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Is 16 the Magic Number?  
Guided self-help CBT intervention for Voices  
Evaluated (GiVE).

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Thesis submitted for the degree of Doctor of Philosophy

School of Psychology

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April 2017

**Statement:**

I hereby declare that this thesis has not been and will not be submitted in whole or in part to another University for the award of any other degree.

Cassie M Hazell

28<sup>th</sup> April 2017

**Declaration:**

The thesis conforms to an ‘article format’ in which the middle chapters consist of discrete articles written in a style that is appropriate for publication in peer-reviewed journals in the field. Chapters one, two, three, four, five, and eleven present synthetic overviews and discussions of the field and the research undertaken.

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## **Summary.**

Hearing distressing voices (also known as auditory verbal hallucinations) is a common symptom associated with a number of mental health problems. Psychological therapies, specifically cognitive behaviour therapy (CBT) can be an effective intervention for this patient group. The aim of CBT for voices (CBTv) is to reduce the distress associated with the experience, by encouraging the patient to re-evaluate their beliefs about the voice's omnipotence, omniscience, and malevolence. Despite the evidence for CBTv, very few patients are offered this therapy; largely due to a lack of resources. The aim of this thesis was to develop and begin to evaluate a CBT-based intervention for voices that was resource-light; in the hope that it could be more easily be implemented into clinical services, and therefore increase access.

This thesis begins with an introduction to the research area, and is followed by a review and evaluation of the methods used in this thesis. Chapter 6 is a systematic review and meta-analysis of the current literature on brief (<16 NICE recommended sessions) CBT for psychosis (CBTp). Chapters 7 and 8 describe the process of developing a brief CBT intervention for voices, based on the CBT self-help book 'Overcoming Distressing Voices'. Both people who hear voices, and mental health clinicians were consulted on the intervention concept and design. The outcome of these studies was guided self-help CBTv, and an accompanying therapy workbook to guide the intervention. Chapters 9 and 10 detail the design and findings of a randomised controlled trial of guided self-help CBTv delivered by Clinical Psychologists, versus a wait-list control group. Data was collected at baseline (pre-randomisation) and 12 weeks post-randomisation. The primary outcome was voice-related distress. The findings across all of the studies are then summarised and reflected upon within the Discussion chapter – including consideration of the extent to which the overall aim of this thesis (increasing access) has been achieved.

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# 1 Hearing Voices.

“You believe in a God we never see or hear, so why shouldn’t you believe in the voices I really do hear?” – Patsy Hague to Marius Romme (founders of the Hearing Voices Movement).

This quote by Patsy Hague signalled a turning point in our understanding of auditory verbal hallucinations (also known as hearing voices). Previously, hearing voices was considered a symptom of an illness, to be suppressed and rejected. Research has since demonstrated the influence of individual differences and past experiences on voice phenomenology, and the potential therapeutic value of talking about voices.

The aim of this chapter is to understand what is meant by the term ‘hearing voices’, how common this experience is, and the relationship between hearing voices and mental health.

## **1.1 Hearing Voices:**

### ***1.1.1 The Experience:***

The hallucinated voice has many of the acoustic qualities that we associate with the human voice, such as volume, location, pitch and direction (Stephane, Thuras, Nasrallah, & Georgopoulos, 2003). People may hear one, multiple or crowds of voices that can remain stable over time, or they may change (Mccarthy-Jones, Trauer, et al., 2014). The voice/s can be perceived to have a gender, personality and name, and they can sometimes sound like someone the hearer knows or has known in the past (Larøi, 2012). It is common for voices to have stock words or phrases that they tend to repeat (Hoffman, Varanko, Gilmore, & Mishara, 2008).

Although voices tend to be highly personalised, there are thought to be several categories that can classify all voices. A large scale, phenomenological survey ( $n=199$ ) of people who hear voices used cluster analysis to find there are four sub-types of voices (Mccarthy-Jones, Trauer, et al., 2014): (1) commenting and commanding voice: this voice gives instructions, and can provide a commentary on the hearer’s life; (2) ‘own thought’ voice: the dialogue of this voice reflects a stream of consciousness and rarely addresses the hearer directly; (3) nonverbal auditory hallucination: this voice may speak nonsensical phrases or make non-speech sounds; (4) replay voice: this voice is akin to reliving a memory but in an auditory format. The survey included people who hear voices with and without a need for care. Most of the participants heard voices from more than one of these clusters. This four cluster structure was replicated when only participants with a schizophrenia diagnosis were included, suggesting these sub-types may be independent of psychiatric diagnosis, and therefore may be applicable to all voice-hearing experiences - although more research is needed on the similarities and differences in the voice hearing experiences across diagnostic groups (see later). Some have argued that these voice sub-types (Mccarthy-Jones, Trauer, et al., 2014) could also be used to

describe types of thoughts, and voices may therefore be the product of a misattribution of inner speech (Morrison, Haddock, & Tarrier, 1995).

At the descriptive level this explanation seems plausible due to the substantial overlap between inner speech and hearing voices (Langdon, Jones, Connaughton, & Fernyhough, 2009); however people who hear voices report experiencing inner speech as well as, and separate to, hearing voices (Langdon et al., 2009), and if voices are simply misattributed inner speech, it is not clear why only some inner speech would be heard as voices. Moreover, voices tend to use the second person ('you'), whereas inner speech typically uses the first ('I') (McCarthy-Jones et al., 2014). This theory falls down further when we consider the subjective experience of hearing voices. A qualitative study on the phenomenology of voices interviewed 50 participants about their voice hearing experiences (Beavan, 2011). Using thematic analysis, five themes were extracted: (1) the voice has an identity, (2) relationship between the hearer and the voice, (3) the voice has a significant impact upon the hearer's life, (4) the voice has a convincing sense of reality, and (5) the voice content has personal meaning. These themes do not consistently apply to inner speech – for example, few people would report being in a relationship with their thoughts, or that their thoughts have an identity different from their own. These findings should be considered in light of the limitation about their applicability to people who hear voices with (58% of the sample) and without (42% of the sample) a need for care. Sub-sample analysis, such as that used by McCarthy-Jones et al. (2014) would address this.

Brain imaging studies offer a more objective verification that inner speech and hearing voices are distinct experiences. The brain activity that occurs during inner speech is markedly different to that when hearing voices, reflecting a difference in the perception of internal (inner speech) versus external stimuli (hearing voices) (Strik, Dierks, Hubl, & Horn, 2008). The parts of the brain associated with the perception of sound, like Heschl's gyrus (Dierks et al., 1999) and Broca's area (Fu & McGuire, 2003), become active when people are hearing voices; whereas inner speech is associated with reduced activity in the primary auditory cortex (Strik et al., 2008). The physiological evidence therefore demonstrates hearing voices is more akin to the perception of speech in the external world, rather than inner speech.

### ***1.1.2 Prevalence:***

In spite of the conflicting perspectives available, the research on defining 'hearing voices' is much clearer than that on the prevalence of this experience. A review of 17 prevalence studies, found a median of 13.2% of people in the general population report hearing voices (Beavan, Read, & Cartwright, 2011); but this value masks substantial variation in prevalence rates that can largely be explained by the differing thresholds used by each study to meet the criteria for having experienced hearing voices. For example, the often cited study by

Posey and Losch (1983) found 71% of their sample reported hearing voices – however, hearing someone call your name when no one was around on one occasion would be enough to meet the criteria for hearing voices. In stark contrast, Johns et al. (2004) found a prevalence rate of just 0.7%. In this study, hearing voices was defined as hearing a few words or sentences without anyone there to account for it on at least one occasion. To add to this heterogeneity, prevalence rates also vary substantially based on the gender and age of participants: hearing voices is generally more common in males than females, until people enter older adulthood (Tien, 1991).

It is likely that the differing level of linguistic complexity in these definitions of hearing voices can account for the majority of the variance between the prevalence rates. But neither of these definitions seems to accurately reflect the real world experience of hearing voices, whereby voices tend to be heard on a regular basis over a significant period of time (Romme, Honig, Noorthoorn, & Escher, 1992). Although the prevalence estimate from Johns et al. (2004) is probably closer to the real figure, the results of Posey and Losch (1983) evidence that most people have had an experience that they can relate to the experience of hearing voices. Statistics like this can then be used to normalise hearing voices at both an individual and societal level.

There are other variables that have been found to moderate prevalence rates of hearing voices, such as age – whereby prevalence rates decrease with age, typically being high in childhood, and reducing when people enter adolescence (Kelleher et al., 2012). Also culture can influence a person's willingness to disclose whether they hear voices or not, which then effects prevalence rates (al-Issa, 1995) – typically being part of a spiritual community is associated with great acceptance and openness about hearing voices, compared to more secular communities (Beavan, 2007). Despite this evidence, it is still most likely that the differing prevalence rates found by Posey and Losch (1983), and Johns et al. (2004) can be attributed to the different definitions of hearing voices used.

## **1.2 Hearing Voices and Psychosis:**

Broadly speaking, studies on the prevalence of hearing voices claim to provide evidence that many people hear voices in the general population, outside of the context of a mental health problem. Despite the general acknowledgement that hearing voices is a common human experience (Romme & Escher, 1989), none of the studies discussed thus far were able to provide evidence that the participants in their study whom reported hearing voices did not have a psychiatric diagnosis. Looking beyond prevalence studies, Sommer et al. (2010) were able to recruit more than 100 participants who heard voices but did not meet diagnostic criteria for either a psychosis or personality disorder when screened. The implication of this finding is that hearing voices in itself does not constitute a mental health problem (Watkins, 1998).

The emotional response to hearing voices is the most robustly endorsed factor in determining whether the experience becomes part of a mental health problem or not. In the context of a mental health issue, voices are generally experienced as distressing, compared to being perceived as either neutral or positive for those who hear voices in the non-clinical population (Daalman et al., 2011). Consequently, experiencing distress in relation to hearing voices is one of the main diagnostic criteria for psychosis disorders (American Psychiatric Association, 2013; World Health Organisation (WHO), 1992), but what causes this distress?

Firstly, negative voice content has been found to be strongly associated with voice-related distress (Beavan & Read, 2010). However, as this study used a correlational design it is not possible to infer causality – for example, people could be distressed by their voices because of the negative content, or the distress could cause the voice content to be perceived as more negative. Secondly, people who hear distressing voices are more likely to think they cannot control their voices (Brett, Heriot-Maitland, McGuire, & Peters, 2014); however, as this study included participants experiencing ‘hallucinations’ across all sensory modalities (not just auditory) these results may not necessarily apply to hearing voices specifically. With specific reference to voices, Ward et al. (2013) experimentally induced hearing voices in participants who reported psychosis-like experiences (PLEs). Those with a pre-existing mental health problem made more external attributions (out of my control), and were less likely to make internal attributions (within my control), compared to those without a mental health problem. Although experimental research is helpful in explaining causality, its low ecological validity makes it difficult to generalise the findings beyond the laboratory. For example, the simulated voices were made to sound like they were coming from just outside of the head – but many people hear voices that are perceived as being far away or coming from inside the head (E. M. Andrew, Gray, & Snowden, 2008). Consequently these results may only be valid for the participants who were able to relate the simulated voice to their own voice hearing experiences.

Thirdly, hearing distressing voices is associated with reduced social support (Brett et al., 2014). The typical patterns of relating that people engage in within their social worlds has been found to mirror the way that people relate to their voices i.e. if social relationships are negative then the voice-hearer relationship is likely to be negative as well (Hayward, 2003). Unsurprisingly, those with a need for care tend to have more negative relationships with their voices than those without (Sorrell, Hayward, & Meddings, 2010). Again, from these studies we cannot ascertain the direction of causality – it could be that hearing distressing voices makes it difficult to maintain positive relationships (Mawson, Berry, Murray, & Hayward, 2011), or that negative relating and social isolation causes mental health difficulties (Cornwell & Waite, 2009).

### **1.3 Hearing Voices and Other Mental Health Problems:**

It is estimated that more than 60% of people with psychosis experience distressing voices (Simon McCarthy-Jones et al., 2017; Slade & Bentall, 1988). Consequently, most of the studies discussed thus far consider distressing voices in the context of a psychosis diagnosis. But if we believe that hearing voices is a common human experience (Romme & Escher, 1989), then it is logical to assume that it could be common for people with non-psychosis mental health problems to also hear voices – and the evidence seems to support this.

In clinical practice, it is not uncommon for people to report hearing voices in the context of bipolar, posttraumatic stress disorder (PTSD), and borderline personality disorder (BPD) to name a few (McCarthy-Jones, 2012). For example, prevalence rates for hearing voices are between 54 and 21% for people with BPD (Schroeder, Fisher, & Schafer, 2013), and between 20 to 40% for combat-related PTSD (Anketell et al., 2010). Even for those who hear voices in the context of psychosis, there is a high incidence of comorbidity (Jacobi et al., 2004). Using hearing voices as a diagnostic criteria is not sufficient to distinguish between those with a psychosis disorder and those with other mental health problems (Pierre, 2010). Hearing voices in adolescence does not predict the development of psychosis more than any other mental health difficulty (Dhossche, Ferdinand, Van Der Ende, Hofstra, & Verhulst, 2002); however this finding may be influenced by selective attrition, as those with psychosis could be more likely to drop out of the study compared to those with more common mental health problems.

Even though hearing voices is prevalent in people with non-psychosis mental health diagnoses, it is still mostly associated with psychosis. There is still some scepticism about the validity of hearing voices in the context other mental health problems, and whether this experience is the same as that experienced within psychosis. Previously, hearing voices in non-psychosis conditions, also known as ‘pseudohallucinations’, were assumed to be less severe (Yee, Korner, McSwiggan, Meares, & Stevenson, 2005). Traditionally these pseudohallucinations were not taken as seriously as ‘proper’ hallucinations (meaning those occurring in psychosis) (Berrios & Denning, 1996). Thankfully, the term pseudohallucinations is rarely used now (Adams & Sanders, 2011); predominantly due to criticisms that it perpetuates stigma, and is in fact inaccurate – as proved by studies that have compared these ‘pseudohallucinations’ to those in the context of psychosis.

#### **1.3.1 Borderline Personality Disorder:**

The Borderline Personality Disorder (BPD) diagnosis is characterised by interpersonal and emotion regulation difficulties (American Psychiatric Association, 2013). The comparison between those with BPD who hear voices, and those with psychosis who hear voices, has



received the greatest research attention. Research studies have reported no significant differences between people who hear voices within psychosis compared to those with a BPD diagnosis, in terms of the voice phenomenology (Slotema et al., 2012), voice impact (Kingdon et al., 2010), and appraisals of voices (Hepworth, Ashcroft, & Kingdon, 2013b). However the gender balance within these studies was dissimilar, with the BPD groups having a higher proportion of female participants. As the experience of hearing voices can vary as a function of gender (e.g. Sharma, Dowd, & Janicak, 1999), it is important for future studies to control for this. The one dimension where voices did differ was in terms of emotional engagement: Hepworth et al. (2013) found that those with psychosis were significantly more likely to emotionally engage with and less likely to resist voices compared to those with BPD. This point of difference highlights an interaction between hearing voices and the other symptoms associated with BPD i.e. emotion dysregulation (Carpenter & Trull, 2013).

### ***1.3.2 PTSD:***

Beyond BPD, voices are frequently experienced as part of posttraumatic stress disorder (PTSD), especially in those who dissociate (Anketell et al., 2010). Neither the severity nor the intensity of voices differed between those with PTSD and psychosis (Hamner et al., 2000).

### ***1.3.3 Other Mental Health Problems:***

There are again no significant differences between the voice hearing experience in relation to psychosis and those with Dissociative Identity Disorder (DID) (Dorahy et al., 2009) (in terms voice-related appraisals), and Bipolar Disorder (BD) (Pini et al., 2004) (in terms of voice frequency). People can also hear voices in the context of more common mental health problems. Those with depression and anxiety are at an increased risk of hearing voices compared to non-psychiatric controls (Varghese et al., 2011), although there is currently no research available to determine whether the experience of hearing voices is similar between these groups.

### ***1.3.4 The Role of Sample Size:***

The overall impression given by these studies is that voices do not differ across these psychiatric diagnoses. However most of these studies were relatively small, and therefore are underpowered to detect anything other than very large between-group differences (i.e. Kingdon et al., 2010:  $n=33$ ; Hepworth et al., 2013:  $n=10$ ; Dorahy et al., 2009:  $n=29$ ). Consequently non-significant findings between diagnostic groups may well be the result of a Type II error. It may be more appropriate, with such small sample studies, to calculate the between-group effect sizes and confidence intervals, as these will give an indication of the size of between-group differences, irrespective of sample size (Aberson, 2002).

Author	Psychosis			Non-Psychosis			Measure	Voice Dimension	<i>d</i> (95% CI)
	Diagnosis	<i>n</i>	<i>M</i> ( <i>SD</i> )	Diagnosis	<i>n</i>	<i>M</i> ( <i>SD</i> )			
Hepworth (2013)	Schizophrenia	23	9.57(5.66)	BPD	10	13.00(4.22)	BAVQ	Beliefs about malevolence	-0.65 [-1.41, 0.11]
			3.60(4.13)			0.30(0.68)		Beliefs about benevolence	0.94 [.17, 1.72]*
			10.48(4.70)			12.00(3.46)		Beliefs about omnipotence	-0.35 [-1.09, .40]
			3.09(3.51)			0.00(0.00)		Emotional engagement	1.05 [.26, 1.83]*
			2.21(2.47)			2.10(2.13)		Behavioural engagement	0.05 [-.70, .79]
			7.35(3.21)			10.90(1.44)		Emotional resistance	-1.26 [-2.06, -.50]*
			8.43(4.98)			8.70(3.74)		Behavioural resistance	-0.06 [-.80, .68]
Hamner (2000)	Schizophrenia	40	4.23(1.23)	PTSD	40	4.23(1.12)	PANSS	Hallucinations scale	0.00 [-.44, .44]

Kingdon (2010)	Schizophrenia	35	2.77(1.57)	BPD	19	2.42(1.39)	PSYRATS	Frequency	0.23 [-.33, .79]
		35	3.40(1.56)		15	4.20(1.01)		Duration	-0.56 [-1.18, .05]
		36	3.25(1.46)		15	3.13(1.30)		Perceived location	0.08 [-.52, .69]
		36	2.97(1.21)		15	3.33(1.05)		Loudness	-0.31 [-.91, .30]
		37	3.11(1.76)		15	3.53(1.36)		Beliefs about origin	-0.25 [-.86, .35]
		35	3.46(1.50)		15	4.53(0.83)		Amount of negative content	-0.80 [-1.42, -.17]*
		34	3.38(1.48)		15	4.53(0.92)		Degree of negative content	-0.86 [-1.49, -.23]*
		34	3.03(1.38)		15	4.20(1.15)		Amount of distress	-0.89 [-1.52, -.26]*
		34	3.74(1.19)		14	4.36(1.15)		Intensity of distress	-0.53

									-1.16, .11]
		34	3.53(1.29)		14	3.43(0.85)		Disruption to life	0.08
									[-.54, .71]
		33	4.00(1.30)		14	3.86(1.23)		Controllability	0.11
									[-.52, .73]
Pini (2004)	Schizophrenia	46	N/A	Mixed	49	N/A	SCID	Frequency	-0.16
				Mania					[-.62, .31]
Slotema	Schizophrenia &	66	3.10(0.95)	BPD	33	2.80(1.00)	PSYRATS	Frequency	0.31
(2012)	Schizoaffective Disorder								[-.11, .73]
			2.80(1.10)			2.70(1.20)		Duration	0.09
									[-.33, .51]
			2.20(1.20)			1.70(1.00)		Perceived location	0.44
									[.02, .86]*
			1.90(0.90)			2.00(1.00)		Loudness	-0.11
									[-.52, .31]
			2.40(1.30)			2.00(1.20)		Beliefs about origin	-0.32
									[-.10, .74]
			2.80(1.20)			2.80(1.40)		Amount of negative	0.00
								content	[-.42, .42]

3.00(1.10)	2.70(1.10)	Degree of negative content	0.27 [-.15, .69]
3.10(1.10)	3.00(1.40)	Amount of distress	0.08 [-.34, .50]
2.60(0.80)	2.60(1.10)	Intensity of distress	0.00 [-.42, .42]
2.40(0.80)	1.80(0.90)	Disruption to life	0.72 [.29, 1.15]*
3.00(1.10)	2.70(1.40)	Controllability	0.25 [-.17, .67]

Table 1. Cohen's *d* effect sizes for dimensions related to hearing voices between psychosis and non-psychosis disorders.

*Note:* N/A where data other than means and standard deviation have been used to calculate effect sizes; BPD = Borderline Personality Disorder; PTSD = Posttraumatic Stress Disorder; effect sizes could not be calculated for Dorahy et al. (2009) because only frequency data was collected; \*  $p < .05$ .

Looking again at these studies, the between group effect sizes varied between small, medium and large (Cohen, 1960) (see Table 1). Overall, the analysis is somewhat ‘messy’, with no clear patterns of differences across the studies. From this data, it seems there are little differences between voices in the context of psychosis, and PTSD and mixed mania. The larger effect sizes were associated with studies where BPD patients were the comparison group. As mentioned previously, these larger between-group effects tended to occur on outcomes related to affect e.g. degree of negative content, emotional engagement, and emotional resistance – which can most likely be explained by the other symptoms associated with a BPD diagnosis (i.e. difficulty managing emotions (American Psychiatric Association, 2013; World Health Organisation (WHO), 1992)). Importantly, there was a small between-group effect on omnipotence beliefs about voices – this may be crucial when considering the appropriateness of cognitive behaviour therapy for voices (CBTv) for people without a psychosis diagnosis. Again, these findings must be interpreted with caution in light of the small study sample sizes, and subsequent wide confidence intervals.

If and how voices differ as a function of the person’s psychiatric diagnosis is not clear from the research to date, given that no studies were sufficiently powered to detect small between-group effects. However the results do support the suggestion that people can hear voices in the context of a variety of mental health problems, other than psychosis. Furthermore, these voices appear to be distressing, thereby challenging the concept of ‘pseudohallucinations’. The prevalence of hearing voices in these non-psychosis diagnoses has prompted many to advocate the symptom specific approach, rather than being diagnosis driven (Bentall, Jackson, & Pilgrim, 1988). This approach assumes that hearing voices has its own causes and predictors that are independent from psychosis (Bentall & Fernyhough, 2008). Grouping people based on their symptoms rather than diagnosis produces a more homogenous population that have a shared target for therapy (Buchanan & Carpenter, 1994).

In line with the symptom specific approach, psychological interventions have been developed to specifically target distressing voices. The most widely researched therapeutic model that has been applied to distressing voices is the cognitive behavioural model that provides the basis for cognitive behavioural therapy (CBT).

## 2 Cognitive Behaviour Therapy.

The aim of this chapter is to describe the development of cognitive behaviour therapy (CBT), and the results from the earlier trials of CBT as it was first applied to common mental health problems.

## **2.1 The Development of Cognitive Behaviour Therapy.**

### **2.1.1 Beck:**

The initial development of cognitive behaviour therapy (CBT) was the innovation of Dr Aaron Beck. The Beck Institute (2014) detail how CBT was developed:

Before CBT, psychoanalysis was the dominant therapeutic approach for most mental health problems (Dolnick, 1998). In the 1960s, Beck was working as a psychiatrist and actively practicing psychoanalysis. He designed and carried out several experiments that were hypothesised to validate the principals of psychoanalysis. When his findings contradicted the psychoanalytic approach, Beck (1963) went on to write his seminal paper describing his clinical observations of ‘cognitive distortions’ seen in patients with depression. These observations became the foundations of a cognitive model of depression, in which Beck linked beliefs to ‘thinking errors’, and how these may cause the symptoms of depression (Beck, 1964).

Beck’s cognitive therapy aimed to understand mental health problems through the same cognitive processes used in everyday information processing and perception. This approach was praised for its ability to normalise mental health problems. CBT was soon adapted for use with other mental health problems, and has now become the dominant psychological therapy offered in the UK (Beck & Haigh, 2014).

### **2.1.2 Ellis:**

While Beck was developing CBT, Dr Albert Ellis had also become disconcerted with psychoanalysis as it was not producing the results promised by Freud – so Ellis sought an alternative (Dalby, 1987). Akin to Beck, Ellis hypothesised that ‘irrational thoughts’ were important in understanding mental health problems, but with the added addition of behaviourism. Ellis’ work was grounded in the Roman philosophy “that there are no legitimate reasons why human beings need make themselves terribly upset, hysterical, or emotionally disturbed, no matter what kind of negative stimuli are impinging on them” (Ellis, 1969, pp. 84).

Ellis’ approach was summarised within the ABC model (Figure 1) (Ellis, 1991). This model compliments Beck's (1964) model as cognitive processes are the key component of both models. Ellis developed his own therapy off the back of this model, called Rational-Emotive Therapy (RET). Although both Ellis and Beck developed their interventions separately, their work occurred almost in parallel. RET has much in common with CBT: both use ‘homework’



to consolidate what was learnt in therapy, and have a ‘here and now’ focus (Ellis, 1969). Both CBT and RET aim to achieve change through the same general process of questioning the patient’s unhelpful beliefs, and constructing an alternative, more adaptive belief (Dryden & Branch, 2008). There are minor differences within their models – notably that Beck's (1976) model (Figure 2) entertains a longitudinal understanding of the mental health problem, whereas Ellis' (1969) does not. Also Beck (1979), unlike Ellis' (1969) RET model, acknowledges a reciprocal relationship between unhelpful beliefs and the presenting mental health symptoms.

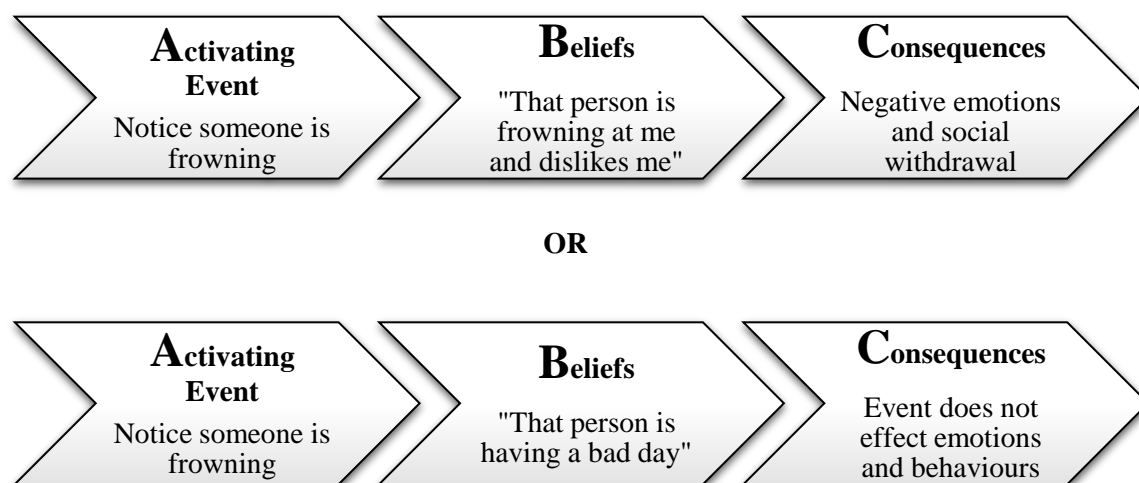


Figure 1: ABC model in practice (Ellis, 1991).

Their combined ideas and research were responsible for confirming the underlying assumption of CBT: that it is the beliefs about an event that can cause distress, not the event itself (Beck, 2011). The CBT model argues that the point of differentiation between different mental health problems occurs at the level of beliefs and thoughts i.e. the form and function of the belief determines the consequences, which in turn determines the presentation of the mental health problem. Consequently, both models suggest that beliefs should be the target of intervention.

To illustrate, Ellis (1991) describes an example of the ABC model where a disturbance has occurred (see Figure 1). The example illustrates how the beliefs related to an event determine the consequences. When the event is interpreted as personal, threatening or salient, this may result in a negative emotional and behavioural reaction – the cognitive model is able to explain how people can have different responses to the same event (Pietrzak et al., 2014). Mental health problems can then develop if these unhelpful beliefs persist (Beck, 2011).

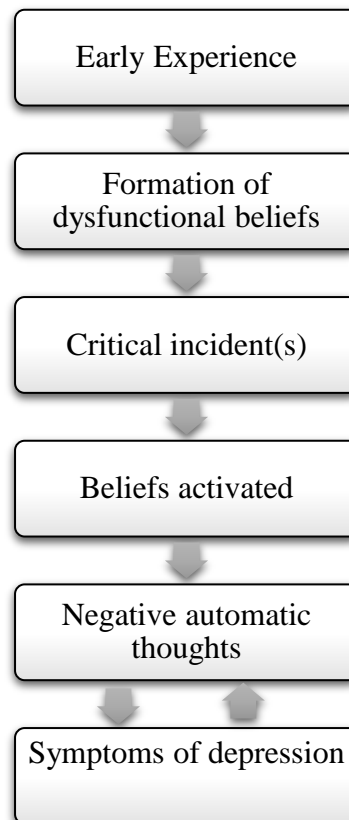


Figure 2. Beck's (1976) cognitive model of depression.

### 2.1.3 *Evaluating the Cognitive Behavioural Model:*

In support of Beck's (1976) model, people with depression and anxiety can be differentiated according to their unhelpful beliefs; those with depression were more likely to endorse hopeless beliefs, whereas those with anxiety endorsed more threat beliefs (Beck, Brown, Steer, Eidelson, & Riskind, 1987). However, this study was not able to falsify the fact that other factors may also discriminate the two diagnoses. And in fact, studies have demonstrated that those with anxiety and depression also report different types of triggers; those with depression report more loss-related triggers, whereas those with anxiety report more danger triggers (Finlay-Jones & Brown, 1981). But these results may be explained by the different attentional and belief biases associated with each diagnosis - for example, people with anxiety are more likely to recall danger-related events than those without anxiety (Muris, Luermans, Merckelbach, & Mayer, 2000).

The mechanisms at play in the cognitive model have been supported at the neurological level (Disner, Beevers, Haigh, & Beck, 2011). Levels of brain activation have been found to shift from the emotion centres of the brain (e.g. amygdala and hippocampus), to the more cognitive parts (e.g. frontal cortex) as thinking biases reduce (D. A. Clark & Beck, 2010). But none of the studies discussed thus far are able to verify the causal direction between constructs

posited by the cognitive model. In contrast to Beck's (1976) hypothesis, it is possible that the dysfunctional beliefs thought to cause depression, are in fact also a consequence of the condition. This notion is supported by research, as feeling depressed can make negative beliefs and thoughts more readily available (Teasdale, 1983). It appears that the relationship between beliefs and depression symptoms is a reciprocal one; but this requires further investigation.

Unlike Ellis (1991), Beck's (1976) earlier work was predominantly cognitive. It therefore neglected the role of unhelpful behaviours, such as safety behaviours, in maintaining mental health problems (Moulds, Kandris, Williams, & Lang, 2008). However these safety behaviours may just be the externalisation of the unhelpful beliefs. The most important means of evaluating the cognitive behavioural model is by assessing its therapeutic value. Cognitive therapy based on Beck's (1976) model was found to reduce depressive symptoms (Fennell & Teasdale, 1987), and produce treatment effects superior to antidepressants on both self-reported and clinician-rated outcomes (Rush, Beck, Kovacs, & Hollon, 1977). However, again these trials cannot rule out the possibility that negative beliefs may be both a consequence and a cause of depression. For example, studies of non-CBT interventions for depression (such as medication or other psychological therapies) are not only effective, but also produce improvements at the cognitive level that are comparable to CBT (Oei & Free, 1995). Therefore, it may not be essential to target negative beliefs in order to bring about positive change (Longmore & Worrell, 2007).

Despite these limitations in the field, the evidence in support of cognitive therapy for depression has accumulated over the years. It is now one of the key treatments recommended for mild, moderate and severe depression both in the UK (NICE, 2011b), and internationally (American Psychiatric Association (APA), 2015; Royal Australian and New Zealand College of Psychiatrists Clinical Practice Guidelines Team for Depression, 2004). Cognitive therapy grew in popularity amongst therapists due to the positive treatment outcomes, and the scientific rigour of its manualised protocol.

## **2.2 Cognitive Behaviour Therapy:**

The content of CBT is driven by both the therapist and the patient. There is considerable room for flexibility and personalisation of the therapy, but there are some key parts of CBT that generally remain constant.

### **2.2.1 Formulation:**

All CBT interventions begin with an assessment, formulation and intervention plan that is developed collaboratively with the patient (Grant, Townend, Mills, & Cockx, 2008). The assessment involves discussing the presenting problem, as well as any relevant developmental

factors (Beck, 1976). The formulation serves to provide an individualised, theory-driven, understanding of how thoughts, behaviours and feelings may contribute to the beginning and maintenance of the presenting problem. A good formulation should identify different levels of dysfunctional cognitions – from the basic automatic thoughts to the more complex core beliefs (Beck, 2010). Being able to support a patient to assemble a coherent, theory-driven formulation is a skill that takes time and training to develop (Kuyken, Fothergill, Musa, & Chadwick, 2005). All forms of cognitive therapy involve some type of formulation (Alford & Beck, 1997).

Creating a CBT formulation requires collaborative empiricism: this assumes that both the therapist and the client are experts (Johnstone & Dallos, 2014). Formulations tend to take the form of diagrams. The most common CBT formulation is the five aspects model, also known as the ‘Hot Cross Bun’ (Figure 3) (Padesky and Mooney (1990). It provides a model that is both sufficiently detailed, and also accessible to clients (Papworth, Marrinan, Martin, Keegan, & Chaddock, 2013). Although the components of the ‘Hot Cross Bun’ do support aspects of the Beck's (1976) cognitive model (i.e. the importance of beliefs, and triggering event), the model’s pathways do not have the same level of empirical support.

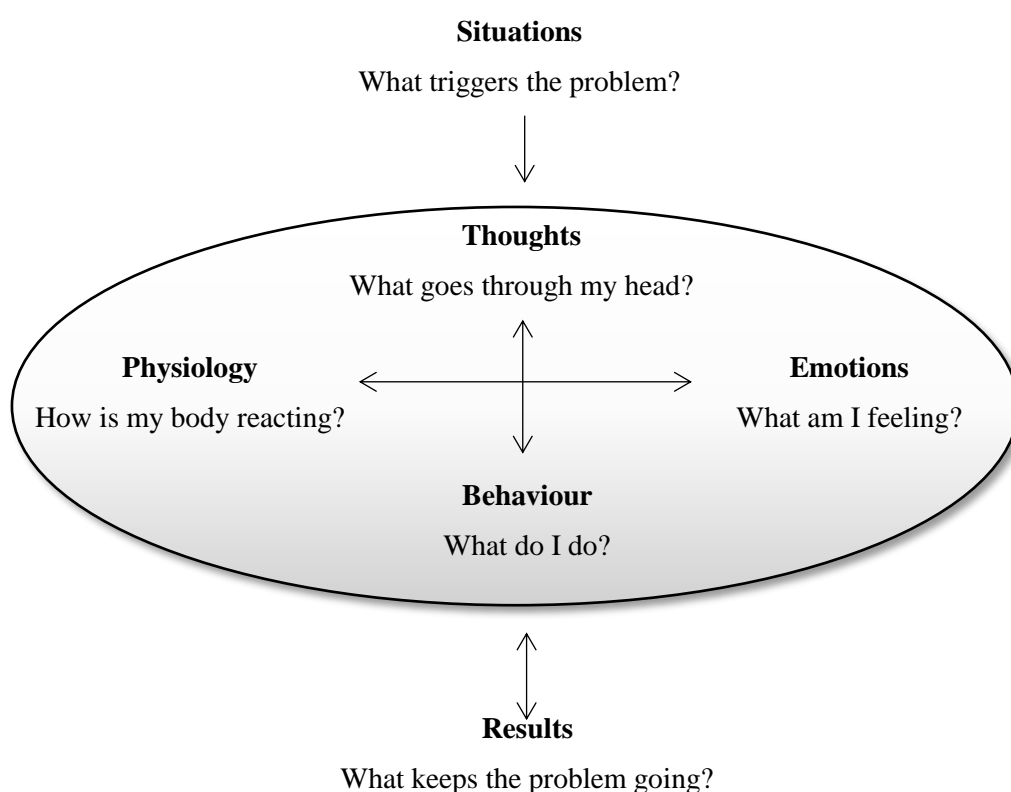


Figure 3. The Hot Cross Bun formulation (Blenkiron, 2010).

### 2.2.2 Identifying Unhelpful Beliefs:

A key part of the formulation process involves identifying the unhelpful beliefs that Beck (1976) argues are instrumental in causing mental distress. Within CBT, these unhelpful

beliefs (referred to as ‘core beliefs’ in Beck’s model) are thought to be the product of early negative life experiences (Dobson & Dobson, 2009). As their name suggests, core beliefs are considered to be at the heart of someone’s (often subconscious) views about themselves, making them difficult to identify and evaluate within therapy (Simmons & Griffiths, 2014). Core beliefs are typically about the self, other people, the world, or the future. As they are ‘core’ they can be expressed as absolute, stable statements (‘I am...’, ‘other people are...’ etc.). Some common negative core beliefs reported by people with depression are: (1) I am not important, (2) I am a failure, and (3) I am not loved (Kovacs & Beck, 1978).

### ***2.2.3 Re-evaluating Unhelpful Beliefs:***

Once an unhelpful or negative core belief has been identified, the therapist’s role is to support the client to assess the accuracy of this belief. The client is encouraged to collect evidence that both supports and contradicts the belief, and then evaluate the quality of this evidence (Beck, 2011). The goal of this process is to enable the person to consider all the evidence, and to arrive at a logical conclusion based on this. In addition to identifying a negative belief, it may also be helpful to identify a positive belief that can be strengthened through the same evidence-gathering approach (Greenberger & Padesky, 1995). This process within CBT aims to provide the patient with the necessary skills to evaluate other unhelpful beliefs in the future (Beck, Rush, Shaw, & Emery, 1979), and cultivate more meaningful, positive ones (Kinsella & Garland, 2008).

