting Responsibility Beliefs in Psychosis

Therapists Information

Therapist Information

Background

The psychological processes associated with anxiety disorders have contributed to our understanding of psychosis (Freeman & Garety, 2003). It has also led to the development of cognitive models of psychosis (Garety, Kuipers, Fowler, Freeman, & Bebbington, 2001). Morrison (2001) proposes that negative interpretations of hallucinations are related to anxiety and associated safety seeking behaviours in psychosis. This pattern is also identified in cognitive models of OCD (Salkovskis, 1985), where negative interpretations of intrusive thoughts are hypothesised to drive anxiety. In addition, there are high levels of co-morbidity between psychosis and OCD (Braga, Mendlowicz, Marrocos & Figueira (2005), and they do seem to share common transdiagnostic processes.

A key psychological process maintaining OCD symptoms is a heightened sense of personal responsibility for feared harmful events (Salkovskis, 1985). Research has examined the role of responsibility beliefs (RBs) in psychosis. In the first study exploring this, Luzon, Harrop and Nolan (2009) found that clients who were in an acute stage of a psychotic illness reported significantly higher sense of RBs than individuals with the same diagnosis but were currently stable and non-clinical controls. It was thought that such beliefs could pose vulnerability to the development of psychotic episodes and associated distress. Subsequently, in the largest study to date (n=156) individuals with both commanding and non-commanding voices exhibited higher levels of RBs than non-clinical controls and clients with OCD (Ellett et al., in submission). Hearers of commanding voices had highest levels of RBs overall. This was also linked to an increase in distress. An increase in RBs and subsequently distress is a consistent finding in this client group (Ellett et al., 2016). These studies also found that people that hear voices hold themselves almost entirely responsible for any potential harm resulting from not complying with their commands, whilst they shared this responsibility almost 50%-50% with their voice if anything bad happened as a result of complying with the command. Responsibility beliefs might, according to these data, be a driver for compliance with command hallucinations, and maintaining unhelpful safety seeking behaviours (Ellett et al., 2016). Cognitive Behaviour Therapy for psychosis (CBTp) seeks to address particular beliefs and behaviours in order to alleviate associated distress. A greater understanding of the maintenance factors implicated in voice-hearers' distress may lead to better focused therapeutic approaches (Birchwood et al., 2014).

Aim

Treatment for RBs in OCD is well established (Salkovskis, 1999), and includes techniques such as devising responsibility pie charts and continuum techniques. Whilst these well-established cognitive techniques are routine elements of CBTp (Morrison, Renton, Dunn, Williams & Bentall, 2003), no study to date has used them as an additional treatment component in psychosis to focused on RBs. The aim of this study is to test the feasibility and effectiveness of adding a treatment component targeting RBs to existing CBTp within routine clinical practice, in the form of two added treatment sessions. The project will employ a single case methodology and will recruit from two inner London NHS Trusts.

Structure and Timing

This intervention consists of two sessions targeting beliefs about responsibility of harm within an empirically validated treatment of psychosis provided in routine clinical practice. In order to allow individualised treatments and flexibility in the application of the strategies suggested here, it is a clinical decision as to when specifically this intervention will be most

suitable for each patient; however, it is suggested that typically will be offered after sessions covering: symptom specific assessment, engagement work, psychoeducation, some work on delusions/ hallucinations, and possibly other topics such as anxiety management, problem solving, activity scheduling, graded exposure, relaxation, or other behavioural skills training, but could also be provided before those if deemed appropriate by the treating clinician.

Intervention

This manual has been informed by existing CBTp manuals and effective treatments for targeting responsibility beliefs in people with Obsessive Compulsive Disorder (see references below for more information). It is designed to be used by experienced clinicians that already have a sound knowledge and training on CBTp and regularly provide this treatment under supervision within an NHS setting.

The intervention is accompanied by patients' worksheets that can be found at the end of the manual. The current manual provides details of specific cognitive and behavioural strategies that have been developed for targeting similar beliefs in people with OCD. It is up to the clinician to decide which of the following strategies would be most suitable; however, it is suggested that strategies aiming at developing an understanding of the role of responsibility beliefs (cognitive strategies) will precede those requiring behavioural engagements. In addition, it is important that every intervention includes, whenever possible, the use of Responsibility Pie Charts and Responsibility Contract/Behavioural Experiment.

Treatment Goal

The goal of this module is to:

1. Develop a shared understanding with the patient about the role of responsibility beliefs in maintaining their distress and driving unhelpful behaviours (e.g., safety seeking, checking, compliance, etc.);
2. To collaboratively explore evidence for and against their responsibility beliefs with the aim of achieving a reduction on belief conviction of maladaptive responsibility beliefs;
3. To collaboratively design and carry out experiments to test out and gather evidence about their responsibility beliefs; and
4. To help patients generate alternative explanations and thoughts that are helpful and healthy.

Therapists' Role

Recruitment

Clients will be recruited from the therapists' service CBTp assessment wait-list (or their caseload) and fit the following criteria:

Inclusion criteria:

Aged between 18 and 65 years, able to read and write in English, and capable of informed consent. They will have active positive symptoms of psychosis (be either currently hearing voices)

In the client's initial assessment with the team, beliefs indicating high levels of responsibility will be assessed by four questions (these questions can be seen in the accompanying documents). Responsibility beliefs are needed to warrant inclusion into the intervention.

Exclusion Criteria:

We will exclude patients if their risk assessment indicates it is not safe for the researcher to interview them, or if the interviews would be too taxing and distressing for them, and/or they have learning difficulties (LD) (considering that the study looks at cognitive processes). Patients with organic brain disease or injury will also be excluded (considering that the study looks at cognitive difficulties). Patients with a primary diagnosis of PTSD or Personality Disorder will also be excluded.

All possible efforts will be made to include people from a variety of ethnic backgrounds and whose English is not their first language. However, in the light of the lack of psychometrically valid translations of the questionnaires used for data collection, if someone's level of English means that they cannot answer the questionnaires we will be unable to offer translated versions, and therefore they will be excluded from the study.

To help identify clients with responsibility beliefs, we have devised screening questions that may help aid recruitment during the assessment stage. These can be added into your normal assessment from referral.

1. Do you sometimes fear something bad will happen to you/someone else/the world? If so, who would be responsible for that bad thing happening?
2. Do you sometimes feel the urge to do things to keep you/others safe?
3. If you were not able or decide not to comply with your voices, and something bad would happen as a result who would be to blame? How responsible would you feel? 0-10.
4. Are you ever troubled by distressing feelings of guilt? If yes, do you feel guilty when you don't do what the voices tell you to do?

Training

To attend half a day training session focussing on the delivery of the manual.

Therapy

To provide the two session intervention following the manual, whenever possible taping the sessions, and to complete end of sessions notes.

Process and Outcome Measures

The researcher will conduct an assessment at baseline and follow-ups and will collect the outcome data. However, we require clinicians to record process measures in the form of visual analogue scales during the sessions and the PSYRATs-AH and WEMWBS. The clinician also needs to complete the OCI prior to the assessment start. We will also ask clinicians to record the specific strategies they have used in the sessions as documented in the manual.

Worksheets

A number of worksheets are included at the end of this manual to facilitate the clinical work undertaken in the session. Copies of worksheets should be given to clients at the end of the session and also kept on their clinical notes.

Relevant References

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CBTp MODULE:

Targeting Responsibility Beliefs in Psychosis

Therapist Manual

6

Session 1

Date: _____ Patient's ID:_____ Therapist ID: _____ CBTp Session No: _____

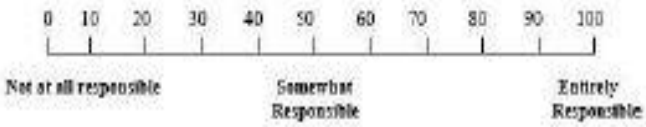
Agenda: FYI: Point 6 is not prescriptive, please do the psychoeducation and pie chart. The behavioural techniques can be done next session, but if you feel it is appropriate to set them up as homework, please do)

1. Progress, Mood and Homework review
2. Re-obtain informed consent for the study
3. Start audio-taping if consented
4. Shared agenda including the aim of the session and go through the psychoeducation worksheet.
5. Identify their responsibility belief (and to rate the process measures)
6. Main cognitive and/or behavioural strategies (please see strategy section and worksheets):
    a. Use the psychoeducation worksheet to help link responsibility belief with formulation (e.g. using a vicious flower)
    b. Pie Chart
    c. Behavioural Techniques
7. Summary of the session
8. Homework task (fill in the Session Summary and Homework Worksheet)
9. Process measures (Visual Analogue Scales), PSYRATs (just section A- voice hearers) completion and WEMWBS to fill in at the END OF THE SESSION

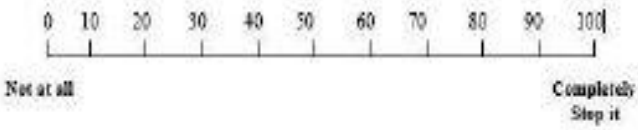
At the start of the session:

Responsibility belief (Please identify and rate) _____

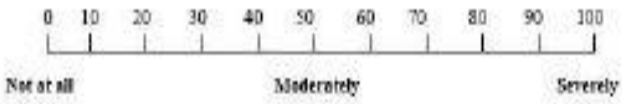
1. If something bad happened tomorrow to you or someone else you know, how responsible would you feel about it?



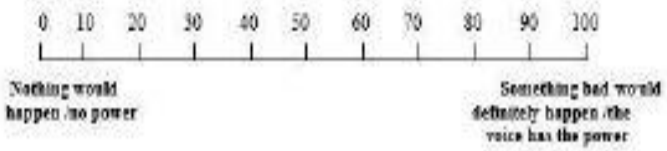
2. How much do you think you can stop this bad thing from happening?



3. How distressed do you feel about the belief?

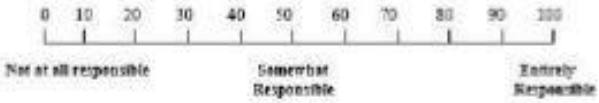


4. How much do you believe that something bad would happen to you or someone else if you did not do what the voices tell you to do (e.g. the voice has all the power/or you do)

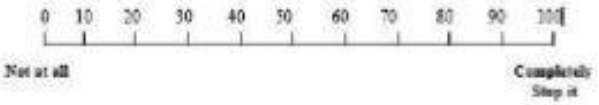


At end of session: Rerate the same RB

1. If something bad happened tomorrow to you or someone else you know, how responsible would you feel about it?

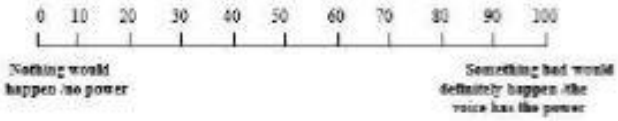


2. How much do you think you can stop this bad thing from happening?



3. How distressed do you feel about the belief?

4. How much do you believe that something bad would happen to you or someone else if you did not do what the voices tell you to do (e.g. the voice has all the power/or you do)



Clinical Observations:

Question for the therapist to fill out at the end – we will be having a debrief session around April time though but it might be useful to fill this in at the time for that particular client so you remember later down the line.

1. What techniques did you use in this session?

_____
_____
_____
_____

2. What was helpful about the techniques?

_____
_____
_____
_____

3. What was not helpful about the techniques?

_____
_____
_____
_____

Session 2

Date: _____ Patient's ID:_____ Therapist ID: _____ Session # CBTp: _____

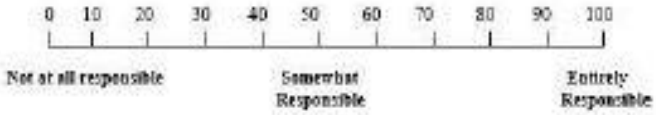
Agenda: Point 5 is not prescriptive – please do what you can with your particular client.

1. Progress, Mood and Homework review
2. Re-obtain informed consent for the study
3. Start audio-taping if consented
4. Shared agenda including the aim of the session and re-establish the main RB you are working on.
5. Main cognitive and/or behavioural techniques
    a. Reviewing/complete behavioural techniques
    b. Continuum Technique if time
    c. Review pie chart technique if time
6. Summary of the session
7. Homework task (e.g. generalising the learning and implementing it in any future sessions – could set another responsibility pie chart for example)
8. Fill in the Session Summary and Homework Worksheet.
9. Process measures (Visual Analogue Scales), PSYRATs (just section A- voice hearers) completion and WEMWBS AT THE END OF THE SESSION

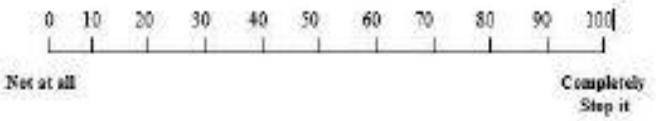
At the start of the session:

Responsibility belief (state) _____

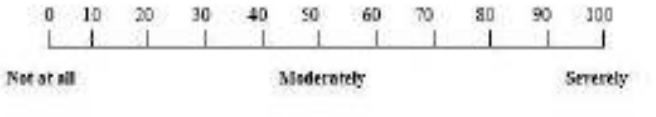
1. If something bad happened tomorrow to you or someone else you know, how responsible would you feel about it?



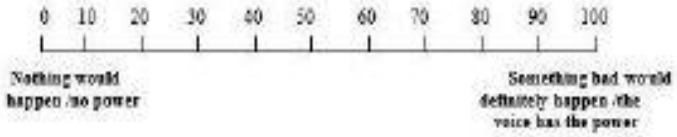
2. How much do you think you can stop this bad thing from happening?



3. How distressed do you feel about the belief?

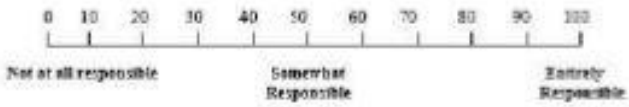


4. How much do you believe that something bad would happen to you or someone else if you did not do what the voices tell you to do (e.g. the voice has all the power/or you do)

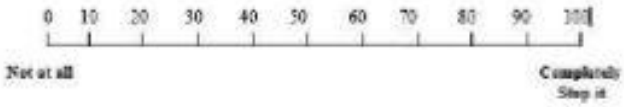


At end of the session, rerate the responsibility belief:

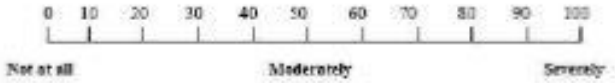
1. If something bad happened tomorrow to you or someone else you know, how responsible would you feel about it?



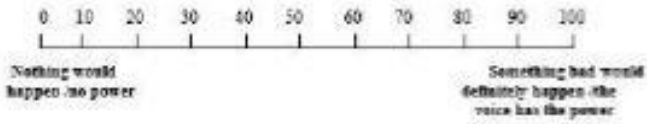
2. How much do you think you can stop this bad thing from happening?



3. How distressed do you feel about the belief?



4. How much do you believe that something bad would happen to you or someone else if you did not do what the voices tell you to do (e.g. the voice has all the power over you do)



Clinical Observations:

Question for the therapist to fill out at the end:

1. What techniques did you use in this session?

_____
_____
_____
_____
_____

2. What was helpful about the techniques?

_____
_____
_____
_____
_____

3. What was not helpful about the techniques?

_____
_____
_____
_____
_____

STRATEGIES

15

1. Psychoeducation and Formulation

Aim:

Ensure a shared understanding between the client and the therapist on the role of RBs by providing some psychoeducation and linking it with their working formulation. It might be helpful to use a vicious flower worksheet to help with this (see worksheets below).

2. Responsibility Pie Chart

Aim:

The aim of the pie-chart strategy is to help redistribute responsibility.

It is useful to give the client a few examples of how to assess responsibility.

An example could be: "If somebody/ a friend was broken into, whose responsibility would be it?" "How responsible would be everyone that lived in the house be" "How responsible would the burglar be?" "How responsible would somebody/your friend be for the break in?"

Setting up the Responsibility Pie Chart for the client: Please adapt this for commands/non command clients

Prompts: Who do you think was responsible for you doing/not doing what the voice asked you to do?

Is there anyone or anything else responsible for you doing/not doing what the voice tells you to do? (If they don't identify themselves, prompt)

If something bad did happen because you didn't do what the voice said, who would you say is responsible for this bad thing happening?

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

And now thinking about these people / things that you identified as responsible (prompt if they've forgotten), how much would you say each was responsible, if you have to give a percentage to them? You don't need to give a percentile – you can just visually draw it out without.

[Let client/you draw this out] – please use the accompanying Responsibility Pie Chart sheet

Addressing their Responsibility Pie Chart:

- Make a list of all possible factors that could account for the outcome
- Assign percentage responsibility to all factors and include these in a pie chart
- Assign the percentage relating to the participant's responsibility last
- Now try and link this with a BE.

3. Behavioural Techniques- Responsibility Contract and Responsibility Belief Behavioural Experiment

The behaviours techniques can be less prescriptive than the cognitive techniques. It is important to remember the aim and what we are testing out: 'I can cause things to happen' (positive and negative things) rather than focusing on the feared negative responsibility belief, as we may not be able to test this out behaviourally.

Decide together what you and the client can do (or the client individually at home) and test whether reducing compliance also reduces responsibility belief and associated distress.

It is important to link back to the formulation here to explain why we are testing this out behaviourally (as we are predicting that responsibility beliefs lead to distress, and the compliance and other safety behaviours maintain this)

It may helpful to fill out the behavioural experiment sheet which is included in the worksheet section.

Responsibility Contract

Aim

The aim of the responsibility contract is to facilitate the transfer of responsibility and reduce the responsibility belief. The therapist will help the client draw up two responsibility contracts, one where the client accepts all responsibility for the feared event and a second one where the responsibility is shared between the client and therapist. It is important that all therapists refer to the videos in Radomsky, Shafran & Rachman (2010), which they will have watched during the training session.

This contract should only be used for a specific feared catastrophe over which it is clear that neither the participant nor the clinician could have any control. Therefore the contract will only refer to situations where the outcome is independent of the client's own actions (for example: the end of the world, natural disasters, their house getting burgled or transport crashes).

Psychoeducation around what we mean by "responsibility beliefs" will be important at this stage, so that the term heightened responsibility is not confused with responsibility for actions.

How to set the contract up with the client (Adapted from Radomsky, Shafran & Rachman, 2010)

We are now going to be doing a different type of technique, we call this an experiment. I was wondering if we could do some work on changing how responsible you feel.

I thought it may be helpful for us to fill out a contract in order to help shift the responsibility that you feel.

The first thing we need to do on the contract is agree on a date and a proportion of responsibility. So what we will do is pick one day where you will be completely responsible for (X), and we will put it in writing. So, as it says here:

"I agree to have 100% responsibility for X. For any harm or danger that might result (SPECIFY THE FEAR), I take full responsibility for on (INSERT DATE)"

Which day shall we make this contract active? (INSERT DATE). There is a place here for you to sign. There is a place for me to sign.

The next part of the experiment is to transfer some of the responsibility to me. So it has the same words but instead says "I agree to share responsibility for (X-belief) with (X the therapist) on (X) date. This results in me agreeing to accept more than X responsibility for this particular outcome during this time.

So first of all, how much responsibility can you give me for one day for (INSERT BELIEF)

After agreeing the percentage of responsibility, then both therapist and client to sign the contract. This will be the homework for the week.

Responsibility Belief Behavioural Experiments

As mentioned earlier, we need to make clear that we are testing out the general belief of 'I can cause things to happen' (both positive and negative) as it may be difficult to test the feared responsibility belief out.

This can be either in session with someone, or set up the week before.

If someone is hearing voices for example in the session, a behavioural experiment would be to get the person to not listen to their voices (for example for two minutes). A responsibility belief rating / compliance/ distress rating could be conducted before and after this experiment.

If someone is not hearing voices in session, another way of trying to manipulate responsibility could be:

1) Take belief ratings of responsibility of causing a negative event (could link it to their specific responsibility belief, or general overall responsibility)
2) Complete a behaviour intervention that reduces the perceived ability to influence positive events (e.g. prove that you can't cause a positive outcome) by thinking about it – for example thinking that someone is going to bring a cake into the room/ that a bird will fly into the room. Another way could be to set this up would be using the lottery example below.
3) Re-rate the belief ratings of responsibility of causing a negative event.

An example of this could be (to set this up the week before by buying a lottery ticket)

Imagine that a person feels that they are responsible for a fire happening at their house because the voices said there would be if they didn't do the voices told them to do. A rating of perceived responsibility for this negative event (say the person says 80% responsible) is firstly taken. Then a belief rating for a positive event is also taken – for example how much does the person believe they would be responsible for winning the lottery if the voices said they would win the lottery if they didn't do something (for example the person says 60%). Other cognitive techniques will then be used to show how the participant cannot influence or hold responsibility for winning the lottery. The negative

responsibility belief is then re-rated, and we are looking to see whether the 80% responsibility for negative events shifts through your work on the positive events.

4. Continuum technique

Aim:

The continuum technique is designed to reduce black and white thinking and introduce flexibility of thought (e.g. I am 100% responsible to I am 100% completely irresponsible).

Setting up with a client:

If you don't wish to start with responsibility, sometimes it is helpful to start with drawing a visual analogue scale with the anchors "Best person I know" and "Worst person I know" on the opposite end points:

Worst person — Best Person

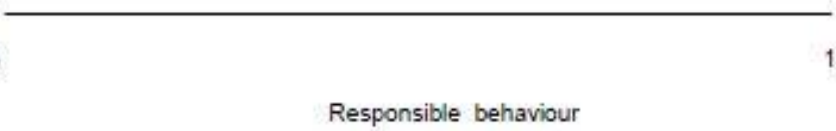
The client is then asked to place him or herself on that continuum and to identify a number of other people who provide a range of "goodness" on the continuum.

A second continuum is drawn, directly underneath the first one, with the anchors "most responsible person I know" and "least responsible person I know." The people who were rated in the first continuum are reassigned spots on the responsibility continuum.

Least responsible — Most responsible person

Each case often has one or two instances of a striking lack of correlation between "goodness" and "responsibility" (i.e., someone who is quite good but also irresponsible, and/or someone who is high on the responsibility end but low on the goodness end). Clearly, this double standard should be identified and followed. Discussion around the double standard may identify additional feared consequences specific to the patient and not to others (i.e., that somehow it is worse for the patient to be irresponsible compared to others)

Finally, we want the client to look at their own behaviour and what constitutes as responsible behaviour.



Ask the client to provide examples of behaviours that would qualify for each of the extremes and for the middle point of the scale. It should become clear fairly quickly that both extremes of the scale can be problematic because they represent absolute thinking. Many situations require judgement to deal with competing responsibilities. Use this scale to determine what degree of responsibility your client considers reasonable in some situations and to identify where your patients actual responses would lie. Determine whether your client's earlier evaluation of these behaviours with regard to responsibility matches his or her rating of them on this new scale.

WORKSHEETS

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Psychoeducation: Responsibility Beliefs

Sometimes people blame themselves for a feared event that may happen. They may also give themselves more than their fair share of that blame and responsibility. This then can cause people to feel even more upset.

From working with people who hear voices, we know that sometimes people believe they would be fully responsible if something bad happened as a result of not obeying/doing what their voice told them to do. We also know that people feel responsible for bad things happening when they obey/do what the voice told them to do also.

Therefore we think that one of the key features of people that hear voices is that they have something called an 'inflated sense of responsibility' or 'responsibility beliefs'.

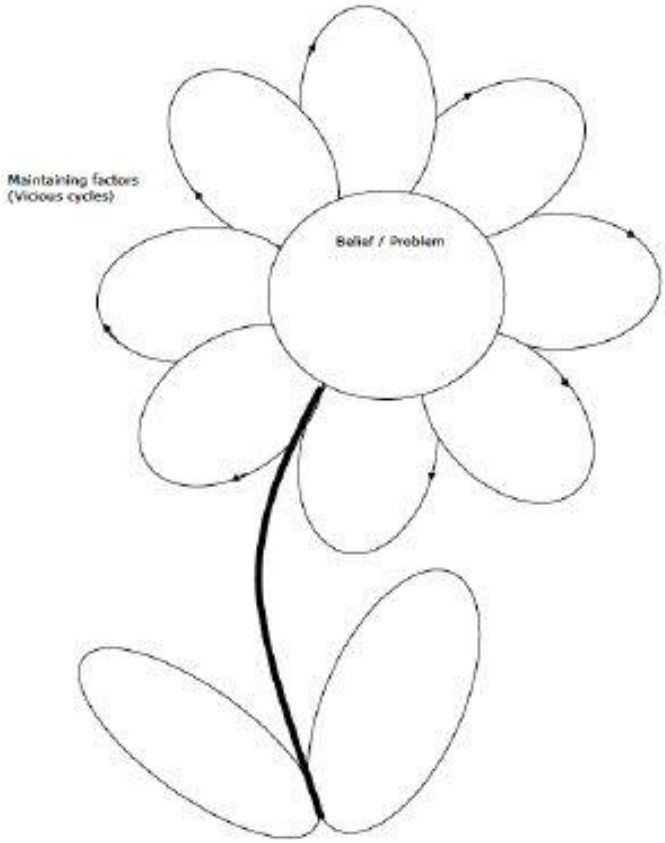
A definition of this is:

The belief that you have the power to bring about or prevent negative things from happening

By having an inflated sense of responsibility we know that also causes people to feel more upset.

Therefore in the next two sessions, we are going to focus on helping you to re-evaluate your sense of responsibility that you may possibly feel and how useful it may or not may be. We are going to be using techniques that are similar to ones you have used so far in therapy and ask you to practice them in between sessions like you have been doing already.

Vicious Flower



Continuum Technique

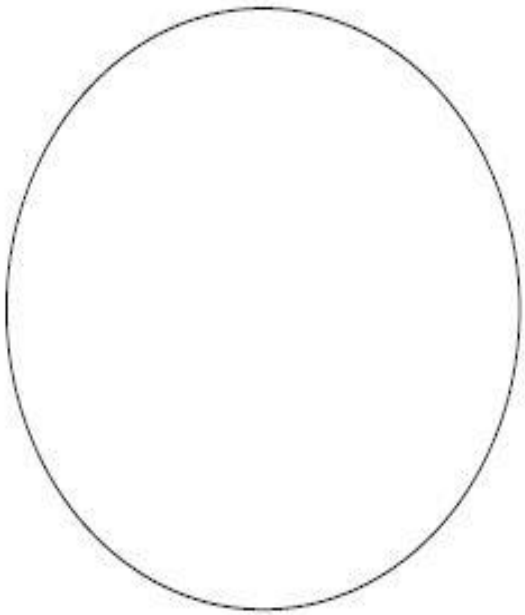
Least responsible — Most responsible person

0% Responsible Behaviour — 100% Responsible Behaviour

Responsibility Pie Chart (x 2)

Who would you say is responsible for this bad thing happening?

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____



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Responsibility Belief Behavioural Experiment Form

Patient's ID_____ Date_____

Belief to be tested:

_____

Behavioural experiment to be completed (either in or out of session):

_____

Feared consequences:

_____

Strength of belief in the feared consequences (0-100%):_____

Discomfort at the beginning of the experiment (0-100%):_____

Alternative prediction:

_____

What did actually happen?

POSITIVE AND NEGATIVE BELIEF RATINGS

What is the negative responsibility belief: _____

What is the positive responsibility belief: _____

1. Rate negative responsibility belief _____
2. Rate positive responsibility belief _____
3. Re-rate negative responsibility belief _____

Responsibility Contract

Patient's ID_____ Date_____

Proportion of responsibility to hold: _____

Responsibility for:

I (INSERT THERAPIST NAME) agree to have 100% responsibility for X (INSERT FEARED CATASTROPHE). I agree to take full responsibility until (INSERT DATE).

This contract will only apply to the specific feared catastrophe referred to below

Signatures:

Therapist: _____

Client: _____

Shared Responsibility Contract:

Date: _____

Proportion of responsibility to be transferred to the therapist: _____

Responsibility:

I agree to share responsibility for X this (insert date) with X (person – the therapist). This results in my agreeing to accept more than X responsibility for this particular outcome during this time.