The process of re-evaluating unhelpful beliefs can be very difficult as for many patients these are beliefs that have been held for a long time. It is generally much easier to find evidence that supports the unhelpful belief, as a function of the confirmation bias (Nickerson, 1998). The patient and therapist must work together to overcome this innate bias, and make progress towards a more objective evaluation of their beliefs. The patient’s conviction in their belief is more likely to change if the collection of evidence is led by the patient rather than the therapist (Blenkiron, 2010). One method used to achieve this is Socratic questioning, also known as guided discovery, and sometimes referred to as the ‘Columbo’ technique. The therapist asks a series of questions that aim to draw attention to evidence that may question the accuracy of the unhelpful belief (Padesky, 1993). Another method used to re-evaluate unhelpful beliefs are behavioural experiments (Bennett-Levy et al., 2004). The experiment is designed to gather further evidence in relation to unhelpful beliefs.

### ***2.2.4 The Therapeutic Relationship in CBT:***

In addition to CBT techniques, the quality of the therapeutic relationship is also an important part of the intervention. The therapeutic relationship provides an opportunity for the

therapist to model a positive relationship that is characterised by a balance of power (Martina Mueller, 2010). A positive therapeutic relationship is associated with the patient's increased willingness to disclose (Wright, Basco, & Thase, 2006), and long-term positive treatment outcomes (Zuroff & Blatt, 2006), and so is seen as integral to CBT

## **2.3 Cognitive Therapy for Common Mental Health Problems.**

Beck's (1976) cognitive model was firstly used in the treatment of depression (Beck, 1964); and secondly in the treatment of generalised anxiety, as Beck (2010) observed substantial overlap in the underlying processes between the two mental health problems.

### **2.3.1 CBT for Depression:**

Since its conception (Beck, 1964), there have been many trials assessing the effectiveness of CBT for depression and anxiety – collectively known as common mental health problems. These trials of CBT have since been summarised into meta-analyses. One of the most highly cited meta-analyses of CBT for depression found cognitive therapy significantly reduced symptoms of depression compared to antidepressants, other psychological interventions, and wait-list control groups (Gloaguen, Cottraux, Cucherat, & Blackburn, 1998). The meta-analysis only included high-quality studies (only RCTs) that all used the same, psychometrically robust, outcome measure (Beck Depression Inventory) (Beck, Steer, & Carbin, 1988). However, there are issues of within-sample heterogeneity that were not addressed. For example, the authors included both individual and group formats of cognitive therapy, without any moderation analysis to account for this. As the paper did not report on the effect sizes of individual studies, it is not possible to calculate this moderation analysis. Although, the available research suggests that in fact group and individual CBT produce equivalent benefits for people with depression (Brown et al., 2011), therefore potentially rendering this point moot. Also the studies in the intervention arm delivered cognitive therapy over different periods of time, ranging from 5 to 79 weeks. The duration of therapy may have an effect on depression symptoms – but again there was no moderation analysis included to explore this possibility.

Another potential problem with the meta-analysis is the way in which they defined cognitive therapy. Firstly, group cognitive therapy was classed as the intervention arm for some studies (e.g. Covi & Lipman, 1987), but the control arm for others where it was compared to individual cognitive therapy (e.g. Ross & Scott, 1985). Secondly, in this meta-analysis of cognitive therapy they included one study that was actually rational-emotive therapy (RET) based on Ellis' (1991) model. Although these two interventions are very similar (as discussed earlier) they are not the same, making it questionable for inclusion in this meta-analysis.

From the data available in the paper by Gloaguen et al. (1998) it is not possible to carry out any of the additional analyses that have been suggested. If any of these variables did moderate the treatment effects then it is likely this heterogeneity would be reflected by wide confidence intervals around the overall effect size. However, the 95% confidence intervals in this meta-analysis were narrow for all of the effect sizes: (1) cognitive therapy versus wait-list:  $d = -.82$ , (95% CI:  $-.83, -.81$ ); (2) cognitive therapy versus antidepressants:  $d = -.38$ , (95% CI:  $-.39, -.37$ ); (3) cognitive therapy versus other therapies:  $d = -.24$ , (95% CI:  $-.25, -.23$ ). On the basis of this, it is likely that, despite these methodological flaws, the results are likely to be an accurate reflection of the effect of cognitive therapy for depression.

### **2.3.2 CBT for Anxiety:**

Similarly, the numerous trials of CBT for anxiety have been summarised into multiple meta-analyses. One of the largest meta-analyses in this field found a large between-group effect size ( $g = .73$ , 95% CI:  $.56, .90$ ) in favour of CBT for anxiety, compared to control conditions (Hofmann & Smits, 2008). The meta-analysis included all anxiety disorders i.e. obsessive compulsive disorder (OCD), posttraumatic stress disorder (PTSD), and generalised anxiety disorder (GAD).

Like the meta-analysis of CBT for depression (Gloaguen et al., 1998), this meta-analysis lacks important moderation analyses. The overall effect size may be moderated by the type of anxiety disorders the participants were diagnosed with (Norton & Price, 2007), but as there was no statistical evidence of heterogeneity (i.e. non-significant Q statistic) this may not be an issue. The authors did calculate the individual effect sizes for the effect of CBT for each type of anxiety disorder – although all of the effect sizes do favour CBT for anxiety over the control conditions, there were some distinct differences in the size of these effects i.e. small effect for Panic Disorder:  $g = .35$  (95% CI:  $0.04-0.65$ ); and a large effect for OCD:  $g = 1.37$  (95% CI:  $0.64-2.20$ ). As the confidence intervals around the two effect sizes overlap this is likely to mean there is no significant difference between the effect sizes.

The inclusion of moderation analysis would have enabled a more statistically robust method of comparing the effect of CBT across the different anxiety disorders. However, as this meta-analysis included 27 studies, comparing sub-groups of these studies for the purposes of moderation analysis are likely to be compromised by small sample sizes. The effect sizes obtained for the specific anxiety disorders are akin to those found in other meta-analyses; for example, other meta-analyses of CBT for OCD have found similarly large between-group effect sizes ( $g = 1.39$ ; 95% CI:  $1.04-1.74$ ) (Olatunji, Davis, Powers, & Smits, 2013). The findings from the moderation analyses they did conduct demonstrated that neither the number of sessions

nor the type of control condition moderated effect sizes. But these analyses may be vulnerable to Type II error due to the problem of small sample sizes discussed previously.

Both the meta-analysis of CBT for depression (Gloaguen et al., 1998) and anxiety (Hofmann & Smits, 2008) are limited by their lack of moderation analyses. Despite this, the overall effect sizes for both meta-analyses were large i.e. depression:  $d = .73$  (Gloaguen et al., 1998), and anxiety:  $g = .82$  (Hofmann & Smits, 2008), and consistent with other meta-analyses in this field. On the basis of such evidence, CBT is a recommended primary treatment for depression (NICE, 2011b), and all anxiety disorders (NICE, 2014a).

### **2.3.3 Findings from Routine Practice:**

Although the results from trials are important and informative, it is more important that these effects can be translated into clinical practice. There is little meta-analytic evidence on the effects of CBT for depression in routine practice. For anxiety disorders, one meta-analysis found that effect sizes decrease slightly as research studies become more representative of clinical practice, but that overall effect sizes were still large ( $g = 1.29$ , 95% CI: .76, 1.83) (Stewart & Chambless, 2009); however, again this effect includes all types of anxiety disorders. Similar to the meta-analysis by Hofmann and Smits (2008), pre-post effect sizes, although all still favoured CBT, did vary as a function of the type of anxiety disorder (social anxiety (lowest):  $g = .73$ , 95% CI: 0.55-1.29; to PTSD (highest):  $g = 2.59$ , 95% CI: 2.06-3.13). These findings should be interpreted in light of the limitation that pre-post effect sizes cannot control for natural symptom changes over time.

Overall, the findings still suggest that CBT is an effective intervention for both anxiety and depression as shown in both controlled trials and in routine clinical practice. The success of CBT for anxiety disorders and depression led to its adaptation for other mental health problems, with varying levels of success (Butler, Chapman, Forman, & Beck, 2006). CBT is recommended in the treatment of: (1) Common mental health disorders (NICE, 2011a), (2) Depression (NICE, 2011b), (3) Anxiety (NICE, 2014a), (4) Obsessive Compulsive Disorder (OCD) (NICE, 2005a), (5) Generalised Anxiety Disorder (GAD) (NICE, 2011c), (6) Post Traumatic Stress Disorder (PTSD) (NICE, 2005b), (7) Social anxiety (NICE, 2013), (8) Panic Disorder (NICE, 2011c), (9) Antisocial Personality Disorder (NICE, 2009), (10) Bipolar Disorder (NICE, 2016), and (11) Psychosis (NICE, 2014b).



### 3 Cognitive Behaviour Therapy for Voices.

The aim of this chapter is to evaluate the cognitive behaviour therapy (CBT) model as it is applied to distressing voices, the therapeutic value of such models, and what is preventing the implementation of CBT for distressing voices (CBTv) into clinical practice.

### **3.1 Cognitive Behavioural Therapy for Voices (CBTv).**

CBT consistently produces medium treatment effects for people with psychosis (CBTp) (Jauhar et al., 2014; Wykes, Steel, Everitt, & Tarrier, 2007). In line with the symptom-specific approach (Bentall et al., 1988), it was hypothesised that these treatments effects could be enhanced if interventions were developed to target a specific symptom associated with psychosis, such as distressing voices, rather than the broader diagnostic label. Much like the CBT models for depression (Beck, 1976; Ellis, 1991), the cognitive-behavioural models for distressing voices acknowledge that it is not the experience of hearing voices itself that is problematic, but the way the experience is appraised (van Os, Hanssen, Bijl, & Ravelli, 2000). There are four main cognitive models that have been used to understand distressing voices: (1) model of positive symptoms (Garety, Kuipers, Fowler, Freeman, & Bebbington, 2001), (2) model of psychosis (Morrison, 2001), (3) model of voices (Chadwick & Birchwood, 1994), and (4) model of command hallucinations (Byrne, Birchwood, Trower, & Meaden, 2006). These will now be reviewed in turn.

#### ***3.1.1 Model of Positive Symptoms:***

The model of positive symptoms (Garety et al., 2001) aims to describe how all positive symptoms associated with psychosis (i.e. hallucinations and delusions) develop and are maintained (see Figure 4). As in Beck's (1976) original cognitive model of depression, the impact of early life experiences, and the role of a triggering event on the presenting problem, are acknowledged. Trauma (Van Nierop et al., 2014), poor attachment (Harder, 2014), and a genetic predisposition (Hall, Trent, Thomas, O'Donovan, & Owen, 2015) are all early life experiences commonly associated with later psychosis symptoms.

The model offers two possible paths to the development of psychosis symptoms. The first is more in line with the generic cognitive model (Beck & Haigh, 2014) whereby a change in mood causes an experience to be appraised as external (Hanssen, Bak, Bijl, Vollebergh, & Os, 2005). For example, higher symptoms of depression in the context of a psychosis diagnosis was found to be associated with hearing more negative and distressing voices (Smith et al., 2006). The second path is believed to be the route that the majority of people with psychosis symptoms follow, whereby a cognitive experience is appraised as being anomalous (Garety et al., 2001). This path combines the work of Hemsley (1993) and Frith (1992): Hemsley (1993) posits that positive symptoms (such as hearing voices) occur as a result of an inability to filter

out unnecessary information, leading to unrelated information becoming inappropriately connected; whereas Frith (1992) hypothesises that positive symptoms occur when an internal cognitive process is attributed as external (i.e. not self-initiated). Paths one and two are not thought to be independent – the cognitive dysfunction can lead to changes in affect, or vice versa

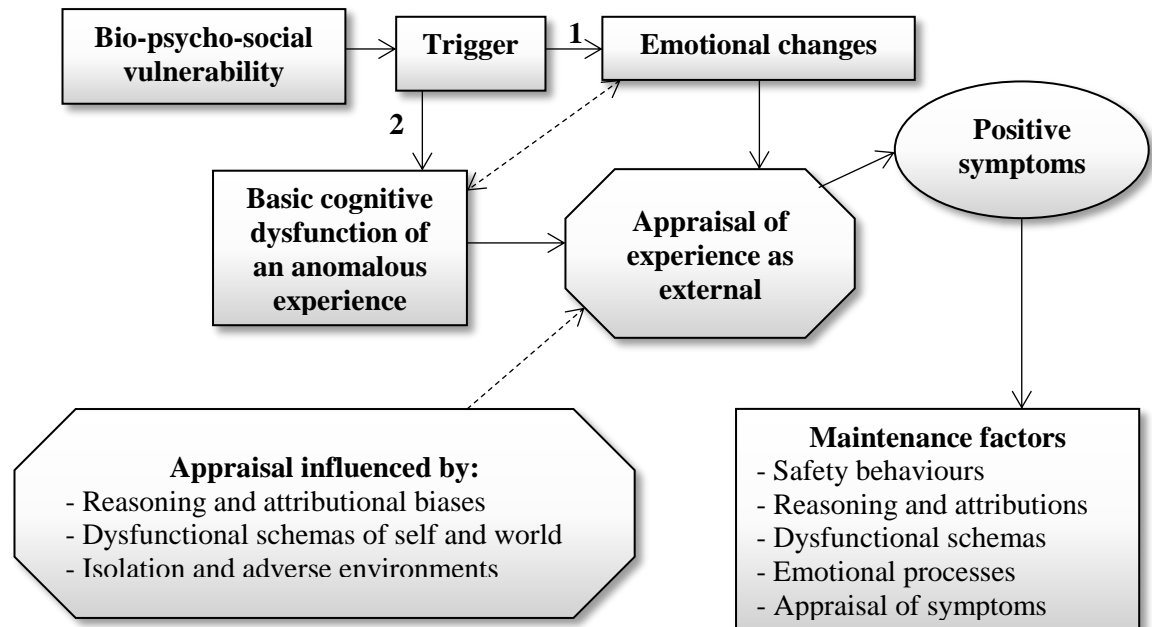


Figure 4. Cognitive model of positive psychotic symptoms (Garety et al., 2001).

The later part of the model describes how psychosis symptoms are maintained. Both safety behaviours (Freeman, Garety, & Kuipers, 2001), and reasoning biases (Kuipers et al., 2006) are well-evidenced as contributing to the maintenance of the positive symptoms of psychosis. These maintenance factors are consequently prime targets within CBT for psychosis (CBTp).

Very few trials of CBTp have acknowledged this model as the theoretical model upon which the therapy protocol is based upon (as determined by a search of RCTs that have cited Garety et al. (2001)). In those trials where CBTp was explicitly based on the model of positive symptoms, CBTp had no effect on relapse rates, but improved depression (Garety et al., 2008), and symptoms of psychosis (Dunn et al., 2012). This model has largely been applied to delusions, which has led to the development of an adapted version of the model specifically for persecutory delusions (Freeman, Garety, Kuipers, Fowler, & Bebbington, 2002). By contrast, there has been far less attention given to the validity of this model in describing the development and maintenance of distressing voices, and whether it can be used to inform a CBT for voices (CBTv) intervention.

### 3.1.2 Model of Psychosis:

Produced around the same time, the Morrison (2001) model (Figure 5) is very similar to that of Garety et al. (2001). Both models acknowledge the importance of past experiences, and acknowledge the role of affect, cognitions and behaviour in the development and maintenance of psychosis symptoms. However, where the Garety et al. (2001) model is more aligned to the CBT model of depression (Beck, 1976), the Morrison (2001) model is based upon the cognitive model of anxiety (Clark, 1986). Those experiencing anxiety often interpret neutral events as being salient (Clark, 1986) – for example people with an OCD diagnosis often interpret intrusive thoughts as having great importance (van Oppen & Arntz, 1994). Morrison (2001) compares hearing distressing voices to the cognitive mechanisms involved in panic disorder, whereby a common human experience (either shortness of breath for Panic Disorder, or hearing voices) is negatively misinterpreted (Morrison, 1998). In further support of the anxiety-based interpretation of psychosis, people who hear voices are more likely to catastrophize in relation to their thoughts and voices compared to non-psychiatric controls (Morrison & Baker, 2000).

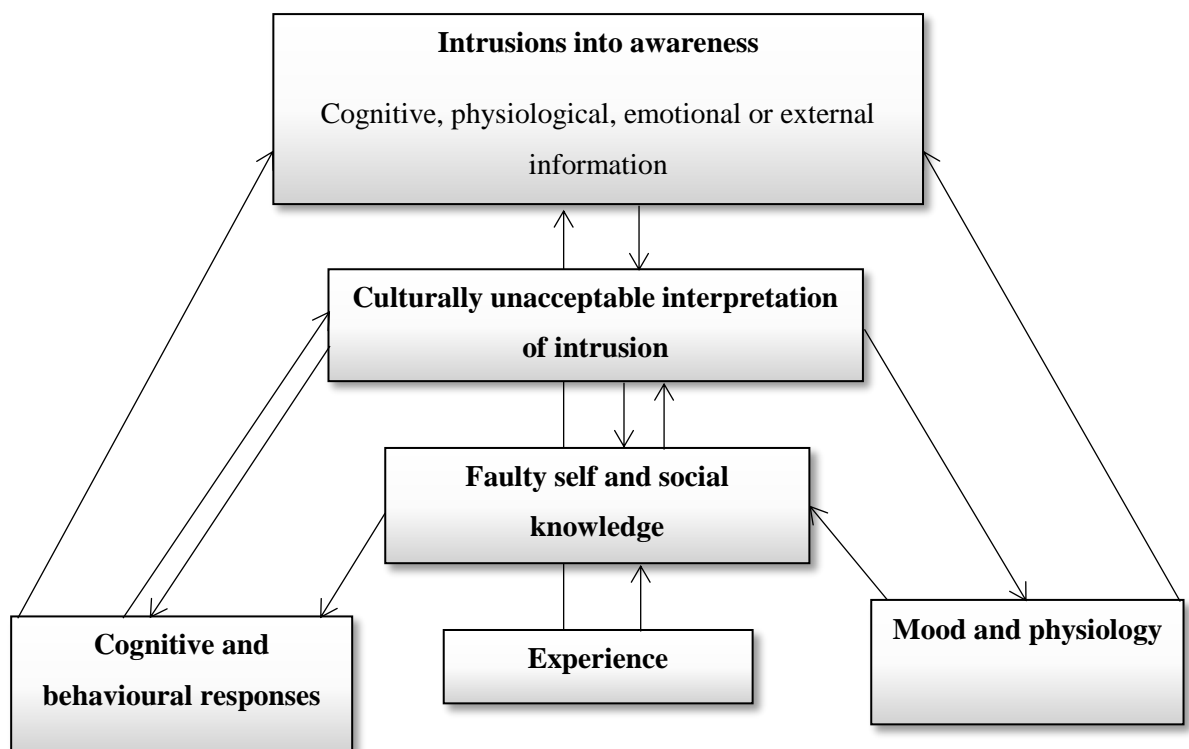


Figure 5. Cognitive model of psychosis (Morrison, 2001).

The point of novelty for Morrison's (2001) model is the explicit push to consider psychosis symptoms within the person's cultural context. Appraising a voice as important and salient would be appropriate within some more spiritual cultures (Watkins, 1998). For example, hearing voices within a Shamanist culture is something to be celebrated, and is

believed to connect the hearer to a higher power (Stephen & Suryani, 2000). The consequence of framing this model (Morrison, 2001) within the cultural context is that it assumes psychosis as a ‘mental illness’ is socially constructed. This is in line with more critical psychosis and emancipatory approaches to mental health and hearing voices (e.g. Romme et al., 1992).

There has been considerably more research on the application of Morrison's (2001) model to the development and maintenance of distressing voices, compared to the model of positive symptoms (Garety et al., 2001). However both models were devised as generic models of psychosis. People with a psychosis diagnosis are a heterogeneous population (Allardyce, Gaebel, Zielasek, & van Os, 2007), so to account for all the possible symptoms of psychosis both models are non-specific as to the content at each level of the models – for example, what are the common appraisals associated with distressing voices? The consequence of these non-symptom-specific cognitive models is that the resultant intervention becomes elusive. Within a Delphi consultation, experts identified more than 70 components of CBTp that were considered essential (Morrison & Barratt, 2010). The ‘black box’ nature of CBTp has led to increased interest in the symptom specific approach. That is, interventions, and the models on which they are based, should be devised to address a single symptom (i.e. distressing voices) rather than the broader diagnostic category (Bentall, Jackson, & Pilgrim, 1988). With this approach in mind, specific cognitive models for distressing voices have been developed.

### 3.1.3 *Model of Voices:*

The Chadwick and Birchwood (1994) cognitive model of voices is based on Ellis' (1991) ABC model. The model hypothesises that it is not the experience of hearing voices itself that is distressing, but that the person’s beliefs about the voice’s power, identity and intentions that determine the emotional and behavioural impact of the voice (Birchwood & Chadwick, 1997).

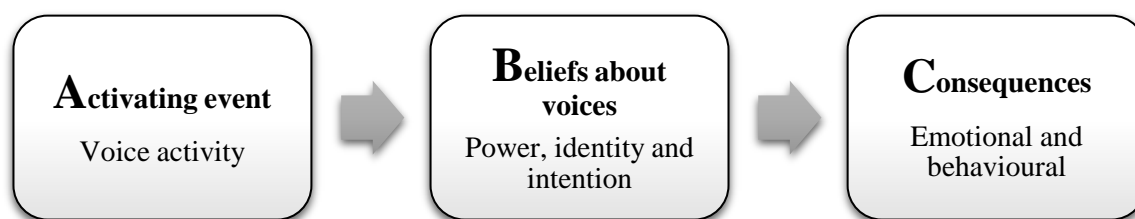


Figure 6. Cognitive model of voices (Chadwick & Birchwood, 1994), as diagrammed by Strauss (2014).

There is strong evidence that beliefs regarding the voice’s intentions (malevolent or benevolent) and power (omnipotence) are related to the hearer’s behavioural (engagement or resistance) and emotional (distress) response to the voice. If a voice is perceived as benevolent

this leads to engagement with the voice, whereas if a voice is perceived as malevolent this leads to voice-related resistance (Lawrence, Jones, & Cooper, 2010). Increased symptoms of depression and anxiety are positively associated with believing the voice is malevolent and omnipotent, but negatively correlated with level of voice engagement (Chadwick, Lees, & Birchwood, 2000).

Because these studies are correlational we cannot infer causality – that is, we do not know whether these beliefs cause the emotional and behavioural responses, or the responses lead to the formation of these beliefs. However, Chadwick and Birchwood (1994) postulate the former (as shown in Figure 6). Intervention studies have helped to somewhat clarify the directionality of this model. As hypothesised, CBTv based on this model resulted in reduced conviction in unhelpful beliefs and distress, and increased adaptive behaviours, for all participants (Chadwick & Birchwood, 1994).

But one could argue that without falsifying the alternate pathway (i.e. that C causes B) this study can only provide partial support for the model (i.e. that B causes C). Chadwick and Birchwood (1994) delivered CBTv to a small sample. When delivering this same therapy to a larger pool of participants, again there was a reduction in maladaptive voice-related beliefs, but there was no change in affect post-therapy (Chadwick, Sambrooke, Rasch, & Davies, 2000). The results from this second study could be taken to disprove the cognitive model for voices, as a change in beliefs is hypothesised to cause a change in affect (Chadwick & Birchwood, 1994). However, without appropriate measurement of voice-related distress this test of the model is limited. CBTv does not claim to improve or address any aspect of the voice phenomenology – yet most measures of voices focus on this aspect of the experience. Furthermore, measures of depression, such as the measure used in this study (Chadwick, Sambrooke, et al., 2000), do not necessarily correspond with voice-related distress, and may in fact better represent the presence of the negative symptoms of psychosis (Mawson, Cohen, & Berry, 2010). Until a validated measures of voice-related distress is developed, it is not possible to conclusively validate this model (Chadwick & Birchwood, 1994).

In the absence of such a measure, more research attention has been given to the relational element of this model. By asserting that a voice can be perceived as powerful this generates a relational dyad, in which one agent is powerful (in this case, the voice) and the other is less powerful (the hearer). When asked, people who hear voices describe the experience using a relational framework and language (Chin, Hayward, & Drinnan, 2009). Aspects of relating, such as believing the voice is dominant, was associated with believing the voice was omnipotent and malevolent; all of these voice-related beliefs were associated with negative behavioural and emotional responses (Sorrell et al., 2010).

Some argue this model neglects other important factors in understanding voices – such as the role of self (Fielding-Smith et al., 2015a), and the temporal mood-state (Close & Garety, 1998). Also that this model fails to acknowledge the different sub-types of voices that people hear (Mccarthy-Jones, Trauer, et al., 2014), and what aspects of the model may differ between these sub-types. For example, hearing a voice that instructs the hearer to carry out certain tasks (also known as a command hallucination) is associated with increased dependency, and beliefs related to self-punishment compared to other voice sub-types (Rogers, Gillis, Turner, & Frise-Smith, 1990). The CBTv model (Chadwick & Birchwood, 1994) could be adapted to adequately reflect the development and maintenance of command hallucinations by adding additional maladaptive beliefs to the model, such as social acceptability and appeasement beliefs (Beck-Sander, Birchwood, & Chadwick, 1997). Alternatively it may be more appropriate to produce separate models for each voice sub-type.

### 3.1.4 *Model of Command Hallucinations:*

The distinctiveness of command hallucinations, and the elevated level of risk associated with the experience (Shawyer, Mackinnon, Farhall, Trauer, & Copolov, 2003), has led to the development of a specific cognitive model for this voice sub-type (Byrne et al., 2006). Similar to the cognitive model of voices (Chadwick & Birchwood, 1994), the model is based on Ellis' (1991) ABC model. Additional beliefs and consequences have been added to this model, such as beliefs about compliance that are influenced by both the behavioural and emotional consequences (Meaden, Trower, & Birchwood, 2010).

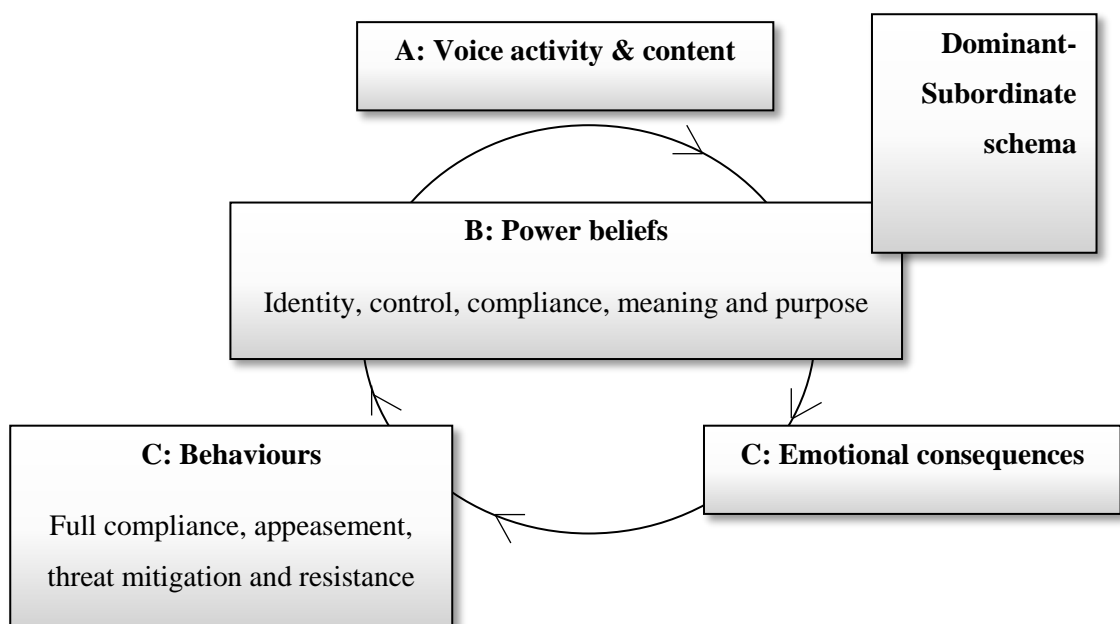


Figure 7. Cognitive model of command hallucinations (Byrne et al., 2006).

Because this model aims to understand a specific type of voices, command hallucinations, the authors are able to be specific about the possible behavioural consequences that can come from this experience: these range from full compliance (the hearer fully complies with the command) and appeasement (the hearer partially complies with the command e.g. self-harm instead of suicide), to threat mitigation (putting systems in place to prevent the hearer from being able to comply) and resistance (not complying with the command). These behaviours are hypothesised to act as safety behaviours that work to prevent the hearer from seeing what would happen if they did not comply (Byrne et al., 2006). As with all cognitive models, it is the person's beliefs about an event that are believed to determine the emotional and behavioural consequences. Believing a voice is omnipotent positively predicts both distress and compliance-related safety behaviours (Hacker, Birchwood, Tudway, Meaden, & Amphlett, 2008).

In contrast to Chadwick and Birchwood's (1994) model of voices, and echoing back to the work of Beck (1976), this model of command hallucinations includes potential premorbid factors that could influence the presenting problem. However these premorbid factors are not targeted within CBT – instead the aim of therapy based on this model is to reduce compliance to command hallucinations (Trower et al., 2004). The pilot trial recruited 38 patients, randomised to either receive command CBT or to continue with their usual treatment (Trower et al., 2004). Command CBT was associated with large between-group improvements on the primary outcome of compliance behaviour. Improvements were also found on secondary outcomes of voice-related omnipotence beliefs, the need to comply, distress, and depression post-intervention and one year post-randomisation.

The results of a large-scale trial (197 participants) of the same intervention found compliance was reduced compared to the control condition at the 18 month follow-up, but not post-intervention (at 9 months) (Birchwood et al., 2014). There were no significant improvements on any of the secondary outcomes; including, psychosis symptoms, distress, depression, hopelessness, beliefs about voices, and suicidal ideation. This finding could be interpreted to mean command CBT has limited or unsustainable benefits. However, the authors argue that the null results at follow-up time points were the result of improvements in the control condition – this explanation implies that compliance to command hallucinations can improve over time, but perhaps command CBT can accelerate these improvements. The findings from both trials need to be interpreted with caution, as neither used an active control condition. Therefore, we do not know whether compliance behaviour could have improved after receiving a more generic form of CBTp, compared to this adapted version.



### **3.2 Choosing a Model for CBTv:**

As suggested previously, the more general models of psychosis symptoms (Garety et al., 2001; Morrison, 2001) may have limited usefulness when attempting to address a specific symptom. In contrast, the model of command hallucinations (Byrne et al., 2006) is too specific. Not all people who hear voices experience command hallucinations (Larøi et al., 2012). Also, voices frequently change over time in terms of number, form and content (Nayani & David, 1996). From the available models, the model of voices (Chadwick & Birchwood, 1994) appears to be the most appropriate to be the basis for a CBTv intervention for the full range of distressing voice-hearing experiences. The simplicity of the model means it is suitable for use within the collaborative formulation process. Even though the model was developed as the basis for a CBT intervention, it can be used to understand the development and maintenance of negative, neutral, and positive voices (Birchwood & Chadwick, 1997). The true test of the cognitive model for voices (Chadwick & Birchwood, 1994) is whether it has any therapeutic value.

### **3.3 Evaluating the Evidence for CBTv:**

A recent meta-analysis aimed to evaluate the effects of CBT when tailored to either voices or delusions (Van der Gaag, Valmaggia, & Smit, 2014). CBT for voices produced medium between-group treatment effects in favour of CBT. This effect remained when only trials with an active control or blinded data collection were included. These results suggest CBT is an effective treatment for voices, and that this effect is robust against moderation analyses. These findings provide support for the implementation and dissemination of CBT for voices. However, there are some limitations with this meta-analysis.

Although the effect of CBTv according to this meta-analysis is significant (albeit modest in size), a pressing problem with this meta-analysis, and the CBTv literature more broadly, is the use of measures of voice phenomenology to evaluate treatment effectiveness. Ten out of the eleven (90.91%) studies included used the PSYRATS auditory hallucinations (AH) scale (Haddock, McCarron, Tarrier, & Faragher, 1999) as their voice-related outcome measure. The 11<sup>th</sup> study used the BAVQ (Chadwick & Birchwood, 1995). Of the 11 items on the PSYRATS AH scale, only two measure voice-related distress: (1) Have you found your voices to be distressing over the last week? And (2) Over the last week when your voices have been distressing, how distressing has that been? The PSYRATS AH scale mostly measures phenomenological aspects of the voice hearing experience (e.g. frequency, duration, loudness), which is at odds with the treatment aims of CBTv (to reduce the distress and disturbance associated with voices) (Birchwood & Trower, 2006). The two distress items on the PSYRATS AH scale are not sufficient to fully capture changes in voice-related distress. The BAVQ

(Chadwick & Birchwood, 1995) and subsequent revised version (Chadwick, Lees, et al., 2000) are also flawed as primary outcomes as these measures are geared to capture any changes in the beliefs about voices (postulated mechanisms), not the consequences of these beliefs (not outcomes). Without a valid measure of voice-related distress we cannot confidently assess the effectiveness of CBTv.

Another potential flaw with this meta-analysis is rooted in the authors' inclusion of trials of both CBTv (conceptualised as an intervention that specifically targets voices) and CBTp (conceptualised as a CBTp intervention where a measures of voices was included). If voices are not targeted within the intervention, then we would not expect them to change. Consequently, the overall effect size does not represent the effectiveness of CBTv (where voices are the specific target). When the effect sizes are separated by whether they aim to specifically target voices, or are CBTp with a voices measure included, there appears to be a difference in the effect sizes (see Table 2). The majority of the studies were trials of CBTp with a voices measure (8/11; 72.73%). Although there are fewer studies of CBT that specifically targets voices, it seems that taking the symptom-specific approach is associated with moderate to large effects compared with the small to medium effects of CBTp studies with a voices measure. To verify this initial finding more high quality studies of CBTv are needed that include an appropriate primary outcome measure.

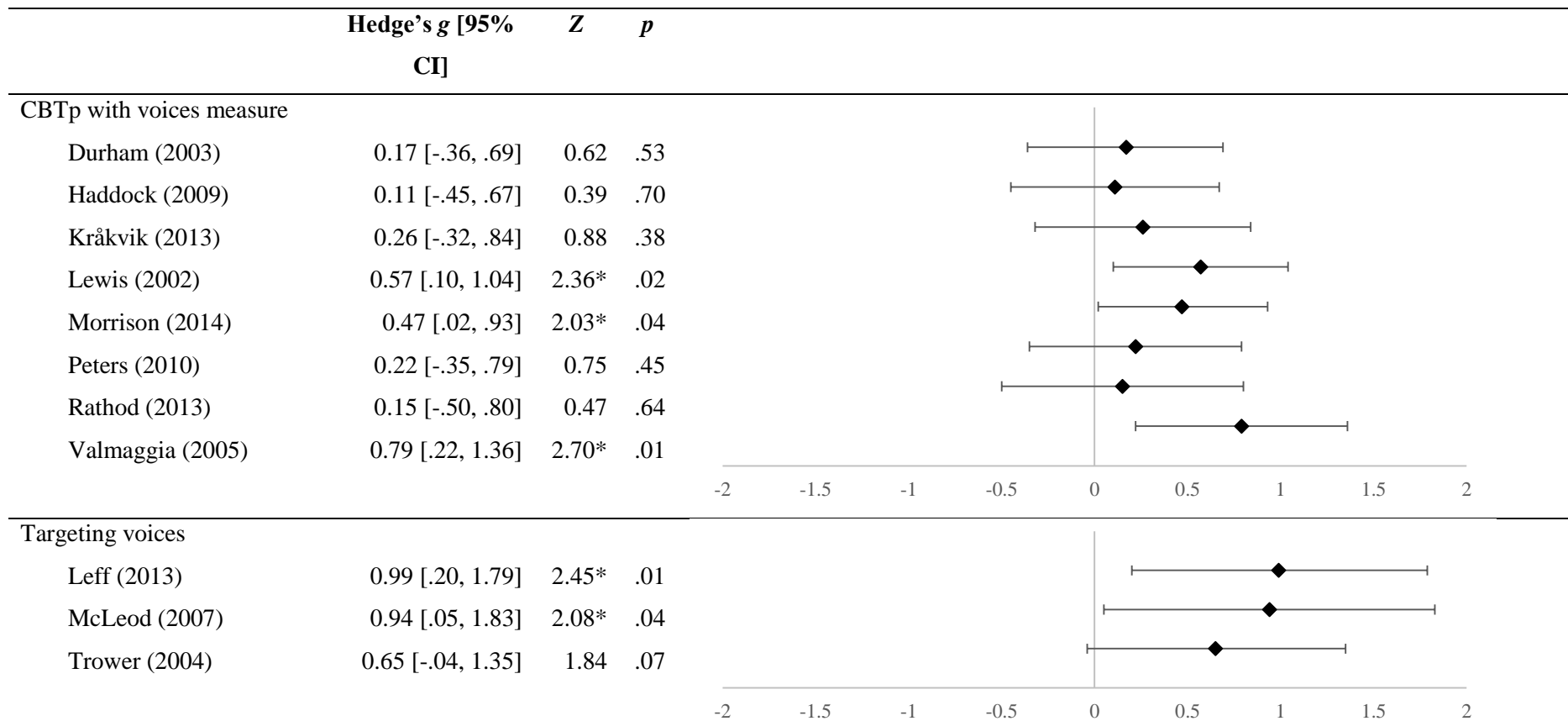


Table 2. Effect sizes and forest plots of studies from Van der Gaag et al. (2014) separated by therapy target. \*  $p < .05$ .

### 3.4 Issue of Access.

In addition to the lack of robust CBTv evidence, there is also the issue of access to contend with. Despite NICE (2014b) recommending that everyone with psychosis should be offered at least 16 sessions of CBT, the Schizophrenia Commission (2012) found that only 10% of people with schizophrenia were offered CBTp. A more recent audit of one mental health Trust found this value had dropped to only 6.9% (Haddock et al., 2014). These figures suggest that either the dissemination of CBTp has worsened, or that clinical services ability to disseminate CBTp is a ‘postcode lottery’ (Appleby & Gregory, 2008). There are no dissemination or implementation rates specifically for CBTv – but as there is less evidence for this intervention it is probable that the rates are lower than these rates for CBTp.

	<b>Barriers Identified</b>
Berry et al. (2008)	Lack of skills Lack of CBT training opportunities Poor communication between clinics and research CBT is not a priority for services
Ince et al. (2015)	Lack of skills Lack of clinician confidence to refer clients for CBT CBT is not a priority for services Lack of protected time Lack of CBT training opportunities Poor service management Service instability Clinicians’ negative attitudes towards CBT High workload pressures Clients are overmedicated Clinicians’ belief that the client is too ill for CBT Inability to provide supervision

Table 3. Summary of barriers to the implementation of CBTp identified through systematic reviews.