Signatures:

Therapist: _____

Client: _____

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Session Summary & Homework Sheet

Patient's ID_____ Date_____

Session Summary:

What was most helpful today:

Things I agreed to do until next session:

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APPENDIX B – Approval Letters and Information Sheets

NHS
Health Research Authority
London - Camberwell St Giles Research Ethics Committee
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 02071048044

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

20 September 2016

Miss Rosanna Michalczuk
Trainee Clinical Psychologist
Camden and Islington NHS Foundation Trust
4th Floor, East Wing, St Pancras Hospital, 4 St Pancras Way, London
NW1 0PE

Dear Miss Michalczuk,

Study title:	**A pilot study of a two session responsibility intervention for auditory hallucinations.**
REC reference:	**16/LO/1439**
IRAS project ID:	**212222**

Thank you for your letter of 8th September 2016, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Assistant, Mr Alex Martin, nrescommittee.london-camberwellstgiles@nhs.net.

NHS
Health Research Authority

Miss Rosanna Michalczuk
Trainee Clinical Psychologist
Camden and Islington NHS Foundation Trust
4th Floor, East Wing, St Pancras Hospital, 4 St Pancras Way, London NW1 0PE
NW1 0PE

Email: hra.approval@nhs.net

30 September 2016

Dear Miss Michalczuk

Letter of HRA Approval

Study title:	**A pilot study of a two session responsibility intervention for auditory hallucinations.**
IRAS project ID:	**212222**
REC reference:	**16/LO/1439**
Sponsor	**Royal Holloway University**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

Royal Holloway Approval

To: Rosanna Michalczuk

From: Gary Brown (on behalf of the Research Sub-Committee and Course Executive)

Date: 11th February 2016

Copy To: Olga Luzon

Re: Main Research Project Proposal

The Research Sub-Committee has considered your Main Research Project Proposal response and has decided to give you Approval with comment below. Your research costs have also been approved. Please note that if these costs change and you do not re-submit an amended form for approval prior to incurring any additional costs, these additional costs will not be reimbursed**.** It will be important to sketch out the exact measures that are given at each time point. Given that your baseline actually occurs during active therapy, you will want to have measures that are relevant to your question that would not be expected to have changed appreciably as a result of general therapy.

SLaM ethical approval

Dear Miss Michalczuk,

IRAS ID: 212222

Study Title: Reviewing and modifying beliefs in people who hear voices (A pilot study of a two-session responsibility intervention for auditory hallucinations)

Sponsor: Royal Holloway University

Trust R&D Ref: R&D2016/074

Please take this e-mail as confirmation that South London and Maudsley NHS Foundation Trust (SLaM) has the capacity and capability to host this research study. This study can therefore now commence at SLaM. Your Trust reference number has been quoted above and should be used at all times when contacting this office about this study.

The confirmation of capacity and capability to host this research study relates to work in the Psychosis CAG and to the specific protocol and informed consent procedures described in approved by the REC and the HRA. Any deviation from this will be deemed to invalidate this confirmation.

You have committed to recruit 4 patients between 25th October 2016 and 30th June 2017. We would also like to take this opportunity to remind you that, because this study is a clinical trial, we are required to report to the National Institute for Health Research (NIHR) on the following:

The date of first patient recruitment in SLaM; and Whether the study recruited its first participant within 70 days of the SLaM R&D office receiving a valid local information package from the sponsor. For studies where the recruitment timeline exceeds 70 days, we are required to provide the NIHR with reasons for this.

For your convenience, I can confirm that the date of valid local information package for this study was 18/10/2016. This means that the 70-day benchmark date will be 27/12/2016. Please be aware of the importance of the 70-day metric, as the NIHR scrutinises the performance of every clinical trial and where there is not an adequate reason for not recruiting within this timescale there is the risk of financial penalty which will impact on the Trust and thus the CAGs. Should you have any queries about this, please feel free to contact us.

Honorary contracts: Members of the research team must have appropriate substantive or honorary contracts or letters of access (as appropriate) with the Trust prior to conducting any research on Trust premises. Any additional researchers who join the study at a later stage must also hold a suitable contract or must contact the R&D department to arrange an honorary contract/letter of access. For any researchers requiring an honorary contract or letter of access via their research passport, please contact the R&D office to organise this for you.

Protocol Amendments: Please alert the R&D Department if there is an amendment to the study. An amendment may include changes to study documentation, a decision to use advertising, changes to staff or revisions to study timelines. Trust confirmation of capacity and capability must be issued prior to the implementation of any amendment.

Study status, annual progress reports and end of study declaration reports: Under the Research Governance Framework, SLaM maintains responsibility for keeping an accurate record of study status for all research on Trust premises. Please notify the R&D department if your study ends before the end date declared on your original application.

Annual Progress Reports: http://www.hra.nhs.uk/resources/during-and-after-your-study/nhs-rec-annual-progress-report-forms/ The Chief Investigator must submit an annual progress report to the Health Research Authority, sending a copy to the R&D department at each participating site. These reports must be sent each year on or before the anniversary of the Health Research Authority Ethics approval.

End of study declaration forms: http://www.hra.nhs.uk/research-community/end-of-study-and-beyond/notifying-the-end-of-study/ The Chief Investigator of a study must notify the Health Research Authority, within 90 days of the end of a study, sending a copy to the R&D department at each participating site.

Within SLaM, please also send a copy of any reports or publications which result from this study to the Trust Departments involved in the study if requested.

Compliance with Trust policies and procedures: All policies and procedures of the Trust which relate to research must be complied with: http://www.slam.nhs.uk/about-us/policy-and-publications/policies-and-procedures

Adverse events / complaints: Please inform the Trust's Health and Safety Coordinators and/or the Complaints Department or of any adverse events or complaints, from participants recruited from within this Trust, which occurs in

relation to this study in line with Trust policies. Contact details are available from the R&D Office if required.

Audit and Inspection: The Chief Investigator must notify the R&D department as soon as they receive notification of an inspection by an external body. Your study may be inspected by the Trust internally at any point.

Best wishes,

Carol

_____

Carol Cooley

Research Governance Facilitator

Joint R&D Office of SLaM NHS Foundation Trust and Institute of Psychiatry, Psychology & Neuroscience (IoPPN)

PO05, Institute of Psychiatry, Psychology & Neuroscience (IoPPN),

King's College London, De Crespigny Park, London SE5 8AF

Tel: +44 (0) 207 848 0339

carol.cooley@kcl.ac.uk

NELFT approval

NELFT NHS
NHS Foundation Trust

Research and Development Office
North East London NHS Foundation Trust,
1st Floor Maggie Lilley Suite,
Goodmayes Hospital,
Barley Lane,
Goodmayes,
Essex, IG3 8XJ

Date: 15/11/2016

Dear Rosanna Michalczuk

Letter of access for research

As a holder of an existing NHS honorary clinical you do not require an additional honorary research contract with the North East London NHS Foundation Trust. We are satisfied that such checks as are necessary have been carried out by your employer. This letter confirms your right of access to conduct research through the North East London NHS Foundation Trust for the purpose and on the terms and conditions set out below. This right of access commences on **15/11/2016** and ends on **01/04/2017** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct activities associated with such projects as you have received authorisation confirmed in writing from the Research and Development Director of the North East London NHS Foundation Trust. Please note that you cannot start the research until the Chief Investigator for the research project has received a letter from us giving permission to conduct the project.

You are considered to be a legal visitor to the North East London NHS Foundation Trust premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this Trust, in particular that of an employee.

While undertaking research through the North East London NHS Foundation Trust, you will remain accountable to your employer **Camden and Islington NHS Foundation Trust** but you are required to follow the reasonable instructions of your nominated manager **Dr Madiha Shaikh** in this Trust or those given on her behalf in relation to the terms of this right of access.

You must act in accordance with the North East London NHS Foundation Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Your substantive employer **Camden and Islington NHS Foundation Trust** is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

You are required to co-operate with the North East London NHS Foundation Trust in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on North East London NHS Foundation Trust premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998.

Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

The North East London NHS Foundation Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by the North East London NHS Foundation Trust in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

Please also ensure that while on the premises you wear your NHS ID badge at all times, or are able to prove your identity if challenged. Please note that this Trust accepts no responsibility for damage to or loss of personal property.

If your circumstances change in relation to your health, criminal record, professional registration or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform your employer through its normal procedures. You must also inform the Research and Development Department and your nominated manager in North East London NHS Foundation Trust.

Yours sincerely

Sandeep Toot

Research and Development Deputy Director, North East London NHS Foundation Trust

Approval Email 16/LO/1439

Dear Rosanna Michalczuk,

Study title: **A pilot study of a two session responsibility intervention for auditory hallucinations.**

IRAS project ID: 212222

Ethics Ref: **16/LO/1439**

Sponsor: Royal Holloway University

I am writing to confirm capacity and capability for the above titled research to proceed at North East London NHS Foundation Trust with the site participating as a recruiting site.

This confirmation is based on the HRA approval letter dated 30 September 2016 and the attached Statement of Activities and corresponding appendix B. The study is considered to be commencing at NELFT today 15 November 2016.

Please could I ask you to change the IRAS number on the schedule of events as it is the Rec reference which was provided instead, to avoid confusion.

I also have pleasure in attaching the NELFT letter of access. You should inform Alberta Adomako (NELFT Research Data Manager) when your study has completed so that we can provide you with a monitoring form for return. I have copied Alberta in here for your convenience.

Should you have any other queries regarding the research here at NELFT please do feel free to contact me. We are delighted to be participating as a site and wish you every success with your work here at the Trust.

Kind regards, Krisha

Krisha Hirani

Research and Development Administrator

Research and Development Department

1st Floor Maggie Lilley Suite

Goodmayes Hospital

Barley Lane, Ilford, Essex.

IG3 8XJ

Tel: 0300 555 1200 Ext. 64478

http://www.nelft.nhs.uk/research

South London and Maudsley NHS Foundation Trust | NELFT NHS Foundation Trust | Royal Holloway University of London

Patient Information Sheet

Reviewing and modifying responsibility beliefs in people who hear voices

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it would involve for you. The research is being conducted for an educational qualification and has been reviewed and approved by an NHS Research Ethics Committee (Camberwell and St Giles Research Ethics Committee)

Please take time to read this information sheet carefully. Rosanna Michalczuk (the main researcher) will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about ten minutes. Please feel free to talk to others about the study if you wish. Your therapist can also answer any questions about the research.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part. Then we give you more detailed information about the conduct of the study. Do ask if anything is unclear.

What is the study about?

Psychology helps people better understand how the way they feel and act is linked to their thoughts. Some of the thoughts that we have everyday are less helpful than others, they make us feel more stressed, worried or low. We know that if someone feels very responsible for preventing anything bad happening to themselves or others, they can also feel distressed and anxious. Sometimes people listen to and do what the voices tell them, otherwise they feel they would be personally responsible for anything bad that may happen to them or others. This can then make them feel even more upset and anxious. The belief that someone can bring about or cause a negative outcome (such as a fire) is called a 'responsbility belief'.

If you decided to take part in the study, you will be receiving two extra psychology sessions on top of your treatment as usual by your therapist to better understand how feeling very responsible for stopping something that you really fear can be contributing to your emotions and difficult symptoms. You will learn ways of coping with this. During these two sessions you will learn which thoughts are less helpful, and what can you do to better cope with your symptoms.

These sessions are based on the best treatments available for common anxiety problems, will be offered by your therapist approximately half way through your therapy. The two sessions will follow the same structure and principles of your treatment as usual, but the focus of these two sessions will be on helping you understand the role of beliefs about responsibility. By understanding a bit more about these thoughts and the impact they have on our lives, we hope that people will feel less fearful and responsible about bad things happening and therefore less distressed.

Why have you been asked to take part?
You have been asked to take part because you are currently are on the waiting list/currently receiving Cognitive Behavioural Therapy for Psychosis (CBTp) and your therapist thought you might be interested in the study.

Do I have to take part in the study?
No, you do not have to take part in the study. If you choose not to take part, this will not affect your rights or your care plan in any way.

If you would like to take part in the study, we will ask you to sign a consent form. Even after you agree to take part, you will still be able to change your mind and withdraw from the study at any time. If you decide you would like to withdraw from the study, you will not be asked to provide a reason why. Withdrawing from the study will not affect your treatment in any way.

What would you have to do to take part?
If you agree to take part, you will be invited to meet with me, Rosanna (trainee clinical psychologist). You will have the opportunity to ask me any questions you have about taking part in the study. If you decide to go ahead, I will then ask you to sign a consent form (which includes possibly taping the two sessions if you felt ok with this). If you would like your therapist in the assessment sessions to make you feel more comfortable, that would be fine and something that can be arranged.

First assessment session: Rosanna will ask you some questions about your experience of hearing voices and will ask you to complete four questionnaires, which will ask you about your thoughts and responsibility beliefs in different situations, and how you have been feeling generally. You do not have to answer any questions you do not feel comfortable answering. This meeting should take up to 45 minutes and will be at your normal clinic.

Second and third assessment session: Rosanna will then ask you some questions about your experience of hearing voices and ask you to complete two questionnaires after two of your CBT for psychosis therapy session (taking up to 20 minutes).

Two therapy sessions: You will then have two additional sessions to your treatment which last the same time as your normal therapy. Your therapist will conduct these sessions. These sessions will involve techniques that look at your thoughts and also ask you to test out your behaviours which we hope will reduce the levels of responsibility you feel. The techniques are similar that you have already been doing in therapy, but more focussed on your feelings on responsibility. The therapist/Rosanna can talk you through the techniques prior to inclusion in the study

if you would feel more comfortable with this. Your therapist after your two therapy sessions will then ask you some questions about your experience of hearing voices and ask you to complete two questionnaires.

End asessment: After that Rosanna will repeat the first assessment again a week after the two therapy sessions has ended to further see if the two therapy sessions have had an impact on responsibility beliefs and general well-being.

Follow up assessment: Rosanna will ask you to repeat the second and third assessment questionnaires. She will also ask your opinions on the two additional sessions and your experience of hearing voices, plus ask you some questions about the intervention. This will take approximately forty minutes.

Your therapist will also fill in an information sheet about your demographic information (e.g. your gender/age) and some clinical information which you can do together if you feel more comfortable. This is completely anonymous.

Will what I say be confidential?
Yes. No identifiable information will be used to link you to your questionnaires in the study. Your personal details will be kept separately from any of your answers to the questions. Anything that will identify you will be removed from the dataset.

What you say is confidential, unless you tell us something that suggests that makes me worry about harm to yourself or to other people. In this case, the necessary information will be shared with the duty clinician in your team. If this happened, we would discuss this with you.

What will happen to my questionnaire data and/or audio-tapes?
The data from your questionnaires will be entered into database that will contain no identifiable information. Only the researchers involved in the study will have access to this database. Your paper questionnaires will be secured in a locked filing cabinet at Royal Holloway University for three years. Only the researchers involved in the study will have access to these. If you consent to audio-taping, then audio tapes will be transcribed and stored safely and then destroyed, as once as they are transcribed. The electronic data (e.g. the data file) will be kept for five years.

What are the possible disadvantages of taking part?
Most people who have taken part in similar studies have found this useful, however, it is possible that you might find it difficult or upsetting to answer some of the questions that cover sensitive topics. You do not have to answer any questions you do not feel comfortable answering. If you become upset, the researcher will talk to you about this and give you the opportunity to stop or take a break if you need to. You will also have the opportunity to discuss any concerns with the researcher and your clinical psychologist at the end.

What are the possible benefits of taking part?
We think that it might be a positive experience for people to be able to talk about their experience of hearing voices and how they feel. We hope that the two

additional sessions will reduce any distress that you feel by having a high sense of responsibility. It may help us understand how to help other people who are experiencing similar things.

We will also give you a payment of **£15** as a way of reimbursing any expenses that you may incur as a result of taking part in the study. However, this reimbursement will not offset any risks you may experience as a result of taking part in the study.

What will happen if you don't want to carry on with the study?
If at any time you decide that you would like to withdraw from the study, testing will stop immediately and any data that you have provided will not be used. Withdrawing from the study will not affect the standard of care you will receive in any way.

What if something goes wrong?
If you have a concern about any aspect of the study, you should ask to speak to Rosanna Michalczuk (the principal investigator) who will do her best to answer your questions (please see contact details below). If you remain unsatisfied, or do not wish to speak to her and wish to complain formally, you can do this through the NHS Complaints mechanism. The telephone number to call in order to make a complaint is 0345 0154033.

For further details, you can visit the NHS complaints procedure website at:

http://www.nhs.uk/NHSEngland/complaints-and-feedback/Pages/nhs-complaints.aspx

Additional information can also be ontained by the service that you are seen at

If you need help with any part of the process, you can get it from the NHS Patient Advice and Liaison Service (PALS; telephone 0800 731 2864).

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Royal Hollloway university, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen to the results of the study?
The results of the study will be published in anonymised form, so you will not be identified in any report or publication. As the research is being conducted as part of an educational qualification, the results will be published in an academic report. The results might also be used for scientific journals and conference publications. You will also be asked by the researcher if you would like to receive a summary of the results of the study.

Who is running the study?
The study is being run by Rosanna Michalczuk who is a Trainee Clinical Psychologist at Royal Holloway, University of London. The research is being carried

out as part of her training course. The project is being supervised by Dr. Olga Luzon (Clinical Psychologist) at Royal Holloway, University of London.

Who has reviewed the study?
All research in the NHS is reviewd by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by Camberwell and St Giles Research Ethics Committee and Royal Holloway Committee.

Who can I contact for further information?
If you want any more information or have any questions, please email the researcher (Rosanna Michalczuk): Rosanna.michalczuk.2014@live.rhul.ac.uk or telephone **01784 414 012** during normal office hours.

If you have read this information sheet and decided that you want to take part in this study, please get in touch with the researcher on the above number so she can arrange a time to meet you. Alternatively, please let your clinical psychologist know that you would like to participate and the researcher can get in touch with you.

Thank you!

South London and Maudsley NHS Foundation Trust | NELFT NHS Foundation Trust | Royal Holloway University of London

CONSENT FORM

Study Title: Reviewing and modifying beliefs in people who hear voices

Principle Investigator: Rosanna Michalczuk

Participant ID number:

Study site:

Please initial the box

1. I confirm that I have read and understand the participant information sheet for the above study, I have had the opportunity to ask any questions to the investigator(s) and have had these questions answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. ☐

3. I understand that the information I provide will be collected fairly, will remain secure and confidential, and held no longer than necessary for the purposes of this research. ☐

4. I consent to the audio recording of my therapy sessions. I understand that the tapes / files will be stored securely and deleted at the end of the study. ☐

5. I consent to my therapist filling in my demographic information. I understand that this demographic information will be stored securely and destroyed at the end of the study ☐

6. I understand that if the researcher has any concerns about harm either to myself or to other people, that this information will be disclosed to relevant clinical staff, and that the researcher will discuss this with me. ☐

7. I want to be informed about the results of the study. ☐

8. I agree to take part in the above study. ☐

Name of participant:	Date:	Signature:

I have explained the study to the participant and answered their questions honestly and fully. A copy of the consent form will be retained by the researcher and one copy is added to the clinical file.

Name of Consenter	Date:	Signature:

South London and Maudsley NHS Foundation Trust | NELFT NHS Foundation Trust | Royal Holloway University of London

Patient Debrief Statement

Reviewing and modifying beliefs in people who hear voices

Thank you for your participation in this research study.

The purpose of this research is to investigate different types of thoughts and beliefs in people who hear voices. In particular, we want to try and help you review thoughts and beliefs of feeling responsible for potential negative events that may happen in the future by adding two sessions of talking therapy onto your treatment as normal.

We hope that by investigating and understanding more about these thoughts and beliefs, that we will be able to help other people that sometimes hear voices and feel distressed about them. The research will help us us to think about different things that might be helpful to work on in psychological therapy with people who hear voices. We hope that the intervention will help us work out who benefits from it and if people think it is useful.

Your participation in this study is greatly appreciated, and any contribution you have made will be treated in the strictest confidence. However, if you wish to withdraw any data you may do so now and will not be asked to give a reason.

Who can I contact if I have any questions or need some support?

We hope you have found the two sessions useful in gaining a better understanding of the role that feeling very responsible for stopping a feared catastrophe can have in making you feel distressed, worried or down, and in doing things to stop such things. We hope that if you had any questions your clinician would have been able to answer or you can ask me at any point after your participation in the study. If you need to contact me at any point, please contact me (Rosanna Michalczuk) at: rosanna.michalczuk.2014@live.rhul.ac.uk, or the study supervisor (Dr. Olga Luzon) at: olga.luzon@rhul.ac.uk.

If you require additional support as a result of taking part in this study, please speak to your care co-ordinator or another member of you mental health team.

Other contacts you mind find helpful are below:

Useful contacts:

- **Your team**

Insert relevant team contact details and duty numbers

- **Hearing Voices Network**

For information on groups run by the Hearing Voices Network in the London area please contact:
Telephone: 020 7625 9042
Email: LHVN@mindincamden.org.uk
Website: www.hearing-voices.org

- **MIND**

'Mind' is a mental health charity who can provide information and support to people experiencing mental health difficulties.

Mind helplines are open Monday to Friday, 9.00am to 5.00pm.

Telephone: 0845 766 0163
Email: info@mind.org.uk
Website: www.mind.org.uk

- **Samaritans**

The Samaritans can help people who are in crisis. They provide confidential, non-judgmental, emotional support to people who are experiencing feelings of distress or despair, including feelings which could lead to harm or suicide.

They are open 24 hours a day.

Telephone: 08457 90 90 90
Email: jo@samaritans.org
Website: www.samaritans.org

- **What shall I do if I am worried that I am about to harm myself or another person?**

Call 999 and ask for help. The call is free. Alternatively you can go to your nearest Accident & Emergency department (A&E).

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RISK MANAGEMENT PROTOCOL

Reviewing and modifying beliefs in people who hear voices

Risk management has been an important consideration for the authors, and the following guidelines will be adhered to during the course of the study. Limits to confidentiality will be explained to all participants prior to the commencement of the research testing procedures.

- Each referral to the study is has had a full risk assessment as they will be known to mental health services. Potential participants will either be in touch with a care co-ordinator (CMHT and E.I), or a Consultant Psychiatrist (CMHT, E.I) Following Trust policy, all participants will have had a brief assessment of risk completed by their clinicians. Referring staff will therefore be aware of any risks associated with the participant, and any which require ongoing consideration.

- Details of any risks presented will be requested by RM at the time of referral to the study.

- All participants will be met during working hours and at their normal clinical base to ensure that mental health staff are available for liaison purposes if needed.

- Regular discussions will be held with the academic supervisor (OL) to ensure that RM is aware of the relevant departmental health and safety guidelines, and to identify and manage potential risk during data collection. OL is an experienced Clinical Psychologist who has worked clinically and has conducted research involving the interviewing of patients in the acute stages of mental health crises both in their homes and in hospital settings. Furthermore, RM is skilled in evaluating risk, and in dealing with situations in which unaccounted risks may present.

Management of risk to the researcher

- Any potential participants which are seen as presenting a possible risk to the safety of RM in the course of the intervention will not be included in the study.

- All participants will be seen in NHS premises – on either community mental health team (CMHT) or E.I office sites. This will be at times when the teams are in the building, using the interview room booking system applicable for each site. Staff will therefore be aware of where the interview is being conducted and the approximate length of time it will take. RM will familiarise herself with site specific risk management protocols.

- Should any risks be encountered in the course of the research interview, e.g. the participant becomes agitated or hostile, the interview will be terminated.

Management of risk to the participant/others

- Any observations made by RM in the course of the interview which would have implications for the safety of the participant, for workers, or any others, will be reported to the care coordinator or any person with immediate responsibility for the care.

- In the event of a participant making a disclosure which indicates risk of harm either to themselves or to other people, RM will assess any risk to self/others and in the case of serious concerns she will contact the patient's care coordinator or another professional who can assume responsibility for the patient's care at the time (e.g. on-call psychiatrist). Limits to confidentiality and the course of action described here will be made explicit to all participants before the testing procedure begins.

- Should participants become upset during testing, RM will offer the participant the option to terminate testing, and to either have some time alone, or to continue testing again at another time if desired by the participant. Clinical judgment will be used in making this decision. RM will inform mental health staff involved in the participant's care should the participant require additional support following the interviews/questionnaires.

APPENDIX C - Measures

PSYRATS – AH

Frequency

0 Voices not present or present less than once a week

1 Voices occur for at least once a week

2 Voices occur at least once a day

3 Voices occur at least once an hour

4 Voices occur continuously or almost continuously i.e. stop for only a few seconds or minutes

Duration

0 Voices not present

1 Voices last for a few seconds, fleeting voices

2 Voices last for several minutes

3 Voices last for at least one hour

4 Voices last for hours at a time

Location

0 No voices present

1 Voices sound like they are inside head only

2 Voices outside the head, but close to ears or head. Voices inside the head may also be present

3 Voices sound like they are inside or close to ears and outside head away from ears

4 Voices sound like they are from outside the head only

Loudness

0 Voices not present

1 Quieter than own voice, whispers.

2 About same loudness as own voice

3 Louder than own voice

4 Extremely loud, shouting

Beliefs re-origin of voices

0 Voices not present

1 Believes voices to be solely internally generated and related to self

2 Holds < 50% conviction that voices originate from external causes

3 Holds ~ 50% conviction (but < 100%) that voices originate from external causes

4 Believes voices are solely due to external causes (100% conviction)

Amount of negative content of voices

0 No unpleasant content

1 Occasional unpleasant content (< 10%)

2 Minority of voice content is unpleasant or negative (< 50%)

3 Majority of voice content is unpleasant or negative (> 50%)

4 All of voice content is unpleasant or negative

Degree of negative content

0 Not unpleasant or negative;

1 Some degree of negative content, but not personal comments relating to self or family; e.g. swear words or comments not directed to self;

2. Personal verbal abuse, comments on behavior; e.g. ' shouldn't do that or say that.'

3. Personal verbal abuse relating to self-concept;e.g. 'you're lazy, ugly, mad, perverted.

4. Personal threats to self; e.g. threats to harm self or family, extreme instructions or commands to harm self or others.

Amount of distress

0 Voices not distressing at all

1 Voices occasionally distressing, majority not distressing (< 10%)

2 Minority of voices distressing (< 50%)

3 Majority of voices distressing, minority not distressing (~ 50%)

4 Voices always distressing

Intensity of distress

0 Voices not distressing at all

1 Voices slightly distressing

2 Voices are distressing to a moderate degree

3 Voices are very distressing, although subject could feel worse

4 Voices are extremely distressing, feel the worst he/she could possibly feel

Disruption to life caused by voices

0 No disruption to life, able to maintain social and family relationships (if present)

1 Voices causes minimal amount of disruption to life e.g. interferes with concentration although able to maintain daytime activity and social and family relationships and be able to maintain independent living without support

2 Voices cause moderate amount of disruption to life causing some disturbance to daytime activity and/or family or social activities. The patient is not in hospital although may live in supported accommodation or receive additional help with daily living skills

3 Voices cause severe disruption to life so that hospitalisation is usually necessary. The patient is able to maintain some daily activities, self-care and relationships while in hospital. The patient may also be in supported accommodation but experiencing severe disruption of life in terms of activities, daily living skills and/or relationships

4 Voices cause complete disruption of daily life requiring hospitalization. The patient is unable to maintain any daily activities and social relationships. Self-care is also severely disrupted.