To understand why services are not offering CBTp, two reviews were conducted to identify what the main barriers to implementation are. One review found organisational barriers to be the most frequently endorsed (Berry & Haddock, 2008), whereas the second found a broader range of perceived barriers (Ince, Haddock, & Tai, 2015) (see Table 3). The different results produced by these reviews is most likely related to an increase in research in this area between the publication dates of the two papers. Some of the studies within these reviews proposed

initiatives to overcome the barriers they found. For example, offering CBT training to mental health clinicians (Jolley et al., 2012), and adapting NICE guidelines to make them more accessible (Michie & Lester, 2005). While intentions to implement CBTp may have improved (Michie & Lester, 2005), actual implementation did not (Jolley et al., 2012; Michie & Lester, 2005).

The issue of access is not specific to CBTp. Previously access to psychological therapies for people with common mental health problems was also poor (Clark, 2011), with the same kind of barriers to implementation that are shown in Table 3 (Collins, Westra, Dozois, & Burns, 2004). Several years ago, only 8% of people with a mental health problem were given a choice regarding therapy, and 20% of people had to wait more than a year to receive treatment (We Need to Talk Coalition, 2010). The issue of access for people with common mental health problems has now been improved by the Increasing Access to Psychological Therapies (IAPT) initiative (Clark, 2011), and this has important implications for widening access to CBTp/CBTv.

## 4 Low Intensity Cognitive Behaviour Therapy.

The aim of this chapter is to evaluate the efficacy and effectiveness of low intensity CBT interventions as they were first applied to common mental health problems, and the emerging evidence for low intensity CBT for voices.

#### **4.1 Low Intensity CBT for Common Mental Health Problems.**

The IAPT initiative has been able to increase access to psychological therapies by adopting a stepped care model – whereby low intensity interventions (i.e. those that use less resources) are offered in the first instance. Only those who have not improved are then offered the higher intensity interventions (i.e. use more resources) (see Figure 8).

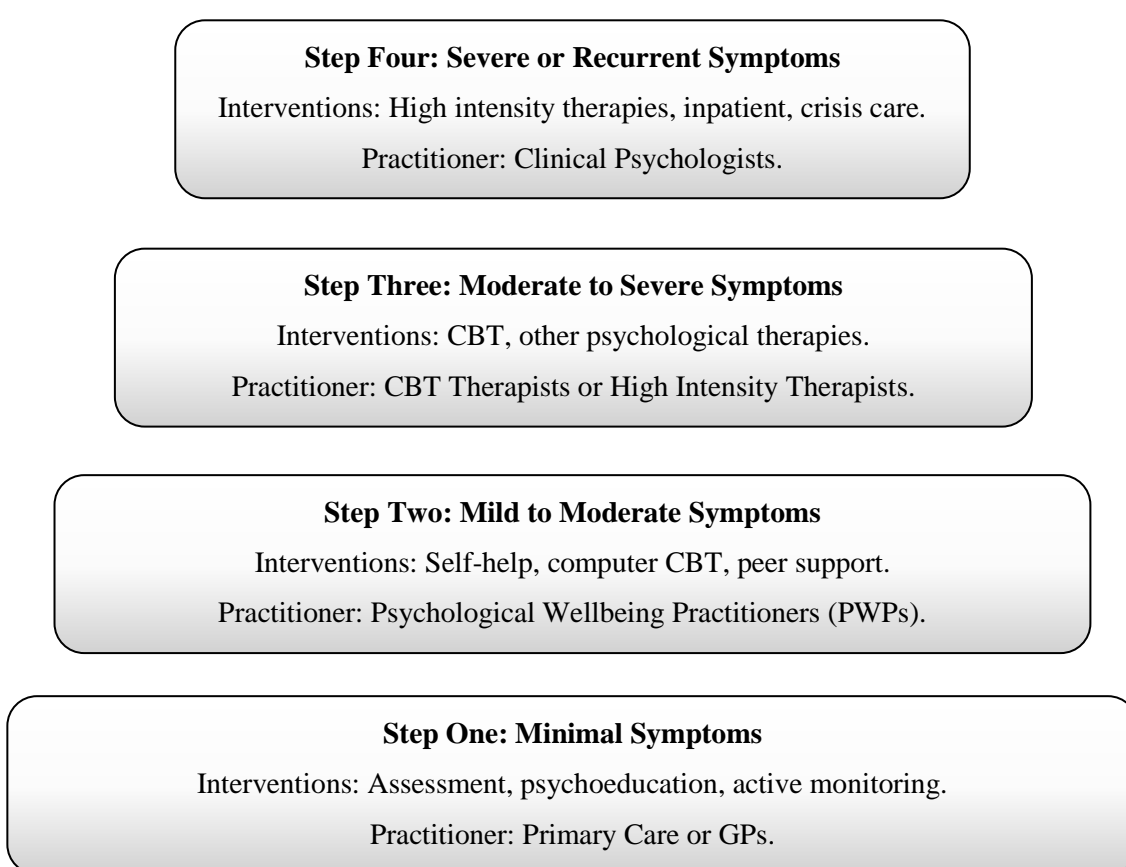


Figure 8. IAPT stepped care model for common mental health problems (NICE, 2011).

The IAPT approach has been criticised for over-simplifying the complex nature of human distress (Rizq, 2012), but the results are compelling. The initial demonstration sites found that 55% of clients who had attended at least two sessions met the criteria for recovery, and 5% had improved employment status – these improvements were maintained at the 10 month follow-up (Clark et al., 2009). In the first year of IAPT, 42% of clients who had attended at least two sessions met the criteria for recovery (Gyani, Shafran, Layard, & Clark, 2011). After the first three years more than one million people had accessed IAPT services; the

recovery rates were found to be similar to those found in RCTS (>45%) (Improving Access to Psychological Therapies (IAPT), 2012).

The stepped care model used within IAPT was possible because of the strong evidence base demonstrating the effectiveness of low intensity CBT for common mental health problems (i.e. depression and anxiety disorders). The term low intensity here refers to any CBT-based intervention that uses less resources i.e. fewer sessions and/or little to no specialist therapist time (Peter Bower & Gilbody, 2005). There are several common methods for reducing the intensity of a therapy; these include: (1) using technology (e.g. internet, computer, and SMS forms of CBT), (2) using less time-consuming forms of therapist-patient communication (e.g. email, phone, and mail CBT), (3) increasing patient autonomy (e.g. self-help, guided self-help, and written therapies), (4) changing who is delivering the intervention (e.g. non-specialist delivery or peer led CBT), or (5) reducing the therapist contact time (e.g. less therapy sessions or group CBT) (Bennett-Levy et al., 2010). The evidence for these forms of low intensity CBT have been summarised within multiple meta-analyses.

#### ***4.1.1 Using technology:***

As technology has become more accessible, one method of increasing access to CBT is by using this technology as the therapy delivery method. A meta-analysis by Andrews, Cuijpers, Craske, McEvoy and Titov (2010) looked at the effects of computer therapy for anxiety and depression. They found large treatment effects in favour of computer CBT that were maintained when the analysis was separated by diagnosis. The numbers needed to treat (NNT) ranged from 1-2 depending on the type of common mental health problem.

This meta-analysis used the database of studies that was cultivated as part of a much larger systematic review of all forms of CBT for common mental health problems. The larger systematic review was last updated more than two years before the publication of this meta-analysis meaning the findings presented are likely to be outdated, and missing some important but more recent studies. An additional systematic search of the literature should have been conducted to identify those relevant studies published since the large review. Also, although they reported on a number of variables related to the study design (e.g. study quality, the type of control group, and therapist contact time), none of these variables were used within moderation analyses. Identifying whether any aspects of the study or therapy protocols is associated with treatment outcomes can help to inform and refine future studies and clinical practice. Overall this meta-analysis provides compelling evidence that computer CBT is effective for people with anxiety or depression.



#### ***4.1.2 Using less time-consuming forms of therapist-patient communication:***

There are currently no meta-analyses exploring the effects of mail- and email-delivered CBT. Telephone-delivered CBT has received greater research attention. The results of a meta-analysis found small to moderate effect sizes in favour of telephone psychotherapy for people with depression. Also therapy attrition rates were smaller than those found for face-to-face therapy (Mohr, Vella, Hart, Heckman, & Simon, 2008).

Although this meta-analysis purports to look at the effects of this intervention on symptoms of depression, many of the participants included in this study were experiencing depression in the context of, and as a consequence of, a physical health problem. Whether the effects of this intervention are similar between those with or without a comorbid physical health problem was not investigated. The only significant moderator was therapy orientation, whereby those with a stronger CBT component were most effective. The other moderators (number of sessions, therapist qualifications, and therapy format) were non-significant; but this could reflect a Type II error due to small within-group sample sizes.

#### ***4.1.3 Increasing patient autonomy:***

In practice, self-help materials are often supplemented with guidance from a psychological wellbeing practitioner (Turpin, 2010) because the effects of pure self-help tend to be much smaller (Gellatly et al., 2007). In a meta-analysis of guided self-help CBT compared to face-to-face therapy for people with anxiety and depression both interventions were found to be effective, with no significant difference between the two on any clinical outcome or dropout rates (Pim Cuijpers, Donker, van Straten, Li, & Andersson, 2010). The meta-analysis was statistically powered.

Much like the meta-analysis by Mohr et al. (2008), many aspects of the study design are reported but none were explored using moderation analysis. For example, study quality, the self-help format (e.g. book or computer), amount of contact time, format of contact (e.g. email, face-to-face, phone), use of CBT principles (e.g. exposure therapy or cognitive restructuring) may moderate treatment effects, and participant's diagnosis (either anxiety or depression). Similar to other meta-analyses of guided self-help CBT, people with anxiety and depression were not analysed separately (e.g. Coull & Morris, 2011). Conducting the meta-analysis this way relies on the assumption that measures of anxiety and depression represent the same underlying latent variable. The results of several factor analyses have consistently shown that depression and anxiety are separate constructs (e.g. Depression, Anxiety and Stress Scale (DASS): Lovibond & Lovibond, 1995; the Hospital Anxiety and Depression Scale (HADS): Zigmond & Snaith, 1983). Also, there is some evidence to suggest that treatment effects are

somewhat larger for people with anxiety ( $d=0.94$ , 95% CI: 0.73, 1.08) compared to those with depression ( $d=0.57$ , 95% CI: 0.25, 0.89) (Marrs, 1995). Overall, meta-analyses consistently find medium to large effect sizes that favour guided self-help CBT compared to control (van't Hof, Cuijpers, & Stein, 2009).

#### ***4.1.4 Changing who is delivering the intervention:***

IAPT services mostly employ psychological wellbeing practitioners (PWP) to deliver low intensity therapies rather than fully accredited therapists (i.e. clinical psychologist), whom require more training and cost services more to employ (Clark, 2011). PWPs are generally trained to a Masters level, whereas clinical psychologists are trained to a doctoral level. A large-scale service evaluation of PWPs, including more than 6000 patients, found large pre-post effect sizes for people with anxiety and depression (Firth, Barkham, Kellett, & Saxon, 2015). Similarly, more than 1000 patients from across 6 IAPT sites, also found PWP-delivered CBT produced beneficial effects – although the effect size was more moderate (Green, Barkham, Kellett, & Saxon, 2014). The differing effect sizes between these two studies could be related to differences in sample size, or could reflect differing levels of PWP skill between these IAPT sites i.e. larger effect sizes are found when sites with highly-skilled PWPs are included. Moderation analyses support the later explanation as the within-group variance could be explained in part by the PWP's confidence, knowledge, resilience, and experience. Although the size of the effect may vary, overall it seems that PWP-delivered CBT is effective for people with anxiety and depression.

#### ***4.1.5 Reducing the therapist contact time:***

A meta-analysis of brief CBT produced large treatment effects for anxiety disorders, but more medium to small effects for depression, and mixed anxiety and depression (Cape, Whittington, Buszewicz, Wallace, & Underwood, 2010). However, the definition of 'brief' is confusing in light of the NICE (2011a) guidelines for common mental health problems. CBT was considered brief if therapy was delivered using between two to ten sessions, but NICE (2011a) state that 10 sessions is the maximum number of CBT sessions that should be offered for people with a common mental health problem. The authors partially addressed this issue by entering the number of therapy sessions as a covariate in all moderation analyses, but perhaps a meta-regression would be a more appropriate test of the impact that therapy length has on treatment outcomes.

A number of limitations have been identified with this and the other meta-analyses of low intensity CBT interventions such as a lack of statistical power, missing moderation analyses, and inconsistent application of the inclusion/exclusion criteria. These flaws may alter

the magnitude of these effect sizes – making them either larger or more conservative. But it is clear that low intensity CBT is an effective intervention for common mental health problems. This evidence led to NICE (2011a) recommending everyone with anxiety and depression should be offered low intensity CBT (usually guided self-help CBT) within a stepped care model.

Increasing access to psychological therapies for people with more severe mental health problems, like psychosis, is a priority for the NHS (Independent Mental Health Taskforce, 2016). The success of the IAPT model for people with common mental health problems has led to increased interest in the suitability and the efficacy of this model for people with psychosis symptoms (Kingdon, 2013). An initial pilot of the IAPT model applied to people with psychosis went some way to improving access (Jolley et al., 2015). However, this adaptation of the IAPT model did not offer any low intensity therapies, because there was no high quality evidence for such interventions. In line with the symptom-specific approach (Thomas et al., 2014), and in replication of the development of IAPT, researchers have begun to explore the feasibility and effectiveness of briefer forms of CBT that target the specific symptoms associated with psychosis, rather than the broader diagnostic label.

## **4.2 Low Intensity CBT for Voices.**

Attempts to develop low intensity CBTp interventions have largely reduced therapy intensity by reducing the number of therapy sessions offered, while still being offered by expert therapists. The majority of these brief CBTp interventions target delusions. The results of these studies are very promising (Foster, Startup, Potts, & Freeman, 2010; Freeman et al., 2014; Freeman, Dunn, Startup, Pugh, Cordwell, Mander, Černis, et al., 2015; Freeman, Waite, Startup, Myers, Lister, McInerney, Harvey, et al., 2015a, 2015b). Less attention has been given to the effects of brief CBT on voices (CBTv). Those individual studies that have investigated the effects of brief CBTv tended to be small, pilot or exploratory studies, but the preliminary findings appear to be somewhat promising (Gottlieb, Romeo, Penn, Mueser, & Chiko, 2013; Pinkham, Gloege, Flanagan, & Penn, 2004; Wykes et al., 2005; Zanello, Mohr, Merlo, Huguelet, & Rey-Bellet, 2014). However, 3 out of 4 of these studies were testing the effects of group CBT interventions. For psychosis symptoms more broadly, group-based CBT is not recommended by NICE (2014b) because it is not considered to be as effective as 1:1 therapy. Moreover half of these studies were uncontrolled, and only one used a randomisation protocol to allocate participants to each condition.

There have been far fewer studies that have explored the effects of non-expert therapists delivering CBTp as a means of reducing therapy intensity. The findings of these studies are mixed. CBTp delivered by frontline mental health practitioners improved general

psychopathology outcomes, but did not have a significant effect on the positive symptoms of psychosis (Guo et al., 2017; Turkington et al., 2014). There is some evidence that clinicians can support patients with psychosis to reach a personal goal, using CBT techniques (Waller et al., 2013), but these results are yet to be confirmed using a between-group research design (Waller et al., 2014). These mixed findings are compounded further when we consider most frontline mental health practitioners do not have the time to deliver therapy, in addition to their care management responsibilities (Waller, Garety, Jolley, Fornells-Ambrojo, Kuipers, Onwumere, Woodall, & Craig, 2013).

Based on the available evidence, it appears that symptom-specific interventions are able to retain their effectiveness when delivered in briefer formats. Also, that 1:1 interventions are preferable over group therapies. In line with the interventions that have been developed for delusions, there is a need for high quality research investigating the effects of brief CBTv. Research must first establish whether CBTv can still be effective when delivered by accredited therapists using fewer sessions. If the results are positive, and the issue of access still remains, then it may be pertinent to consider other means of reducing therapy intensity i.e. non-expert therapist delivery.

### **4.3 Thesis Outline:**

The overall aim of this thesis is to develop and evaluate a brief form of CBTv that can be delivered by accredited therapists. The intervention will be based on the CBT self-help book 'Overcoming Distressing Voices' (Hayward et al., 2012). All other aspects of the intervention design and delivery will be the product of reviewing the current literature, and consultations with mental health clinicians and people who hear voices. Each chapter of this thesis details a stage of this intervention development process, until the final chapters which will present the design and results of a pilot randomised controlled trial of this brief CBTv intervention.

Chapter 6 presents a systematic review and meta-analysis of low intensity (defined as less than the NICE (2014b) recommended 16 sessions) forms of CBTp. This review of the literature was widened to CBTp, as opposed to CBTv, because there were not enough studies of brief CBTv to justify a literature review. Meta-regressions and ANOVAs were used to explore the potential moderators of these effect sizes, e.g. number of sessions, amount on contact time.

Chapters 7 and 8 detail the results from two consultation studies: one with mental health clinicians, and one with people who hear voices. Chapter 7 reports on the quantitative data (with only mental health clinicians), and chapter 8 reports on the qualitative data (both clinicians and voice-hearers). The findings from both consultations were essential in the development of this brief CBTv intervention. The end product was a guided self-help CBTv

intervention, delivered over 8 sessions with a clinical psychologist as the guide. The intervention and trial protocol is detailed within chapter 9.

Chapter 10 reports on the results of the pilot RCT described in chapter 9. Quantitative outcome data is reported on the acceptability and effectiveness of guided self-help CBTv compared to a wait-list control condition.

## 5 Review of Methods.

This PhD adopts a mixed methods approach – whereby both qualitative and quantitative methods were used. The design of each study was based on the most appropriate method to address the research question, and was informed by both current precedents within the literature, and consideration of each method’s reliability, validity, practicality, and ethicality.

## 5.1 Role of the Researcher:

My role within the field of Clinical Psychology research is that of a ‘Clinical Scientist’. That is, I conduct clinically-relevant research, but I am not a practitioner. Although mental health practitioners may want to be involved in research, the majority do not have the time, money or support to do so (Castonguay, Pincus, & McAleavey, 2015). This position affords me the opportunity to conduct research into clinical phenomena so as to pass on any learning to evidence-based practitioners (Cherry, Messenger, & Jacoby, 2000). At present, it is therefore necessary for there to be research-focussed workers, to ensure that research is not neglected within the discipline.

## 5.2 The Research Cycle:

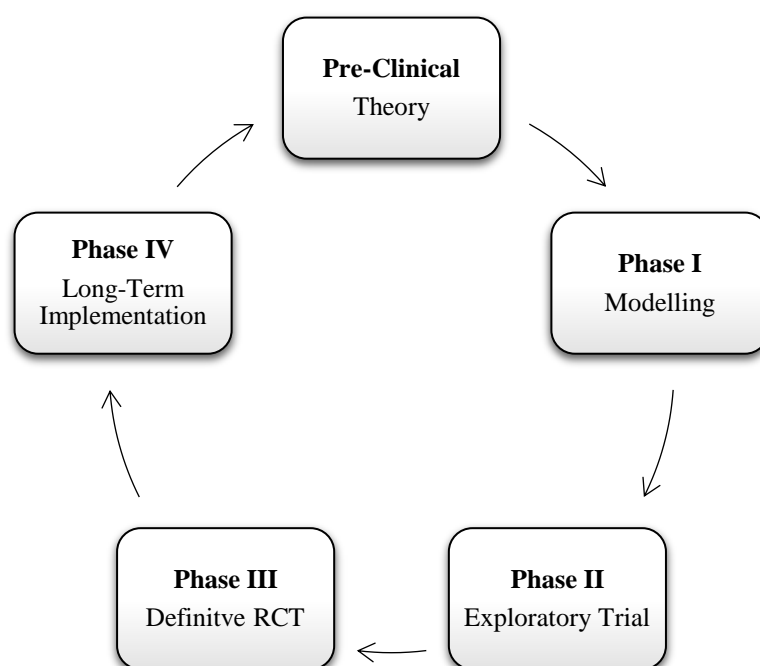


Figure 9. Cycle for the development and evaluation of RCTs for complex interventions (Medical Research Council (MRC), 2000).

The research cycle taken from the MRC guidelines (Medical Research Council (MRC), 2000) for developing complex interventions (see Figure 9), describes the process of conceptualising, testing, and implementing a psychological therapy. The pre-clinical Phase requires the researcher to establish a theory upon which to base the intervention. With regard to this PhD, this Phase had already been completed prior to the commencement of this thesis. For

example, evidence already exists supporting the application of the cognitive-behavioural model to distressing voices (Chadwick & Birchwood, 1994; Garety et al., 2001; Morrison, 2001); the results of these studies are reviewed within the Introduction to this thesis. The specific CBT model for voices hypothesises that it is a person's beliefs about the voice's omnipotence, omniscience, and malevolence that determine their emotional and behavioural response to the voice (Chadwick & Birchwood, 1994) – each of these pathways are supported in the literature (Birchwood & Chadwick, 1997).

Moving around the research cycle, once a theory has been established, the research can progress to Phase I where the intervention idea is considered in terms of its possible mechanisms and design. This Phase describes the studies reported in chapters 6 to 8. Firstly I reviewed the existing literature to establish whether the available evidence suggests CBT for psychosis can still be effective if delivered using less than the 16 sessions recommended by NICE (2014). Chapter 6 describes the findings from this systematic review and meta-analysis of the literature. Secondly I consulted the relevant stakeholders on how the findings from the meta-analysis could be applied therapeutically (chapters 7 and 8): one consultation was with mental health clinicians, and the other with people who hear voices. The outcome of these consultations was a brief, guided self-help CBT intervention for voices (CBTv), based on the *Overcoming Distressing Voices* self-help book (Hayward, Strauss, & Kingdon, 2012), with an accompanying workbook developed specifically for this thesis.

This thesis then ends with research at Phase II: the intervention and study design were tested. Our intervention was piloted as part of a randomised controlled trial (RCT) (chapters 9 and 10). The main aim of these studies was to provide the necessary parameters to conduct a definitive trial, if justified. The results suggest guided self-help CBTv, and the study design, was feasible and acceptable. The between-group results from this trial are promising, and support the continued investigation of this intervention. Thus, the research cycle can continue with guided self-help CBTv being assessed within a definitive RCT (Phase III). If found to be effective, then it may be appropriate to evaluate the implementation of this intervention in mental health services (Phase IV). Evaluating the feasibility, acceptability and effectiveness of guided self-help CBTv in practice will offer opportunities for further observations that can then inform new theories, and the continuation of the research cycle.

The MRC (2000) research cycle for the development and evaluation of RCTs for complex interventions (Figure 9) describes a macro-level research process that is likely to take place over a number of years. At the more micro-level, the National Institute for Health Research (NIHR, 2017) cycle (Figure 10) gives a more in-depth account of the processes undertaken within this thesis. The first stage within this cycle is similar to that taken within the



MRC (2000) research cycle. We identified from both a research and clinicians perspective that people distressed by hearing voices were unable to access psychological therapies (Thomas et al., 2014). The funders agreed this was a research priority, and commissioned this PhD.

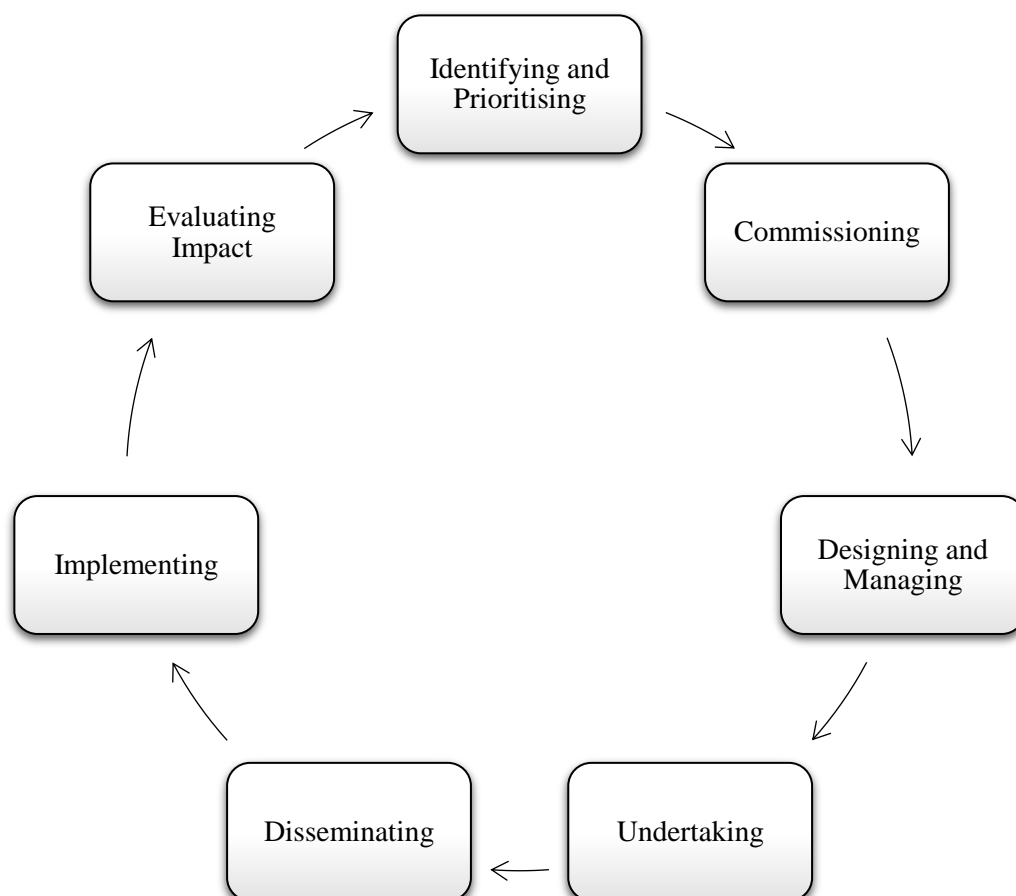


Figure 10. The Research Cycle (NIHR, 2017).

The next two steps of this research cycle are where the majority of this PhD work sits. Each study was firstly outlined in a research protocol. As the Principal Investigator for each study, I was then responsible for the study/trial management, maintaining adherence to the protocol, and ensuring studies completed in line with time and recruitment targets. For example, because the feedback from the consultations with clinicians and patients (chapters 7 and 8) was to inform the therapy and trial protocols, these studies had to be completed prior to the finalisation of the RCT protocol. The window available to recruit participants was somewhat narrow, and required strict project management. The relationship between the consultation studies and the trial can be understood as a research sub-cycle, whereby the process of undertaking one study informs the design and management of the next (see Figure 11).

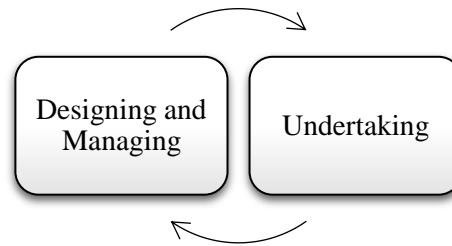


Figure 11. Research Sub-Cycle, based on NIHR (2017).

The final part of the research cycle addressed within this thesis is the dissemination stage. Multiple strategies were used to communicate the research findings to all of the relevant parties. Initially, the findings of each study were written for publication in a peer-review journal so as to disseminate the research within the academic community. Frequently researchers neglect disseminating research to anyone else, or, if they do, they rarely consider the barriers to effective dissemination amongst non-academic persons (Addis, 2006). In this thesis, less traditional forms of dissemination, such as presentations and non-academic reports, were used to communicate research findings to mental health clinicians, and people distressed by hearing voices.

Dissemination activities were guided by the social marketing model of health research (Formoso, Marata, & Magrini, 2007). The model is comprised of five principles that need to be considered to effectively disseminate research to a wider population: (1) Contextualisation/enrichment: giving some background to the research study; (2) Validity/critical appraisal: acknowledging any conflicts of interest, and presenting findings in an honest and unbiased way; (3) Comprehensibility of data on clinical benefits and harms: providing short explanations of how the analysis was carried out, and how this translates into actual risks and benefits; (4) Applicability and relevance: ensuring the findings are communicated to those it effects, and describing what the practical implications will be; and (5) Straightforwardness and appeal: making the document easy to read (i.e. short statements, question and answer format), and visually engaging. Table 4 gives examples of the dissemination activities that addressed each principle.

Some elements of the social marketing model (Formoso et al., 2007) were easier to apply than others. For example, as this was a pilot study we were not able to calculate the Numbers Needed to Treat (NTT) or Numbers Needed to Harm (NNH) as recommended by the model, under the ‘comprehensibility of data on clinical benefits and harms’ principle. Overall, the dissemination activities met each principle of the model. Any future opportunities to disseminate the findings of this thesis will be planned in accordance with the principles of the social marketing model (Formoso et al., 2007).

Principle of Model	How it was Applied
Contextualisation/enrichment	Prior to reporting the research results, an explanation of the issue of access was always given so as to situate the study in the literature. This information was conveyed in an accessible manner using facts and figures wherever possible.
Validity/critical appraisal	Results were always presented honestly. For example, the effect sizes obtained from the pilot RCT were presented with the caveat that the trial was small, and more research is needed to confirm these effects before they can be implemented.
Comprehensibility of data on clinical benefits and harms	When communicating the results of the pilot RCT, information was given about the number of participants that dropped out of the study and therapy, as well as data on the patient experience. There were no adverse events to communicate. Also, a brief explanation was given as to how to interpret effect sizes, and their relationship to the perceived clinical benefits.
Applicability and relevance	The findings from each study were communicated to everyone that had been involved in the research studies e.g. participants, referrers, patient's care teams, and the wider research team (including trial therapists). Study results were also presented at conferences that clinicians attend (e.g. BABCP), and local research events that were open to the public.
Straightforwardness and appeal	Research findings for all studies were presented as A5 leaflets (four pages long). Lots of colour was used, and images were used in place of text wherever possible. Where longer pieces of text were required, this was broken down into smaller 'chunks' using text boxes, and a question/answer format. Wherever possible the findings were also disseminated in the form of a presentation. The slides were designed in keeping with the leaflet.

Table 4. The Social Marking Model of Health Research Dissemination (Formoso et al., 2007) applied to this thesis.

The final two stages of the NIHR (2017) research cycle are not addressed in this thesis. Further research, including a definitive trial at Phase III, is needed before guided self-help CBTv can be implemented into clinical practice. If the results of such a trial find this intervention to be effective at reducing voice-related distress, then commissioners may decide to offer this intervention within their mental health services. The impact of this implementation can then be evaluated in terms of clinical outcomes, patient experience, and services ability to deliver the intervention. The outcomes of this evaluation can help identify any further issues that require research attention.

### **5.3 Mixed Methods Approach:**

This PhD has utilised a mixed methods approach – combining both quantitative and qualitative methods wherever possible. In isolation, both quantitative and qualitative methods can be critiqued in terms of their approaches to knowledge generation. Quantitative methods tend to be more deductive, whereas qualitative methods are largely inductive (Gelo, Braakmann, & Benetka, 2008). Consequently, quantitative methods are critiqued for being blinkered by hypothesis testing, whereas qualitative methods are criticised for their subjectivity (Johnson & Onwuegbuzie, 2004). Neither method is perfect. However, by combining them to answer a range of related research questions, the weaknesses of one approach can be compensated for by the strengths of the other. For example, the standardisation typical of quantitative methods can provide more objective evidence; and the qualitative methods give the researcher space to engage with the research question in a more exploratory fashion, which may lead to the generation of new theories. Wherever possible in this thesis, mixed methods were used, in the hope that this would give a richer level of data.

The main mixed methods study included in this thesis is described in chapters 7 and 8. Mental health clinicians were asked to complete a questionnaire that included both Likert scales (quantitative), and free-text response boxes (qualitative). Using the mixed methods approach here was particularly illuminating. The quantitative results suggested that clinicians generally supported the concept and implementation of guided self-help CBTv. By contrast, the qualitative results evidence a number of barriers and drawbacks to implementing this intervention. This study highlights the value of the mixed methods approach. If we had used a single-method approach then we would only have part of the story. I have also adopted a mixed methods approach for the pilot RCT of guided self-help CBTv – although the results of the qualitative component are not presented here (the study and analysis plans are outlined in chapter 9), they are currently being written up for publication.

Much like the single-method approach, using mixed methods is not without its problems. One weakness is that it is often impractical i.e. more expensive, requires more

resources, takes more time, involves more training (Johnson & Onwuegbuzie, 2004). Fortunately, there were sufficient resources to adopt a mixed methods approach in this PhD. A more pressing issue with the mixed methods approach concerns the conflict between their epistemological standpoints. Quantitative methods typically align with a Realist perspective (the assumption that there is an objective reality that can be measured), whereas qualitative methods often subscribe to non-realist perspectives such as the Social Constructivist perspective (there is no such thing as objective reality, what we perceive as reality is a product of personal interpretations) (Yilmaz, 2013). An epistemological conflict can then present when trying to draw overarching conclusions in the context of a mixed methods study. However, this issue may be less relevant to this thesis as each type of qualitative analysis has its own epistemology (Vaismoradi, Turunen, & Bondas, 2013); and methods like Thematic Analysis (used in chapter 8) can be approached from a Realist perspective (Braun & Clarke, 2006). Qualitative analysis from a Realist perspective is often used within mixed methods research to triangulate the results of a quantitative study (Madill, Jordan, & Shirley, 2000) – thereby avoiding an epistemological conflict for the researcher.

This thesis aligns with a more nuanced philosophical standpoint. I have adopted a Critical Realist perspective. Critical Realism offers an understanding of the philosophy of science that marries the Realist and Social Constructivist approaches together: it is assumed that there is an objective reality (Realism), but that our experience of this reality will always be subjective (Social Constructionism) (Harrits, 2011). Critics of Critical Realism argue this approach ‘sits on the fence’ (Walters & Young, 2001). However, support is growing for the Critical Realist perspective, in the context of mixed methods research (Pluye & Hong, 2014). The Realist aspect of this approach gives the researcher permission to make generalisations about their findings (as they are representing an objective truth), and the Social Constructivist aspect concedes that these findings are likely to be influenced by the participants’ individual differences (owing to the subjective nature of most psychology data).

In practice, Critical Realism advocates the use of triangulation of the quantitative and qualitative methods to either: (1) confirm research findings from multiple perspectives, thereby increasing reliability/credibility; or (2) to cultivate a more complete answer to the research question, thereby increasing validity (Mcevoy & Richards, 2006). In this thesis, mixed methods were used for completeness. For example, the quantitative questionnaire data collected during the pilot RCT was used to identify any changes in clinical symptoms and therapy mechanisms, whereas the qualitative interview data will provide insight into the patient’s subjective experience of therapy.

## **5.4 Methodological Assumptions:**

When producing the protocol for each study, consideration was given to each part of the methodology, including the sample, design, procedure, and outcome measures. For some studies there was a clear methodological precedent that could be followed, whereas for others there was somewhat less clarity.

### **5.4.1 *Meta-analysis:***

The aim of this chapter was to summarise the available literature on brief CBTp. To achieve this aim, I conducted a systematic review and meta-analysis. Alternatively, I could have carried out a narrative review, but this type of review lacks reliability and can be subject to selection bias (Uman, 2011). Carrying out a systematic review in line with PRISMA guidelines ensures transparency and allows replication. The systematic review question was devised using the Cochrane PICO framework (Higgins & Green, 2011). The decision was made to present the results of this review as a meta-analysis. The decision to use a random effects model and weighting meant that the overall effect size was sensitive to the studies' sample sizes and variance. Meta-analyses provide a more objective assessment of the effectiveness of an intervention as the results are quantified, compared to a descriptive review. These results can then be used to make a judgement about the relative effectiveness of brief CBTp, compared to other therapies. For example, the effect sizes obtained can then be compared to those obtained in meta-analyses of CBTp more broadly (i.e. where CBTp was generally delivered in line with NICE (2014) recommendations). If these effect sizes were similar in magnitude, and the confidence intervals overlapped, then this would provide strong evidence that reducing the number of therapy sessions is unlikely to significantly reduce the effectiveness of CBTp.

Meta-analyses are not without their flaws. For example, there is an inherent assumption when conducting a meta-analysis that all of the studies included have similar methods, interventions, and outcome measures. To make this decision you are largely reliant on the information presented in the research article – due to word count and publishing restraints this can be problematic. To determine the extent to which studies are similar, there are a number of ways to quantify heterogeneity within meta-analyses (Higgins & Thompson, 2002). While these methods can tell you if there is likely to be heterogeneity, they cannot identify the cause. I conducted several moderation analyses that were designed a priori to try to identify what (if any) variable(s) could explain any heterogeneity.

### **5.4.2 *Factor analysis:***

The questionnaire data collected as part of the consultation study with mental health clinicians (chapter 7) was used to test the validity of the Normalisation Process Theory (NPT)

model of implementation (C. R. May et al., 2009). The data were subjected to an exploratory factor analysis (EFA). An argument could be made for using confirmatory factor analysis (CFA) as the questionnaire was based on a pre-existing model comprised of four components – which could have been entered as separate factors. However, this model is purely theoretical – there is currently no factorial or quantitative evidence to validate this model. Consequently, an EFA analysis was considered to be more appropriate, and a stronger test of the model's validity (as any factorial structure could have emerged).

#### **5.4.3 *Thematic analysis:***

All of the qualitative data collected during this thesis (chapter 8) was analysed using thematic analysis in line with the Braun and Clarke (2006) protocol. The objective of Thematic analysis (TA) is to identify patterns within the data, and to organise these into a thematic structure (Braun & Clarke, 2006). This descriptive level of analysis was conducive with the aims of these qualitative studies. TA is often criticised for being too simplistic and lacking any interpretation (Braun & Clarke, 2014). However the analysis guidelines explicitly state that a successful thematic structure should be data-driven, and not just a replication of the interview guide (Braun & Clarke, 2006). Also, simplicity is not necessarily a bad thing: if TA is simple then it makes it accessible to a wider audience. Moreover, complexity is not necessarily an indication of validity or reliability.

TA strives to evidence validity of the thematic structure by encouraging the researcher to stay close to the data, and stipulating that all themes and sub-themes should be adequately supported by the data (Braun & Clarke, 2012). Reflexivity is encouraged throughout the analysis process (Clarke & Braun, 2013). In the context of this thesis, all of the qualitative data analysis adhered to the Braun and Clarke (2006) protocol, and all themes and sub-themes were supported with multiple illustrative quotes. The credibility of the final thematic structures were assessed by researchers independent of the study team that had experience in qualitative methods.