Controllability of voices

0 Subject believes they can have control over the voices and can always bring on or dismiss them at will.

1 Subject believes they can have some control over the voices on the majority of occasions.

2 Subject believes they can have some control over their voices approximately half of the time.

3 Subject believes they can have some control over their voices but only occasionally. The majority of the time the subject experiences voices which are uncontrollable

4 Subject has no control over when the voices occur and cannot dismiss or bring them on at all

PSYRATS - Delusions

Amount of preoccupation with delusions

0 No delusions, or delusions which the subject thinks about less than once a week

1 Subject thinks about beliefs at least once a week

2 Subject thinks about beliefs at least once a day

3 Subject thinks about beliefs at least once an hour

4 Subject thinks about delusions continuously or almost continuously

Duration of preoccupation with delusions

0 No delusions

1 Thoughts about beliefs last for a few seconds, fleeting thoughts

2 Thoughts about delusions last for several minutes

3 Thoughts about delusions last for at least 1 hour

4 Thoughts about delusions usually last for hours at a time

Conviction

0 No conviction at all

1 Very little conviction in reality of beliefs, < 10%

2 Some doubts relating to conviction in beliefs, between 10-49%

3 Conviction in belief is very strong, between 50-99 %

4 Conviction is 100 %

Amount of distress

0 Beliefs never cause distress

1 Beliefs cause distress on the minority of occasions

2 Beliefs cause distress on < 50% of occasions

3 Beliefs cause distress on the majority of occasions when they occur between 50-99% of time

4 Beliefs always cause distress when they occur

Intensity of distress

0 - No distress

1 - Beliefs cause slight distress

2 - Beliefs cause moderate distress

3 - Beliefs cause marked distress

4 - Beliefs cause extreme distress, could not be worse

Disruption to life caused by beliefs

0 No disruption to life, able to maintain independent living with no problems in daily living skills. Able to maintain social and family relationships (if present)

1 Beliefs cause minimal amount of disruption to life, e.g. interferes with concentration although able to maintain daytime activity and social and family relationships and be able to maintain independent living without support

2 Beliefs cause moderate amount of disruption to life causing some disturbance to daytime activity and/or family or social activities. The patient is not in hospital although may live in supported accommodation or receive additional help with daily living skills

3 Beliefs cause severe disruption to life so that hospitalisation is usually necessary. The patient is able to maintain some daily activities, self-care and relationships while in hospital. The patient may be also be in supported accommodation but experiencing severe disruption of life in terms of activities, daily living skills and/or relationships

4 Beliefs cause complete disruption of daily life requiring hospitalization. The patient is unable to maintain any daily activities and social relationships.

Hospital Anxiety and Depression Scale (HADS)

Patients are asked to choose one response from the four given for each interview. They should give an immediate response and be dissuaded from thinking too long about their answers. The questions relating to anxiety are marked "A", and to depression "D". The score for each answer is given in the right column. Instruct the patient to answer how it currently describes their feelings.

A **I feel tense or 'wound up':**

Most of the time	3
A lot of the time	2
From time to time, occasionally	1
Not at all	0

D **I still enjoy the things I used to enjoy:**

Definitely as much	0
Not quite so much	1
Only a little	2
Hardly at all	3

A **I get a sort of frightened feeling as if something awful is about to happen:**

Very definitely and quite badly	3
Yes, but not too badly	2
A little, but it doesn't worry me	1
Not at all	0

D **I can laugh and see the funny side of things:**

As much as I always could	0
Not quite so much now	1
Definitely not so much now	2
Not at all	3

A **Worrying thoughts go through my mind:**

A great deal of the time	3
A lot of the time	2
From time to time, but not too often	1
Only occasionally	0

D **I feel cheerful:**

Not at all	3
Not often	2
Sometimes	1
Most of the time	0

A **I can sit at ease and feel relaxed:**

Definitely	0
Usually	1
Not Often	2
Not at all	3

D **I feel as if I am slowed down:**

Nearly all the time	3
Very often	2
Sometimes	1
Not at all	0

A **I get a sort of frightened feeling like 'butterflies' in the stomach:**

Not at all	0
Occasionally	1
Quite Often	2
Very Often	3

D **I have lost interest in my appearance:**

Definitely	3
I don't take as much care as I should	2
I may not take quite as much care	1
I take just as much care as ever	0

A **I feel restless as I have to be on the move:**

Very much indeed	3
Quite a lot	2
Not very much	1
Not at all	0

D **I look forward with enjoyment to things:**

As much as I ever did	0
Rather less than I used to	1
Definitely less than I used to	2
Hardly at all	3

A **I get sudden feelings of panic:**

Very often indeed	3
Quite often	2
Not very often	1
Not at all	0

D **I can enjoy a good book or radio or TV program:**

Often	0
Sometimes	1
Not often	2
Very seldom	3

Scoring

Add the As = Anxiety. Add the Ds = Depression.

The norms below will give you an idea of the level of Anxiety and Depression.

0-7 = Normal

8-10 = Borderline abnormal

11-21 = Abnormal

Responsibility Interpretations Questionnaire (RIQ)

We are interested in your reaction to intrusive thoughts that you have had in the last 2 weeks. Intrusive thoughts are thoughts that suddenly enter your mind, may interrupt what you are thinking or doing and tend to recur on separate occasions. They may occur in the form of words, mental image, or an impulse (a sudden urge to carry out some action). We are interested in those intrusive thoughts that are unacceptable. Research has shown that most people experience or have experienced such thoughts which they find unacceptable in some way, at some point in their lives to a greater or lesser degree, so there is nothing unusual about this.

Some examples of unpleasant intrusions are:

Repeated image of attacking someone.

Suddenly thinking that your hands are dirty and you may cause contamination.

Suddenly thinking you might not have turned off the gas, or that you left a door unlocked.

Repeated senseless images of harm coming to someone you love.

Repeated urge to attack or harm somebody (even though you would never do this).

These are just a few examples of intrusions to give you some idea of what we are looking at; people vary tremendously in the type of thoughts that they have.

IMPORTANT

Think of INTRUSIONS OF THE TYPE DESCRIBED ABOVE that you have had in the last 2 weeks, and answer the following questions with that intrusion in mind. The questions do NOT relate to all thoughts but specifically to your negative intrusions.

Please write down intrusions that you have had in the last 2 weeks:

_____

_____

_____

_____

This questionnaire has two parts:

Overleaf are some ideas that may go through your mind when you are bothered by worrying intrusive thoughts which you know are probably senseless or unrealistic. Think of times when you were bothered by intrusive thoughts, impulses and images in the last 2 weeks.

Frequency

Indicate how often each of the ideas listed below occurred when you were bothered by these intrusive thoughts, impulses or images. Circle the number that most accurately describes the frequency of the occurrence of the ideas using the following scale:

Over the LAST TWO WEEKS:

Idea never occurred

Idea rarely occurred

Idea occurred during about half of the times when I had worrying intrusive thoughts

Idea usually occurred

Idea always occurred when I had worrying intrusive thoughts

F1

	Never occurred	Rarely occurred	Half the time	Usually occurred	Always occurred
If I don't resist these thoughts it means I am being irresponsible	0	1	2	3	4
I could be responsible for serious harm	0	1	2	3	4
I cannot take the risk of this thought coming true	0	1	2	3	4
If I don't act now then something terrible will happen	0	1	2	3	4

and it will be my fault					
I need to be certain something awful won't happen	0	1	2	3	4
I shouldn't be thinking this type of thing	0	1	2	3	4
It would be irresponsible to ignore these thoughts	0	1	2	3	4
I'll feel awful unless I do something about this thought	0	1	2	3	4

Because I've thought of bad things happening then I must act to prevent them	0	1	2	3	4
Since I've thought of this I must want it to happen	0	1	2	3	4
	Never occurred	Rarely occurred	Half the time	Usually occurred	Always occurred
Now I've thought of things which could go wrong I have a	0	1	2	3	4

responsibility to make sure I don't let them happen					
Thinking this could make it happen	0	1	2	3	4
I must regain control of my thoughts	0	1	2	3	4
This could be an omen	0	1	2	3	4
It's wrong to ignore these thoughts	0	1	2	3	4
Because these thoughts come from					

my own mind, I must want to have them	0	1	2	3	4

Now rate these items:

F2

	Never occurred	Rarely occurred	Half the time	Usually occurred	Always occurred
Thoughts can NOT make things happen	0	1	2	3	4
This is just a thought so it doesn't matter	0	1	2	3	4
Thinking of something happening doesn't make me responsible for whether it happens	0	1	2	3	4
There's nothing wrong with letting such thoughts come and go naturally	0	1	2	3	4

Everybody has horrible thoughts sometimes, so I don't need to worry about this one	0	1	2	3	4
Having this thought doesn't mean I have to do anything about it	0	1	2	3	4

Belief

Over the last two weeks. When you were bothered by these worrying intrusive thoughts, how much did you believe each of these ideas to be true? Rate the belief you had of these ideas when you had the intrusions, using the following scale; mark the point on the line that most accurately applies to your belief at the time of the intrusion.

B1

	I did not believe this idea at all										I was completely convinced this idea was true
If I don't resist these thoughts, it means I am being irresponsible	0	10	20	30	40	50	60	70	80	90	100
I could be responsible for serious harm	0	10	20	30	40	50	60	70	80	90	100
I cannot take the risk of this thought coming true	0	10	20	30	40	50	60	70	80	90	100
If I don't act now, then something terrible will happen and it will be my fault	0	10	20	30	40	50	60	70	80	90	100
I need to be certain something awful won't happen	0	10	20	30	40	50	60	70	80	90	100

I should not be thinking this kind of thing	0 10 20 30 40 50 60 70 80 90 100
It would be irresponsible to ignore these thoughts	0 10 20 30 40 50 60 70 80 90 100
I'll feel awful unless I do something about this thought	0 10 20 30 40 50 60 70 80 90 100
Because I've thought of bad things happening then I must act to prevent them	0 10 20 30 40 50 60 70 80 90 100
Since I've thought of this I must want it to happen	0 10 20 30 40 50 60 70 80 90 100
Now I've thought of things which could go wrong I have a responsibility to make sure I don't let them happen	0 10 20 30 40 50 60 70 80 90 100
Thinking this could make it happen	0 10 20 30 40 50 60 70 80 90 100
I must regain control of my thoughts	0 10 20 30 40 50 60 70 80 90 100

This could be an omen	0 10 20 30 40 50 60 70 80 90 100
It's wrong to ignore these thoughts	0 10 20 30 40 50 60 70 80 90 100
Because these thoughts come from my own mind, I must want to have them	0 10 20 30 40 50 60 70 80 90 100

Now rate these items:

B2

	I did not believe this idea at all	I was completely convinced this idea was true
Thoughts can NOT make things happen	0 10 20 30 40 50 60 70 80 90 100	

This is just a thought so it doesn't matter	0 10 20 30 40 50 60 70 80 90 100
Thinking of something happening doesn't make me responsible for whether it happens	0 10 20 30 40 50 60 70 80 90 100
There's nothing wrong with letting such thoughts come and go naturally	0 10 20 30 40 50 60 70 80 90 100
Everybody has horrible thoughts sometimes, so I don't need to worry about this one	0 10 20 30 40 50 60 70 80 90 100
Having this thought doesn't mean I have to do anything about it	0 10 20 30 40 50 60 70 80 90 100

The Warwick-Edinburgh Mental Well-being Scale (WEMWBS)

Below are some statements about feelings and thoughts.

Please tick the box that best describes your experience of each over the last 2 weeks

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future	1	2	3	4	5
I've been feeling useful	1	2	3	4	5
I've been feeling relaxed	1	2	3	4	5
I've been feeling interested in other people	1	2	3	4	5
I've had energy to spare	1	2	3	4	5
I've been dealing with problems well	1	2	3	4	5
I've been thinking clearly	1	2	3	4	5
I've been feeling good about myself	1	2	3	4	5
I've been feeling close to other people	1	2	3	4	5
I've been feeling confident	1	2	3	4	5
I've been able to make up my own mind about things	1	2	3	4	5
I've been feeling loved	1	2	3	4	5
I've been interested in new things	1	2	3	4	5
I've been feeling cheerful	1	2	3	4	5

Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)

OCI

The following statements refer to experiences which many people have in their everyday lives. Under the column labelled FREQUENCY, please CIRCLE the number next to each statement that best describes how FREQUENTLY YOU HAVE HAD THE EXPERIENCE IN THE PAST MONTH.

The numbers in this column refer to the following labels:

0 = Never 1 = Almost never 2 = Sometimes 3 = Often 4 = Almost always

Unpleasant thoughts come into my mind against my will and I cannot get rid of them	0 1 2 3 4 5
I think contact with bodily secretions (perspiration, saliva, blood, urine, etc) may contaminate my clothes or somehow harm me.	0 1 2 3 4 5
I ask people to repeat things to me several times, even though I understood them the first time.	0 1 2 3 4 5
I wash and clean obsessively.	0 1 2 3 4 5
I have to review mentally past events, conversations and actions to make sure that I didn't do something wrong.	0 1 2 3 4 5
I have saved up so many things that they get in the way.	0 1 2 3 4 5

I check things more often than necessary	0 1 2 3 4 5

I avoid using public toilets because I am afraid of disease or contamination.	0 1 2 3 4 5

I repeatedly check doors, windows, drawers etc.	0 1 2 3 4 5

I repeatedly check gas and water taps and light switches after turning them off	0 1 2 3 4 5

I collect things I don't need.	0 1 2 3 4 5

I have thoughts of having hurt someone without knowing it.	0 1 2 3 4 5

.

I have thoughts that I might want to harm myself or others.	0 1 2 3 4 5

I get upset if objects are not arranged properly.	0 1 2 3 4 5

I feel obliged to follow a particular order in dressing, undressing and washing myself.	0 1 2 3 4 5
I feel compelled to count while I am doing things	0 1 2 3 4 5
I am afraid of impulsively doing embarrassing or harmful things.	0 1 2 3 4 5
I need to pray to cancel bad thoughts or feelings.	0 1 2 3 4 5
I keep on checking forms or other things I have written.	0 1 2 3 4 5
I get upset at the sight of knives, scissors and other sharp objects in case I lose control with them.	0 1 2 3 4 5
I am excessively concerned about cleanliness	0 1 2 3 4 5
I find it difficult to touch an object when I know it has been touched by strangers or certain people.	0 1 2 3 4 5
I need things to be arranged in a particular order.	0 1 2 3 4 5
I get behind in my work because I repeat things over and over again.	0 1 2 3 4 5

I feel I have to repeat certain numbers.	0 1 2 3 4 5

After doing something carefully, I still have the impression I have not finished it.	0 1 2 3 4 5

I find it difficult to touch garbage or dirty things	0 1 2 3 4 5

I find it difficult to control my own thoughts.	0 1 2 3 4 5

I have to do things over and over again until it feels right.	0 1 2 3 4 5

I am upset by unpleasant thoughts that come into my mind against my will.	0 1 2 3 4 5

Before going to sleep I have to do certain things in a certain way.	0 1 2 3 4 5

I go back to places to make sure that I have not harmed anyone.	0 1 2 3 4 5

I frequently get nasty thoughts and have difficulty in getting rid of them.	0 1 2 3 4 5

I avoid throwing things away because I am afraid I might need them later.	0 1 2 3 4 5

I get upset if others change the way I have arranged my things.	0 1 2 3 4 5

I feel that I must repeat certain words or phrases in my mind in order to wipe out bad thoughts, feelings or actions.	0 1 2 3 4 5

After I have done things, I have persistent doubts about whether I really did them.	0 1 2 3 4 5

I sometimes have to wash or clean myself simply because I feel contaminated.	0 1 2 3 4 5

I feel that there are good and bad numbers.	0 1 2 3 4 5

I repeatedly check anything which might cause a fire.	0 1 2 3 4 5

Even when I do something very carefully I feel that it is not quite right.	0 1 2 3 4 5

I wash my hands more often or longer than necessary.	0 1 2 3 4 5

Semi-Structured Interview to Assess Feasibility and Acceptability

i) Did you find the intervention helpful? What was / was not helpful?

ii) What techniques were useful/ not useful?

iii) Do you feel less responsible following the intervention? Yes/No – why?

iv) Did you comply less to your voices?

v) What would you change about the intervention?

vi) Would you recommend it to someone else in your position? If yes/no – why?