Methods such as interpretative phenomenological analysis (IPA) and grounded theory give researchers permission to interact with the data in a way that can influence the eventual findings. IPA invites the researcher to bring their personal experiences into the analysis of the data, in order to understand how an individual makes sense of their experiences in an idiographic way (Smith, 2004). Similarly, grounded theory advocates a deductive approach to analysis, especially in the later stages (Heath & Cowley, 2004). The researcher is able to be selective in their coding, in search of evidence that supports the initial theory – where contradictory evidence is found, the researcher can then adapt their theory (Willig, 2013).

Although there can be no guarantee that the analysis is free from researcher bias, TA is far less vulnerable to this bias, compared to other methods of qualitative analysis.

#### **5.4.4 Sample size:**

Deciding on the target sample size for the majority of the studies included in this thesis was largely unequivocal. For example, the number of participants recruited to the questionnaire study described in chapter 7 was based on the agreed recommendation that a sample of 200 is appropriate for factor analysis (Fabrigar, Wegener, MacCallum, & Strahan, 1999; Field, 2013; MacCallum, Widaman, Zhang, & Hong, 1999). Also, the sample size used for the focus group study described in chapter 8 was designed in line with numerous guidelines that recommend holding three focus groups, with approximately 8-12 people in each (Bender & Ewbank, 1994; Carlsen & Glenton, 2011; Krueger & Casey, 2000). However deciding on the sample size for the pilot randomised controlled trial (RCT), described in chapters 9 and 10, was far more contentious.

One aim for all pilot and feasibility studies should be to establish the parameters from which the sample size can be calculated for the trial proper (Craig et al., 2008). However this does not help determine how many participants should be included in the pilot study. Although there are sample size guidelines available, there is a lot of variability in the sample sizes used in pilot RCTs, ranging from 8 to 114 participants per arm, with a median of 30 (Billingham, Whitehead, & Julious, 2013). The majority of pilot studies (65%) do not provide any justification for the sample size they have used (Arain, Campbell, Cooper, & Lancaster, 2010). The target sample size for the pilot RCT conducted as part of this thesis was based on the rule of thumb that each group should have 12 completers per arm (Julious, 2005). This criteria has been used in a number of intervention-based pilot RCTs with psychosis patients (Bucci et al., 2015; Hayward, Strauss, & Bogen-Johnston, 2014; Jacobsen et al., 2016).

There are more recent guidelines that recommend external pilot RCTs should aim to recruit 35 participants per arm (Teare et al., 2014) – more than double the recommendation by Julious (2005). The main reason for this larger sample size recommendation is to reduce the variation around the parameter estimates, which in turn is hoped to increase the validity of subsequent sample size calculations (Lancaster, Dodd, & Williamson, 2004). However, the results of Julious' (2005) original study demonstrate that the width of the 95% confidence intervals remains unchanged beyond recruiting 12 participants; that is, having a sample larger than 12 participants per arm does not improve the precision of the parameter estimates (Moore, Carter, Nietert, & Stewart, 2011). Because of the conflict in these findings, alternative means were used to decide which sample size guideline should be followed.



The reason for conducting a pilot RCT in the first place, as opposed to a Phase III trial (definitive trial), is that the researcher does not have the evidence to guarantee the feasibility of the study (Thabane et al., 2010). In line with the Medical Research Council guidelines for developing complex interventions (MRC, 2006), pilot studies are the important first step in addressing any parts of the study or intervention protocols that the researcher is unsure about. It is possible that the results of the pilot RCT will find the intervention to have no effect or be potentially harmful (Lenth, 2001). From an ethical standpoint, it is therefore unethical to recruit a sample that is larger than necessary to answer the research question; the study may not be feasible, participants could be put at unnecessary risk, and resources are being wasted without having any scientific value (Altman, 1980).

From the statistical perspective, there is no strong evidence to argue the benefit of using the 35 per arm rule (Teare et al., 2014) over the 12 (Julious, 2005). However, looking at the ethical argument, there is greater support for using Julious' (2005) sample size recommendation. The intervention we trialled (see chapters 9 and 10) contradicts current healthcare guidelines that CBTp should be delivered over a minimum of 16 sessions (NICE, 2014b) – so it was possible that the intervention would have no effect, or even cause harm (although this was considered to be unlikely). Moreover, we did not know if the study would be feasible – so all of the study aims were designed to assess different aspects of the study's feasibility. The 12 participants per arm rule of thumb (Julious, 2005) was therefore selected because recruiting a further 23 participants per arm (in line with Teare et al. (2014)) would have increased the burden on the target population, without improving our ability to meet the study aims.

#### ***5.4.5 Transdiagnostic Recruitment:***

Where studies in this thesis recruited participants distressed by hearing voices, psychiatric diagnosis was not included as an exclusion criterion. Hearing voices is a diagnostic criteria for the psychosis spectrum diagnoses (i.e. schizophrenia, schizoaffective disorder, delusional disorder, and psychosis not otherwise specified) (American Psychiatric Association, 2013; World Health Organisation (WHO), 1992); but is commonly experienced in the context of other mental health problems. The decision to adopt a transdiagnostic approach to recruitment was primarily based on the findings of numerous studies that have found no consistent differences between the experience of hearing voices in those with and without a psychosis diagnosis (Dorahy et al., 2009; Hepworth, Ashcroft, & Kingdon, 2013a; Slotema et al., 2012; Toh, Castle, Thomas, Badcock, & Rossell, 2016; Toh, Thomas, & Rossell, 2015); the validity and reliability of these studies is discussed further within the Introduction to this thesis.

Moreover, the use of diagnosis as an exclusion criteria seemed inappropriate in light of criticisms surrounding the construct validity of the various psychosis disorders (Bentall et al.,

1988). Methods for diagnosing psychosis are fraught with issues, and involve a level of subjective judgement. Inter-rater agreement is at best moderate, with more than 25% of patients being misclassified (McGorry et al., 1995). The argument for restricting this thesis to include only those with a psychosis diagnosis becomes even less compelling when you consider the substantial within-diagnostic group variance. There are 15 different sets of symptoms that two people can present with and both receive a psychosis, yet have no symptoms in common (Read & Dillon, 2013). Designing interventions and treatments for a specific diagnosis is based on the assumption that these diagnoses represent an underlying disorder or disease – of which there is little evidence of for psychosis (Kendell & Jablensky, 2003). The diagnostic categories used within mental health services are the product of expert panel discussions and votes of consensus (Davies, 2013). This type of evidence would be considered weak according to the NICE (2006) hierarchy of evidence.

A more recent re-conceptualisation of diagnosis draws on the symptom specific approach (Bentall et al., 1988). Stratified psychiatry aims to understand a patient's mental health problem within a multidimensional space, rather than basic categories (Joyce, Kehagia, Tracy, Proctor, & Shergill, 2017). A prototype is created across each dimension (symptom); the patient's experiences are then compared with the prototype to understand the extent to which this dimension features in the patient's presentation. Patients can be clustered together if they have the same relationship to the prototype. Using dimensions to understand psychosis symptoms, rather than diagnostic categories, is more predictive of prognosis (Demjaha et al., 2009). This approach therefore admonishes a dichotomous understanding of mental health symptoms, and embraces the psychosis continuum perspective (van Os et al., 2000).

Despite the evidence, there are problems with adopting a symptom specific approach. Notably that this approach juxtaposes the main stream understanding of mental health problems, and mental health service structure. Whether this would cause problems at the point of implementation, if the evidence supports this, remains to be seen. There is a real need for more research into the experience of hearing voices in the context of non-psychosis diagnoses – this issue is discussed further in the Discussion chapter of this thesis. Unfortunately, the sample sizes within each study presented here did not allow for any secondary analyses to explore the moderating role of diagnosis. Again, how this can be addressed by future research studies is considered in the Discussion chapter.

#### **5.4.6 *Management of Bias:***

Good quality research design requires an awareness of potential sources of bias. Bias in a research study can have detrimental effects on the reliability, validity and credibility of the results. If bias is managed inappropriately, it can lead to the results being attributed to

extraneous variables (also known as confounding variables), rather than the study manipulation. To reduce the impact of confounds, it is important to maintain standardisation throughout the study; that is, all aspects of the study are kept the same except for the independent variable (Field & Hole, 2003). Efforts were made to standardise each of the studies in this thesis. For example, all of the focus groups with people who hear voices (chapter 8) were guided by the same discussion guide, and all of the mental health practitioners (chapters 7 and 8) were posed the same questions, both multiple choice and free-text responses. Although each study was designed with bias in mind, there are sometimes additional variables that are either beyond the researcher's control or were not considered a priori that may influence the study results. In the spirit of transparency, these potential confounds are acknowledged in the discussion section of each chapter, as well as the final discussion chapter of this thesis.

With regard to the pilot RCT reported in this thesis, the trial was designed and reported in accordance with the CONSORT guidelines (Eldridge et al., 2016). The impact of bias in this RCT can be assessed using the Cochrane Risk of Bias Tool (Higgins & Green, 2011). This tool outlines six elements of the RCT methodology where bias commonly occurs: (1) Random sequence generation: participants should be allocated to the study conditions based on pure chance; (2) Allocation concealment: ensuring that all the necessary parties are not informed of the participants group allocation; (3) Blinding of participants: participants are unaware of the intervention they are receiving and/or whether this intervention is hypothesised to be the most effective intervention ; (4) Blinding of researcher: outcome data is collected by a member of the research team that is not aware of what intervention the participant received; (5) Incomplete outcome data: where missing data is systematic; (6) Selective reporting: not all of the research findings are reported, especially those that were non-significant. Table 5 outlines how (if at all) each type of bias was addressed within the pilot RCT (chapters 9 and 10).

Domain	Actions Taken
<i>Selection Bias</i>	
Random sequence generation	<p>Participants were randomly allocated to each group by a statistician independent from the research team, using a 1:1 ratio random permuted block randomisation. The randomisation was carried out using random sequence generation software. Participants were randomised using their unique participant identification number – the statistician did not have access to any of the participants' identifiable information.</p> <p>Likelihood of bias: LOW</p>
Allocation concealment	<p>The research assistant working on the RCT was not informed of participants' group allocation until data collection was complete. However the trial manager, trial therapists, and participants were made aware of the allocations after the baseline assessments. It was necessary for the trial manager and therapists to know participants' group allocations so that they could make the necessary arrangements for participants to begin therapy. This trial was single-blind, so participants knew whether they were allocated to the intervention or control group.</p> <p>Likelihood of bias: MEDIUM</p>
<i>Performance Bias</i>	
Blinding of participants	<p>As mentioned above, this was a single-blind RCT. Participants were aware of what group they had been allocated to, and whether that group was considered the intervention arm or the control.</p> <p>Likelihood of bias: HIGH</p>
<i>Detection Bias</i>	

Blinding of researcher	<p>The research assistant responsible for collecting the post-intervention data was blinded to the participants' group allocation.</p> <p>Blinding was only broken once. The unblinding occurred partway through an assessment with a participant; the research assistant was instructed to continue with the assessment.</p> <p>Likelihood of bias: LOW</p>
<i>Attrition Bias</i>	
Incomplete outcome data	<p>Attrition from both the study and therapy was low. The trial statistician did not deem the missing data to be systematic. The reasons for each attrition were independent from each other.</p> <p>Likelihood of bias: LOW</p>
<i>Reporting Bias</i>	
Selective reporting	<p>To avoid this bias, the trial protocol was published (chapter 9) before recruitment had completed. The report of the RCT results (chapter 10) follows the analysis and reporting plans outlined in this protocol. The between-group effect sizes are reported for all of the outcome measures used in the study – regardless of their size or significance.</p> <p>Likelihood of bias: LOW</p>

Table 5. The Cochrane Risk of Bias Tool (Higgins & Green, 2011) applied to this thesis.

After review of the Cochrane Risk of Bias Tool (Higgins & Green, 2011), the one type of bias where this trial may be vulnerable is that participants were aware of their group allocation. It is possible that participants might have been influenced by demand characteristics. Because the participants in the intervention arm knew they were receiving treatment, they may have exaggerated any post-intervention benefits so as to ‘please’ the researcher. This is a problem with most trials of psychological therapies, especially those that use treatment as usual (TAU) as the control comparison. Using a single-blind design means we cannot control for non-specific therapy effects; such as expectation of benefit, therapist attention, and therapist empathy – which could account for some or all of the post-therapy benefits. It is difficult to determine whether there was any performance bias in this study. However, by using a mixed methods approach, the quantitative findings can be triangulated with the qualitative findings (not reported here) to observe whether they are confirmatory or not. Moreover, during the next steps of this research programme alternative, active and/or placebo control conditions can be considered to better disguise the study aims and hypotheses (see discussion chapter).

All other aspects of the RCT design fared well against the Cochrane Risk of Bias Tool (Higgins & Green, 2011). Randomisation was conducted fairly by an independent party, outcome data was collected blind, and the delivery and reporting of the study adhered to the trial protocol. These aspects of good practice can give us more confidence in the reliability and validity of the research findings; while reducing the influence of confounding variables.

#### **5.4.7 Outcome Measures:**

Arguably, one of the most important methodological decisions required for the pilot RCT (chapters 9 and 10) was the selection of the primary outcome. The primary outcome should be the outcome that the researcher considers to be the intervention target, and the construct that is most imperative to change (Sedgwick, 2010). If there is no effect on the primary outcome then this implies the intervention is ineffective (Andrade, 2015). It is therefore important to select the right primary outcome so that any null results cannot be attributed to inappropriate outcome measurement.

As the CBTv model aims to reduce voice-related distress (Chadwick & Birchwood, 1994), this was selected as the study’s primary outcome. The most commonly used measure in trials of CBTv is the PSYRATS auditory hallucination scale (Haddock et al., 1999); however this measure only has two items that specifically ask about distress – the rest of the items focus on voice phenomenology. Furthermore, the PSYRATS needs to be carried out as an interview with the participants. Because this trial was exploring the effectiveness of a guided self-help intervention, it was important to promote autonomy from the start of the study – therefore a self-

report measure would be more appropriate to give participants the opportunity to complete the assessment independently.

In light of this, the Hamilton Program for Schizophrenic Voices Questionnaire (HPSVQ) voice impact scale (Van Lieshout & Goldberg, 2007) was selected as the primary outcome for the trial. The HPSVQ is a self-report measure, and the voice impact scale is made up of four items: (1) How bad are the things the voices say to you? (2) How much do the voices interfere with your daily activities? (3) How distressing are the voices that you hear? And (4) How bad (worthless/useless) do the voices make you feel about yourself? The questionnaire has strong psychometric properties (Kim et al., 2010): specifically, strong internal consistency that remained stable across time points (all  $\alpha > .83$ ) (Tavakol & Dennick, 2011), and fair test-retest reliability across items (all Intra-Class Correlations (ICC)  $> .49$ ) (Cicchetti, 1994). Although the HPSVQ is statistically robust, it has been used far less in the field, which could make it more difficult to compare our effect sizes to those obtained in other trials of CBTv that have used the PSYRATS. However, the strong concurrent validity between the two measures (all  $r_s > .80$ , all  $p_s < .001$ ) (Kim et al., 2010) suggests that it would be appropriate to make these comparisons. Four items again is perhaps not sufficient to cover all aspects of voice-related distress, but it is arguably a more comprehensive measure of voice-related distress than the alternatives.

## **5.5 Reflections:**

All of the methodological decisions made within this thesis were grounded in previous literature, and accepted precedents. However, just because these practices may be accepted, does not necessarily mean they are the best practice. For example, although the HPSVQ (Van Lieshout & Goldberg, 2007) may have been the best measure of voice-related distress available, there is clearly a need for a more extensive measure. Additionally, taking a top-down approach to explore the significant heterogeneity within the meta-analysis, using planned moderation analyses, can mean the real explanation is never explored.

To my knowledge, there is currently no solution to these limitations, but this may not always be the case. It is therefore important for researchers to have a well-informed awareness of the most recent developments in methodology and statistics. Notably, in recent years there has been a growth in the popularity of Bayesian methods in psychology as an alternative to the dominant frequentist approach (Andrews & Baguley, 2013). Bayes methods are less sensitive to sample size, and can unpack non-significant results (Dienes, 2014). The use of Bayes methods to evaluate the results of pilot RCTs may help to eliminate the debate surrounding the appropriate sample size.

In time, there may be further methodological and statistical developments that can address the inherent flaws of the accepted practices that have been discussed here.



## 6 A systematic review and meta-analysis of low intensity CBT for psychosis.

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### **Contributions:**

Conceptualisation:	All authors
Methodology:	All authors
Data Collection:	CMH
Data Analysis:	CMH
Initial Draft:	CMH and CS
Reviewing and Editing:	All authors*

\*Plus comments from peer-reviewers during the publication process.

## **6.1 Abstract:**

Sixteen sessions of individual cognitive behavior therapy for people with psychosis (CBTp) is recommended. However, access to CBTp is poor, so the potential of low intensity CBTp (fewer than 16 sessions of face-to-face contact) is being explored. A systematic review and meta-analysis was conducted of 10 controlled trials evaluating low intensity CBTp. Significant between-group effects were found on the primary outcome, symptoms of psychosis, at post-intervention ( $d=-0.46$ , 95% CI: -0.06, -0.86) and follow-up ( $d=-0.40$ , 95% CI: -0.06, -0.74). Study quality did not moderate post-intervention psychosis outcomes, nor did contact time/number of sessions or therapy format (individual versus group). Between-group effects on secondary outcomes (depression, anxiety and functioning) were not significant at post-intervention, but became significant at follow-up for depression and functioning outcomes (but not for anxiety). Overall, findings suggest that low intensity CBTp shows promise with effect sizes comparable to those found in meta-analyses of CBTp more broadly. We suggest that low intensity CBTp could help widen access. Future research is called for to identify mechanisms of change and to ascertain moderators of outcome so that low intensity CBTp targets key mechanisms (so that scarce therapy time is used effectively) and so that interventions offered are matched to patient need.

## **6.2 Keywords:**

Low intensity; CBT; cognitive therapy; psychosis; schizophrenia; improving access to psychological therapies; IAPT; meta-analysis

### **6.3 Highlights:**

- 16+ sessions of CBT for psychosis is recommended, but this is not widely available
- A meta-analysis of low intensity (i.e. fewer sessions) CBT for psychosis is reported
- Small-medium between-group effects were found for psychosis symptoms at post-therapy
- Small-medium between-group effects for psychosis symptoms remained at follow-up
- Effects were not moderated by study quality or therapist contact or therapy format

## **6.4 Introduction:**

A number of meta-analyses demonstrate benefits of cognitive behavioral therapy for psychosis (CBTp) (Gould, Mueser, Bolton, Mays, & Goff, 2001; Jauhar et al., 2014; Pilling et al., 2002; Wykes, Steel, Everitt, & Tarrier, 2007; Zimmermann, Favrod, Trieu, & Pomini, 2005). Such findings led the UK National Institute for Health and Care Excellence (NICE, 2014b) to recommend that CBTp should be offered to everyone with a psychotic disorder. The guideline states CBTp should be delivered by qualified staff in an individual format and consist of a minimum of 16 sessions. These practice guidelines are endorsed internationally, for example, in the United States (National Guidelines Clearinghouse, 2009), and in Australia and New Zealand (Royal Australian And New Zealand College Of Psychiatrists Clinical Practice Guidelines Team For The Treatment Of Schizophrenia and Related Disorders, 2005). Despite the clarity of the guidelines, access to CBTp is poor.

The most recent report by the UK's Schizophrenia Commission (2012) estimated only 10% of people with psychosis are offered CBTp. The limited availability of CBTp could be explained by multiple factors, such as lack of trained staff, conflicts between service priorities and an emphasis in psychosis services on monitoring mental health rather than intervening (Berry & Haddock, 2008b). Outside of the UK, a lack of appropriate health insurance (Chamberlin, 2004), and poor access to basic psychological health facilities (World Health Organisation (WHO), 2014) may be a further barrier to accessing psychological therapies.

The limited availability of CBT does not just apply to people with psychosis (Shafran et al., 2009) and attempts to address this have been widely discussed. Low intensity CBT interventions, which require fewer resources, may provide a partial solution (Bennett-Levy, Richards, & Farrand, 2010). Low intensity CBT interventions are effective for anxiety and depression (Andrews, Cuijpers, Craske, McEvoy, Titov, et al., 2010; Farrand & Woodford, 2013; Grist & Cavanagh, 2013) and, in the UK, are recommended by NICE (2011) for those with mild to moderate symptoms of anxiety and depression. Since 2008 low intensity CBT has been offered to people with mild to moderate symptoms of anxiety and depression as part of the UK's Improving Access to Psychological Therapies (IAPT) initiative with some success (Clark, 2011; Clark et al., 2009; Department of Health, 2012).

In order to address the poor access to CBTp for those with psychosis, a similar approach could be applied. Indeed, interest concerning the feasibility and effectiveness of low intensity interventions for those with psychosis is growing, and a UK pilot is currently underway (Jolley et al., 2015; Kingdon, 2013). Low intensity interventions may have the potential to be of benefit to a much larger population of people experiencing psychosis without increasing costs but their effectiveness is not well established.

Previous meta-analyses of CBTp have not systematically explored whether low intensity CBTp is effective and the aim of the current meta-analysis is to evaluate the effectiveness of low intensity CBTp (i.e. CBTp delivered in fewer than the NICE recommended 16 face-to-face therapy sessions). In line with meta-analyses of CBTp more broadly (e.g. Jauhar et al., 2014; Wykes et al., 2007) the primary outcome in this meta-analysis is symptoms of psychosis. Additional secondary outcomes of depression, anxiety and functioning are also examined. We will also investigate whether effects are moderated by study quality, therapist contact (hours/number of sessions) and therapy format (individual or group).

We plan to address the following questions: (1) Is low intensity CBTp (< 16 contact hours) effective in improving psychosis symptoms in comparison to control conditions? (2) Is study quality associated with psychosis outcomes? (3) Is therapist contact (hours/number of sessions) associated with low intensity CBTp psychosis outcomes? and (4) Is the format of low intensity CBTp (group or individual) associated with psychosis outcomes? (5) Is low intensity CBTp effective in improving secondary outcomes of depression, anxiety and functioning?

## **6.5 Method:**

### **6.5.1 Literature Search:**

A comprehensive search of the literature was conducted. Titles and abstracts were searched using PsycInfo, Web of Knowledge and Scopus databases for studies up to 10<sup>th</sup> December 2015 using the following terms: (COGNITIVE BEHAVIO\* or COGNITIVE THERAPY or CBT) and (PSYCHOSIS or PSYCHOTIC or SCHIZO\*).

All articles types were searched for, including dissertations, peer reviewed and non-peer reviewed studies. The studies included in two major meta-analyses of CBTp were screened for possible inclusion in this meta-analysis (Jauhar et al., 2014; Wykes et al., 2007). Both the Clinical Trials and ISRCTN research registers were searched to find studies relevant to this meta-analysis that had recently finished or had not yet published. The reference sections of all papers that met inclusion criteria were also checked to identify any further studies.

### **6.5.2 Inclusion Criteria:**

To be considered for inclusion in the meta-analysis: (1) the study tested the effectiveness of low intensity CBTp (defined as CBTp interventions designed with fewer than 16 sessions of face-to-face contact time); (2) the study was a controlled trial; (3) participants were diagnosed with a psychotic disorder (as defined by NICE guidelines (2014)), according to either DSM (American Psychiatric Association, 2013) or ICD (World Health Organisation (WHO), 1992) criteria; (4) the study included at least one quantitative measure of the following:

psychosis, depression, anxiety, or functioning; and (5) the empirical paper or dissertation must be available in English.

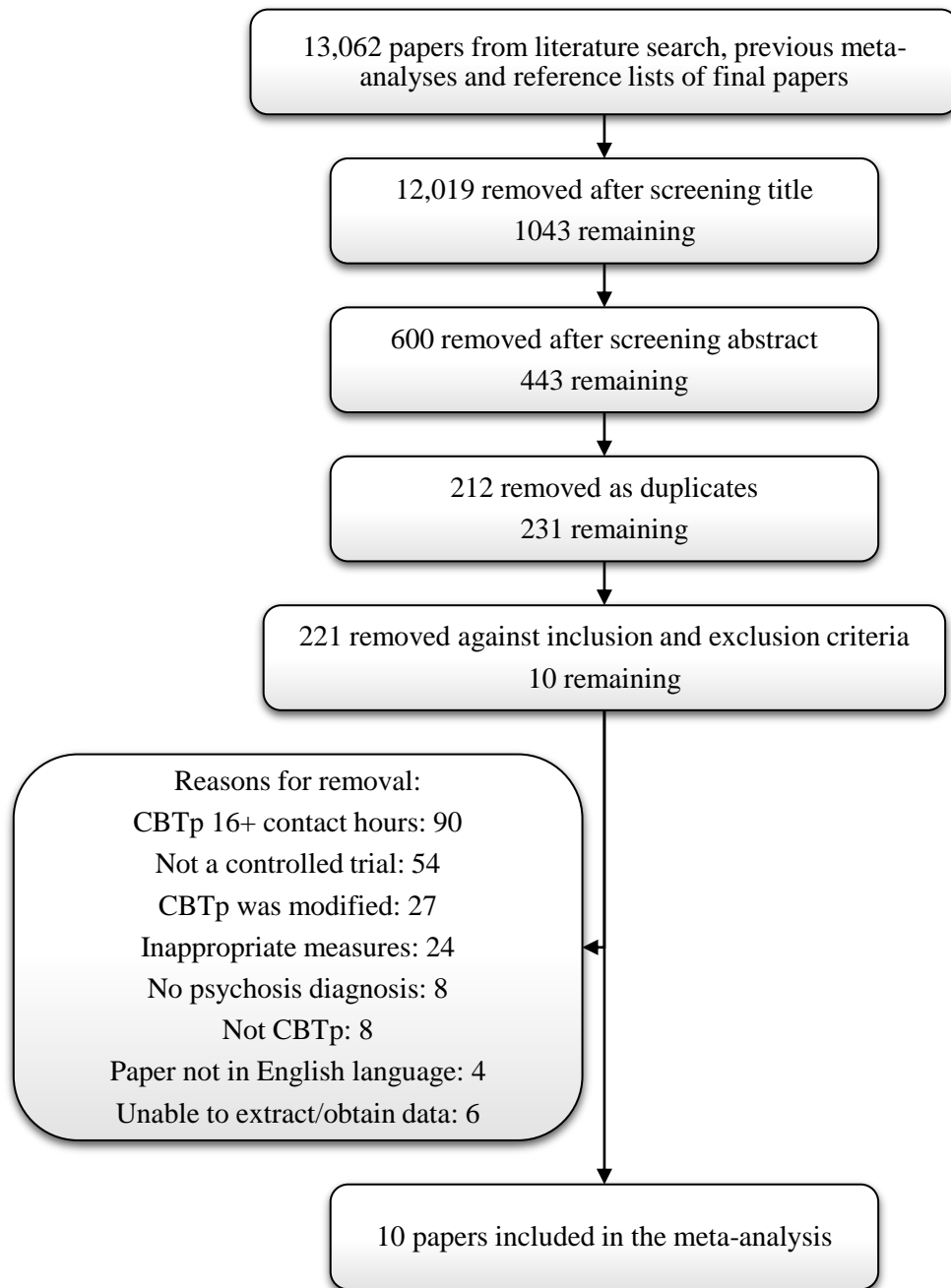


Figure 12. PRISMA diagram detailing the literature search process, and reasons for study exclusion.

### 6.5.3 Exclusion Criteria:

Studies were excluded from the meta-analysis if: (1) CBTp was integrated with another psychological intervention, as it would not be possible to attribute outcomes to CBTp alone; (2) substance misuse was the primary mental health disorder; (3) an effect size could not be

obtained from either data provided in the paper or from unpublished data obtained from the authors. Figure 12 shows the PRISMA diagram detailing the process by which papers were screened and removed.

#### **6.5.4 Data Extraction:**

Post-intervention and follow-up (where available) means and standard deviations on primary and secondary outcomes were extracted for both intervention and control arms. We also coded multiple features of the therapy protocols. The number of contact hours were extracted; we defined this as the total amount of practitioner time spent directly delivering low intensity CBTp. Any direct face-to-face “booster sessions” that were used to deliver CBTp were included in the total contact time. Interventions that delivered low intensity CBTp using alternative formats e.g. web-based CBTp, without any face-to-face contact were given a contact time of zero. Studies were also coded as to whether low intensity CBTp was delivered within a group or individually. Prescribed medication and study drop-out were also extracted.

#### **6.5.5 Quality Assessment:**

Downs and Black's (1998) index was used to assess the methodological robustness of studies included in the meta-analysis. This index includes 27 items within five categories (range 0-31): reporting, external validity, internal validity, selection bias and power, and was devised especially for research relating to healthcare interventions. A higher score reflects a study of higher quality. Studies were scored by the first author, and half were also rated by an independent researcher. There was substantial agreement between the two raters as per the criteria of Landis and Koch (1977) ( $K = .79$ ).

#### **6.5.6 Measures:**

Four outcomes were included in the meta-analysis. The primary outcome was psychotic symptom severity and secondary outcomes were depressive and anxiety symptom severity and functioning.

#### **6.5.7 Meta-Analysis Procedure:**

The meta-analysis was conducted using SPSS version 20. Post intervention between-group Cohen's  $d$  effect sizes were calculated (see appendix for equations). Effect sizes were weighted according to the guidance of Hedges and Olkin (1985) (see appendix for equations).

A random effects model with a restricted-information maximum likelihood estimate was used, in line with the recommendations of Viechtbauer (2005). The meta-analysis was conducted using SPSS macros by Lipsey and Wilson (Wilson, 2011).

ANOVA and regression meta-analytic analogues were used to test moderation hypotheses on psychosis outcomes. Number of contact hours and number of sessions were entered as predictors into separate regression analysis to test their association with the effects of low intensity CBTp psychosis outcomes. ANOVAs were conducted comparing outcomes when low intensity CBTp was delivered in an individual or group format. Spearman's *rho* was calculated between study quality and low intensity CBTp psychosis symptom effect sizes.

Homogeneity analysis was carried out using the *Q* statistic. A significant *Q* value means there is significant heterogeneity within the effect sizes, which was explored using the moderation analyses outlined above. Rosenthal's fail safe *N* and a funnel plot was used to test for publication bias. If data points on the funnel plot are unevenly distributed around the mean effect size, this indicates that publication bias might be present (i.e. that a disproportionate number of unpublished studies with non-significant effects might exist).

## **6.6 Results:**

The literature search produced a total of 13,062 papers (see Figure 12). After screening titles and abstracts, and removing duplicates, 230 papers remained. Full text articles were then screened against the inclusion and exclusion criteria, leaving a total of 16. Where insufficient data were reported in the paper, all lead and corresponding authors were contacted at least three times to obtain data that could be used to calculate effect sizes. Six studies were removed due to insufficient data reported and appropriate data being unobtainable from the research team (this information is available from the first author on request). A final set of 10 studies remained and entered into the meta-analysis. The average quality score for these studies (using the Downs and Black (1998) index) was 24.80 out of 31 (range: 18-29). See Table 6 for details of the final 10 studies.

The following outcome measures were included in the meta-analyses: (1) psychotic symptoms: Positive and Negative Syndrome Scale (PANSS) (Kay, Fiszbein, & Opler, 1987), psychotic symptom rating scales (PSYRATS) (Haddock et al., 1999), Scale for the Assessment for Positive Symptoms (SAPS) (Andreasen, 1982); (2) depression: Beck Depression Inventory (BDI) (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961), Beck Depression Inventory II (BDI II) (Beck, Steer, Ball, & Ranieri, 1996), Hospital Anxiety and Depression Scale (HADS) depression scale (Zigmond & Snaith, 1983); (3) anxiety: Beck Anxiety Inventory (BAI) (Beck, Epstein, Brown, & Steer, 1988), Hospital Anxiety and Depression Scale (HADS) anxiety scale (Zigmond & Snaith, 1983), Hamilton Anxiety Inventory (HAI) (Hamilton, 1959); (4) functioning: Personal and Social Performance Scale (PSP) (Morosini, Magliano, Brambilla, Ugolini, & Pioli, 2000), Social Functioning Scale (SFS) (Birchwood, Smith, Cochrane, Wetton, & Copestake, 1990), Social Behavior Scale (SBS) (Wykes & Sturt, 1986).



### **6.6.1 Participant Characteristics:**

Across the 10 studies, a total of 631 participants were included: 315 received low intensity CBTp, and 316 received the control interventions. All of the participants were experiencing ongoing psychosis symptoms. The average of the reported mean participant age was 38.77 years and 35% were female. All participants in all studies were prescribed psychiatric medication, however we are unable to report on exact details of medication use because this information is not available for most the studies. Where studies did report medication use participants were mostly prescribed multiple medications, including at least one antipsychotic.

### **6.6.2 Low intensity CBTp Characteristics:**

The mean number of low intensity CBTp contact hours was 9.50 ( $SD = 3.47$ ), ranging from 6 to 15 and the mean number of sessions used to deliver low intensity CBTp was 9.00 ( $SD = 2.91$ ), with a range from 6 to 15 sessions. Five of the studies delivered low intensity CBTp individually, and five within a group. Where CBTp was delivered in a group, the mean number of group members was 5.75 ( $SD = 0.96$ ); however this information was not available for one of the studies. All interventions were delivered by practitioners with a formal psychological therapy qualification.

The CBTp interventions varied in their content and focus. In particular, whilst some studies focused on single, specific mechanisms theorized to maintain psychosis-related distress, other studies employed a broader range of CBTp techniques to target a broader range of proposed mechanisms. Five studies targeted specific mechanisms: self-esteem/self-confidence (Freeman et al., 2014; Hall & Tarrier, 2003), worry (Freeman, Dunn, Startup, Pugh, Cordwell, Mander, Černis, et al., 2015), sleep (Freeman, Waite, Startup, Myers, Lister, McInerney, Harvey, et al., 2015a) and cognitive dissonance in relation to explanations for delusions (Levine, Barak, & Granek, 1998). Five studies targeted a broader range of mechanisms (Li et al., 2015; Mortan, Tekinsav Sütcü, & German Köse, 2011; Penn et al., 2009; Pinkham et al., 2004; Wykes et al., 2005).

### **6.6.3 Control Conditions:**

All ten studies included a control condition: two were non-randomized, and the remaining eight were randomized controlled trials (RCTs). Six of the control conditions were treatment as usual, two compared low intensity CBTp to supportive psychotherapy, one to a supportive psychotherapy group, and one compared low intensity CBTp to a full intensity form of group CBTp (20 contact hours).

First Author	Participants	Intervention (I)/ Control (C)	Intervention Format	Contact Time (hours)	Delivered by Therapist?	Measures	Follow Up Period (months)	Quality Rating (/31)	Assessments Blinded?
Freeman et al. (2014)	All experiencing a persistent delusion and negative beliefs about the self.  Age: $M=41.70$  66.67% male, 33.33% female	I: CBTp targeting negative beliefs about the self (n=15)  C: TAU (n=15)	I	6	Y  Clinical Psychologists	BDI II, BAI	3	26	Y
Freeman, Dunn et al. (2015)	All experiencing a persecutory delusion, as well as clinically significant worry	I: CBTp aimed at reducing worry (n=73)  C: TAU (n=77)	I	8	Y  Clinical Psychologists	PANSS total	4	29	Y

	Age: $M=41.50$								
	57.50% male, 42.50% female								
Freeman, Waite et al. (2015)	Experiencing distressing hallucinations and delusions. Has sleep difficulties for at least a month	I: CBTp aimed at improving sleep for people with hallucinations and delusions (n=24) C: TAU (n=26)	I	11	Y  Clinical Psychologists	PANSS total	3	26	Y
	Age: $M=40.90$								
	68% male, 32% female								
Hall et al. (2003)	Diagnosed with a psychotic disorder, all experiencing positive symptoms.	I: CBTp using reality testing for self- esteem and increasing conviction in	I	7	Y  CBT therapist	PANSS total, HADS depression, HADS anxiety, SFS	3	25	N

	Recruited from an inpatient acute psychiatric facility	positive beliefs (n=12) C: TAU (n=13)							
	Age: <i>M</i> =38								
	48% male, 52% female								
Levine et al. (1998)	Diagnosed with paranoid schizophrenia, without any religious convictions.	I: CBTp group using cognitive dissonance to consider alternative explanations for delusions (n=6)	G	7	Y	PANSS total	0	21	Y
	Age: <i>M</i> =32.00	C: 7 sessions of a supportive psychotherapy group focusing on coping (n=6)			Therapists trained in cognitive dissonance induction				
	All male								

Li et al. (2015)	Experiencing at least mild psychiatric symptoms.  Recruited from psychiatric hospitals in China.  Age: $M=31.36$  37.50% male, 62.50% female	I: CBTp focusing on both positive and negative symptoms, including relapse prevention work (n=96)  C: 15 sessions of supportive psychotherapy offering emotional support and coping strategies (n=96)	I	15	Y  Clinical Psychologists and trained psychiatrists	PANSS total, PSP	18	28	N
Mortan et al. (2011)	Hearing distressing voices with a diagnosed psychotic disorder.  Recruited from an inpatient unit.	I: CBTp using cognitive restructuring, coping strategies and psychoeducation based on the	G	15	Y  Clinical Psychologists	SAPS, BDI, HAI	12	18	N

	Age: $M=42.3$ All male	diathesis-stress model (n=7)  C: TAU (n=5)							
Penn et al. (2009)	Must have taken part in two previous pharmacological trials, with a diagnosed psychotic disorder.	I: CBTp focus of self-monitoring and coping strategies, including gaining an awareness of triggers and understanding voices (n=32)	G	12	Y  Clinical Psychologist and other professionals	PANSS  total, BDI II, SFS	12	28	Y
	Recruited from both hospitals and community services.  Age: $M=40.65$  53% male, 47% female	C: 12 sessions Supportive psychotherapy focussing on non- symptom based problems (n=33)							

Pinkham et al. (2004)	Experiencing medication- resistant distressing voices.  Referred from an inpatient unit  Age: <i>M</i> =39.60  62.5% male,  37.5% female	I: CBTp focusing on understanding voices, coping strategies and dealing with stigma ( <i>n</i> =5)  C: 20 sessions GCBTp using ABC model and coping strategies ( <i>n</i> =5)	G	7	Y  CBT therapist	PSYRATS total	0	20	N
Wykes et al. (2005)	Diagnosed with Schizophrenia and experiencing distressing voices.  Recruited through community teams  Age: <i>M</i> =39.70	I: CBTp focusing on understanding voices, improving self-esteem and developing coping strategies ( <i>n</i> =45)  C: TAU ( <i>n</i> =40)	G	7	Y  Clinical Psychologists	PSYRATS total, SBS	0	27	N

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58.80% male,  
41.2% female

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Table 6. The studies included in the meta-analysis.

*Note:* I = individual; G = group; N no; Y = Yes; TAU = Treatment As Usual. Age and gender are reported where available.



#### **6.6.4 Drop-Out Rates:**

The mean study dropout rate was 5.53% ( $SD = 5.32$ ), ranging from 0% to 13.50%. Intervention dropout rates were typically not reported.

#### **6.6.5 Follow Up Data:**

Six studies reported follow up data. The mean follow up period across studies was 7.86 months ( $SD = 6.09$ ), ranging from 3 months to 18 months.

#### **6.6.6 Meta-Analysis Results:**

Effect sizes are interpreted in line with Cohen's criteria for Cohen's  $d$  effect sizes (i.e. 0.2=small effect, 0.5=medium effect and 0.8=large effect). Figure 13 shows that all of the post-intervention between-group effect sizes favor low intensity CBTp over the control conditions with small-medium to large effect sizes.

#### **6.6.7 Primary Outcome: Effect of Low Intensity CBTp on Psychosis Symptoms:**

Nine studies included a measure of psychosis symptoms. We found a statistically significant between-group effect on psychosis symptoms at post-intervention in the medium range, with significant heterogeneity ( $d=-0.46$ , 95% CI: -0.86, -0.06;  $Z=-2.24$ ,  $p=.03$ ;  $Q_T = 34.00$ ). When the outlier study, with the largest effect size is removed (Levine et al., 1998), the effect of low intensity CBTp on psychosis outcomes remains significant although smaller in size ( $d=-0.28$ , 95% CI: -0.54, -0.02;  $Z=-2.08$ ,  $p=.04$ ;  $Q_T = 14.11$ ). Moreover, the psychosis symptom effects were maintained at follow-up with a small-medium effect size and significant heterogeneity ( $N=6$ ,  $n=494$ ,  $d=-0.40$ , 95% CI: -0.74, -0.06;  $Z=-2.30$ ,  $p=.02$ ;  $Q_T = 13.79$ ).

We conducted moderation analyses to explore heterogeneity, specifically the effects of study quality, therapist contact (hours/number of sessions) and therapy format (individual of group) on psychosis outcomes were explored (see appendix). None of these moderation analyses were significant: study quality ( $r_s(8)=.39$ ,  $p=.30$ ); number of sessions ( $d=-0.23$ ,  $\beta=.25$ ;  $Z=1.45$ ,  $p=.15$ ), number of contact hours ( $d=-0.23$ ,  $\beta=.17$ ;  $Z=1.00$ ,  $p=.32$ ), or therapy format (*Between Group*  $Q=0.01$ ,  $p=.93$ ; Individual:  $d=-0.23$ , 95% CI: -0.42, -0.03; Group:  $d=-0.24$ , 95% CI: -0.54, 0.06).

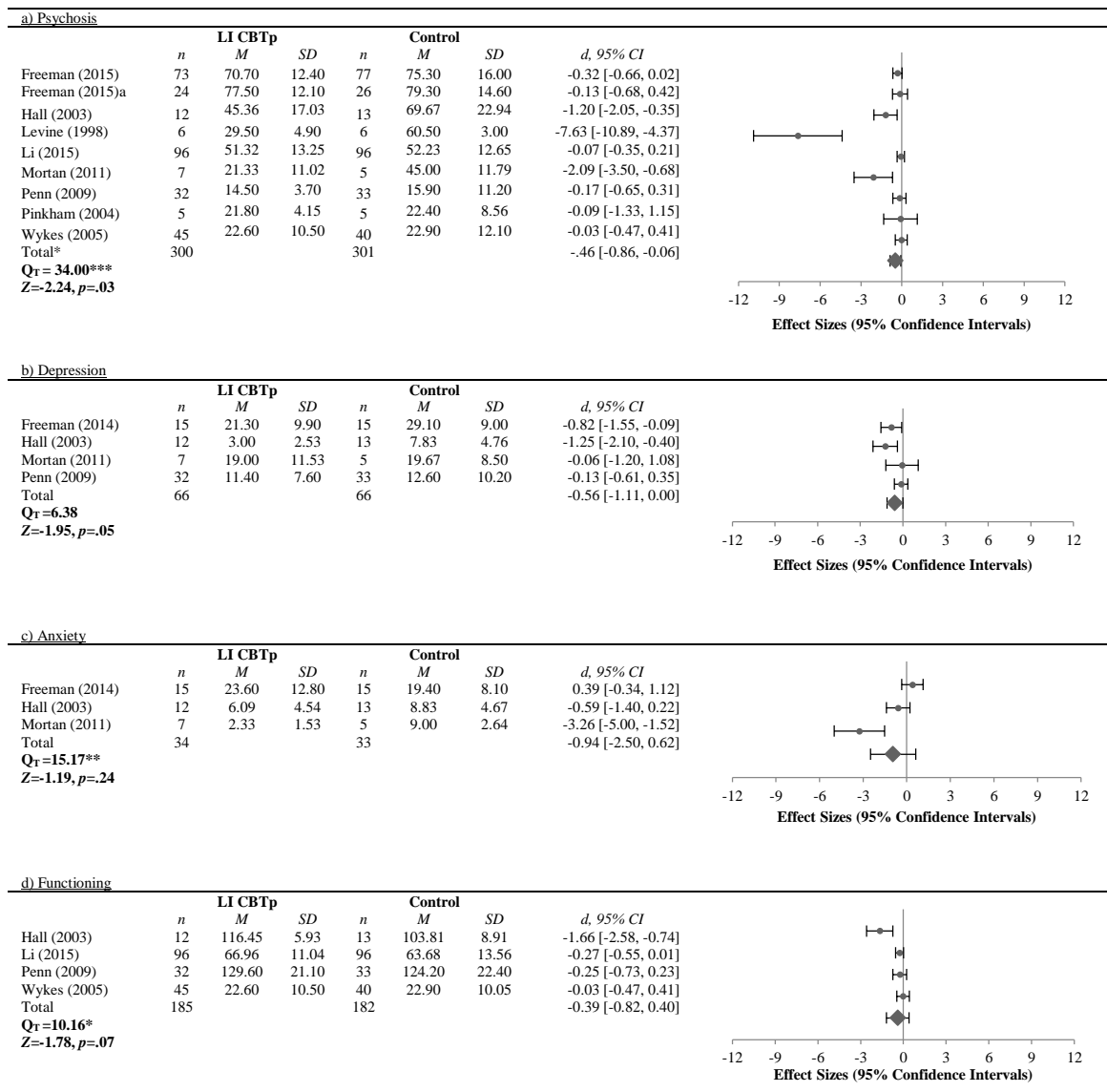


Figure 13. Forest plot of effect sizes and 95% CI for post-intervention between-group effect sizes on psychosis, depression, anxiety and functioning outcomes.

*Note:* ♦ = the overall effect size. A negative effect size favors low intensity CBTp over the control condition. += Effect sizes that were recoded so a negative effect size favors low intensity CBTp. Q<sub>T</sub> = total homogeneity; *z* = *z* score; *p* = exact *p* value. \* *p* < .05, \*\* *p* < .01, \*\*\* *p* < .001.

The quality ratings for these nine studies ranged from 18 to 29 (out a total possible of 31 using the Downs and Black (1998) index), with a mean quality rating of 24.67 (*SD*=4.00). The common methodological pitfalls across these studies were that participants and care team staff not were not blind to allocation, and few studies controlled for potential confounds. The higher quality studies (a quality score that was above the mean quality score) typically had blinded post-intervention assessments, whereas the lower quality studies tended not to. Although we found study quality was not a moderator of psychosis outcomes, this analysis had

low statistical power so the relationship between study quality and psychosis effect sizes were explored further.

As there is no recommended cut-off categorizing study quality for the Downs and Black (1998) index, we split the studies dependent on whether assessors were blind at post-intervention or not (a key quality indicator of CBTp as used by Jauhar et al. (2014)). With the data split in this way both analyses failed to show significant post-intervention between-group effects on psychosis outcomes, possibly due to these subgroup analyses being underpowered. However, it is of note that the mean effect size of the four blinded studies ( $d=-0.57$ , 95% CI: -1.35, 0.20;  $Z=-1.45$ ,  $p=.15$ ;  $Q_T = 20.11$ ) was not lower than for unblinded studies ( $d=-0.47$ , 95% CI: -1.01, 0.07;  $Z=-1.72$ ,  $p=.09$ ;  $Q_T = 13.50$ ). This concurs with the moderation analysis of study quality and suggests that study quality was not associated with smaller effect sizes for the low intensity CBTp studies.

#### **6.6.8 Effects on Secondary Outcomes:**

We also explored the effects of low intensity CBTp on depression (4 studies), anxiety (3 studies) and functioning (4 studies) outcomes. Post-intervention between-group effects on all secondary outcomes were in the small/medium to large range but none were statistically significant (Anxiety:  $d=-0.94$ , 95% CI: -2.50, 0.62;  $Z=-1.19$ ,  $p=.24$ ;  $Q_T = 15.17$ ; Functioning:  $d=-0.39$ , 95% CI: -0.82, 0.40;  $Z=-1.78$ ,  $p=.07$ ;  $Q_T = 10.16$ ), although the effect on depression outcomes only just failed to meet the criteria for statistical significance ( $d=-0.56$ , 95% CI: -1.11, 0.003;  $Z=-1.95$ ,  $p=.05$ ;  $Q_T = 6.38$ ). However, at follow up time points however, effects on depression and functioning outcomes effects were significant (Depression:  $d=-0.56$ , 95% CI: -0.97, -0.15;  $Z=-2.65$ ,  $p=.01$ ;  $Q_T = 3.79$ ; Functioning:  $d=-0.57$ , 95% CI: -0.81, -0.33;  $Z=-4.68$ ,  $p<.001$ ;  $Q_T = 1.80$ ); but for anxiety effects remained non-significant ( $d=0.04$ , 95% CI: -1.28, 1.36;  $Z=0.05$ ,  $p=.96$ ;  $Q_T = 12.20$ ). There were too few studies with measures of secondary outcomes to warrant moderation analysis.

#### **6.6.9 Publication Bias:**

Rosenthal's (1979) fail safe N for the between-group psychosis effect was 64.39. This means more than 64 unpublished studies with null results would have to be included in this meta-analysis for the effect size to become non-significant at the  $p<.05$  level. A funnel plot (see appendix) of the between-group psychosis effect sizes against the related standard errors showed effect sizes generally to be evenly distributed around the overall mean effect size. The plot did suggest that a study with a very strong effect size in favor of control conditions may be missing, although this may be because of an outlier effect size on psychosis outcomes in the

current meta-analysis ( $d=-7.63$ ; Levine et al. (1998)). As noted earlier, when this study is removed, effects on post-intervention between-group psychosis outcomes remains significant. There is therefore no clear indication of publication bias in the present meta-analysis.

## **6.7 Discussion:**

This meta-analysis explored the effects of low intensity CBTp (i.e. fewer than 16 therapy contact hours) on psychosis symptom outcomes for people diagnosed with a psychotic disorder, as well as the effects on secondary outcomes of depression, anxiety, and functioning. We found that low intensity CBTp led to significant post-intervention between-group differences in psychosis symptoms compared to control conditions with a medium effect size. Where follow-up was measured this effect was maintained, with the follow up time period ranging from 3 months to 18 months. Proposed moderators of study quality, therapist contact (number hours/sessions), and therapy format (individual or group) did not significantly predict post-intervention between-group psychosis outcomes.

The post-intervention between-group effects on secondary outcomes of depression, anxiety and functioning were not significant. However, between-group effects on depression and functioning became significant at follow up whilst remaining non-significant for anxiety.

### **6.7.1 Effects on Psychosis:**

Post-intervention effects of low intensity CBTp on the primary outcome, symptoms of psychosis ( $d=0.46$ ), were consistent with those found in meta-analyses of CBTp more broadly (e.g. Wykes et al. (2007): positive symptoms  $d = -0.37$ , 95% CI: -0.23, -0.52; negative symptoms  $d = -0.44$ , 95% CI: -0.17, -0.70; Jauhar et al. (2014): overall psychosis symptoms:  $d = -0.33$ , 95% CI: -0.47, -.19). Moreover, effects on psychosis symptom outcomes remained at follow-up. Therefore, our findings show great promise for low intensity CBTp and suggest that effects of low intensity CBTp on psychotic symptoms may be comparable to CBTp more broadly, although this possibility would require testing with a direct comparison between low and high intensity CBTp.

In contrast to two of the major previous meta-analyses of CBTp (Jauhar et al., 2014; Wykes et al., 2007), we found no effect of study quality on psychosis outcomes and we found that the mean effect size of higher quality studies (i.e. with blinded assessments) was not smaller than that found for lower quality (i.e. non-blinded) studies ( $d=0.57$  versus  $d=0.47$  respectively) on post-intervention psychosis outcomes (although the absence of a statistically significant difference may be due to lack of power). The lack of association with study quality may reflect the generally high study quality ratings for many of the studies in our analyses and signal a move in the field towards conducting higher quality studies. Overall therefore, the

effect on psychosis outcomes, the maintenance of effects at follow-up coupled with the lack of association with study quality shows that benefits may be achieved with fewer than the recommended 16 sessions of CBTp.

These findings raise the possibility that the same scarce CBTp therapist resource could be used to widen access as, by definition, low intensity therapies require less clinician time to deliver. The studies in our meta-analysis delivered CBTp using an average of nine sessions, this means that almost two patients could be seen by the same therapist for every one patient offered the recommended 16 sessions of CBTp. Moreover, half of the interventions included were delivered in a group with a mean of 5.75 participants per group. Therapy format (individual or group) did not moderate post-intervention psychosis symptom outcomes and therefore low intensity group CBTp could help to widen access further. In a time when healthcare funding is limited, and is unlikely to improve in the near future (Karanikolos et al., 2013; Roberts, 2015), service providers and clinicians must weigh up the balance between maximizing therapy effectiveness and widening access to all who might benefit. With limited therapist resources available our findings suggest that low intensity CBTp could be an important way to widen access whilst maintaining treatment effectiveness.

While findings for low intensity CBTp show promise, there is potentially room to improve the effectiveness of CBTp more broadly as effect sizes from meta-analyses, including the current one, are in the small-medium range (Jauhar et al., 2014; Wykes et al., 2007). CBTp has become an umbrella term that encompasses many different techniques targeting different theorized mechanisms: a Delphi study by Morrison and Barratt (2010) identified 77 components to CBTp that were described as ‘important or essential’. This is exemplified in the current meta-analysis where the CBTp interventions varied in their content and focus: half the studies targeted single mechanisms of psychosis-related distress (Freeman, Dunn, et al., 2015; Freeman, Waite, et al., 2015; Hall & Tarrier, 2003; Levine et al., 1998) whilst the other half targeted a broader range of mechanisms (Li et al., 2015; Mortan et al., 2011; Penn et al., 2009; Pinkham et al., 2004; Wykes et al., 2005). Therapy format also differs between studies with CBTp offered in both individual and group formats and the diagnostic focus is sometimes on psychosis in general (e.g. Hall & Tarrier, 2003) and sometimes on specific psychosis symptoms such as delusions (e.g. Freeman, Dunn, et al., 2015) or distressing voices (e.g. Mortan et al., 2011).

The relative benefits of these different ways of delivering CBTp has not been well explored. Does it maximize therapeutic benefits: To focus on single or multiple mechanisms? To target psychosis in general or to focus on specific psychosis symptoms? To offer CBTp in a group or individual format? These are important questions for future research. For low intensity CBTp in particular there may be value in targeting a single mechanism linked to a single

symptom (e.g. Freeman, Dunn, et al., 2015) as therapy time is limited and a focused approach may be most effective. Indeed, there is evidence from a recent meta-analysis that this taking this approach in CBTp for delusions may be more effective than broader focused CBTp (Mehl, Werner, & Lincoln, 2015). We need further research to allow us to answer these questions more fully and to identify the most effective modes of delivery for CBTp more broadly and for low intensity CBTp in particular.

### **6.7.2 *Effects on Secondary Outcomes:***

Psychosis symptoms were the primary outcome in our meta-analysis, as is the case in previous meta-analyses of CBTp more broadly (Jauhar et al., 2014; Wykes et al., 2007). However, CBTp also aims to reduce distress and disturbance associated with psychosis symptoms (Birchwood & Trower, 2006) and in our meta-analysis we did not find significant between-group post-intervention effects for distress (as measured by depression and anxiety outcomes) or disturbance (as measured by functioning outcomes). Yet, at follow-up, between group differences on depression and functioning outcomes (although not anxiety) were statistically significant. This may be an important finding as there is indication in the CBTp literature that beneficial effects may be delayed and not always seen immediately post-intervention (e.g. Sensky et al., 2000). Indeed, this is consistent with the CBT approach where internalizing therapy techniques comes with practice and where a period of post-therapy consolidation is often recommended in order to gain maximum therapeutic benefit (Jones-Smith, 2016). Our findings are consistent with this suggestion and delayed effects of depression and functioning could indicate that, as patients practice and become more familiar with CBTp techniques, benefits beyond psychosis symptoms emerge.

### **6.7.3 *Acceptability:***

The mean study dropout rate was low (5.53%, range = 0-13.5%) and smaller than study dropout reported in meta-analyses of CBTp more broadly (e.g. median = 14.5%, range = 0%-45%; Wykes et al. (2007). This is an indication of high study quality and that trials of low intensity CBTp are acceptable to participants, but there was limited information provided on intervention engagement and acceptability to both service users and providers. More research is needed to specifically examine facilitators and barriers to engagement in low intensity CBTp interventions.

### **6.7.4 *Strengths and Limitations:***

Strengths of the meta-analysis include a rigorous search strategy and application of eligibility criteria to strike a balance between study rigor (i.e. all were controlled trials with participants meeting diagnostic criteria for a psychotic disorder) and a sufficient number of

studies to allow for meaningful conclusions to be drawn. Study quality was rated and independently verified in order to explore the possibility that study quality moderated findings. Finally, a range of possible moderators of psychosis symptom outcome were tested including therapist contact time and therapy format. However, a limitation of the meta-analysis was that only a small range of possible moderators were examined due to the small study sample size. Future research would benefit from examining the effects of other moderators of outcomes such as severity of symptoms at baseline or level of therapist training. In relation to this question of therapist training, the Improving Access to Psychological Therapies (IAPT) initiative in the UK (Department of Health, 2012) aims to increase access to evidence-based psychological therapies for common mental health problems (i.e. depression and anxiety). This has been achieved, in part, through training psychological wellbeing practitioners (PWPs) to offer low intensity CBT within a stepped-care approach (i.e. low intensity CBT is offered first, followed by full intensity CBT with a CBT therapist where necessary). These PWPs typically do not have a prior professional training in mental health care, but receive specialist, typically in-service training. Evaluation of IAPT shows that this approach helps to widen access whilst achieving good clinical outcomes (Department of Health, 2012). Whether the PWP curriculum can be adapted to effectively offer low intensity CBTp is currently being evaluated (Jolley et al., 2015) and, dependant on outcomes, this approach offers further potential to widen access to CBTp without increasing resources.

A further limitation of the meta-analysis is that findings from the controlled clinical trials may not generalize to routine clinical practice both because of the efforts made in trials to retain participants that would not be realistic to employ in clinical settings and because participants taking part in trials may not be representative of the wider population. A future research question therefore is whether findings from the current meta-analysis generalize to routine clinical practice.

Strengths of the included studies were that most were of reasonably high quality, although not all studies had blind post-intervention assessments, and studies generally provided a clear description of participant demographic and diagnostic details and about the nature of the CBTp intervention that was administered. In terms of the primary outcome the studies used assessor-administered measures of psychosis symptoms which are seen as preferable to relying on self-report measurement tools. However, there were a number of limitations with the included studies which are outlined below.

First, most (6/10) of the studies had a treatment-as-usual control condition and these studies therefore do not allow for specific effects of CBTp to be separated from non-specific

effects such as therapist attention and expectation of benefit. Future studies would benefit from including active control conditions in order to allow for specific CBTp effects to be elucidated.

Second, it could be argued that the participants involved in trials of low intensity CBTp are not comparable to those included in trials of CBTp more generally; for example, those that are offered trials of low intensity CBTp may be experiencing less complex and severe forms of psychosis. To address this potential limitation, we used the same exclusion criteria as two major meta-analyses of CBTp (Jauhar et al., 2014; Wykes et al., 2007) and only included trials where participants met diagnostic criteria for a psychosis disorder. Moreover, there is no indication in inclusion/exclusion criteria for individual studies that people with more complex/severe form of psychosis were excluded. However, this is an interesting question for future research where initial symptom severity could be tested as a moderator of effects of low intensity CBTp.

Third, whilst study drop-out was well reported, details of intervention engagement were generally missing. Providing information on the number of low intensity CBTp sessions attended and amount of homework completed is crucial for fully understanding the effectiveness of the intervention. Per protocol analysis would allow for the effectiveness of low intensity CBTp for intervention completers to be examined separately to intention-to-treat effectiveness. That is, it is possible that intervention completers show greater benefits than non-completers and, in this case, a focus on methods to increase intervention completion would be warranted. In future, studies of low intensity CBTp would benefit from measuring and reporting on indicators of intervention engagement.

#### **6.7.5 Research Implications:**

Our findings raise a number of questions for future research, in particular as regards mechanisms of change and moderators of outcome for low intensity CBTp. First, we suggest that low intensity CBTp interventions might be most beneficial when targeting specific symptoms of psychosis and linked mechanisms, particularly as a limited number of sessions are available. There are already trials taking this approach (e.g. Freeman, Dunn, et al., 2015) and showing that changes on the proposed mechanism (in this case worry) mediate effects on the targeted outcome (in this case paranoia). Future studies of low intensity CBTp could take forward this causal-interventionist approach and help to elucidate the most important mechanisms of change in low intensity CBTp. Second, we suggest a focus on moderators of outcome in order to more fully understand who benefits from low intensity CBTp, and who might not. Moderators to test include baseline severity/complexity of psychosis symptoms, the nature of psychosis symptoms (e.g. paranoia, hearing voices, negative symptoms) and the presence of co-morbid symptoms of depression or anxiety disorders. Such research would help



to elucidate how best to allocate scarce CBTp therapist resource most effectively and efficiently. Therapist training (i.e. whether therapists have a specialized CBTp training or not) should also be examined as a moderator of low intensity CBTp outcomes; if non-specialists can achieve similar outcomes to specialist practitioners this could further widen access by increasing the pool of practitioners able to offer the therapy.

#### **6.7.6 Clinical Implications:**

Our meta-analysis found that low intensity CBTp can have beneficial effects on symptoms of psychosis both at post-intervention and follow-up. Given this, low intensity CBTp could be offered in mental health services, perhaps as part of a stepped-care model. Within a stepped-care model people with psychosis would be offered low intensity CBTp in the first instance, and then, if difficulties remain, people would be ‘stepped up’ to high-intensity CBTp (Bower & Gilbody, 2005). This approach to service delivery could increase access to CBTp, without denying those who need it access to higher intensity therapy. Alternatively, a matched care approach may be deemed appropriate, where the intensity of CBTp (low or high) would be matched to people’s presenting needs (Martinez & Williams, 2010). The suggested research highlighted above will help to elucidate moderators of low intensity CBTp outcomes and will help to match people to the most appropriate form of the therapy.

#### **6.7.7 Conclusion:**

This meta-analysis shows that low intensity CBTp relative to control conditions leads to fewer symptoms of psychosis at both post-intervention and follow-up with effect sizes broadly in line with the wider CBTp literature. Post-intervention effects on psychosis were irrespective of intervention format (group or individual) or therapy duration (number of contact hours and sessions). Findings support offering low intensity CBTp in mental health services and thereby widening access to scarce CBTp therapist resource. We suggest future research on low intensity CBTp could focus on evaluating mechanism-specific interventions for specific symptoms of psychosis as well as on exploring moderators of low intensity CBTp outcomes. Fulfilment of these recommendations will enable us to see if the promise of low intensity CBTp can be achieved.

# 7 Understanding clinician attitudes towards implementation of guided self-help cognitive behaviour therapy for those who hear distressing voices: Using factor analysis to test Normalisation Process Theory.

Chapter 7 is under review with BMC Health Services Research as:

**Hazell, C. M.,** Strauss, C., Hayward, M., & Cavanagh, K. (2017). Understanding clinician attitudes towards implementation of guided self-help cognitive behaviour therapy for those who hear distressing voices: Using factor analysis to test Normalisation Process Theory. *BMC Health Services Research*.

## **Contributions:**

Conceptualisation:	All authors
Methodology:	All authors
Data Collection:	CMH
Data Analysis:	CMH
Initial Draft:	CMH and CS
Reviewing and Editing:	All authors*

\*Plus comments from peer-reviewers during the publication process.

## **7.1 Abstract:**

### **7.1.1 Background:**

The Normalisation Process Theory (NPT) has been used to understand the implementation of physical health care interventions. The current study aims to apply the NPT model to a secondary mental health context, and test the model using exploratory factor analysis. This study will consider the implementation of a brief cognitive behaviour therapy for psychosis (CBTp) intervention.

### **7.1.2 Methods:**

Mental health clinicians were asked to complete a NPT-based questionnaire on the implementation of a brief CBTp intervention. All clinicians had experience of either working with the target client group or were able to deliver psychological therapies. In total, 201 clinicians completed the questionnaire.

### **7.1.3 Results:**

The results of the exploratory factor analysis found partial support for the NPT model, as three of the NPT factors were extracted: (1) coherence, (2) cognitive participation, and (3) reflexive monitoring. We did not find support for the fourth NPT factor (collective action). All scales showed strong internal consistency. Secondary analysis of these factors showed clinicians to generally support the implementation of the brief CBTp intervention.

### **7.1.4 Conclusions:**

This study provides strong evidence for the validity of the three NPT factors extracted. Further research is needed to determine whether participants' level of seniority moderates factor extraction, whether this factor structure can be generalised to other healthcare settings, and whether pre-implementation attitudes predict actual implementation outcomes.

## **7.2 Keywords:**

Normalisation process theory, implementation, questionnaire, CBTp, CBTv, psychosis, hearing voices, auditory hallucinations, self-help, IAPT.

### 7.3 Introduction:

Cognitive behaviour therapy (CBT), delivered over a minimum of 16 sessions, is the only individual psychological therapy recommended for the treatment of psychosis in a number of countries (American Psychiatric Association, 2006; Gaebel, Weinmann, Sartorius, Rutz, & McIntyre, 2005; NICE, 2014b; Royal Australian And New Zealand College Of Psychiatrists Clinical Practice Guidelines Team For The Treatment Of Schizophrenia and Related Disorders, 2005). However, access to CBT for psychosis (CBTp) is poor, with recent figures from the UK suggesting only 10% of people with a psychosis diagnosis are offered CBTp (Schizophrenia Commission, 2012). The poor implementation of CBTp is not just limited to the UK, but is an international problem that is reported in the United States (Burns et al., 2004; Eisenberg, Golberstein, & Gollust, 2007; Kataoka, Zhang, & Wells, 2002; Mueser & Noordsy, 2005), Canada (Myhr & Payne, 2006), and Australia (Morley et al., 2007). The CBTp access rates are not available for many countries, but it is likely that if these more affluent countries are not able to facilitate access, then countries with less economic resource would also experiencing implementation challenges.

One of the most commonly cited reasons for the poor access to CBTp is a lack of resources, including lack of protected time and staff shortages (Ince et al., 2015). One possible approach to increase access to CBTp is by developing interventions that can be delivered using comparatively less resources. A recent meta-analysis found briefer forms of CBTp (i.e. fewer than the recommended 16 therapy sessions) led to a significant reduction in psychosis symptoms compared to control conditions (Hazell, Hayward, Cavanagh, & Strauss, 2016). These brief CBTp interventions typically targeted a specific symptom associated with psychosis (e.g. delusions or voices). Consequently, there is potential for brief forms of symptom-specific CBTp to be offered in the first instance. Drawing on a stepped care approach (Bower & Gilbody, 2005), more resource intensive forms of CBTp could then be delivered only to those still in need. However, based on the broader CBTp literature, we know demonstrating effectiveness does not necessarily lead to widespread implementation. For example, a recent audit of CBTp implementation within a NHS healthcare trust found that only 6.9% of people with psychosis were offered CBT, despite NICE (NICE, 2014b) recommending that everyone with psychosis should be offered CBTp (Haddock et al., 2014). Therefore, in addition to investigating the effects of brief CBTp, we need to consider the potential challenges and facilitators to implementing this novel intervention.

This problem of implementation does not just apply to CBTp. It is common for healthcare services to experience delays in the process of implementing new treatments more broadly (Grol, 2001). The difficulties associated with implementation has led to the

development of numerous theoretical models that aim to understand and simplify this process (May, 2013). A review by Tabak, Khoong, Chambers, and Brownson (2012) identified 12 separate models of implementation; however only two of these (Conceptual Model of Implementation Research, (Proctor et al., 2009); Normalisation Process Theory, (May et al., 2009)) consider implementation at multiple levels, including the individual and system levels.

The Conceptual Model of Implementation Research (Proctor et al., 2009) synthesises previous theories of implementation to create a model that suggests different ways that implementation can be conceptualised (i.e. systems environment, organisational, learning, supervision, individual providers), and measured (i.e. feasibility, fidelity, penetration, acceptability, sustainability, uptake, and costs). The main purpose of this model is to explain the different outcomes that can be used to assess implementation, and the relationship between these outcomes (Proctor et al., 2011). Although this model is useful, it is not appropriate to be used within the present study, as its purpose is not in line with our study aims. This study aims to explore the barriers and facilitators to implementing a brief CBTp intervention prospectively; whereas the Conceptual Model of Implementation Research considers implementation retrospectively, and does not include a framework for exploring what these barriers and facilitators could be.

Conversely, the flexibility of the Normalisation Process Theory (NPT; (May et al., 2009)) means it can be appropriately applied to the present research study. NPT provides a theoretical framework to guide the implementation process. The theory specifies four factors that may enhance the likelihood of successfully implementing a new idea into an existing service: (1) coherence: the attitude of staff towards the new idea, (2) cognitive participation: the willingness of staff to be involved in implementation, (3) collective action: service level pragmatics involved in implementation, and (4) reflexivity: how the implementation process should be evaluated. This model can be used to consider the implementation of a brief CBTp intervention prospectively, and the NPT factors provide a theoretical basis from which barriers and facilitators can be explored.

NPT (May et al., 2009) has been applied to many different healthcare interventions and contexts, including physical health, service infrastructure, and mental health (McEvoy et al., 2014). Looking specifically at the mental health related research, NPT (May et al., 2009) has been used to explore the implementation of stepped care (Franx, Oud, de Lange, Wensing, & Grol, 2012), depression interventions (Gunn et al., 2010) and collaborative care (Gask et al., 2010), primary mental health care (Gask, Rogers, Campbell, & Sheaff, 2008), bipolar treatment guidelines (Morris, 2008), and problem-solving therapies (May et al., 2007). All of the named studies used qualitative research methods to understand implementation within the NPT

framework. There are currently no studies that have explored the validity of the NPT model using a quantitative, questionnaire design in a mental health context.

A NPT questionnaire has recently been developed (NoMAD; (Finch et al., 2015)). The psychometric properties of this measure are currently under assessment (Finch et al., 2013). Similar to the Conceptual Model of Implementation Research (Proctor et al., 2009), the items are phrased to look at implementation retrospectively. Furthermore, while the NoMAD measure is suitably vague to enable its use across multiple settings, this does limit its practical use in certain contexts. For example, one item on the NoMAD asks whether ‘sufficient resources are available to support the intervention’. In the context of our brief CBTp intervention, resources can be taken to mean the number of clinicians, clinician’s time, training, or information (Ince et al., 2015). Consequently, we have developed our own questionnaire measure based on the NPT model (May et al., 2009) that has been specifically developed to investigate the prospective implementation of a brief CBTp intervention.

The brief CBTp intervention we plan to implement into services is guided self-help CBT for psychosis, specifically targeting distressing voices (CBTv) (Hazell, Hayward, Cavanagh, Jones, & Strauss, 2016). Accredited therapists generally have a positive attitude towards, and frequently use, self-help materials in their clinical work (MacLeod, Martinez, & Williams, 2009). In contrast, mental health nurses have reported feeling sceptical about the value, and even the appropriateness, of talking to people about their voice hearing experiences (Coffey & Hewitt, 2008). These differing attitudes towards these aspects of guided self-help CBTv, suggests that mental health practitioners as a workforce may not be a homogeneous population. This has implications for our study as the findings from our NPT questionnaire could be moderated by the sample characteristics.

In light of this research, our study aims to: (1) test the validity of the four factor NPT model within our questionnaire using factor analysis; and based on the established factor structure, (2) identify mental health practitioner views on the implementation of guided self-help CBTv, and what sample characteristics may moderate these views. To meet our second study aim we will explore the following research questions: (a) Do attitudes differ between those who do and do not have accreditation to deliver therapy? (b) Do attitudes differ depending on the participants’ level of experience working with people who hear voices?

## **7.4 Method:**

### **7.4.1 Design:**

This was a cross-sectional study using self-report questionnaires to seek clinicians’ views about guided self-help CBTv.

### 7.4.2 Ethics, consent and permissions:

The study received ethical approval from the Sciences and Technology C-REC at the University of Sussex, UK (Reference: ER/CH283/4). NHS Research Governance approval was granted by the Sussex Partnership NHS Foundation Trust. Participants gave informed consent for their participation in this study.

### 7.4.3 Participants:

The study inclusion criteria required that participants were clinicians working in an NHS mental health service, and also had experience of delivering psychological therapy and/or experience of working with clients who hear voices. Consequently all participants either had relevant experience of working with people in the target population and/or psychological therapy experience. There were no exclusion criterion.

A total of 201 mental health clinicians, working in an NHS mental health trust in the South of England, participated in the survey. See Table 7 for information on the participant characteristics.

Age (years) $M(SD)$		42.68 (10.58)
Gender %	Male	25.9
	Female	73.6
	Prefer Not to Say	0.5
Team %	Primary Care	5.0
	Secondary Care	86.5
	Early Intervention in Psychosis	8.5
Profession %	Psychological Therapist	27.9
	Psychological Wellbeing Practitioner (PWP)	1.5
	Mental Health Professional	56.6
	Support Worker	14.0
Duration in Profession (years) $M(SD)$		13.71 (10.40)

Table 7. Participant Characteristics:  $N=201$ .

### 7.4.4 Materials:

We developed a questionnaire to assess clinicians' attitudes towards guided self-help CBTv in relation to each of the four NPT factors (May et al., 2009). The NPT questionnaire was developed in three phases, in line with the questionnaire development guidelines by Finch et al. (2012): (1) use of empirical knowledge, (2) use of expert opinion, and (3) use of theory.

Phase One (Use of Empirical Knowledge): Items were informed by the findings of a meta-analysis of briefer forms of CBTp (i.e. <16 sessions) (Hazell, Hayward, Cavanagh, & Strauss, 2016). Notably, the meta-analysis supported continued research on brief CBTp, as well as the adoption of the symptom-specific approach. Items were also informed by the implementation literature for CBTp more broadly, and included all of the known barriers to CBTp e.g. lack of time, high workloads, inadequate training (Berry & Haddock, 2008; Prytys, Garety, Jolley, Onwumere, & Craig, 2011).

Phase Two (Use of Expert Opinion): Members of the research team included two experts in CBTp and an expert in self-help CBT approaches. They drew on their expertise to generate items for the self-report questionnaire.

Phase Three (Use of Theory): As mentioned previously, this questionnaire was based upon the NPT model (May et al., 2009). Items were developed to address each of the NPT factors: (1) coherence (12 items) e.g. “I would be happy to refer a client who hears distressing voices to receive guided self-help CBT for distressing voices”; (2) collective action (9 items) e.g. “The resources needed to trial guided self-help CBT for distressing voices are available”, (3) cognitive participation (10 items) e.g. “I would like to be involved in research that is trialling guided self-help CBT for distressing voices”; and (4) reflexive monitoring (9 items) e.g. “Measures of symptom severity e.g. psychosis measures, are a good way to evaluate the effectiveness of guided self-help CBT for distressing voices”.

The resultant items were discussed amongst the research team, editing and removing items as required until consensus amongst the team was reached. The subsequent questionnaire included 40 items (see supplementary material). In line with questionnaire design best practice (Lindell & Whitney, 2001), eight items were negatively worded. The questionnaire also included four free text boxes, to give participants the opportunity to elaborate on their responses. The questionnaire used a 7 point Likert scale, from strongly agree to strongly disagree. A score of 7 reflects a strong negative attitude, 4 reflects a neutral response, and 1 reflects a strong positive attitude.

#### **7.4.5 Procedure:**

Mental health clinicians meeting the inclusion criteria were invited to complete the questionnaire either online (using Bristol Online Survey) or on a hard copy. Participants were informed that consent was to be assumed if they returned their completed questionnaire. All of the items and free text boxes were optional questions so that participants could decline to answer any of the items. The questionnaires were completed anonymously to allow clinicians the freedom to express negative views.



#### **7.4.6 Planned Analysis:**

Participants' responses to the NPT questionnaire were transferred to SPSS version 22. All items that were negatively worded were reverse-scored at this point. Items were initially screened using the criteria suggested by Field (2013) to determine whether they met criteria for factor analysis: the standard deviations, skew and kurtosis of the items were screened to ensure that none were outliers or significantly non-normal. The inter-item correlations and multicollinearity statistics were also checked to ensure that items were related and additive.