Demographic and Clinical Information for the Clinician to Fill out

(1) Gender: ☐ Male ☐ Female (2) Age: _____

(3) Ethnicity:

White: ☐ White British ☐ Irish ☐ Other White background
Black or Black British: ☐ Caribbean ☐ African ☐ Other black background
Asian or Asian British: ☐ Indian ☐ Pakistani ☐ Bangladeshi ☐ Other asian
Mixed: ☐ White and Black Caribbean ☐ White and Black African
☐ White and Asian ☐ Other mixed background
Chinese or other: ☐ Chinese ☐ Other ethnic group

(4) Highest level of education achieved:

☐ None
☐ GCSE's or equivalent (e.g. BTEC Levels 1 & 2, NVQ Levels 1 & 2)
☐ A-Levels or equivalent (e.g. International Baccalaureate, BTEC or NVQ Level 3+)
☐ Undergraduate degree / PGCE ☐ Postgraduate certificate or diploma
☐ Masters degree ☐ PhD or doctoral degree
☐ Other. Please specify:
_____

(5) Employment status

☐ Employed full-time ☐ Employed part-time ☐ Student ☐ Unemployed

(6) Does the client have a diagnosis of obsessive compulsive disorder?

☐ Yes ☐ No

(7) Any previous hospital admissions?

☐ Yes ☐ No

(8) Has the client had any CBT previously? ☐ Yes ☐ No

(9) Any significant life events during the therapy ☐ Yes ☐ No If yes, what?

(10) Anti-psychotic medication ☐ Yes ☐ No If yes: Any change in medication during the therapy?

(11) Length of illness

☐ 0-3 years
☐ 3-5 years
☐ > 5 years

12. How many sessions of therapy before the intervention?

13. What had been focussed on in sessions before the intervention started/ What sort of techniques would have been used?

14. How many sessions between follow up 1 and follow up 2 / what was focussed on in these sessions?

15. OCI score:

APPENDIX D – Phase 3 documents

Focus Group Schedule

Q1: How did you find recruitment?

Prompts for this question

Difficulties of recruitment rates (how long does it take to recruit enough participants/refusal rates)

How feasible and suitable are the eligibility criteria (e.g. too inclusive or too restrictive)

Obstacles to recruitment

How relevant is the intervention to the intended population (do study participants show evidence of need for the intervention or is it too specific?)

Were the screening questions useful to identify RBs?

How many were screened / then approached / not suitable / suitable / reasons

Q2: How did you find the procedure of the study? What did you think of the outcome measures?

Prompts:

How feasible and suitable are the data collection procedure – ideally wouldn't do a SCED but because of ethics stipulation/ How else would you want to measure efficacy of intervention in a pilot study?

Do participants understand the questions VAS?

How feasible and suitable is the amount of data collection? e.g. too much time/burden

Do the measures appear to be performing in a consistent way with the intended population e.g. does the VAS appear to the sensitive to the effects of the intervention

Does a suitable outcome measure need to be developed – e.g. how to adapt the VAS questions, or PSYRATS?

Q3: What did you think of the manual?

Prompts:

How does intervention fit with daily life activities of study participants / does it create an additional burden to participants / therapists / teams?

To what extent is the intervention acceptable and appealing to participants?

Do the techniques seem feasible/acceptable/useful?

Any unexpected adverse events / risk of techniques?

How would you change the techniques (e.g. is this intervention more useful as a cognitive intervention rather than cognitive and behavioural?) / pie chart feasibility / contract feasibility?

Q4: How do you think the team found the study?

Prompts:

Does the research team have the skills, expertise, space and time to conduct the intervention?

Can the time efficiently and effectively manage data entry and analysis?

Q5: What do you think the participants made of the intervention?

Table 6: 15-point checklist of criteria for good thematic analysis (Braun & Clark, 2006)

PROCESS	NUMBER	CRITERIA
TRANSCRIPTION	1	The data have been transcribed to an appropriate level of detail, and the transcripts have been checked against the tapes for 'accuracy'
CODING	2	Each data item has been given equal attention in the coding process
	3	Themes have not been generated from a few vivid examples (an anecdotal approach), but instead the coding process has been thorough, inclusive and comprehensive
	4	All relevant extracts for all each theme have been collated
	5	Themes have been checked against each other and back to the original data set
	6	Themes are internally coherent, consistent, and distinctive
ANALYSIS	7	Data have been analysed – interpreted, made sense of - rather than just paraphrased or described
	8	Analysis and data match each other – the extracts illustrate the analytic claims
	9	Analysis tells a convincing and well-organised story about the data and topic
	10	A good balance between analytic narrative and illustrative extracts is provided
OVERALL	11	Enough time has been allocated to complete all phases of the analysis adequately, without rushing a phase or giving it a once-over-lightly
	12	The assumptions about, and specific approach to, thematic analysis are clearly explicated
	13	There is a good fit between what you claim you do, and what you show you have done – i.e., described method and reported analysis are consistent
	14	The language and concepts used in the report are consistent with the epistemological position of the analysis
	15	The researcher is positioned as active in the research process; themes do not just 'emerge'

Table 7: An example of a code and its extracts

Code	**Extract**
Small pool of participants	that did not particularly leave a large pool of people because you are only ever going to get such a small amount of people, I think. I think there is a handful that fit into the FEP pathway, If you had the luxury of time, then you would be able to get the handful of people that this applies to quite well I think it is just that handful, so it is hard But you are back to the issue of how many people on our caseload of will that of actually happened with? But that is where the CBTp research is going, actually all the Daniel Freeman work and introducing specific modules – you know, they are saying also that this is only going to work for a handful of people, but at least we have a good enough intervention that works very well for those people presenting with sleep problem, or self esteem. So you are going to try and take out of a pool of 1000 and you might end up with only, say 10, at most, but at best – well you can say 'well it works very well for these 10 people' So I just think that you have to be realistic that in psychosis services, those that hear voices and particularly those that hear commands, is a really small proportion of what we are actually getting through and what actually makes their way to psychology services

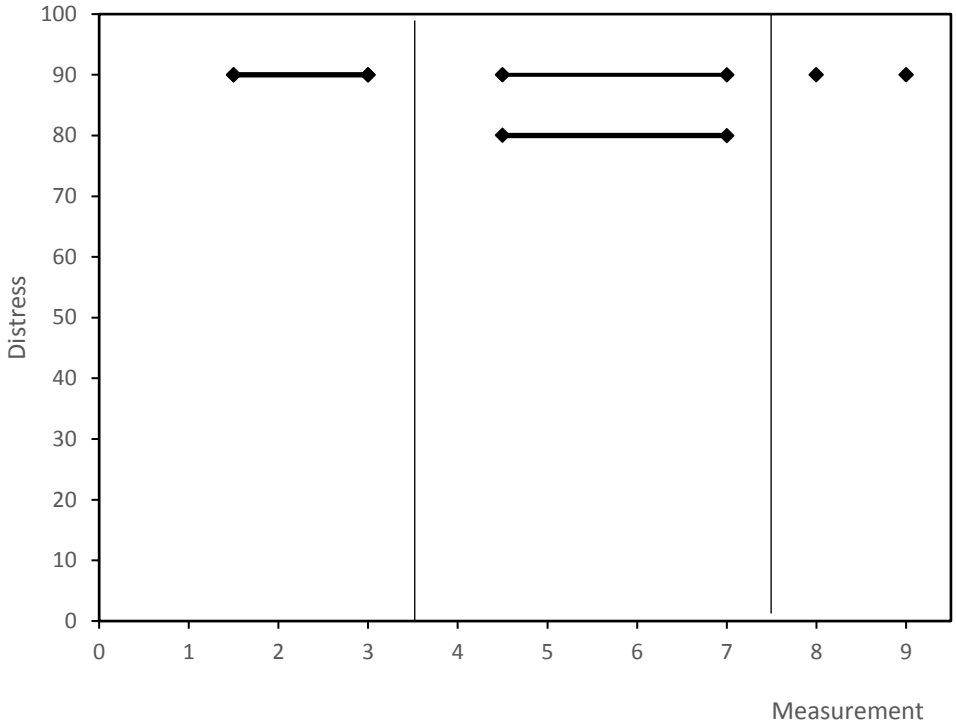
APPENDIX E – Phase 2 additional documents

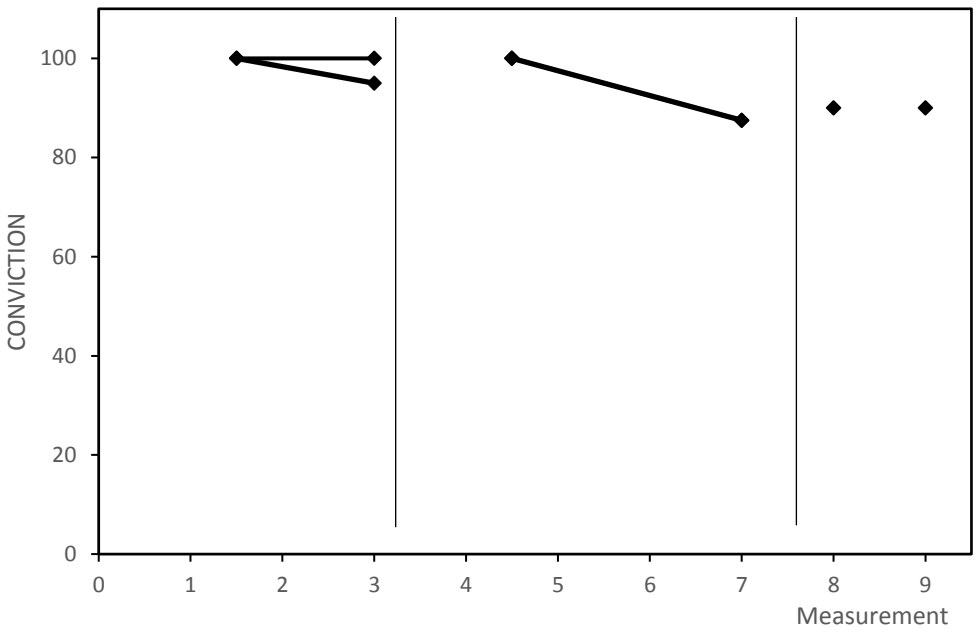
Table 8: OCI scores for each participant (pre-intervention)

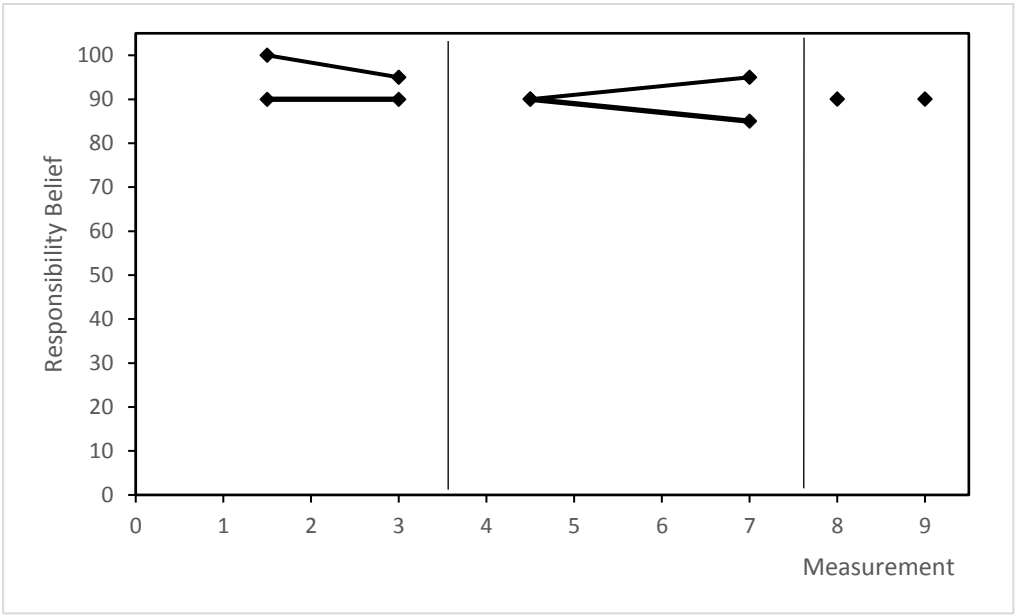
OCI Subscale	**P1**	**P2**	**P3**
Washing	0	0	0
Checking	22	1	26
Doubting	9	0	9
Ordering	12	0	15
Obsessions	26	4	22
Hoarding	5	0	8
Neutralising	14	0	16
Total Score	110	5	121