To address our first aim, an exploratory factor analysis (EFA) with a principal axis factoring method was used to establish a factor structure. An oblique rotation (specifically Direct Oblimin) was used as factors are expected to be related; the number of iterations for the rotation was set to 50. Exploratory factor analysis was chosen in favour of confirmatory factor analysis (CFA) as this is the first empirical assessment of the NPT model, and EFA does not make any assumptions about the model that will emerge. EFA will therefore provide a more rigorous test than CFA of the NPT model. That is, EFA will allow the model with the best fit to the data to emerge without any theoretical constraints. If the resultant factor structure supports the NPT model this would provide strong evidence for the model (as any model was free to emerge). Factor extraction was initially based upon eigenvalues reaching greater than one, as per the recommendations of Kaiser (1974). This criteria for factor extraction can only be used if Kaiser's (1974) criteria are met (i.e. there are fewer than 30 items and all communalities after extraction are greater than 0.7). The second of Kaiser's (1974) criterion does not apply to this analysis as the sample size is less than 250 ( $n=201$ ). If Kaiser's (1974) criteria was not met, then, as the sample contains more than 200 participants, factor extraction can be conducted using a Scree plot. Factor loadings that were less than .4 were suppressed. Where items loaded onto more than one factor at .4 or greater, the item was assigned to the factor with which it made most conceptual sense. The reliability of the factors was assessed using Cronbach's alpha; the interpretation of scale reliability follows the guidance suggested by Tavakol and Dennick (2011). Subsequently, a scale was interpreted as reliable if the value of Cronbach's alpha was between .70 and .95.

In order to address the second aim, mixed-design ANOVAs were planned to explore group-level differences. The following research questions were explored: (a) Do attitudes differ between those who do and do not have accreditation to deliver therapy? (b) Do attitudes differ depending on the participants' level of experience working with people who hear voices? Post hoc tests with Bonferroni corrections were used where significant main effects were found. The post hoc test used for between group analyses was chosen in line with recommendation from Field (2013) based on whether group sizes and variances were equal or not.

## 7.5 Results:

### 7.5.1 Aim 1: Establishing the Factor Structure:

Items were initially removed if more than 20% of the inter-item correlations were non-significant at the  $p < .05$  level; this resulted in 7 items being removed (J1, K1, N1, P1, A2, H2 and K2). Secondly, items were removed if either the item standard deviation was greater than 2.5, or both skew and kurtosis Z scores were significantly different from normal at the  $p < .001$  level; 7 more items were removed (C1, M1, D2, E2, J2, M2 and O2). None of the inter-item correlations suggested multicollinearity (all  $r_s < .80$ ). The remaining 26 items were included in the subsequent principal axis factor analysis.

Kaiser's (1974) criteria were not met, as communalities were below 0.7 after extraction (lowest 0.26); therefore the factor structure extracted based on the eigenvalues is not reliable. Consequently we used a Scree plot to determine the number of factors to be extracted. The inflexion on the Scree plot suggested a three factor solution. The EFA was re-run forcing three factors to be extracted. Six more items were removed at this stage, as factor loadings were below .4 (B2, C2, G2, I2, L2 and P2); resulting in 20 items being included in the final EFA. The present sample size was deemed 'meritorious' ( $KMO = .88$ ;  $\chi^2(190) = 1940.18$ ,  $p < .001$ ) (Hutcheson & Sofroniou, 1999).

The EFA required five iterations to converge. The three factor structure explained 50.14% of the total variance. Table 8 shows the results of the final factor structure. None of the items cross loaded. The first factor includes 8 items that all relate to attitudes towards the concept of guided self-help CBTv and conceptually fits with the NPT construct of 'coherence'. The 6 items within the second factor all enquire about willingness to be involved in different aspects of the intervention and conceptually fits with the NPT construct of 'cognitive participation'. The final factor has 6 items that ask about the different ways that the intervention could be evaluated to examine if it has been effective. This factor conceptually fits with the NPT construct of 'reflexive monitoring'. It is noteworthy that three of the four proposed NPT factors emerged from the EFA, with one of the NPT factors ('collective action') not being represented.

All of the scales had good internal consistency (lowest Cronbach's  $\alpha = .79$ ; see Table 8). The reliability of all scales could not be improved by removing any of the items. Furthermore all of the items correlated moderately well with the associated scale total (Idea: lowest  $r = .57$ ; Involvement: lowest  $r = .54$ ; Evaluation: lowest  $r = .52$ ).

	<i>M</i>	<i>SD</i>	<i>α</i>	1	2	3
1 <i>Coherence</i>	2.63	0.92	.89			
Guided self-help CBT for distressing voices is an appropriate treatment option					0.86	
I would be happy to refer a client who hears distressing voices to receive guided self-help CBT					0.80	
I would be willing to refer a client who hears distressing voices to receive guided self-help CBT as part of a research project					0.69	
Guided self-help CBT for distressing voices would be effective for those with long standing symptoms					0.68	
Guided self-help CBT for those who hear distressing voices would be unsafe*					0.67	
It is a waste of resources to trial guided self-help CBT for those who hear distressing voices*					0.64	
Guided self-help CBT for those who hear distressing voices will be very effective					0.61	
People who hear distressing voices would not be able to engage in guided self-help CBT*					0.61	
2 <i>Cognitive participation</i>	2.76	1.11	.86			
I would be willing to have training to be able to deliver guided self-help CBT for distressing voices					0.86	
I would be willing to deliver guided self-help CBT for distressing voices as part of my job					0.79	
It would be possible to find the time to attend two day training course on how to deliver guided self-help CBT for distressing voices					0.66	
I would be willing to be involved in the development of guided self-help CBT for those with distressing voices					0.62	
I would be willing to be involved in research that is trialling guided self-help CBT for distressing voices					0.57	
I would not be prepared to receive training to deliver guided self-help CBT for distressing voices*					0.55	
3 <i>Reflexive Monitoring</i>	2.28	0.74	.79			

Research is a good method of testing a new intervention	0.72
Following clients up after a period of several months to administer clinical measures is a good way to evaluate the effectiveness of guided self-help CBT for distressing voices	0.68
Measures of the distress experience from hearing voices is a good way to evaluate the effectiveness of guided self-help CBT for distressing voices	0.68
Measures of symptom severity e.g. psychosis measures, are a good way to evaluate the effectiveness of guided self-help CBT for distressing voices	0.60
Randomised controlled trials e.g. comparing the treatment to a control group, is a good way to evaluate the effectiveness of guided self-help CBT for distressing voices	0.52
Measures of other clinical symptoms e.g. anxiety and depression, are a good way to evaluate the effectiveness of guided self-help CBT for distressing voices	0.49

Table 8. Final factor structure of staff questionnaire on guided self-help CBT invention for Voices.

*Note:*  $\alpha$  = Cronbach's alpha; \*Items have been reverse scored; Scale scores: from 1 (positive attitude) to 7 (negative attitude).

### 7.5.2 Aim 2: Clinicians' attitudes towards guided self-help CBT for voices

The attitude scores, for all of the factors, were significantly lower than 4 (representing a neutral attitude) (Coherence:  $t(200)=-21.03, p<.001$ ; Cognitive Participation:  $t(199)=-15.76, p<.001$ ; Reflexive Monitoring:  $t(200)=-33.04, p<.001$ ). This finding suggests that attitudes were generally positive in relation to each of the factors; see Tables 8 and 9 for the descriptive statistics.

Mauchly's test indicated that the assumption of sphericity had been violated ( $W=.95$ ;  $\chi^2(2)=10.35, p=.006$ ); therefore a Greenhouse-Geisser correction was used for all ANOVAs involving repeated measures (as  $\epsilon>.75$ ).

	<i>n</i>	Coherence		Cognitive Participation		Reflexive Monitoring	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Accredited Therapist							
Yes	59	2.94	0.90	3.00	1.20	2.30	0.80
No	140	2.52	0.90	2.66	1.07	2.28	0.71
Experience working with people who hear voices							
A lot to moderate	166	2.61	0.90	2.76	1.12	2.27	0.71
Little to none	34	2.80	1.00	2.76	1.13	2.36	0.87

Table 9. Descriptive statistics for all factors across participant characteristics.

#### 7.5.2.1 Are attitudes different across the factors between those who do and do not have accreditation to deliver therapy?

There was a significant main effect of therapist qualification on the ratings given across factors ( $F(1, 197)=5.01, p=.03$ ). Those qualified to deliver psychological therapy ( $EMM=2.75$ ;  $SE=0.10$ ) gave generally higher (less favourable) ratings than non-therapists ( $EMM=2.49$ ;  $SE=0.06$ ). There was a significant interaction between the factors and whether participants were qualified to deliver therapy or not ( $F(1.89, 371.27)=3.79, p=.03$ ). The only factor where therapists and non-therapists differed significantly was on the Coherence factor, where therapists gave significantly less favourable ratings compared to non-therapists (Therapists:  $M=2.94$ , 95% CI [2.71, 3.17]; Non-therapists:  $M=2.52$ , 95% CI [2.37, 2.67]).

#### 7.5.2.2 *Do attitudes differ across the factors depending on the level of experience the participant has working with people who hear voices?*

There was no significant main effect of experience working with people who hear voices on subscale scores ( $F(1, 198)=0.47, p=.49$ ). Also the interaction between the factors and level of experience with clients who hear voices was non-significant ( $F(1.90, 377.01)=.52, p=.58$ ). These findings suggest that ratings on subscales were not affected by participant's level of experience of working with people who hear voices.

### 7.6 Discussion:

The first aim of our study was to test the proposed factor structure of Normalisation Process Theory (NPT) (May et al., 2009) using exploratory factor analysis. We found partial support for the NPT model as the three factors extracted were akin to three of the NPT factors: (1) coherence, (2) cognitive participation, and (3) reflexive monitoring. This study seems to be the first test of the NPT model using factor analysis, although the findings of the NoMAD factor analysis are imminent (Finch et al., 2013). Our findings suggest that coherence, cognitive participation, and reflexive monitoring are important facets of implementation that should be considered prior to the dissemination of brief CBTp interventions. This result is particularly compelling as the use of EFA meant that any factor structure could have emerged. It is possible that these three factors would also emerge as important when understanding the implementation of healthcare interventions more generally. However, as our study asked participants about a specific intervention (guided self-help CBTv) further research using factor analysis is required to determine the generalizability of the NPT model.

We failed to find support for the fourth NPT factor, collective action, which speaks to the feasibility of implementing the new intervention into the existing service. This study recruited clinicians currently working in mental health services, rather than staff in more senior positions – such as service managers. Clinicians generally do not have the power or responsibility to make service-level decisions. As the collective action factor describes a facet of implementation that occurs at the service-level, this factor could be argued as inconsequential to our sample, and therefore explain why this factor did not emerge in our analysis. If participants in these more senior positions had been recruited to the study, it is possible that we may have found support for the collective action factor.

Akin to our study, most NPT studies in mental health settings recruited practitioners (Gask et al., 2010; Gunn et al., 2010; May et al., 2007). However the NPT studies by Gask et al. (2008) and Franx et al. (2012) did include service leads and managers to investigate the implementation of mental health care, and stepped care, into primary care services respectively.

Both of these studies found qualitative support for the Collective Action factor, as having coherent and consistent leadership across the services was associated with successful implementation. However, neither study explored the moderating effect of profession, nor did they validate the NPT model quantitatively. Consequently we suggest that future tests of the NPT model should include participants of varying levels of seniority. These studies would benefit from the use of quantitative, moderation analysis to explore the effects of seniority, and address this limitation of our study and previous research.

The second aim of our study was to examine clinicians' attitudes towards guided self-help CBTv, and whether these differed as a function of therapy training (therapist versus non-therapist) and experience working with clients who hear voices. We found that clinicians' attitudes were favourable across all three factors (all  $M_s < 3$ ; see Table 8). Only therapist training significantly moderated the clinicians' attitude, with qualified therapists reporting significantly less favourable attitudes on the coherence subscale compared to non-therapists. This finding suggests that therapists still support the concept of guided self-help CBTv, but are more sceptical than those mental health clinicians without therapist accreditation. The majority of the literature suggests therapists view psychosocial interventions for psychosis with a greater optimism compared to other mental health professionals (Caldwell & Jorm, 2001). However there is some evidence that concurs with our findings, as therapists seem to be more pessimistic than mental health nurses about their ability to 'treat' psychosis (Hugo, 2001). Therapists also report that delivering brief CBTp interventions can be problematic owing to the limited number of sessions involved, and the complex nature of many patients' presenting problems (Waller, Garety, Jolley, Fornells-Ambrojo, Kuipers, Onwumere, Woodall, & Craig, 2013). Whether the therapists' reservations are realised in practice requires further research.

Overall, it seems clinicians show support for implementing guided self-help CBTv, which is encouraging. This finding contrasts with previous research that suggests mental health clinicians may not be supportive of interventions that invite people to talk about the voices they experience (Coffey & Hewitt, 2008). Perhaps the recent growth of emancipatory approaches to voices, such as the Hearing Voices Movement, has helped to demonstrate the therapeutic value of openly discussing voices (Oakland & Berry, 2015). Whether clinicians' positive pre-implementation attitudes will aid the actual implementation process remains to be seen. There is evidence to suggest that negative clinician attitudes are associated with poorer intervention outcomes (Harper Romeo, Meyer, Johnson, & Penn, 2014). The favourable attitudes of clinicians in the present study are therefore welcome as this will help to create the optimal service environment, from which we can explore the effectiveness of this intervention.

### **7.6.1 Limitations:**

It is possible that the reason we did not find support for the fourth NPT factor is because the items developed to target this factor were poor representations of the collective action factor. That is to say, our items may not have sufficiently examined implementation at the service-level. Before accepting this as a study limitation, it is important to first explore whether the sample characteristics may have contributed to the factor structure extracted. As mentioned previously, future studies should aim to include participants in more senior-level positions to see whether this causes the emergence of the collective action factor.

Our questionnaire was designed to investigate implementation prospectively. Our findings are therefore indicative of mental health practitioners anticipated barrier and facilitators to implementation – our study cannot determine whether this will translate into practice. This limitation highlights the benefits of longitudinal implementation research. Using this research design will help to determine whether positive pre-implementation attitudes translate into a successful initial implementation, and the sustained employment of the intervention. To our knowledge, there are currently no quantitative studies that have looked at the NPT's model ability to predict implementation outcomes; however this is one of the study aims of the NoMAD psychometric assessment (Finch et al., 2013) which is currently underway.

### **7.6.2 Research Implications:**

Our study has identified a number of areas for future research. For example, future studies assessing the validity of the NPT model (May et al., 2009) should aim to recruit participants of varying levels of seniority, and determine whether pre-implementation attitudes correspond to the subsequent ease of implementation. As our study seems to be the first to use factor analysis to test the NPT model, more factor analysis studies are needed to see whether the NPT factor structure can be generalised to the implementation of other interventions in both mental health and physical health contexts.

### **7.6.3 Conclusions:**

The present study used exploratory factor analysis to test the application of the NPT model (May et al., 2009) in a mental health setting. We found support for three of the NPT factors when considering the implementation of a brief CBTp intervention. The fourth factor, collective action, was not extracted. Clinicians generally supported the implementation of the intervention. The feedback from clinicians can be used to inform both research and intervention protocols. In time, we will be able to assess whether clinicians' pre-implementation attitudes impact upon the subsequent implementation process.



## 8 Ideas are easy, implementation is hard: Barriers to disseminating brief CBT for voices from a lived experience and clinician perspective.

Chapter 8 is under review with PloS One as:

**Hazell, C. M.,** Strauss, C., Hayward, M., & Cavanagh, K. (2017). Ideas are easy, implementation is hard: Barriers to disseminating brief CBT for voices from a lived experience and clinician perspective. *Plos One*.

### **Contributions:**

Conceptualisation:	All authors
Methodology:	All authors
Data Collection:	CMH
Data Analysis:	CMH
Initial Draft:	CMH and MH
Reviewing and Editing:	All authors*

\*Plus comments from peer-reviewers during the publication process.

## **8.1 Abstract:**

Access to psychological therapies continues to be poor for people experiencing psychosis. To address this problem, researchers are developing brief interventions that address the specific symptoms associated with psychosis i.e. hearing voices. As part of the development work for a brief CBT intervention for voices (specifically, guided self-help CBTv) we collected qualitative data from people who hear voices (study 1) and clinicians (study 2) on the potential barriers and facilitators to implementation and engagement. Thematic analysis of the responses from both groups revealed a number of anticipated barriers to implementation and engagement. Both groups believed the presenting problem (voices and psychosis symptoms) may impede engagement. Furthermore clinicians identified a lack of resources to be a barrier to implementation. The only facilitator to engagement was reported by people who hear voices who believed a compassionate, experienced and trustworthy therapist would promote engagement. The results are discussed in relation to how these barriers could be addressed in the context of a brief intervention using CBT techniques.

## **8.2 Keywords:**

Hearing voices, psychosis, auditory hallucinations, self-help, qualitative, CBT, barriers, engagement, implementation.

### **8.3 Introduction:**

Psychosis is a term used to describe a range of unusual experiences that cause distress or impede functioning i.e. delusions, hallucinations, or disorganised thoughts and behaviours (American Psychiatric Association, 2013). Cognitive behaviour therapy is the only recommended individual psychotherapy for psychosis (CBTp) (American Psychiatric Association, 2006; Gaebel et al., 2005; NICE, 2014b; Royal Australian And New Zealand College Of Psychiatrists Clinical Practice Guidelines Team For The Treatment Of Schizophrenia and Related Disorders, 2005). However, very few patients are able to access this therapy (Schizophrenia Commission, 2012), with limited resources often identified as a significant barrier to implementation (Berry & Haddock, 2008; Dark et al., 2015; Prytys, Garety, Jolley, Onwumere, & Craig, 2011). One approach to improve access could be to offer CBTp using less resources (i.e. fewer sessions). Recent meta-analyses have suggested that brief CBTp produces moderate treatment effects when compared to treatment as usual (Hazell, Hayward, Cavanagh, & Strauss, 2016; Naeem et al., 2016).

Consistent with the emerging literature suggesting that symptom-specific therapies (i.e. focusing solely on voices or delusions) may be more effective than broadly-focused CBTp (Mehl et al., 2015; Thomas et al., 2014), we are developing a brief form of CBTp targeting distressing voices (auditory verbal hallucinations) using a guided self-help format. Guided self-help CBT for voices (CBTv) will be based on the CBT self-help book 'Overcoming Distressing Voices' (Hayward, Strauss, & Kingdon, 2012). As part of the therapy development process we wanted to learn about the potential facilitators and barriers to therapy implementation from the stakeholders who deliver (mental health clinicians) and receive (people who hear voices) therapy within the NHS.

This paper presents the findings from two consultations: study one explored the perspective of people with lived experience of hearing voices, and study two explored the perspective of mental health clinicians. Both studies aimed to address the following research questions: (1) What are the potential barriers/facilitators to engagement in guided self-help CBTv? (2) What are the potential barriers/facilitators to the implementation of guided self-help CBTv? Identifying potential facilitators and barriers to implementation will enable us to formulate an implementation plan that maximises the possibility of successfully implementing the results of this programme of research

## 8.4 Study 1: The lived experience perspective.

### 8.5 Methods:

#### 8.5.1 Design:

This study used a focus group methodology and recruited people who hear voices to one of three focus groups, each including between 6-10 participants (Krueger & Casey, 2000). All of the focus groups were facilitated using the same discussion guide (available from corresponding author on request) and were audio recorded, then transcribed and analysed using thematic analysis (Braun & Clarke, 2006).

#### 8.5.2 Participants:

Inclusion criteria required that participants were aged 18 or over, and had at least one year's experience of hearing voices, irrespective of psychiatric diagnosis. Diagnosis was not used as an exclusion criteria in response to a number of studies that have reported little to no difference in the experience of hearing voices as a function of diagnosis (Dorahy et al., 2009; Hamner et al., 2000; Hepworth et al., 2013). Exclusion criteria specified that participants must be able to read and write in English.

A total of 21 participants consented to take part in the focus group (see Table 10 for demographic information). They were divided into three focus groups based on their locality.

Age M(SD)		42 (11.12)
Gender %	Male	47.6
	Female	42.9
	Other	9.5
Diagnosis %	Schizophrenia	52.4
	Depression	14.3
	Schizoaffective Disorder	9.5
	Borderline Personality Disorder	9.5
	Dissociative Identity Disorder	4.8
	Did not know	9.5
Number of years hearing voices M(SD)		17.43 (14.52)
Age voices started M(SD)		24.57(14.54)

Table 10. Demographic information of participants in study 1.

*Note:* Participants' psychiatric diagnosis was self-reported.

### **8.5.3 Discussion Guide:**

The discussion guide structure was based on the recommendations of Greenbaum (2000) and its content was based on the 4 Ps model (Cavanagh & Millings, 2013). The 4 Ps model identifies four factors that can facilitate or hinder intervention engagement: specifically, (1) programme – the intervention e.g. structure, length, style; (2) problem – the presenting mental health difficulty e.g. complexity, severity, comorbidity; (3) person – individual differences e.g., demographics, patient expectations; and (4) provider – the intervention delivery e.g. amount and quality of therapist contact. Participants were also invited to share any other thoughts about the intervention at both the start and end of the discussion. Each focus group was scheduled for 90 minutes.

### **8.5.4 Procedure:**

Participants were recruited through four sources: (1) via clinician referrals from local NHS mental health services; (2) a research database of staff, patients and carers who have consented to be contacted about research studies; (3) the third sector, including mental health charities and hearing voices support groups; (4) self-referral in response to advertising materials. Potential participants were given the study information, and at least 24 hours to decide if they would like to take part. Those who decided to take part, met with the first author to discuss the study, provide consent, and receive a copy of the self-help book the intervention would be based on: *Overcoming Distressing Voices* (Hayward et al., 2012). Participants were asked to read any chapter of the book prior to the focus group. There was a minimum time lapse of two weeks between receiving the book and attending the focus group for all participants.

Each of the focus groups was facilitated by the first author, with support from a research assistant. All of the participants were paid £15 for their consultation services.

### **8.5.5 Ethics:**

Ethical approval was granted by the Research Ethics Committee South East Coast – Surrey (REC reference: 14/LO/1880). Local governance approval was given by the Kent, Surrey and Sussex Clinical Research Network. This research was sponsored by the University of Sussex. Participants were required to give informed consent in writing prior to participating in this study.

### **8.5.6 Analysis:**

All of the recordings were transcribed by the first author into QSR International's NVivo 10 software. At the point of transcription, all identifiable information was removed, and

replaced with pseudonyms where necessary. The transcripts were analysed by the first author using thematic analysis, in line with the Braun and Clarke (Braun & Clarke, 2006) protocol. This six-stage approach to analysis involved immersion within the data, coding of the smallest units of meaning within each transcript, and the clustering of codes into themes and sub-themes within and across transcripts. The subsequent refinement and naming of the themes involved the constant interplay between data, codes and themes, ensuring the final results were grounded in participants' views. All of the participants consented to their direct quotes being used within this report.

The codes and themes were shared with the rest of the research team to assess the credibility of the analysis. The transcript was also shared with an independent group of doctoral researchers studying qualitative methods. They double coded an excerpt of the transcript (approximately a third), and verified the credibility of the themes derived. There were no points of disagreement concerning the content and meaning of the themes derived, although some of the theme labels did differ. Where differences occurred these were discussed until a consensus was reached.

## **8.6 Results:**

Seven main themes emerged from the analysis, containing 20 sub-themes (Table 11). Two themes ('the therapist' and 'the presenting problem') will be described in full as they pertain specifically to the research question; these are supported by illustrative quotes. The remaining themes detail the participant's opinions of the intervention protocol, and materials (e.g. self-help book). For the full qualitative analysis (with illustrative quotes) please see the supplementary material.

### **8.6.1 *The Therapist:***

There was consensus across all of the focus groups as to the ideal therapist to deliver this intervention. The subthemes outline the characteristics that were important to participants if they were to engage in guided self-help CBTv.

#### **8.6.1.1 *Personal Qualities:***

The first criteria for a therapist discussed across all the focus groups was related to their personal qualities and traits:

Jillian: 'It's about being able to trust the person [therapist] that you're with and um to get a good rapport going and to allow somebody to allow you to help you change you know.'

Jillian acknowledged the importance of building a relationship with the therapist and the importance of their role in the process of change that may occur during therapy.

Jimmy: 'Having the compassion to want to help, not just because they're interesting to work with but because you know they do have that passion to want to help people.'

Bobby: 'Someone who is kind and compassionate. Someone who can use empathy, you know, because it's when you talk to all these doctors and psychiatrists you feel like they can't relate to you, because they are sat in the chair and they're professionals and they're reading from their textbooks, you know... But just someone who is kind and compassionate, someone whose can understand you.'

These comments demonstrate the importance of the non-specific elements of psychological therapy, and importance of developing a genuine and humanistic therapeutic relationship. The word 'compassion' was used by both Jimmy and Bobby. These responses give some insight into the importance of rapport when working with people who hear voices.

#### *8.6.1.2 Therapist Skills:*

Another important criteria that was identified by two out of the three focus groups was the need for the therapist to be skilled:

Nikki: 'Fairly qualified stuff as well isn't it. It's not just a therapist is it, it's fairly qualified stuff.'

Tim: 'I have found that the people with specific interests and training in working with voices um are able to extract information from me in really helpful ways, and steer conversations to bring it back to the voices and not going off on a tangent and getting lost somewhere else.'

The comments suggest that Nikki and Tim believe they could not be helped by just any therapist or mental health clinician. Firstly it is important the therapist is sufficiently qualified to deliver therapy more generally (i.e. CBT trained), and secondly they should have specialist knowledge about voices and how to deliver therapy for this client group.

Jimmy: 'I think what I was going to say is someone who knows their stuff but doesn't have the arrogance they think they know it all. So kind of what Tim was saying about um, so having that specialism, and yeah have that experience of working with people who hear voices.'

These responses imply that the participants feel voice hearing is a complex mental health difficulty that requires a therapist to be skilled and have experience of working with people who hear voices. This theme has the potential to be at odds with the first theme (Personal Qualities), as illustrated by Jimmy: it is important for the therapist to be a skilled therapist and have specialist knowledge of voices, but it is of equal importance that this knowledge does not become 'arrogance'.

Main Themes	Sub-Themes	Example Quote
<i>Study 1 (lived experience)</i>		
1 The Self-Help Book	Positive feedback	‘Yeah referring back to this [the book], um I think that I can relate to all of what’s in here um which is quite amazing reading it.’
	Negative feedback	‘It takes a very basic level of um sort of voice hearing and it can be a lot more complex than that.’
	Self-reflection	‘I think the way it worked for me I started having some sort of intuitions, the voices saying this and that and it expanded, and it confirmed my suspicions.’
2 Therapy Protocol	Self	‘Self-esteem is important because if your self-esteem is really low then you’re less likely to be able to challenge your voices because um I think you give them more power. ‘
	Voices	‘I think the voices themselves are not as bad as the thing they can do with you in terms of how you respond. I mean it could be self-neglect or some other things.’
	Relationships	‘It’s all down to the way you reply to them [voices], even verbally, so if you improve your relationship with your voices you will then improve your relationship with the outside world.’
	Coping Strategies	‘I have learned coping mechanisms. I will say ‘oh yes I can’ which has given me a bit of strength.’
3 The Therapist	Personal qualities	‘Having the compassion to want to help, not just because they’re interesting to work, with but because you know they do have that passion to want to help people.’
	Therapist skills	‘I think what I was going to say is someone who knows their stuff but doesn't have the arrogance they think they know it all.’



	Confidentiality in therapy	‘I think therapy is therapy and it stays completely confidential in therapy, and that’s a relationship with my therapist.’
4	Pragmatics of the Therapy	Therapy Structure ‘I would prefer to do it [therapy] one to one because then you can talk more. People won’t pressure you to talk about things that you don’t want to talk about.’
	Timing	‘You need to have a certain level of wellness in order to engage with the book.’
5	The presenting problem	Voices as saboteurs ‘If I’m focussing on something that is specifically about hearing voices and how to help that situation, my voices will not like that.’
	Cognitive processes	‘I find it really hard to read um at the best of times let alone when my concentration is down because I’m more unwell um.’
6	Networks	Clinical relationships ‘I have contacted A&E, I have contacted my mental health worker, and they have done absolutely jack sh*t about it.’
	Nonclinical relationships	‘Like my family are in denial still, so I will tell them something that’s been going on and they think it’s nothing, its fine.’
	Stigma	‘I was thinking because I was on a packed bus with it [the book] and I thought if anyone asks me I will tell them I am a psychologist.’
	Group dynamics	‘I think it’s quite amazing. I think you’re quite special to have experienced voices for such a long period of time and still be here.’
7	Therapy Flaws	Theory ‘It says that ‘hearing voices in itself is not a problem’ but I can’t agree with that because hearing voices itself is a problem.’

	Missing elements	‘This just concentrates on voices, but usually there is a lot more symptoms that come along when... I know that when I have been ill there is a lot more going on.’
<i>Study 2 (clinician)</i>		
1 Positive attitude toward therapy	GSH in the context of IAPT	‘It could help increase access to therapy which is at the moment very poor.’
	Staff willingness to be involved	‘My desire to be involved in this project is very high, the aim of the project is sound and patient focused.’
2 Negative attitude toward therapy	Not a stand-alone treatment	‘It could be a co-treatment.’
	GSH not an equal treatment option	‘I would be concerned that guided self-help is used in place of face to face therapy.’
3 Support for therapy with a caveat	Importance of clinician training	‘The provision of Self-directed CBT in voices needs the support and backup of trained staff to ensure patient safety.’
	Need for evidence	‘I would be a bit wary about offering CBT self-help for distressing voices as part of routine clinical practice, as the evidence isn't really there.’
4 The presenting problem	Symptoms	‘May be issues around engagement as many of the people on our unit who hear voices often don't have insight into their illness or are acutely unwell.’
	Cognitive Abilities	‘Due to some client's lack of motivation, I feel that giving them a self-help guide is not necessarily the way forward.’

5	Practical Barriers	Lack of resources	‘All staff are asked to do unrealistic amounts of work, and this [guided self-help CBTv] may simply need too much time.’
		Conflict with service priorities	‘I think there will be resistance from practitioners who rely solely on the medical model.’

Table 11. Results of thematic analysis for studies 1 and 2.

*Note:* GSH = Guided self-help; IAPT = increasing access to psychological therapy.

### *8.6.1.3 Confidentiality in Therapy:*

This sub-theme was not specific to guided self-help CBTv, but a reflection of the concerns that many participants had about what constituted confidentiality in psychological therapies more generally:

Nikki: 'I think therapy is therapy and it stays completely confidential in therapy, and that's a relationship with my therapist. The relationship with my psychiatrist who gives me medication is different and I think I would probably trust my psychiatrist. I would probably tell him some things but not necessarily tell him everything I do in therapy. So therapy is therapy and that's a different thing.'

The client-therapist relationship was described as being distinct and separate from the relationships that participants would have with other mental health practitioners (e.g. psychiatrist), even though, for these participants, they would be working for the same health service. Consequently they believe the rules around confidentiality and the sharing of information should be distinct.

Abe: 'For me your caveats around confidentiality will always be the most important because I've just had a problem with [name of an organisation]. I used to go in there, you know and um I told the girl I had stopped taking a particular medication and she said well I will need to inform your doctor of that, and I said I'm not sure you do because you said to me at the start of these sessions that everything I say to you is confidential and she said but I had to balance that against my duty of care... I was telling her I was stopping taking one of the trivial medications, and I said to her if you do contact my doctor I will disengage with your organisation and she did, so I did.'

Jeff: 'It depends what happens really. It depends what the outcome of the um course was like. Um I might decide that there is some stuff I didn't want [my care coordinator] to know but I don't know what's going to come out. I don't know how successful it's going to be.'

It is clear that breaking confidentiality is likely to threaten engagement with the therapy. Confidentiality was often discussed in relation to past negative experiences where the 'rules' had been unclear around confidentiality. This is a problematic issue for the therapist who is bound by the duty of care and confidentiality policies of their employer (e.g. NHS). Complete confidentiality, as requested by many of the participants, is largely not possible within public healthcare settings. Where these rules cannot be negotiated, the participants wanted total, upfront transparency around the rules. This theme has some synergy with the first theme (Personal Qualities) as being clear about confidentiality will help to foster a trusting therapeutic

relationship.

### **8.6.2 *The Presenting Problem:***

Participants were asked if they thought there was anything that might hinder their engagement in guided self-help CBTv. Two barriers related to the presenting problem were identified across all three of the focus groups:

#### **8.6.2.1 *Voices as saboteurs:***

Although the aim of guided self-help CBTv would be to reduce the distress associated with the experience of hearing voices, many participants felt that the voices themselves could get in the way:

Tim: ‘If I’m focussing on something that is specifically about hearing voices and how to help that situation, my voices will not like that. And they will try and distract me from that or find a way around it um so that it doesn't make sense, um they don't like being talked about.’

Mia: ‘What I also find distressing is if I’m talking to someone, I’m seeing my support worker, and I’m talking about my voices; the voices don't like me talking to people about them so they will say things like tell [them] to ‘eff off’ and I hate that... that's not me you know.’

Both Tim and Mia expressed concerns that their voices would react negatively to being talked about or questioned within therapy. Even though the therapy aims to reduce the distress associated with hearing voices, participants were worried that voices could actually get worse, or at the very least sabotage attempts to engage in the therapy. Ways to address this potential backlash from the voices needs to be considered so as to facilitate engagement.

#### **8.6.2.2 *Cognitive Processes:***

In addition to voices, many of the participants reported experiencing cognitive difficulties, and believed this could make it difficult to engage in guided self-help CBTv.

Nikki: ‘I have read it [the self-help book] once and I am reading it again because there’s bits in it that I have forgotten, because I have short term memory loss. So yeah I am reading it again and I’m finding bits in it I obviously missed the first time around.’

This barrier to engagement identified by Nikki is arguably of greater importance when considering this guided self-help CBTv intervention that makes use of a self-help book. Guided self-help CBTv requires more independent work compared to traditional CBTp. Nikki did not report having any difficulty in reading the book (i.e. comprehending the words); the problem for her was retaining the information. Within an intervention that requires reading as a homework task there needs to be some consideration of how this task can be modified or adapted for those

who, like Nikki, experience memory difficulties.

Tim: ‘Another thing I thing I find, especially if I’m unwell is concentration. I find it really hard to read um at the best of times let alone when my concentration is down because I’m more unwell um. I re-read the same thing so that could be a barrier to accessing the therapy.’

Sue: ‘I agree with that. That’s why I couldn’t finish this book because I read it over and over, and haven’t got the concentration to read it all very quickly.’

All of the participants speak of reading the same passage multiple times to try and take in the necessary information. Where the required reading for the guided self-help CBTv intervention is substantial, this would be time consuming and potentially frustrating for the client – which is likely to impede engagement. It is important to note that these participants describe their cognitive difficulties as fluctuating states. Consequently, consideration should be given to the changeable nature of cognitive abilities, and the techniques that can be used to compensate for any periods of cognitive difficulty.

## **8.7 Study 1 Discussion:**

The findings from study 1 demonstrate that people who hear voices were worried that guided self-help CBTv could make their voices worse. Additionally cognitive difficulties were thought to be a potential barrier to engagement. One potential facilitator identified was a therapist whom took the time to create a positive therapeutic relationship based on respect and trust. Study 2 will identify whether mental health clinicians anticipate any of the same barrier or facilitators that were identified within study 1.

## **8.8 Study 2: The clinician perspective.**

### **8.9 Method:**

#### **8.9.1 Design:**

This study used a questionnaire design. We collected both quantitative and qualitative data, however only the qualitative data are presented here. All participants completed the same questionnaire, and the qualitative data was collected using free-text response boxes.

#### **8.9.2 Participants:**

Inclusion criteria required that participants were mental health clinicians working in an NHS trust in the South of England, whom had experience of either delivering psychological therapy and/or working with people who hear voices. This meant that all responses were grounded in some level of expertise. A total of 201 participants completed the questionnaire,

and 124 (62% of the sample) provided qualitative data using the free-text response boxes (Table 12).

Age (years) <i>M(SD)</i>		43.07 (10.99)
Gender %	Male	25.8
	Female	73.4
	Prefer Not to Say	0.8
Team %	Primary Care	4.8
	Secondary Care	88.7
	Early Intervention in Psychosis	6.5
Profession %	Psychological Therapist	33.1
	Psychological Wellbeing Practitioner (PWP)	1.6
	Mental Health Professional	56.4
	Support Worker	8.9
Duration in Profession (years) <i>M(SD)</i>		13.70 (10.56)
Experience working with people who hear voices %	A lot to moderate	84.7
	Little to none	15.3

Table 12. Participant Characteristics in study 2.

*Note:* PWP = psychological wellbeing practitioner.

### 8.9.3 Questionnaire:

The questionnaire was based on the Normalisation Process Theory (NPT) (May et al., 2009). NPT is comprised of four factors that are intended to explain the components needed to successfully implement a new idea into clinical practice. Participants were asked a free-text response question related to each factor: (1) coherence – attitudes towards the concept (What do you think about the idea of offering CBT for distressing voices using guided self-help?), (2) cognitive participation – willingness to be involved (How willing would you be to be involved in the development of guided self-help CBT for distressing voices?), (3) collective action – feasibility of implementation within the current system (How feasible do you think it would be to implement guided self-help CBT for distressing voices in the Trust?), and (4) reflexivity – evaluation of the idea (How should guided self-help CBT for distressing voices be evaluated?). All of the free-text boxes were optional, and participants could write as much or as little as they wanted to.

#### **8.9.4 Procedure:**

Participants were recruited via internal emails, publicity, and in-person at NHS Trust events. Participants could complete the questionnaire either online (using Bristol Online Survey) or on paper. All responses were collected anonymously. Participants were informed that consent would be assumed when they returned the completed questionnaire. Participants could complete the questionnaire at a time and place that was convenient to them.

#### **8.9.5 Ethics:**

Ethical approval was granted the Sciences and Technology C-REC at the University of Sussex (Reference: ER/CH283/4). Local governance approval was given by the Sussex Partnership NHS Foundation Trust Research and Development Department Kent. Participants were informed that consent was assumed if they returned their completed questionnaire to the research team.

#### **8.9.6 Analysis:**

All identifiable information was removed prior to analysis, and replaced with pseudonyms where necessary. The data was analysed using the same process and method described for study 1. The credibility of the findings were assessed using the process advocated by Chadwick and colleagues (Chadwick, Kaur, Swelam, Ross, & Ellett, 2011). Firstly codes and themes were shared and discussed within the wider research team. Secondly a random sample of 20% of the excerpts were double-coded by an independent researcher. The level of inter-rater agreement was 85.19%. The transcript was also shared with an independent group of doctoral researchers studying qualitative methods. They double coded an excerpt of the transcript (approximately half), and verified the credibility of the themes derived.

#### **8.10 Results:**

Five main themes emerged from the analysis, containing 10 sub-themes (Table 11). Two themes ('the presenting problem' and 'practical barriers') will be described in full as they pertain specifically to the research question; these are supported by illustrative quotes. The remaining themes detail the participant's opinions of guided self-help CBTv and justification for these opinions. For the full qualitative analysis (with illustrative quotes) please see the supplementary material.



### ***8.10.1 The Presenting Problem:***

Many of the clinicians expressed some concerns about the suitability of guided self-help CBTv for this client group. Participants identified barriers that related to the presenting problem:

#### ***8.10.1.1 Symptoms:***

The first patient barrier identified was the view that the mental health symptoms experienced by people who hear voices could hinder engagement in the therapy:

‘I would consider this [guided self-help CBTv] to be helpful although unsure whether this would be aimed at clients with less distress as a result of their psychotic symptoms.’

This first response suggests that the clinician believes that assessing suitability for guided self-help CBTv should be done so based on symptom severity – with those experiencing more severe symptoms being unsuitable for therapy. The implication of this is that the clinician seems to believe that not everyone whom hears voices should be offered this therapy. This may lead to clinicians’, rightly or wrongly, acting as gatekeepers for their clients.

‘May be issues around engagement as many of the people on our unit who hear voices often don't have insight into their illness or are acutely unwell.’

‘It is potentially asking a great deal of the patient to go through this course given that there is a greater proportion of people who experience distressing voices who also lead chaotic lifestyles.’

For these clinicians, it appears that hearing voices in itself is not necessarily a barrier to engagement. Instead it is what the clinicians associate with the experience of hearing voices that may be the barrier i.e. lack of ‘insight’ and ‘chaotic lifestyles’. These clinicians however do not explain the basis for these associations or how these factors may act as barrier. For example, assuming the client does have a chaotic lifestyle, how will this prohibit engagement in guided self-help CBTv?

#### ***8.10.1.2 Cognitive Abilities:***

Clinicians also discussed the role of cognitive processes and motivation, and consequently whether this client group would be able to engage with an intervention that requires an element of self-help, due to the cognitive skills it requires:

‘Due to some client’s lack of motivation, I feel that giving them a self-help guide is not necessarily the way forward.’

‘My experience of this group are that they will require a considerable degree of support to undertake this work, due to high levels of anxiety, and often low levels of self-organisation skills.’

‘The effect of long term medication, impaired cognitive ability learning disability, not only for focus and concentration, but also for processing information and transferring skills into daily life’

It is implicit here that clinicians associate the experience of hearing voices with poor motivation and cognitive impairments, and consequently identify this as a barrier to therapy engagement. Some clinicians did not attribute these cognitive difficulties to voices themselves, but a by-product of ‘medication’ or lifestyle factors. Much like the ‘Cognitive Processes’ sub-theme from study 1, the influence of cognitive abilities on engagement is potentially a more prominent point to consider because of the increased level of independent work required within a guided self-help intervention compared to ‘traditional’ CBT.

#### ***8.10.2 Practical Barriers:***

As well as the patient-related barriers, clinicians identified a number of practical barriers that they foresaw would impede the implementation of guided self-help CBTv. The practical barriers identified are discussed below:

##### ***8.10.2.1 Lack of Resources:***

The most common barrier discussed by clinicians was a feeling that they do not currently have enough resources to be able to implement guided self-help CBTv. It was apparent that most felt they would either need protected time or more staff to be able to support implementation:

‘Despite years of highlighting the resourcing issues on in-patient wards we still do not have enough resources to give time to offer adequate 1:1 time with patients let alone CBT based interventions.’

‘Only feasible if enough staff are involved.’

‘All staff are asked to do unrealistic amounts of work, and this [guided self-help CBTv] may simply need too much time.’

This subtheme demonstrates the high workload that current mental health practitioners have and how this workload can prevent the dissemination of psychological interventions – which are arguably more time consuming than some alternatives (i.e. pharmacological treatments). The comments from clinicians suggest that this issue extends beyond the

implementation of guided self-help CBTv, and instead reflects a tension within mental health services more broadly. It may be that reducing the number of therapy sessions (guided self-help CBTv uses half the sessions recommended for CBTp) is not sufficient to improve implementation.

#### *8.10.2.2 Conflict with Service Priorities:*

Beyond the issue of resources, some clinicians felt that the implementation of guided self-help CBTv was unlikely to be supported at a service-level e.g. by service leads and managers. It appeared that some felt an intervention like this conflicted with the priorities of services on two main fronts: firstly a conflict with the dominant treatment model, and secondly the need to meet targets:

‘I am dependant on managers who may be pressured to achieve targets and may not see interventions such as these as essential. It’s pivotal to have leads and managers on board and offer protected time to learn and use these interventions.’

‘I think there will be resistance from practitioners who rely solely on the medical model.’

The comments within this subtheme may be partly explained by the responses given within the ‘patient barrier’ theme. Clinicians expressed concerns about the suitability of people who hear voices engaging in guided self-help CBTv because of their mental health and cognitive difficulties. The more senior members of the healthcare system may be influenced by these concerns and consequently show reluctance to support the implementation of this intervention.

‘It seems to me that as psychosis does not produce results or turnover suitable to corporate organisations it [treatment provision] will remain the poor relation within services.’

This theme suggests that it is not just the dominance of the medical model within mental health services that could prevent implementation, but also a need for services to meet targets. The implication of this statement is that those experiencing psychosis are a more complex client group that require more resources (and financial investment) to reach a service-defined point of recovery – this is not conducive with a target-driven mental health service. The pressure to meet targets to prevent any further funding cuts is likely to be exacerbated by the current state of mental health funding as described by the ‘Lack of Resources’ sub-theme.

### **8.11 Study 2 Discussion:**

The results from study 2 did not identify any facilitators to engagement. The barriers identified firstly addressed engagement (‘presenting problem’) and secondly implementation

(‘practical barriers’). The ‘presenting problem’ theme found in study 2 mirrors the theme of the same name reported in study 1 – suggesting there is some consensus between people who hear voices and clinicians as to what the barriers to engagement with guided self-help CBTv could be.

## **8.12 Overall Discussion:**

Studies 1 and 2 sought to explore the views of people who hear voices and mental health clinicians respectively on their perceived facilitators and barriers to implementing and engaging with guided self-help CBTv. In study 1, people who hear voices reported that having a therapist who was compassionate, skilled and clear about confidentiality would facilitate therapy engagement. Whereas voices themselves and cognitive difficulties may act as a barrier. In study 2, mental health clinicians believed that the lifestyle, severity of symptoms and cognitive capabilities they associated with hearing voices would inhibit engagement. Furthermore a lack of resources, and support from service managers were identified as barriers to implementation.

Both clinicians and lived experience participants believed the presenting problem, including any associated cognitive impairments, could interfere with engagement. For the lived experience participants, the concern was primarily related to their voices, as voices may object to help-seeking and attempt to sabotage therapy engagement (Meaden, Keen, Aston, Barton, & Bucci, 2013). Whereas clinicians reported a broader concern about the mental state and lifestyle of the patient, and whether the intervention was only suitable for those deemed ‘stable’. The clinicians’ caution could reflect a greater scepticism as to the appropriateness of interventions that encourage patients to talk about their voices (Coffey & Hewitt, 2008), or a pessimistic outlook as to the prognosis for people experiencing psychosis symptoms (Prytys et al., 2011). However the extraction of a similar theme from the lived experience participants could mean that symptoms are a ‘real’ barrier to engagement. However, our findings cannot clarify whether the attitudes from both groups are at all related i.e. are clinicians projecting their opinions onto their patients, or are patients communicating their concerns to their clinician? Regardless of the cause, this barrier needs consideration prior to and within therapy.

The somewhat negative attitudes of clinicians towards the efficacy of therapy for people distressed by hearing voices is further demonstrated by the continued dominance of the medical model, to the detriment of psychological services (Ince et al., 2015). The clinicians reported this barrier to be especially prevalent when considering psychosis spectrum conditions. This point again reflects an underlying belief that clinically-defined recovery is not possible for most patients with psychosis (Prytys et al., 2011). While this attitude remains, commissioners are unlikely to invest in CBTp. However, in light of the findings from our lived experience

participants, we must consider the possibility that engagement in therapy may be difficult for those experiencing psychosis symptoms. Before steps can be taken to address these negative attitudes, we must first identify whether they are justified within our broader research programme on guided self-help CBTv.

The qualities of the therapist were important to the lived experience participants. Some research suggests that some people who hear distressing voices frequently engage in negative patterns of relating to other people – typically being submissive and dependent (Hayward, 2003). It is perhaps unsurprising then that the participants were unanimous in their desire to have a therapeutic relationship that juxtaposes this negative relating. The ideal therapist described by the participants' is akin with Rogers' (1957) concepts of core conditions: (1) empathy, (2) genuineness (also described as congruence), and (3) unconditional positive regard. These conditions form the basis of the person-centred therapeutic approach, and their presence within therapy is associated with positive treatment outcomes (Kirschenbaum & Jourdan, 2005). However the correlational design of these studies is unable to determine whether the core conditions have any causal relationship with treatment outcomes (Farber, 2007). Even if the core conditions do not directly cause beneficial outcomes, our findings suggest therapist qualities may have an indirect influence on treatment outcomes, by increasing intervention engagement (Holdsworth, Bowen, Brown, & Howat, 2014).

Consistent with the CBTp literature more broadly (Dark et al., 2015), clinicians reported insufficient resources to be a barrier to implementation, despite the brevity of the intervention described. This highlights the current pressures upon mental health services (Roberts, 2015), and, perhaps, that reducing the number of therapy sessions is not enough to improve implementation. Whether this concern is realised in practice remains to be seen. However if this is the case, then alternate approaches to the issue of access need to be considered. One approach could be to train frontline clinicians to deliver therapies, rather than accredited therapists. Initial findings for CBTp delivered by clinicians are promising (Waller, Garety, Jolley, Fornells-Ambrojo, Kuipers, Onwumere, Woodall, Emsley, et al., 2013). However, adopting this approach would negate the response from our lived experience participants whom believed guided self-help CBTv should be delivered by therapists whom are both competent therapists *and* have specialist knowledge of working with people who hear voices. Also, at present, there are few controlled trials of CBTp delivered by frontline clinicians (Hazell, Hayward, Cavanagh, & Strauss, 2016). Until a body of high quality evidence is available, the delivery of CBTp by frontline practitioners in routine practice is not recommended.

### **8.12.1 Limitations:**

Studies 1 and 2 utilised different methods to consult with participants, each with their own limitations. For example, study 2 used free response items on a questionnaire to consult clinicians, and probes were not available to explore participants' responses. A more traditional qualitative design could have been used (e.g. interviews) to collect a richer level of data. However, on reflection, using a questionnaire design meant that we could consult a larger, more diverse, and consequently a more representative group of clinicians. In contrast, study 1 may have limited generalisability because of the largely self-selected recruitment method used; especially when considering the representativeness of our participants' literacy levels, and type of voices they experience. Firstly, there is some evidence to suggest people who hear voices have generally lower levels of educational attainment (Shinn et al., 2012). However there is no significant difference between the reading ability of voice hearers and nonclinical controls (Morrison & Haddock, 1997). Consequently, because a required pre-requisite for guided self-help CBTv is the ability to read and write it is likely that our sample represents the intervention's target client base. Secondly, there are numerous subtypes of voices, such as (1) constantly commenting and commanding, (2) replay, and (3) own thought voices (McCarthy-Jones, Trauer, et al., 2014). As we did not ask participants what types of voices they heard, we cannot say whether the themes derived would be applicable to all types of voices-hearers. However, we do know that most people who hear distressing voices (this would include all of our participants) typically hear more than one type of voice (McCarthy-Jones et al., 2014); so it is likely that the majority of these voice subtypes were represented within our sample.

Moreover this study recruited both clinicians and people who hear voices from one mental health trust in the UK. The experience of, and attitudes towards, voices can differ significantly across cultures (al-Issa, 1995). Also, a number of the themes described are related to the health service the participants were a part of (e.g. conflict with service priorities). Therefore the themes extracted may not be generalizable to other mental health care services or trusts, both nationally and internationally. Consequently, the solutions we propose to increasing access (i.e. reducing the duration of therapy) may not be appropriate for all mental health services. Despite this, it is probable that some of the themes extracted will apply to other geographical localities. For example, CBTp dissemination is poor both nationally and internationally due in part to problems with resource (Burns et al., 2004; Haddock et al., 2014; Myhr & Payne, 2006). It is therefore likely that many mental health clinicians outside of this Trust would also report a lack of resources as a barrier to implementation.

The participants from both studies were asked to consult on the guided self-help CBTv intervention without having received or delivered the intervention. Therefore the responses

presented here will be restricted by the extent to which they are grounded in relevant experience. However conducting the consultations described in studies 1 and 2 at this point in the development process of guided self-help CBTv means we can incorporate the feedback more easily into the intervention protocol, and consider how to address the barriers prior to implementation. Once people who hear voices and mental health clinicians experience this intervention their perceptions may change. We plan to use a mixed-methods approach (both quantitative and qualitative) when evaluating the effects of guided self-help CBTv to continue learning about the barriers and facilitators to engagement and implementation.

### ***8.12.2 Clinical Applications:***

The most pertinent clinical application that can be taken from these results is the impact of the shared perception (both clinicians and lived experience) that the presenting problem could be a barrier to guided self-help CBTv. From the clinicians' perspective, this belief may determine who is offered psychological therapy – whereby therapy is not offered to those with the most severe symptoms. And where therapy is offered, clinicians' negative attitudes towards their patient's potential to benefit from the intervention may directly hamper the treatment outcomes (Byrne, Deane, & Caputi, 2008). Clinicians should endeavour to remain hopeful for their patients to promote recovery and motivation (Berry & Greenwood, 2015; Russinova, 1999). The implementation of any psychological therapy should include a programme of work to raise awareness amongst referring clinicians to prevent the unwarranted gate-keeping of patients.

From the lived experience perspective, the concern about the sabotaging role of voices could be responded to both prior to and during therapy. Prior to therapy, the therapist could explicitly recognise the possible responses voices may have to therapy, how this relates to the voices' negative intentions over the hearer (e.g. the voice does not want the hearer to get stronger), and how this can be managed. During therapy, sessions can be used to explicitly evaluate beliefs about the voice's omnipotence (e.g. how therapy engagement can challenge the voices power) (Chadwick & Birchwood, 1994) and of self-efficacy (e.g. how therapy engagement can evidence taking control over from the voice) (Fielding-Smith et al., 2015b) - both common elements of CBT for voices (Birchwood et al., 2014; Hayward et al., 2012).

Beyond the content of therapy, the potential for impaired cognitive abilities to hinder therapy engagement (as reported by both lived experience participants and clinicians) has specific implications for this guided self-help CBTv intervention that uses written materials. These materials need to make use of different formats (e.g. images and text), and cater to varying levels of cognitive ability (e.g. long and short passages). These materials are likely to be most helpful if supplemented with face-to-face contact that collaboratively engages with and

works through these materials. The quality of this face-to-face contact was a concern for the lived experience participants who wanted a therapist who was compassionate, empathetic, and trustworthy. These qualities predict a better therapeutic relationship (Evans-Jones, Peters, & Barker, 2009), which in turn moderates treatment outcomes (Martin, Garske, & Davis, 2000). Thought will need to be given as to how such therapist qualities can be foregrounded within a brief intervention that allows only a limited time to develop the therapeutic relationship.

### ***8.12.3 Conclusions:***

The findings from both study 1 and 2 demonstrate that both clinicians and people who hear voices anticipate a number of barriers and facilitators to the implementation of guided self-help CBTv. Identifying these barriers, from each perspective, will enable all parties to openly and collaboratively consider the possible solutions. Whether these barriers are realised in practice, requires further research.



# 9 Guided self-help cognitive behavioral intervention for VoicEs (GiVE): study protocol for a pilot randomized controlled trial.

Chapter 9 is published in Trials as:

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## Contributions:

Conceptualisation:	All authors
Methodology:	All authors
Data Collection:	Not applicable
Data Analysis:	Not applicable
Initial Draft:	CMH and CS
Reviewing and Editing:	All authors*

\*Plus comments from peer-reviewers during the publication process.

## **9.1 Abstract:**

### **9.1.1 Background:**

Cognitive behavior therapy (CBTp) is an effective intervention for people who hear distressing voices (auditory hallucinations). However, there continues to be a problem of poor access to CBTp. Constraints on healthcare funding require this problem to be addressed without a substantial increase in funding. One solution is to develop guided self-help forms of CBTp to improve access and a symptom specific focus on, for example, distressing voices (auditory verbal hallucinations), has the potential to enhance effectiveness. We term this CBT for distressing voices or CBTv.

### **9.1.2 Methods/Design:**

This trial is an external pilot randomized controlled trial comparing the effects of 12-week guided self-help CBTv (with 8 therapist support sessions) to a wait list control condition. Informed consent will be obtained from each participant. Half of the 30 participants will be randomized to receive guided self-help CBTv immediately; the remaining half will receive the intervention after a 12-week delay. All participants will continue with their usual treatment throughout the study. Outcomes will be assessed using questionnaires, completed at baseline and 12 weeks post-randomization. Interviews will be offered to all those who receive therapy immediately to explore their experiences of the intervention.

### **9.1.3 Discussion:**

The outcomes from this trial, both quantitative and qualitative, will inform the design of a definitive randomized controlled trial of guided self-help CBTv. If this intervention is effective, it could help to increase access to CBT for those who hear distressing voices.

## **9.2 Trial Registration:**

ISRCTN registration number ISRCTN77762753. Date registered 23 July 2015.

## **9.3 Keywords:**

Voices, auditory hallucinations, psychosis, cognitive behavior therapy, CBT, low intensity, self-help.

## 9.4 Background:

Hearing voices (i.e. auditory verbal hallucinations) is a common experience (Beavan et al., 2011); some people find this experience very distressing, and hear voices in the context of a mental health problem (Morrison, Nothard, Bowe, & Wells, 2004). Hearing distressing voices is a symptom of psychotic spectrum disorders such as schizophrenia (World Health Organisation (WHO), 1973), but voices can also be present in the context of other mental health conditions such as Borderline Personality Disorder (Kingdon et al., 2010), Dissociative Identity Disorder (Dorahy et al., 2009), Bipolar Disorder (Pini et al., 2004) and Posttraumatic Stress Disorder (Hamner et al., 2000).

A meta-analysis found cognitive behavior therapy for psychosis (CBTp) to be an effective treatment for distressing voices (Van der Gaag et al., 2014). National treatment guidelines from a number of countries recommend that everyone with a psychotic disorder is offered CBTp (NICE, 2014b; Royal Australian And New Zealand College Of Psychiatrists Clinical Practice Guidelines Team For The Treatment Of Schizophrenia and Related Disorders, 2005; Scottish Intercollegiate Guidelines Network (SIGN), 2013), with the guidelines stating that at least 16 individual sessions of CBTp should be offered.

Despite evidence for its effectiveness and recommendations in national treatment guidelines, CBTp is not widely available. Even though the UK has led the way in promoting the implementation of CBTp (Turkington, Kingdon, & Chadwick, 2003), a report by the UK's Schizophrenia Commission (2012) found only 10% of people with psychosis were offered CBTp. More recent figures suggest this rate may have actually decreased (Haddock et al., 2014).

The most consistently reported barrier to implementation is insufficient resources to meet the demand, including both insufficient numbers of CBTp trained therapists (Tarrier, 2005), and trained therapists lack of protected time (Haddock et al., 2014). The current economic climate has had a deleterious impact on mental health funding across the globe (Karanikolos et al., 2013). Consequently, it is not realistic to expect that resources required to deliver CBTp in line with treatment guidelines will be available in the near future. An alternative approach is to use available resources more efficiently. This could include offering CBTp self-help resources with therapist guidance, an approach that requires less therapist resource than standard interventions (Bennett-Levy, Richards, & Farrand, 2010). We propose a guided self-help form of CBTp could be a suitable intervention for this client group; our approach requires less therapeutic contact time (8 sessions) than the recommended 16 sessions, so the same number of therapists could, in principle, offer an intervention to twice as many people over the course of a year.

Multiple meta-analyses have found that guided self-help CBT is effective for anxiety and depression (Cuijpers, Donker, van Straten, Li, & Andersson, 2010; van't Hof et al., 2009) and, as a consequence, guided self-help CBT is offered routinely in the UK for people experiencing these difficulties (NICE, 2011a). Evidence is emerging that briefer forms of CBTp may also be effective. A meta-analysis found that briefer forms of CBTp (i.e. trials offering fewer than the recommended 16 therapy sessions) in comparison to control conditions significantly improved psychosis symptoms at post-therapy and follow-up (Hazell, Hayward, Cavanagh, & Strauss, 2016). However previous meta-analysis of CBTp more broadly have shown trial quality is an important moderator of treatment effects; with high quality CBTp trials producing smaller effect sizes in comparison to lower quality trials (Jauhar et al., 2014; Wykes et al., 2007). Therefore lower quality trials may overestimate the effectiveness of briefer forms of CBTp.

In addition, in an effort to improve the effectiveness of CBTp, the field is moving away from generic CBTp for the broad range of psychotic symptoms and towards symptom-specific CBTp with recent trials focusing on CBTp for delusions (Freeman, Dunn, et al., 2015) and distressing voices (Birchwood et al., 2014). However, to our knowledge, there has been no research investigating the potential of guided self-help for distressing voices, and this is the aim of the current study.

This study is an external pilot randomized controlled trial (RCT) prior to conducting a definitive trial of guided self-help CBTp for people distressed by hearing voices (which we term CBTv). Guided self-help CBTv aims to reduce the distress associated with the experience of hearing voices. Therefore, the primary hypothesis for the trial will be that those who receive guided self-help CBTv will experience a reduction in the distress associated with voices, compared to the delayed therapy control group. Secondary hypotheses will be that those receiving guided self-help CBTv will report improvement in negative and positive beliefs about voices, self-esteem and assertive relating in comparison to the control group: the mechanisms through which the therapy is proposed to work (Hayward, Strauss, & Kingdon, 2012).

The aims of the current pilot study are: (1) to determine whether a full trial is justified, (2) to establish the effect size on the primary outcome (voice-related distress) for a sample size calculation for a definitive trial, and (3) to address questions concerning study recruitment, retention and acceptability. Specifically, between-group treatment effects will determine whether a definitive RCT of guided self-help CBTv is justified; that is, we will proceed if the effect size on the primary outcome is in favor of CBTv in comparison to the delayed therapy control condition and if the 95% confidence interval for this effect contains the minimum clinically important difference (MCID). If so, this study will provide the parameters needed to

estimate the sample size for a definitive RCT. Finally, the study will assess whether the study design is acceptable to participants using recruitment and retention rates and qualitative interviews with participants. Both study dropout, and therapy dropout rates will be reported with a view to understanding reasons for drop-out and developing strategies to minimize drop-out in a definitive trial.

## **9.5 Methods/Design:**

This study is a pragmatic single-blind external pilot RCT with two parallel arms and 1:1 allocation. A rater blind to allocation will conduct post-intervention assessments. A total of 30 participants will be recruited; half will be randomly allocated to receive guided self-help CBTv immediately (immediate therapy), and half will join a wait-list for the same intervention (delayed therapy). Both groups will maintain their usual mental health care throughout the course of the study.

The randomization of participants will be conducted by an independent statistician, using a 1:1 ratio random permuted block randomization (with block sizes of 2, 4 and 6). The research team will be blind to the block size. Figure 14 illustrates the process of randomization and group allocation.

The outcome data will be collected at Time 0 (before randomization), and at Time 1 (12 weeks post randomization). Time 1 assessments will be conducted by a research assistant blinded to the participant's group allocation. All of the participants allocated to receive immediate therapy will be asked to complete an exit interview to discuss their experience of the therapy.

To assess adherence to the protocol, all therapists will be asked to complete a checklist after each session with each client, indicating the elements of the protocol they have covered. The checklist has been designed specifically for this intervention.

### **9.5.1 Participants:**

Participants will be service users recruited from an NHS mental health trust in the South of England. Clinicians will be asked to refer eligible service users on their caseload. Potential participants will also be identified using a database of people who have agreed to be contacted about research studies.

In line with the recommendations of Julious (2005) for pilot RCTs, 12 participants per arm are required for this pilot RCT. A meta-analysis of briefer forms of CBTp found the maximum dropout rate to be 13.5% (Hazell, Hayward, Cavanagh, & Strauss, 2016). Using this

as a guideline, we have overestimated a potential attrition rate of 20% for the current study, meaning a total of 30 participants will be recruited (15 per arm).

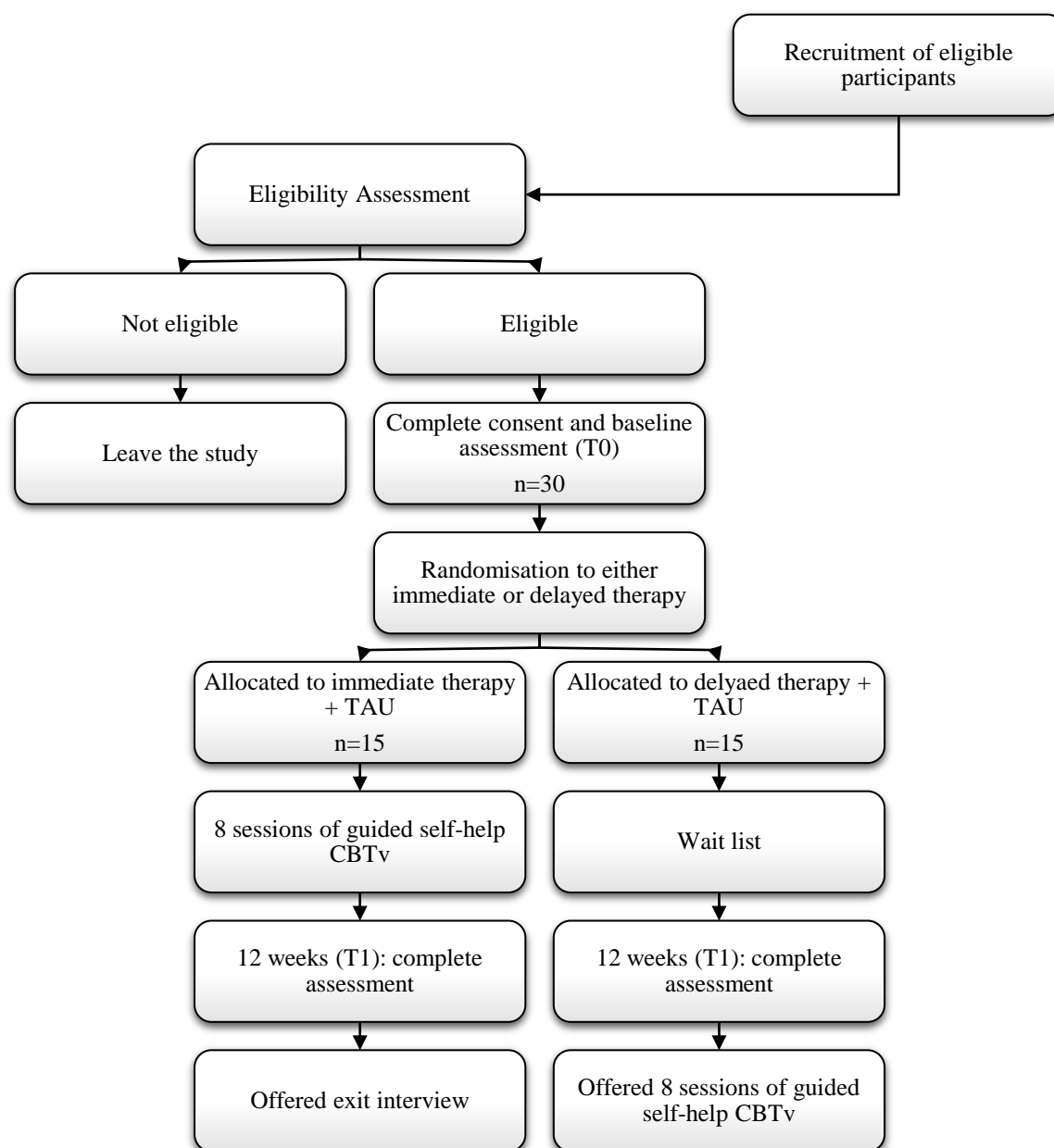


Figure 14. CONSORT diagram of participant progression through the GiVE trial.

Inclusion criteria are that participants: (1) are aged 18 years or older, (2) are distressed by hearing voices: this is operationalized by requiring participants to score at least 3 out of 5 on item 5 (How much do the voices interfere with your daily activities?), 6 (how distressing are the voices that you hear?), or 7 (how bad do the voices make you feel about yourself) on the Hamilton Program for Schizophrenic Voices Questionnaire (HPSVQ) (Van Lieshout &

Goldberg, 2007) – equivalent to moderate levels of interference, distress and impact respectively, (3) have heard voices for the at least a year, (4) are not currently in, or have plans to receive, another psychological intervention during the course of the study, and (5) are able to read and write in English at the level required for the self-help course.

Participants will be excluded from the trial if they have a primary diagnosis of substance misuse or if an organic illness is determined as the reason for hearing voices. Otherwise diagnosis is not an inclusion/exclusion criteria given that distressing voices are common across a range of diagnoses (i.e. Schizophrenia (World Health Organisation (WHO), 1973); Borderline Personality Disorder (Kingdon et al., 2010); Dissociative Identity Disorder (Dorahy et al., 2009); Bipolar Disorder (Pini et al., 2004); Posttraumatic Stress Disorder (Hamner et al., 2000)).

### **9.5.2 *Planned Intervention:***

The 12-week intervention is based on and guided by the self-help book ‘Overcoming Distressing Voices’ (Hayward et al., 2012) and an accompanying workbook that summarizes the key chapters. The therapists and participants will have the same therapy materials (book and workbook). Therapist guidance will be offered over a maximum of 8 sessions (30-60 minutes per session) delivered over the 12 weeks. The intervention will be guided by Clinical Psychologists with expertise in CBTp, and participants will be encouraged to engage with the structured self-help workbook throughout. The intervention protocol has been developed in collaboration with clinicians and people with lived experience of hearing voices.

The intervention consists of 5 modules: (1) The ‘Coping’ module will look at ways of managing voice distress, current coping strategies will be evaluated, and new ones considered; (2) the ‘Me’ module will address self-esteem, negative beliefs about the self will be re-evaluated, and positive beliefs will be strengthened; (3) the ‘My Voices’ module will target unhelpful beliefs that are typically associated with voices, focusing on re-evaluating these beliefs; (4) the ‘My Relationships’ module will give the opportunity to work on a difficult relationship (including the relationship with voices), the aim is to develop more assertive ways of relating; and (5) the ‘Looking to the Future’ module offers an opportunity for reflection and develops a plan for taking learning from the self-help course forward into the future.

Participants will keep the book and workbook after therapy has ended; providing a resource they can return to at a later date. Participants will be free to drop out of the intervention at any point.

Therapists will each receive training in the intervention from CS/MH (authors of the self-help book), and monthly therapist group supervision will be offered.

### 9.5.3 Wait List Control (delayed therapy):

Participants allocated to delayed therapy will join a waiting list for the intervention. The waiting period will be approximately 12 weeks after randomization at which point participants will receive the intervention as outlined above.

Throughout the trial (including the waiting period) participants will continue with their usual mental health care; this will likely involve taking psychiatric medication and regular contact with a clinician. The type of medication participants are taking, as well as any changes in these across the span of the study will be recorded.

	Enrolment	CBT <sub>v</sub> intervention	Close-out
Timepoint	T1		T2
<i>Enrolment:</i>			
Eligibility screen	X		
Informed consent	X		
Random allocation	X		
<i>Intervention:</i>			
Intervention arm		X	
Control arm			
<i>Assessments:</i>			
Baseline assessments	X		
Post-intervention assessments			X

Table 13. Schedule of enrolment, intervention and assessments.

### 9.5.4 Measures:

The primary outcome will be the Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ) voice impact subscale (Van Lieshout & Goldberg, 2007). The HPSVQ voice impact subscale has 5 items rated on a five point (0-4) scale, and measures the level of distress and impact that voices have on the person. The phenomenology subscale (4 items) will also be included in this trial (and will be a secondary measure in the definitive trial). The questionnaire contains 9 items in total, and has strong concurrent validity (all  $r > .80$ ), as well as good internal consistency (all  $\alpha > .82$ ) (Kim et al., 2010).



The following measures of secondary outcomes are also included in this trial:

The Choice of Outcome In Cbt for psychoses (CHOICE) questionnaire (Greenwood et al., 2010) was developed in partnership with service-users. It has 22 items, measuring service-user defined recovery. Two of the items give participants the opportunity to include their own recovery goal for CBT. The severity scale of this questionnaire has a high level of test-retest reliability ( $\alpha = .83$ ).

The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) measures clinical levels of anxiety and/or depression. The HADS has 12 items. The English version of this questionnaire has good internal consistency ( $\alpha = .80$ ) (Herrmann, 1997).

The Short Warwick-Edinburgh Mental Well-being Scale (SWEMBS) (Tennant et al., 2007) uses 7 items to measure psychological wellbeing. The SWEMBS demonstrated good reliability ( $\alpha = .91$ ).

The Rosenberg Self-Esteem Scale (RSES) (Rosenberg, 1965) consists of 10 items. It was originally developed to measure self-esteem amongst adolescents, but has since been used for adults with strong psychometric properties. The RSES has strong levels of test-retest reliability over time ( $r = .85$ ).

The Brief Core Schema Scale (BCSS) self-scale (Fowler et al., 2006) measures participants' endorsement of positive and negative beliefs about themselves. The BCSS self-scale has 12 items, and has strong internal consistency when given to clinical participants ( $\alpha = .84$ ).

The Persons Relating to Others Questionnaire short version (PROQ3) (Birtchnell, Hammond, Horn, De Jong, & Kalaitzaki, 2013) measures social relating (person to person) in terms of their proximity and power. The questionnaire includes 48 items, and all scales show acceptable levels of internal consistency (all scales  $\alpha > .70$ ).

The Voice and You (VAY) (Hayward, Denney, Vaughan, & Fowler, 2008) measures the same relational dimensions as the PROQ3 (Birtchnell et al., 2013) but in the context of the participant's relationship with their voice/s (hearer to voice). The scale has 28 items, and demonstrates good internal consistency across all of the scales (all scales  $\alpha > .80$ ).

The Beliefs about Voices Questionnaire – the revised edition (BAVQ-R) (Chadwick, Lees, et al., 2000) 35 items, and measures the strength of a range of beliefs about voices. All scales have acceptable levels of internal consistency (all scales  $\alpha > .74$ ).

Sessional measures will be taken using six visual analogue scale (VAS) questions, with each question targeting an intended therapy outcome or mechanism.

An exit interview will be administered post-intervention to participants in the immediate therapy condition. This will use the Change Interview (Elliott, Slatick, & Urman, 2001) to ask participants to consider any changes they have experienced over the course of the intervention, and if so what they attribute these changes to. Helpful, unhelpful and missing aspects of the intervention are also explored within the Change Interview. The Change Interview also asks participants to provide feedback on their experience of the research study itself, as well as to provide suggestions for future research in the area. The exit interview will also include additional questions on participants' experiences of the study process (e.g. assessments, consent, randomization) (Notley et al., 2015).

#### ***9.5.5 Data Collection and Storage:***

All data will be collected and stored in line with the Data Protection Act (1998). Assessments will be completed using tablet computers so that data is entered and stored electronically. Anonymized data will be stored on password protected computers and will be available to members of the research team. Any files that contain personal information of participants will be kept in a password protected electronic file or in locked filing cabinets on NHS or university sites. In order to maximize study retention, participants will be invited to complete post-intervention assessments even if they have dropped out of the intervention and all assessments will be conducted at a time and place most convenient to the participant.

#### ***9.5.6 Planned Analysis:***

All of the analyses will be carried out once data collection has been completed. SPSS version 22 will be used to conduct all quantitative analyses. The findings of this trial will be reported using the CONSORT guidelines. The recruitment rates for this trial will be reported as a ratio of the number of potential participants approached, compared to the number whom consented. The retention rates will be reported firstly as the percentage of participants who drop out of the study (do not complete the Time 1 assessments), and secondly as the percentage of participants who drop out of therapy before exposure (receive less than 4 sessions). If study or therapy dropout rates are greater than 33% this will indicate that changes may be needed to the study and/or therapy protocols. The acceptability of the study and therapy will be assessed using retention rates, and feedback obtained through the exit interview.

The analysis for this trial will be mostly descriptive: we will report the means/medians (as appropriate) and standard deviations and minimum and maximum scores at Time 0 and Time 1 for both groups on primary and secondary outcomes. Participants' characteristics will be reported using frequency counts and percentages, including the characteristics of any participants who drop out of the study and/or therapy. ANCOVAs will be used to estimate T1

between-group differences on primary and secondary measures controlling for baseline scores. 95% confidence intervals will be calculated. Effect sizes will be reported as Cohen's *d* (unstandardized effect size divided by the baseline pooled standard deviation). We will look at the effect sizes using both an intention-to-treat analysis approach, and a per protocol analysis (looking only at participants who attended at least 50% of therapy sessions). A definitive trial will be considered to be justified if there is a between-group effect in favor of CBTv on the primary outcome (HPSVQ voice impact subscale (Van Lieshout & Goldberg, 2007)) and if the 95% confidence interval contains the MCID of 2 points in favor of CBTv.

The exit interviews will be transcribed into NVivo, and analyzed using thematic analysis in accordance with the Braun and Clarke (2006) protocol. The analysis will aim to identify common patterns across interviews that reflect the participants' experiences of therapy and of the study processes. These themes, as well as the quantitative results will be used to refine the study and therapy protocols. If a definitive trial is justified, then the power calculations will be based upon the between group effect size on the HPSVQ voice impact subscale (Van Lieshout & Goldberg, 2007).

## **9.6 Research Governance:**

This protocol has been prepared in line with the SPIRIT guidelines (Chan, Tetzlaff, Altman, et al., 2013; Chan, Tetzlaff, Gøtzsche, et al., 2013).