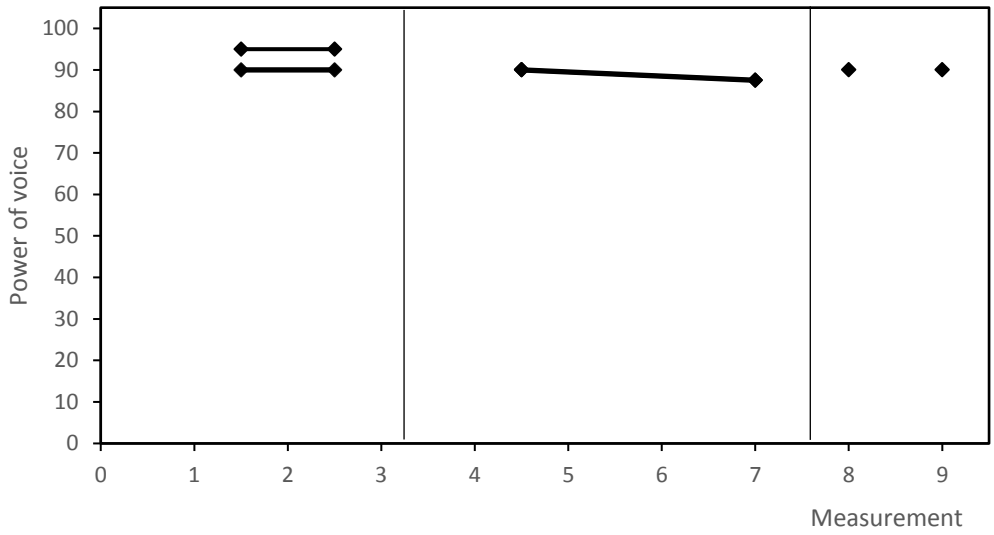
Variability Analysis (Trended Range) for Participant 1: Figures 24- 29

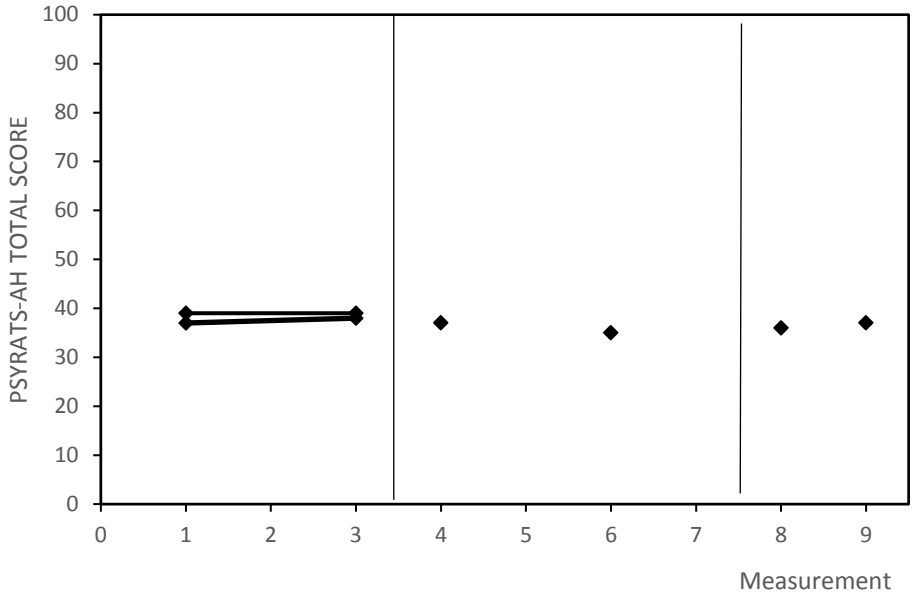
Participant 1

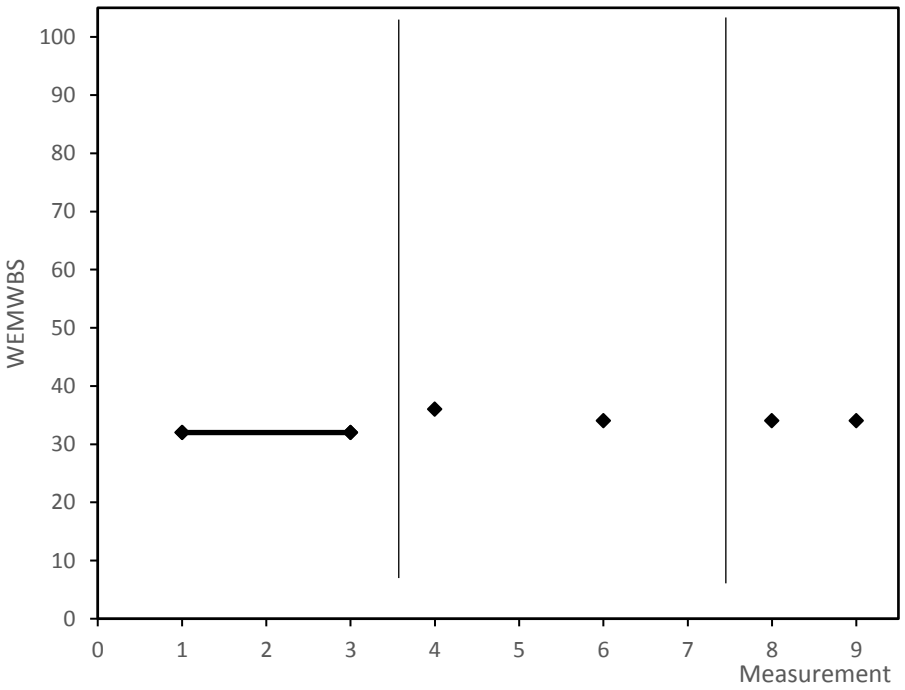




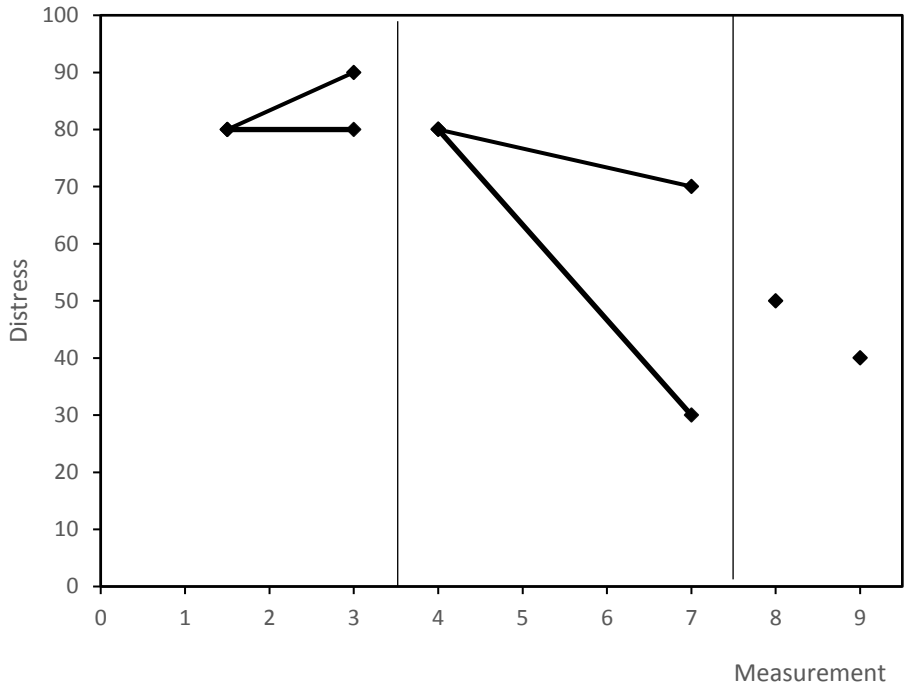

Responsibility Belief
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9
Measurement

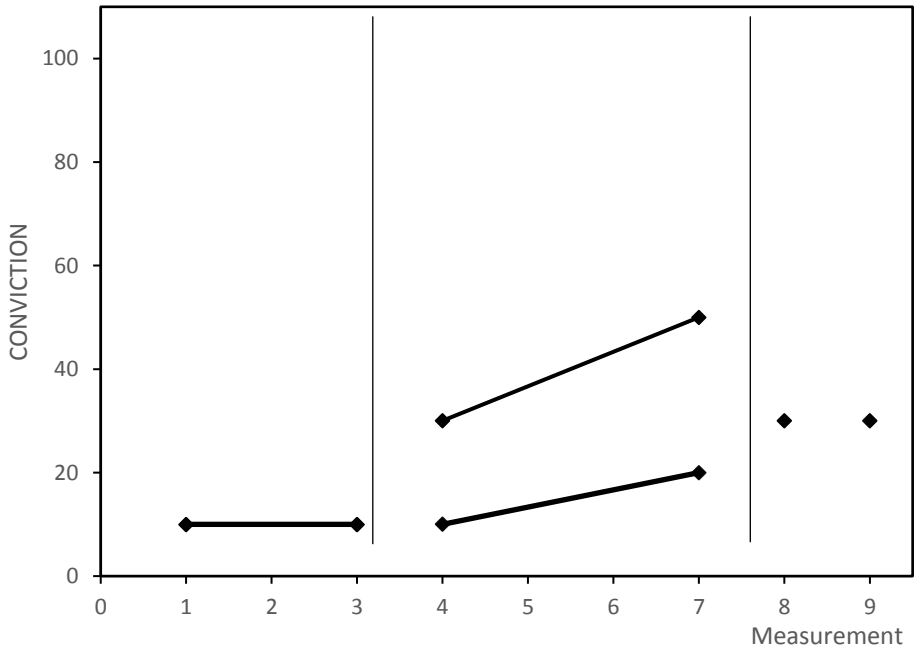

Power of voice
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9
Measurement

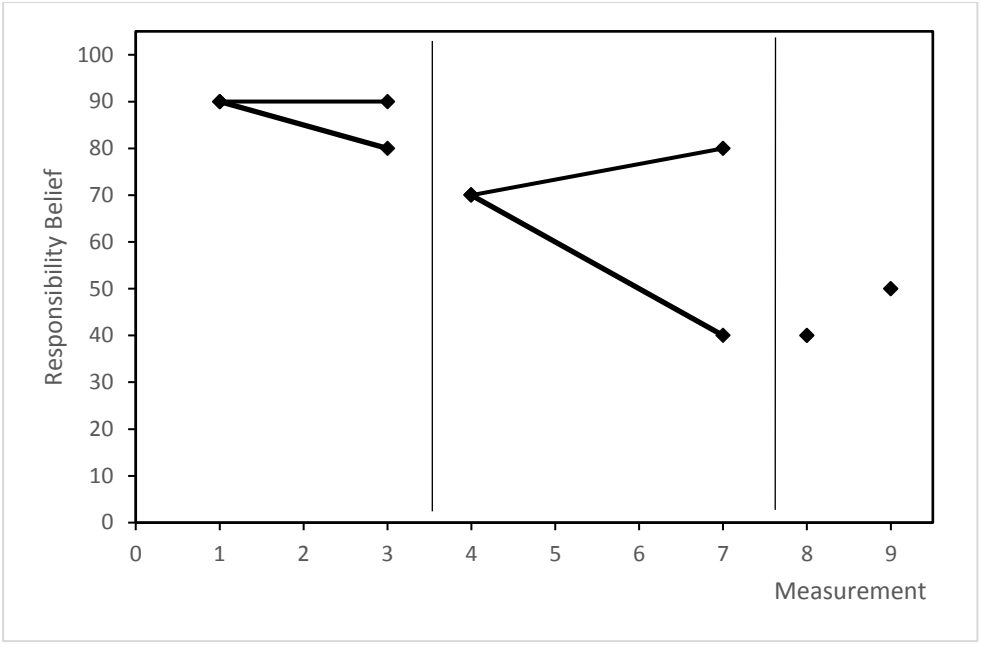

PSYRATS-AH TOTAL SCORE
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9
Measurement

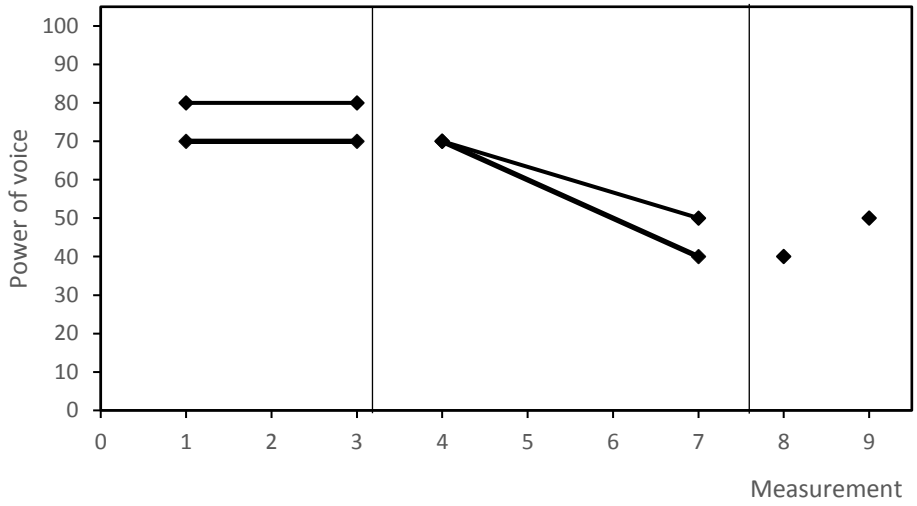

WEMWBS
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9
Measurement

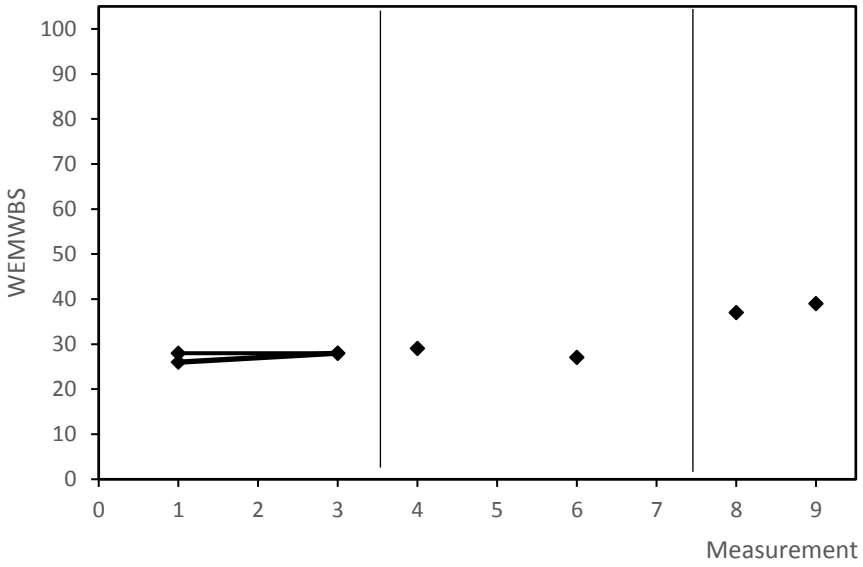
Variability Analysis (Trended Range) for Participant 2: Figures 30- 35






Responsibility Belief
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9
Measurement


Power of voice
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9
Measurement


WEMWBS
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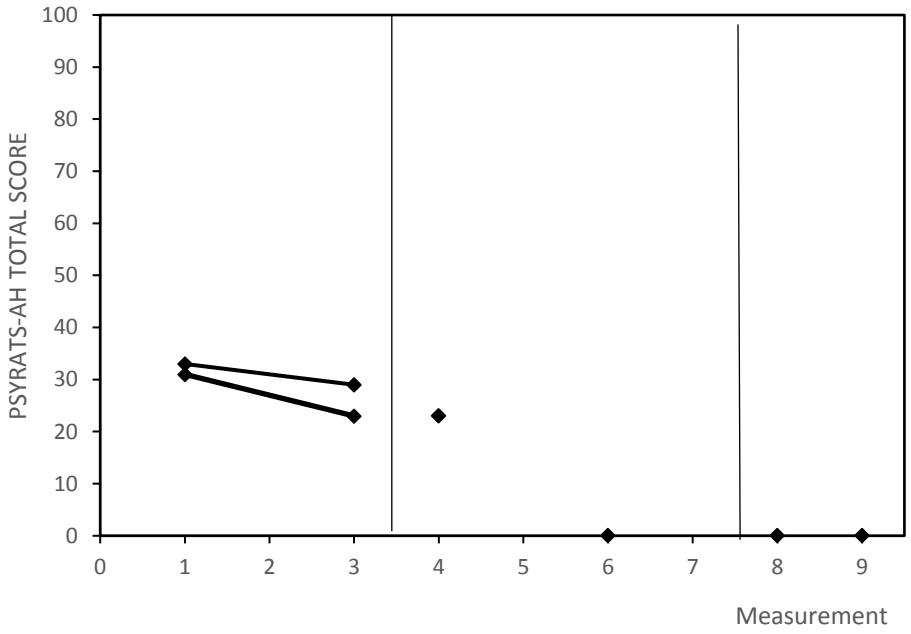
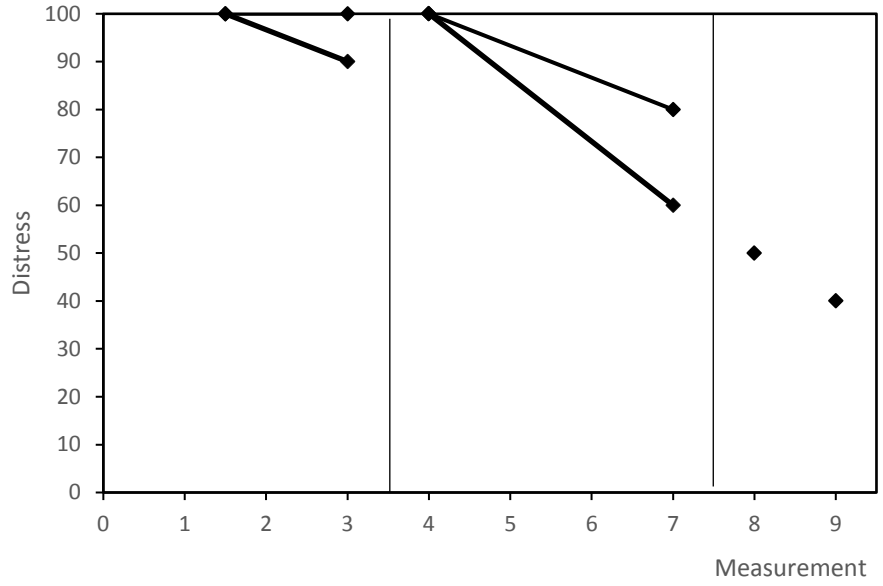
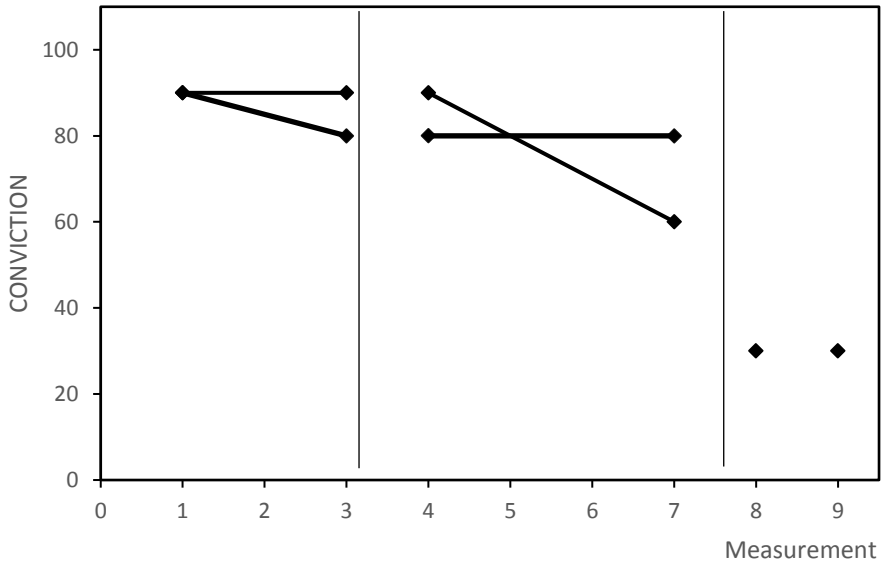
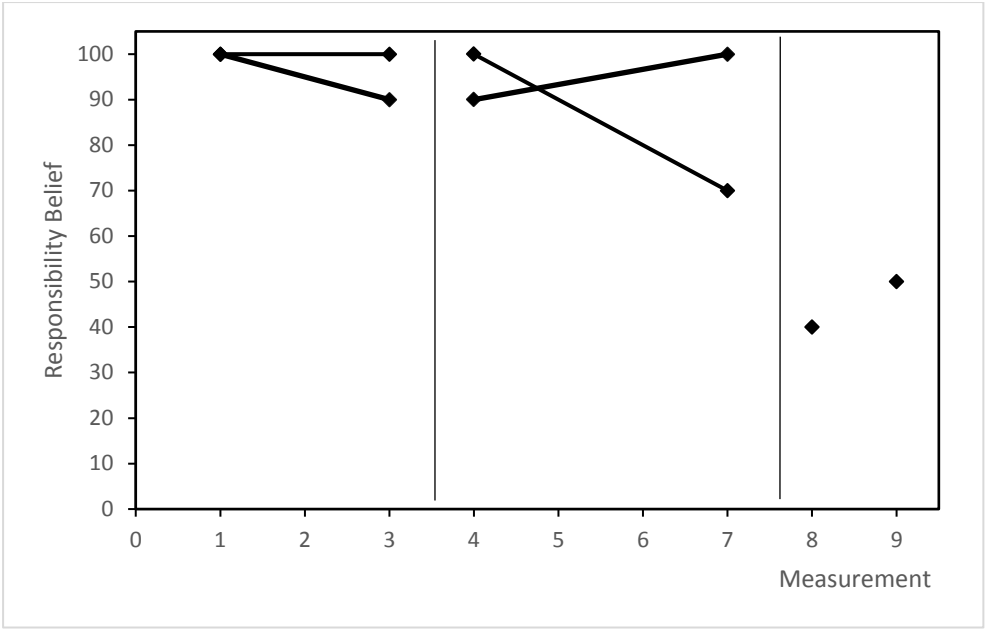
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9
Measurement

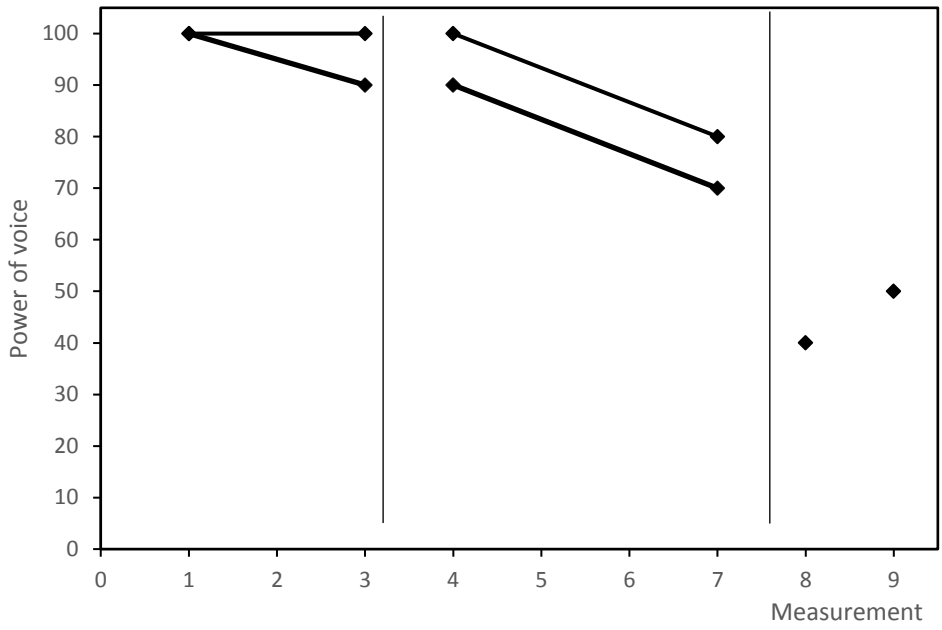

PSYRATS-AH TOTAL SCORE
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9
Measurement

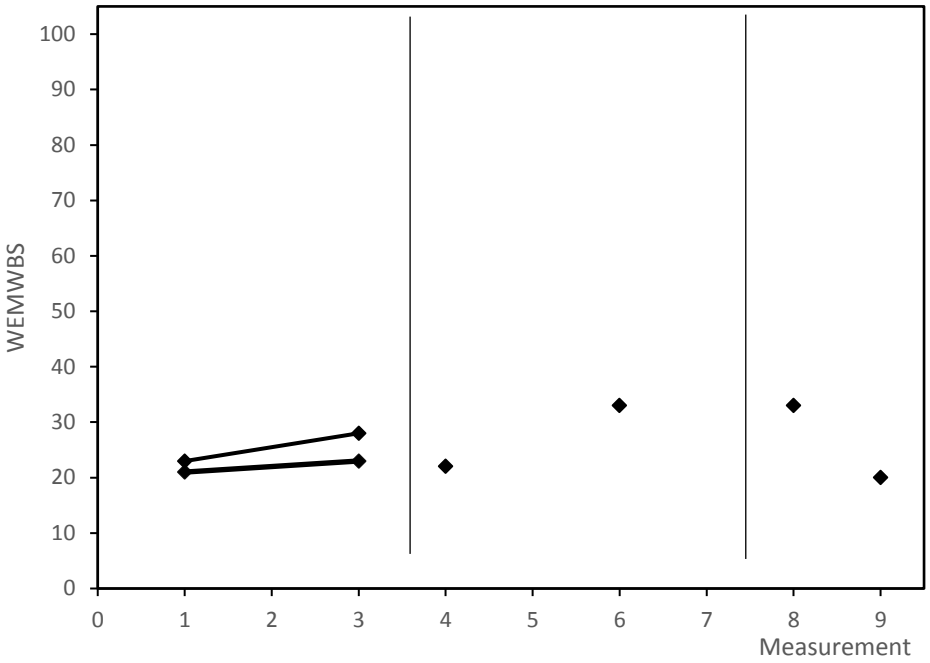
Variability Analysis (Trended Range) for Participant 3: Figures 36- 41

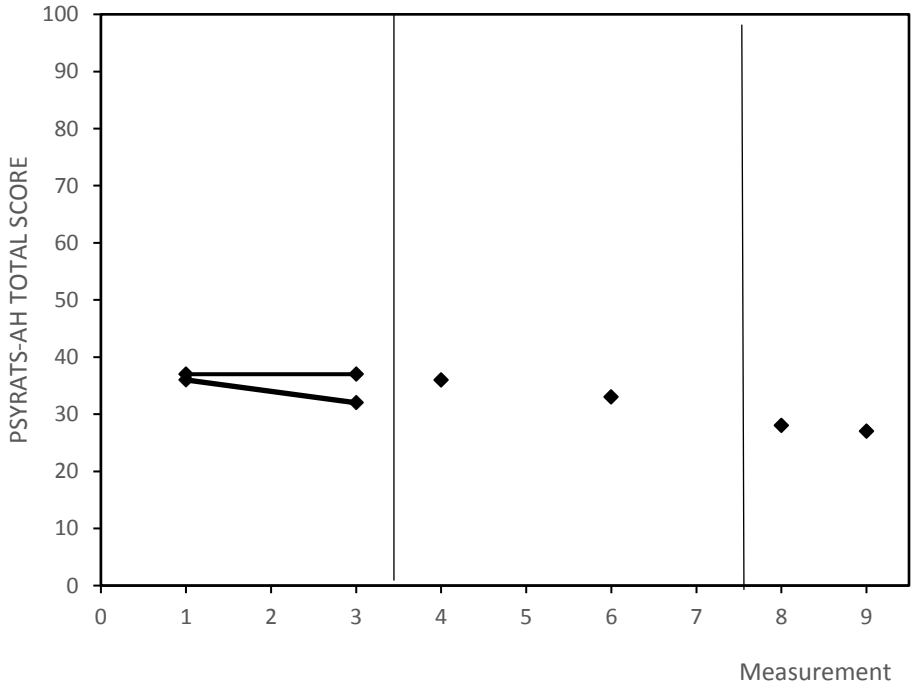





Responsibility Belief
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9
Measurement


Power of voice
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9
Measurement


WEMWBS
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9
Measurement


PSYRATS-AH TOTAL SCORE
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9
Measurement