The trial is sponsored by the University of Sussex, and funded through a doctoral studentship award given to Cassie Hazell by the Economic Social and Research Council (ES/J500173/1) and Sussex Partnership NHS Foundation Trust. Ethics approval has been granted by the Research Ethics Committee (REC) North West – Lancaster (15/NW/0575). Written informed consent will be obtained from each participant by the lead author. A copy of the participant information sheet and consent form can be obtained from the corresponding author.

A Trial Steering Committee (TSC) will be established in accordance with MRC guidelines (Medical Research Council (MRC), 1998) and will monitor the conduct of the trial and adherence to the study protocol. The TSC will include an independent Chair, independent experts and lay members. If necessary, applications to make significant protocol amendments will be made to the REC and study sponsor. A Data Monitoring Committee (DMC) is not deemed necessary given the pilot nature of the current study.

The UK's National Institute of Health Research (NIHR) Good Clinical Practice (GCP) guidelines will be followed, which includes reporting and investigation of any adverse events during the study. In line with these guidelines, the research team will ensure that the patients

care team are aware of an adverse events. If an adverse event is deemed to be related to the study, this will be reported to the study sponsor. The sponsor will then determine whether or not the study needs to be stopped, and if an investigation of the adverse event is needed.

### **9.7 Dissemination:**

Findings will be written up for publication in an open-access, peer-reviewed journal and a lay summary of findings will be sent to all study participants.

### **9.8 Discussion:**

The development of guided self-help CBTv is one approach that could potentially address the problem of limited access to CBT in the UK for people who experience psychosis (Ince et al., 2015). However, it would be inadvisable to offer guided self-help CBTv routinely as we do not yet know if it is acceptable or effective at reducing voice-related distress – an approach that widens access but that is ineffective would be of little use and a waste of limited resources.

This external pilot RCT will generate effect sizes of CBTv in comparison to the wait-list control group on the primary outcome (voice-related distress) and on secondary measures. The trial will also indicate recruitment and retention rates and intervention acceptability. These parameters will inform the design and sample size calculation for a definitive trial.

If found to be effective within a definitive trial, guided self-help CBTv has the potential to widen access to an effective, evidence-based intervention for people distressed by hearing voices.

### **9.9 Trial Status:**

The trial has received ethical and governance approvals. Recruitment began in September 2015, and is planned to end in January 2016.

# 10 Guided self-help cognitive-behaviour Intervention for VoicEs (GiVE): Results from a pilot randomised controlled trial.

Chapter 10 is under review with Schizophrenia Research as:

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## **Contributions:**

Conceptualisation:	All authors
Methodology:	All authors
Data Collection:	CMH and research assistant (LBJ)
Data Analysis:	CMH and AMJ
Initial Draft:	CMH and CS
Reviewing and Editing:	All authors

## **10.1 Abstract**

### ***10.1.1 Background:***

Few patients have access to cognitive behaviour therapy for psychosis (CBTp) even though a minimum of 16 sessions of CBTp is recommended in treatment guidelines. Briefer forms of CBTp could improve access as the same number of therapists could see more patients. In addition, focusing on single psychotic symptoms, such as auditory hallucinations ('voices'), rather than on psychosis more broadly, may yield greater benefits.

### ***10.1.2 Method:***

This pilot RCT recruited 28 participants from NHS mental health services who were distressed by hearing voices. The study compared an 8-session guided self-help CBT intervention for distressing voices with a wait-list control. Data were collected at baseline and at 12 weeks with post-therapy assessments conducted blind to allocation. Voice-impact was the pre-determined primary outcome. Secondary outcomes were depression, anxiety, wellbeing and recovery. Mechanism measures were self-esteem, beliefs about self, beliefs about voices and voice-relating.

### ***10.1.3 Results:***

Recruitment and retention was feasible with low study (3.6%) and therapy (14.3%) dropout. There were large, statistically significant between-group effects on the primary outcome of voice-impact ( $d=1.78$ ; 95% CIs: 0.86-2.70), which exceeded the minimum clinically important difference. Large, statistically significant effects were found on a number of secondary and mechanism measures.

### ***10.1.4 Conclusions:***

Large effects on the pre-determined primary outcome of voice-impact are encouraging, and criteria for progressing to a definitive trial are met. Significant between-group effects on measures of self-esteem, negative beliefs about self and beliefs about voice omnipotence are consistent with these being mechanisms of change and this requires testing in a future trial.

### ***10.1.5 Keywords:***

CBT; psychosis; distressing voices; auditory hallucinations; RCT; self-help

## **10.2 Introduction:**

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

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

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

## **10.3 Method:**

### ***10.3.1 Trial Design:***

This trial is a pragmatic, single-blind, external pilot RCT comparing guided self-help CBTv to a wait-list control using 1:1 allocation ratio (Figure 15). Both groups received usual mental health care throughout the study. The study protocol was published before recruitment ended (Hazell, Hayward, Cavanagh, Jones, et al., 2016).

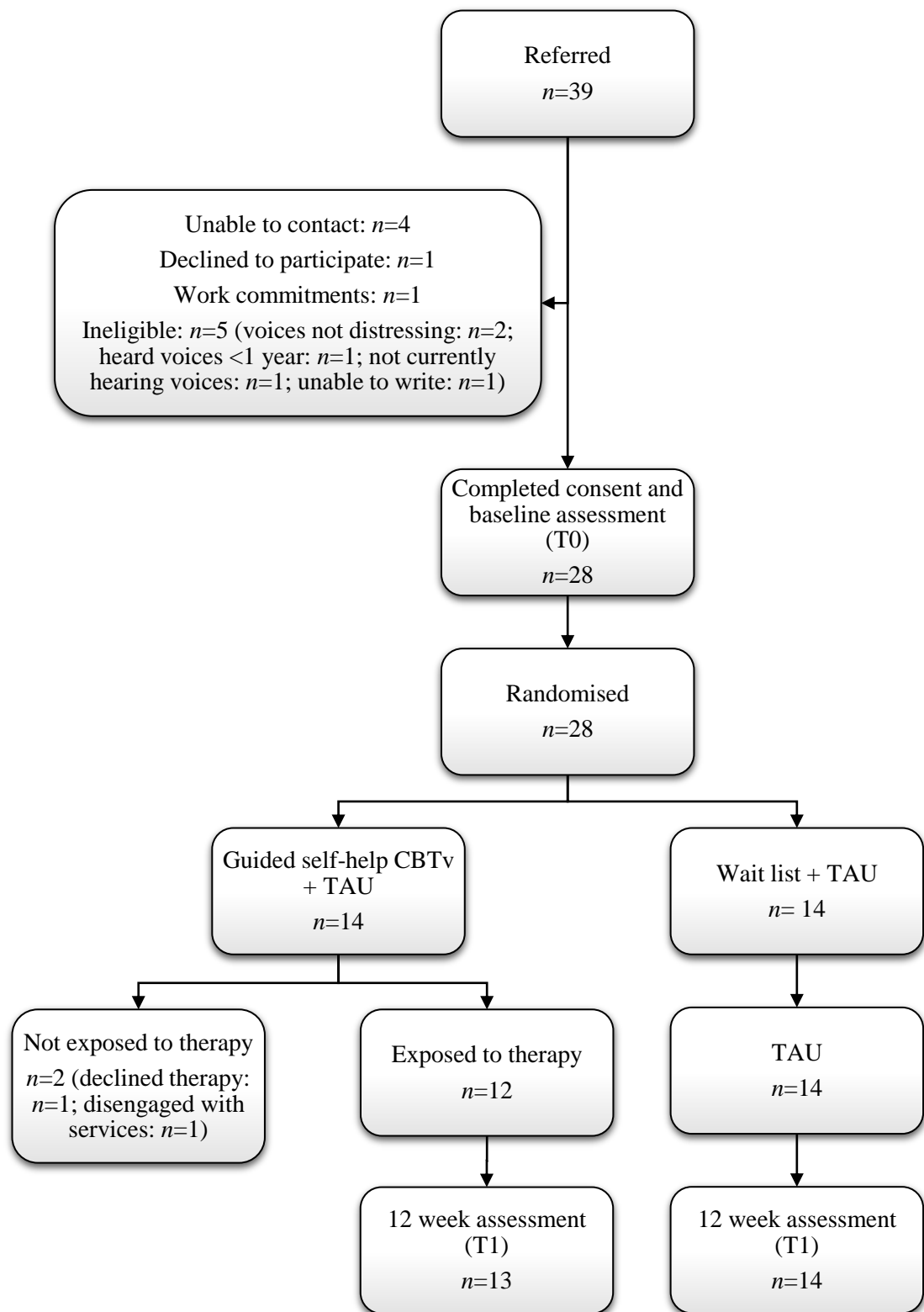


Figure 15. Trial CONSORT diagram.

*Note:* TAU= treatment as usual; CBTv= cognitive behaviour therapy for voices.



### **10.3.2 Participants:**

Participants were recruited between September 2015 and January 2016. All participants were accessing NHS mental health services in the South of England. We recruited 28 participants (14 per arm – in line with pilot RCT guidelines (Julious, 2005)) who met the following inclusion criteria: (1) aged 18 years or older; (2) currently distressed by hearing voices, quantified by a score of at least 3 on either item 5 ('how much do the voices interfere with your daily activities?'), 6 ('how distressing are the voices that you hear?'), or 7 ('how bad do the voices make you feel about yourself?') on the Hamilton Program for Schizophrenic Voices Questionnaire (HPSVQ) (Van Lieshout & Goldberg, 2007); (3) heard voices for the previous 12 months; (4) not currently receiving psychological therapy and not having plans to do so; (5) able to read and write in English.

Exclusion criteria were: (1) primary diagnosis of substance misuse; (2) an organic illness causing voices. With the exception of these criteria, participants were not excluded on the basis of diagnosis in response to a number of studies that have found minimal differences in the experience of hearing voices between those with and without a psychosis diagnosis (e.g. Hepworth et al., 2013; Toh et al., 2015).

Diagnosis was confirmed by the most recent psychiatrist clinic letter; all diagnoses were made in line with ICD-10 criteria (World Health Organisation (WHO), 1992). Two participants (7.1%) (one per arm) were not taking psychiatric medication at the time of the baseline assessment; both had previously taken antipsychotic medication; 21 (75.0%) participants were prescribed at least one antipsychotic medication. See Table 14 and Figure 15 for further recruitment and participant information.

Variable		Guided self-help CBTv + TAU ( <i>n</i> =14)	Wait list + TAU ( <i>n</i> =14)	Total ( <i>n</i> =28)
Age <i>M</i> ( <i>SD</i> )		39.07(10.16)	45.93(13.49)	42.50(12.23)
Gender <i>n</i> (%)				
	Male	4(28.60)	7(50.00)	11(39.30)
	Female	9(64.30)	7(50.00)	16(57.10)
	Other	1(7.10)	0(0.00)	1(3.60)
Employment Status <i>n</i> (%)				
	Employed	3(21.40)	4(28.60)	7(25.00)
	Unemployed	10(71.40)	5(35.70)	15(53.60)
	Other	1(7.10)	4(28.60)	5(17.90)
Marital Status <i>n</i> (%)				
	Single	6(42.90)	7(50.00)	13(46.40)
	Married/Civil Partnership	1(7.10)	3(21.40)	4(14.30)
	Cohabiting	2(14.30)	0(0.00)	2(7.10)
	Separated/Divorced	5(35.70)	2(14.30)	7(25.00)
	Widowed	0(0.00)	2(14.30)	2(7.10)
Country of Birth <i>n</i> (%)				
	England	13(92.90)	10(71.40)	23(82.10)
	Other	1(7.10)	4(28.60)	5(17.90)
Ethnicity <i>n</i> (%)				

	White (British)	13(92.90)	12(85.70)	25(89.30)
	White (Other)	1(7.10)	2(14.30)	3(10.70)
Level of Education <i>n</i> (%)				
	Left school before 16	7(50.00)	4(28.60)	11(39.30)
	Left school at 16	2(14.30)	3(21.40)	5(17.90)
	Left school at 17/18	3(21.40)	4(28.60)	7(25.00)
	Completed/completing college course	1(7.10)	1(7.10)	2(7.10)
	Completed/completing university course	1(7.10)	2(14.30)	3(10.70)
Age of voice onset <i>M</i> ( <i>SD</i> )		28.50(14.22)	23.71(17.76)	26.11(15.97)
Diagnosis <i>n</i> (%)				
	Psychosis spectrum diagnosis	5(35.71)	8(57.14)	13(46.43)
	Borderline Personality Disorder	5(35.71)	3(21.43)	8(28.57)
	Mood Disorder	1(7.15)	3(21.43)	4(14.29)
	Other	3(21.43)	0(0.00)	3(10.71)

Table 14. Baseline participant demographics.

*Note:* TAU = treatment as usual; Employment status ‘Other’ includes student, homemaker, retired and carer; Psychosis spectrum disorder includes schizophrenia, paranoid schizophrenia, schizoaffective disorder, psychosis not otherwise specified and first episode psychosis; Mood disorder includes depression, depression with psychotic features and bipolar disorder; Diagnosis ‘Other’ includes posttraumatic stress disorder (PTSD) and dissociative identity disorder (DID).

### ***10.3.3 Intervention and Control Arms:***

#### ***10.3.3.1 Guided self-help CBTv:***

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

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

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

#### ***10.3.3.2 Wait List Control:***

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

### ***10.3.4 Outcome Measures:***

All outcome measures were collected at baseline (T0), and post-intervention (12 weeks post-randomisation, T1). Assessments were conducted at the participants’ local mental health facility; where participants had mobility issues, home visits were offered. The voice-impact subscale on the Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ) (Van Lieshout & Goldberg, 2007) was the primary outcome (Hazell, Hayward, Cavanagh, Jones, et al., 2016). This subscale has 4 confirmed items (Kim et al., 2010).

The secondary outcome measures were: (1) The Choice of Outcome In Cbt for psychosEs (CHOICE) questionnaire severity subscale (Greenwood et al., 2010): a measure of service-user defined recovery, including two items where participants identify their personal

goals; (2) The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983); (3) The Short Warwick-Edinburgh Mental Well-being Scale (SWEMBS) (Tennant et al., 2007); (4) The Rosenberg Self-Esteem Scale (RSES) (Rosenberg, 1965).

The measures of proposed mechanisms of action were: (1) The Brief Core Schema Scale (BCSS) self-scale (Fowler et al., 2006): a measure of participants' positive and negative beliefs about themselves; (2) The Persons Relating to Others Questionnaire short version (PROQ3) (Birtchnell et al., 2013): a measure of social relating patterns; (3) The Voice and You (VAY) (Mark Hayward et al., 2008): a measure of voice relating patterns; (4) The Beliefs about Voices Questionnaire – revised (BAVQ-R) (Chadwick, Lees, et al., 2000): a measure of participants' positive and negative beliefs about their voices; (5) HPSVQ phenomenology subscale (Van Lieshout & Goldberg, 2007): a measure of voice phenomenology. Participants in the intervention arm were also asked to complete a patient experience questionnaire based on the IAPT service experience questionnaire (Clarke, 2011).

### ***10.3.5 Randomisation and Masking:***

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

### ***10.3.6 Statistical Analyses:***

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

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

### ***10.3.7 Ethics and Research Governance:***

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

### ***10.3.8 Adverse Events:***

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

## **10.4 Results:**

### ***10.4.1 Recruitment, Retention and Adherence:***

Of the 39 study referrals, 28 (71.8%) consented and were randomised (Table 14). Only one participant (3.6%) did not provide data at both time points (Figure 15). Participants were deemed to have been exposed to the intervention if they attended at least four out of the eight intervention sessions. Two participants randomised to the intervention arm did not begin therapy (Figure 15). Of the 12 participants who began the intervention, 1 participant attended four sessions (8.3%), 3 participants (25.0%) attended seven sessions, and 8 participants (66.7%) attended all eight sessions.

### ***10.4.2 Primary Outcome:***

There was a large, statistically significant between-group effect in favour of the intervention group ( $d=1.78$ , 95% CI 0.86, 2.70) on the HPSVQ voice-impact subscale (Table 15). The difference between pre-post change scores (4.05) exceeds the MCID of 2.

### ***10.4.3 Secondary Outcomes:***

All between-group effect sizes for secondary outcomes favoured guided self-help CBTv over the wait-list condition. There were large, statistically significant between-group effects ( $d>0.8$ ) on service-user defined recovery (CHOICE), anxiety (HADS anxiety), and wellbeing (SWEMBS) (Table 15). Effects on depression (HADS) were small and non-significant ( $d=0.27$ ).

Outcome	T0		T1		<i>B</i> ( <i>SE</i> ; 95% CI)	<i>d</i> (95% CI)
	Guided self-help	Wait list control	Guided self-help	Wait list control		
	CBTv + TAU	group + TAU	CBTv + TAU	group + TAU		
	( <i>n</i> =14)	( <i>n</i> =14)	( <i>n</i> =13)	( <i>n</i> =14)		
	<i>M</i> ( <i>SD</i> )	<i>M</i> ( <i>SD</i> )	<i>M</i> ( <i>SD</i> )	<i>M</i> ( <i>SD</i> )		
<i>Primary:</i>						
HPSVQ (voice- impact)	13.14(1.96)	11.21(2.08)	9.31(4.27)	11.43(2.77)	-3.93 (1.31; -6.65, -1.22)	1.78* (0.86, 2.70)
<i>Secondary:</i>						
CHOICE						
Total	3.37(1.80)	3.52(1.68)	5.68(1.78)	3.29(1.97)	2.39 (0.59; 1.17, 3.61)	1.40* (0.54, 2.26)
Goals Only	5.07(4.70)	4.93(3.85)	12.38(4.13)	5.71(4.76)	6.47 (1.65; 3.07, 9.88)	1.54* (0.66, 2.42)
HADS						
Depression	10.42(3.70)	11.58(3.05)	10.32(2.85)	11.92(2.60)	-0.92	0.27

					(0.89; -2.77, 0.92)	(-.50, 1.04)
Anxiety	12.17(2.96)	11.08(3.26)	9.06(2.34)	11.58(2.84)	-2.91	0.94*
					(0.90; -4.77, -1.05)	(0.13, 1.75)
SWEMBS	17.71(4.36)	18.36(4.07)	21.69(5.01)	17.93(5.50)	3.97	0.95*
					(1.69; 0.47, 7.46)	(0.14, 1.76)
HPSVQ						
Phenomenology	14.14(2.68)	14.93(2.73)	12.85(2.73)	14.21(3.09)	-0.87	0.32
					(0.92; -2.78, 1.04)	(-0.45, 1.09)
Total	27.29(3.93)	26.14(3.66)	22.15(6.50)	25.64(4.89)	-4.51	1.20*
					(1.83; -8.29, -0.73)	(0.36, 2.04)
<i>Mechanism:</i>						
RSES	10.07(6.23)	10.79(4.42)	15.07(5.37)	10.71(5.37)	4.41	0.83*
					(1.75; 0.79, 8.03)	(0.03, 1.63)
BCSS						



Negative self	12.50(5.64)	9.36(5.00)	5.15(5.76)	9.64(5.06)	-6.21 (1.68; -9.67, -2.75)	1.13* (0.30, 1.96)
Positive self	4.14(5.16)	6.79(5.71)	8.08(4.99)	7.36(6.55)	2.41 (1.72; -1.14, 5.97)	0.44 (-.34, 1.22)
PROQ3	60.64(17.19)	48.86(12.56)	49.38(15.96)	51.14(15.63)	-9.27 (4.85; - 19.27, 0.74)	0.58 (-0.21, 1.37)
VAY						
Voice dominance	18.14(2.74)	14.50(6.20)	17.23(3.35)	15.50(4.31)	-0.46 (1.00; -2.53, 1.61)	0.09 (-0.68, 0.86)
Voice intrusiveness	9.36(4.38)	9.86(3.88)	10.69(3.79)	10.57(3.23)	0.27 (1.28; -2.38, 2.92)	0.07 (-0.70, 0.84)
Hearer dependence	9.93(4.81)	5.50(3.65)	5.31(3.97)	6.00(4.40)	-2.65 (1.63; -6.02, 0.71)	0.56 (-0.22, 1.34)
Hearer distance	14.64(3.61)	14.43(4.62)	13.92(3.69)	14.71(3.91)	-1.07	0.26

					(1.46; -4.08, 1.94)	(-0.51, 1.03)
BAVQ						
Malevolence	13.29(4.39)	10.43(5.32)	10.62(4.54)	11.14(4.64)	-2.24 (1.31; -4.95, 0.46)	0.45 (-0.33, 1.23)
Benevolence	1.64(2.37)	2.86(3.74)	0.62(1.50)	1.71(3.22)	-.58 (0.82; -2.26, 1.11)	0.18 (-0.59, 0.95)
Omnipotence	13.57(3.72)	11.86(3.30)	10.15(4.18)	12.43(3.61)	-3.11 (1.34; -5.87; -0.36)	0.88* (0.07, 1.69)
Resistance (feelings)	10.50(1.79)	8.50(3.25)	8.62(3.40)	9.14(2.25)	-1.08 (1.16; -3.48, 1.32)	0.39 (-0.39, 1.17)
Resistance (behaviour)	10.14(4.15)	11.50(3.35)	11.69(2.25)	12.64(2.59)	-0.66 (0.87; -2.47, 1.14)	0.18 (-0.59, 0.95)
Engagement (feelings)	0.64(1.34)	1.57(2.41)	0.15(0.38)	0.79(1.72)	-0.31	0.16

					(0.42; -1.17, 0.55)	(-0.61, 0.93)
Engagement (behaviour)	1.86(2.57)	2.38(1.85)	1.23(1.42)	1.64(1.95)	-0.49 (0.68; -1.90, 0.92)	0.22 (-0.55, 0.99)

Table 15. Primary and secondary outcomes at T0 (baseline) and T1 (12 weeks post randomisation).

*Note:* HPSVQ = Hamilton Program for Schizophrenic Voices Questionnaire; CHOICE = Choice of Outcome In Cbt for psychoses; HADS = Hospital Anxiety and Depression Scale; SWEMBS = Short Warwick-Edinburgh Mental Well-being Scale; RSES = Rosenberg Self-Esteem Scale; BCSS = Brief Core Schema Scale; PROQ3 = Persons Relating to Others Questionnaire short version; VAY = Voice and You; BAVQ-R = Beliefs about Voices Questionnaire – the revised edition; \* =  $p < .05$  and 95% CIs do not cross zero;  $B$  = unstandardized effect;  $d$  = standardised effect; 95% CI for  $d$  calculated using the standard deviation for Cohen's  $d$  (Cohen, 1960).

#### **10.4.4 Mechanism Outcomes:**

All between-group effect sizes for mechanism outcomes favoured guided self-help CBTv over the wait-list condition. There were large, statistically significant between-group effects ( $d > 0.8$ ) for negative beliefs about self (BCSS), beliefs about voice omnipotence (BAVQ-R) and self-esteem (RSES) (Table 15). Effects on remaining mechanism measures were small to medium and non-significant (Table 15).

#### **10.4.5 Patient Experience:**

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

Table 16 shows the results of the patient experience questionnaire. Most participants reported benefit across all of the items. The areas where participants most frequently reported no improvement were the management and reduction of medication (‘Not at all/Somewhat’:  $n=5$ ; 41.7%), and physical health (‘Not at all/Somewhat’:  $n=6$ ; 50.0%). Conversely, the areas where participants most frequently reported largest improvements were their mental health and wellbeing (‘Very much so/Quite a lot’:  $n=6$ ; 50.0%), and their ability to engage in meaningful activities (‘Very much so’:  $n=7$ ; 58.3%). All participants (100%) said they would recommend guided self-help CBTv to a friend or family member who was hearing distressing voices.

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

Table 16. Results from the patient experience questionnaire.

*Note:* N/A = not applicable.

## **10.5 Discussion:**

### ***10.5.1 Summary of Results:***

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

We found a large, statistically significant between-group effect on the pre-determined primary outcome of voice-impact, as well as on a range of secondary outcomes (anxiety, wellbeing, and recovery), and mechanisms (self-esteem, beliefs about self, and beliefs about voices). Furthermore, the small therapy (14.3%) and study (3.6%) attrition rates suggest the study design and intervention were acceptable – this is supported by the positive patient experience questionnaire findings.

### ***10.5.2 Primary Outcome:***

The large effect on voice-impact is in contrast with the majority of CBTp trials which have not found an effect on voice-related impact measures (Haddock et al., 2009; Morrison et al., 2014; Valmaggia et al., 2005); despite the cognitive model of voices identifying this as the goal of CBT (Chadwick & Birchwood, 1994). Our findings highlight the potential benefits of symptom-focused CBTp.

### ***10.5.3 Secondary Outcomes:***

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

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

### ***10.5.4 Mechanism Outcomes:***

There were large, statistically significant effects on self-esteem, negative beliefs about self and voice omnipotence. Believing a voice is omnipotent is strongly associated with greater levels of voice distress (Hacker et al., 2008), it is therefore plausible that changes in these

proposed mechanisms may be in part mediating effects on clinical outcomes. This hypothesis should be explored in future research.

Effects on positive beliefs about self and relating measures were in the small-medium range, but consistently favoured the intervention group. This more modest relating outcome could be because two sessions with a relating focus is insufficient to promote substantial changes in negative relating; because Relating Therapy is typically delivered over 16 sessions (Hayward, Jones, Bogen-Johnston, Thomas, & Strauss, 2016) which is not covered in-depth within guided self-help CBTv.

#### ***10.5.5 Recruitment, Retention and Acceptability:***

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

#### ***10.5.6 Limitations:***

As the present study is a pilot RCT, the sample size is intentionally small, which explains the wide confidence intervals. Findings should therefore be interpreted in light of this. A definitive trial with sufficient statistical power is now needed to fully test the effectiveness of this intervention.

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

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

Fornells-Ambrojo, Kuipers, Onwumere, Woodall, & Craig, 2013). Further research is needed to identify whether guided self-help CBTv would be acceptable, feasible, and effective when delivered by frontline practitioners.

#### ***10.5.7 Clinical Implications:***

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

#### ***10.5.8 Research Implications:***

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

#### ***10.5.9 Conclusions:***

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



## 11 Discussion.

The overall aim of this thesis was to develop and evaluate a brief cognitive behaviour therapy for voices (CBTv) intervention based on the Overcoming Distressing Voices self-help book (Hayward, Strauss, & Kingdon, 2012). Reviewing the available literature within a meta-analysis, and consultations with mental health practitioners and people who hear voices, led to the development of guided self-help CBTv intervention. This intervention was delivered over 8 sessions by experienced Clinical Psychologists, and supported with a workbook designed specifically for this thesis. The results from a pilot randomised controlled trial (RCT) of guided self-help CBTv demonstrated the study and intervention to be feasible and suggested it is acceptable and safe; with large between-group improvements on voice-impact (the primary outcome) and on a range of secondary outcomes. It is hoped that in the long term, the brevity of this intervention could be part of the solution to help increase access to psychological therapies for people distressed by hearing voices.

## **11.1 Limitations and Research Implications:**

Although each study was designed robustly, there are some limitations of this thesis. Each of which can be addressed through further research.

### ***11.1.1 Defining Guided Self-Help CBTv:***

We described the intervention developed within this thesis as guided self-help CBTv. This implies that the therapist's role is to act as a guide to support the patient to engage with the self-help materials. The onus is therefore on the patient to take ownership of the therapy and their recovery. Although we intended for patients to be proactive within therapy, we do not have any data to confirm this. Without monitoring participants' use of the self-help materials, or their role within the therapy sessions we cannot be sure to what extent our intervention was guided self-help versus more traditional, albeit it brief, therapy (i.e. with the therapeutic work conducted during rather than between therapy sessions). We know from the IAPT literature that treatment effects increase when self-help materials are supplemented with guidance (Furmark et al., 2009; Pleva & Wade, 2007). But again, we do not know whether this effect is because the guide helps the patient make better use of the self-help materials, or because the presence of a guide creates a more traditional therapy dynamic. If the therapist played a more significant role, then perhaps this intervention would be better conceptualised as a brief, manualised version of CBTv. Hopefully, analysis of the exit interviews (currently underway) with participants whom received therapy will shed light on the therapy-patient dynamics and the extent to which participants engaged in therapy materials between sessions.

The level of self-help engaged with during this intervention could also vary as a function of therapist expertise. In the hands of an expert therapist, this intervention may

become more akin to brief CBTv. Expert therapists may be more confident to take on a prominent role within therapy sessions, and feel more able to discuss CBT principles beyond the self-help materials. By contrast, a non-accredited therapist (e.g. frontline mental health practitioner) may be more inclined to let the patient take the lead during therapy, and more strictly adhere to the role of ‘guide’ rather than ‘therapist’. Findings from the pilot RCT do not tell us the extent to which the expertise of the guider (therapist/non-therapist) might be integral to outcomes and this is an important avenue for future research.

Although we need to consider the label for this intervention, it is also important to consider the impact of this on the patient. Calling this intervention ‘brief CBTv’ can give patients the impression that they are being ‘short-changed’ i.e. that they are not being given the full treatment. This could lead to reduced optimism as to whether the intervention will be helpful or not; which in turn can then act as a self-fulfilling prophecy (Byrne et al., 2008). On the other hand, calling the intervention ‘guided self-help CBTv’ sets up the expectation that the patient will not be passive within therapy, and will be encouraged to engage in some more independent work. Analysis of the qualitative data will go some way to clarifying whether this intervention is truly guided self-help, or more akin to traditional (but brief) therapy. Within future studies, more objective measures of self-help engagement should be included (e.g. amount of reading between sessions, homework completed between sessions).

### ***11.1.2 Trial Design:***

The final study within this thesis, has been described as a pilot randomised controlled trial (RCT), including in the published trial protocol (Hazell, Hayward, Cavanagh, Jones, et al., 2016). While the notion of this study being a randomised controlled trial is uncontentious – participants were randomly allocated to one of two arms by an independent statistician – the use of the term ‘pilot’ is up for debate. This trial could equally have been described as a feasibility RCT, and we argue that this is in part due to the lack of consensus in the literature about the distinction between pilot and feasibility trials. To illustrate, Arain, Campbell, Cooper, and Lancaster (2010) explain that a pilot trial “is a version of the main study that is run in miniature to test whether the components of the main study can all work together” (pp. 5), whereas a feasibility trial is “used to estimate important parameters that are needed to design the main study” (pp. 4). In contrast, Thabane et al. (2010) argue that pilot trials “are conducted to generate data for sample size calculations” (pp. 3). Both of these papers were published in the same year, in the same research methodology journal. Moreover, the term ‘feasibility’ is often used to describe the aims of a pilot study i.e. “The purpose of conducting a pilot study is to examine the feasibility of an approach that is intended to be used in a larger scale study” (pp.

626) (Leon, Davis, & Kraemer, 2011). The only consistent point of agreement is that both pilot and feasibility studies are not intended to assess effectiveness (Lancaster, 2015).

Definitions are also provided by research councils and other research funding bodies. The National Institute for Health Research (NIHR) in the UK, along with their funding streams, including the Health Technology Assessment (HTA), Research for Patient Benefit (RfPB), and Efficacy and Mechanism Evaluation (EME), define a feasibility study as a piece of research aiming to establish whether the trial can be done, whereas when conducting a pilot study the researcher should be confident the study can be conducted, and is instead treated as a small-scale practice-run in preparation for a main trial (Williams, 2016). In line with these definitions, feasibility studies should seek to identify whether recruitment, retention, and adherence rates meet pre-determined criteria for acceptability. Somewhat distinctly, pilot studies can give a preliminary description of the primary outcome data – although hypothesis testing should still be avoided (Leon et al., 2011), which seems sensible given that pilot studies are by definition underpowered to detect effects.

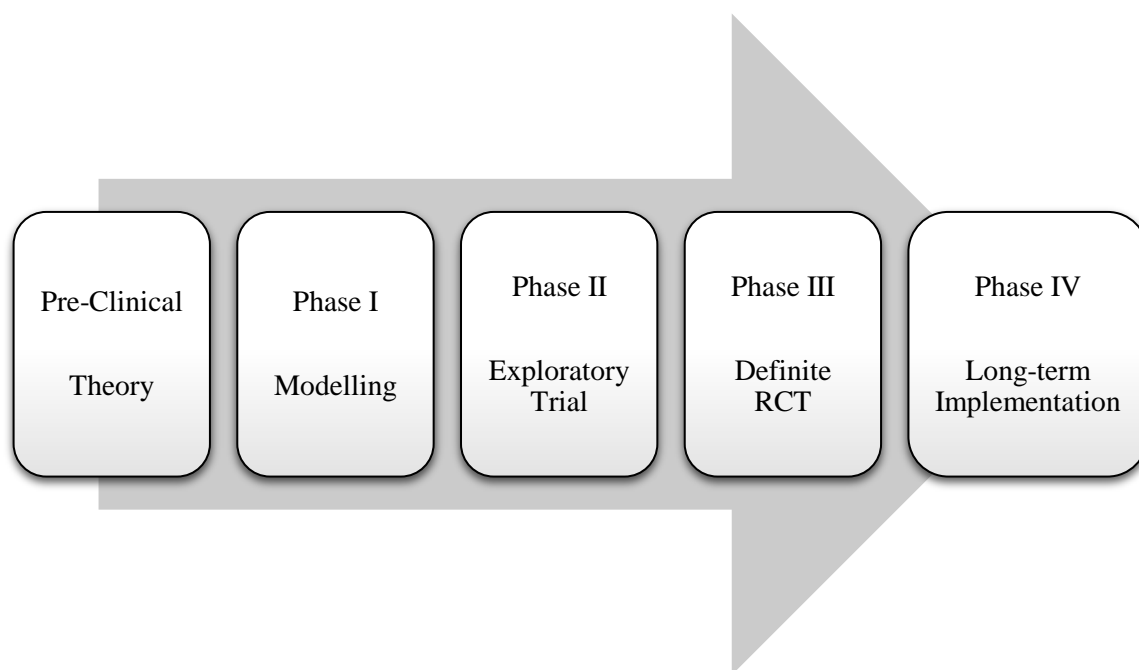


Figure 16. Framework for development and evaluation of RCTs for complex interventions to improve health (Medical Research Council (MRC), 1998).

However, there is again some descent in the ranks as both CONSORT (Eldridge et al., 2016) and the Medical Research Council (MRC) (1998) do not distinguish between pilot and feasibility trials. Instead, the MRC advocate a ‘phased’ approach to clinical trials (see figure 16). This framework posits that both pilot and feasibility trials are phase II studies, as they are not concerned with evaluating the effectiveness of an intervention. The Medical Research Council (MRC) (1998) framework is clear, accessible and pragmatic. Each phase has set aims

that are transferable across disciplines. The pre-clinical phase involves exploring and establishing a theoretical basis for which the intervention should be based on, and how it should produce its effects. At phase I, further research is conducted to test the potential mechanisms of action identified in the pre-clinical phase on a very small scale. The intervention developed is then trialled within phase II, and may include some investigation into the possible mediators and moderators of the treatment effect. It is not until Phase III that the researcher can make any firm statements concerning the effectiveness of the intervention, as determined by adequately powered RCTs. If warranted, the phase IV study should seek to replicate the findings of the RCT on a larger scale over a longer period of time and in real-world settings. The popularisation of this phased framework, which does not necessitate a distinction between feasibility and pilot studies, could help to remedy the confusion described above.

Our RCT of guided self-help CBTv (chapters nine and ten) can be confidently classified as a phase II trial – while studies had evidenced our hypothesised mechanism of action (phase I) we did not have the evidence to justify conducting a definitive RCT (phase III). Determining whether this study was a pilot or feasibility trial, or both, is far more difficult. Despite calling our trial a pilot study, according for the NIHR definitions (Williams, 2016), I believe this study would be better characterised as a feasibility RCT. There were several aspects of the study that we could not be confident in remaining unchanged if we were to progress to a main trial. For example, the intervention itself was developed as part of this thesis, and this was the first time of trialling it, meaning that questions of recruitment, retention and acceptability were without answers. It was possible that participants may have found the intervention to be unhelpful (e.g. symptoms worsening) or non-engaging (e.g. high dropout). If this had occurred the research team would have needed to make some significant changes to the intervention protocol before further feasibility testing. For example, we could not be confident that potential participants would be willing to be involved in an intervention that required an element of self-help. As discussed in chapter eight, there were some concerns that people distressed by hearing voices may not have the necessary motivation to engage in guided self-help CBTv. Again, if this had been the case then significant changes to the research study would have been required. Overall, it is because we were unable to state with confidence, prior to the commencement of this study that the study and therapy protocols would remain unchanged for a definitive RCT that this study needed to address feasibility questions, prior to pilot testing

However, this re-evaluation of our RCT design highlights a significant issue in the field of research methodology. There is a need for consensus between research councils and methodologists concerning the definition, aims, and appropriate types of analysis for pilot and feasibility studies. Alternatively, as suggested previously, it may be more fruitful to replace this

terminology with the ‘phased’ framework developed by the Medical Research Council (MRC) (1998).

### ***11.1.3 The Transdiagnostic Approach:***

All of the participants involved in these research studies who heard voices (chapters 8, 9 and 10) were recruited irrespective of their psychiatric diagnosis. In total, 61.9% and 46.4% of participants had a psychosis diagnosis in the focus group study (chapter 8) and pilot RCT (chapters 9 and 10) respectively. This transdiagnostic approach was a response to studies that have found no clear or consistent differences in the experience of hearing voices between those with and without a psychosis diagnosis (e.g. Dorahy et al., 2009; Hepworth, Ashcroft, & Kingdon, 2013; Toh, Thomas, & Rossell, 2015; Varghese et al., 2011; Waters et al., 2012). However, these studies were generally vulnerable to Type II error as a result of small sample sizes (see chapter 1). Similarly, we were unable to assess the impact of diagnosis on treatment outcomes in the pilot RCT, or the themes derived in the focus group study due to small within-group sample sizes.

There is an urgent need to empirically establish whether the experience of voices is similar across psychiatric diagnoses (Waters et al., 2014). To ensure that this research has clinical implications, it may be most impactful to replicate Chadwick and Birchwood's (1994) validation of the CBTv model, with the added moderator of diagnosis. The results of these studies will establish whether the CBTv model is applicable to those who hear voices without a psychosis diagnosis, and whether this group are likely to find benefit from an intervention based on this model. Most importantly, any transdiagnostic study of voices needs to address the flaws of previous research by recruiting samples large enough to detect small between-group differences. This becomes somewhat impractical when you consider how common voice-hearing is across a range of psychiatric diagnoses (Pierre, 2010) – and then how many participants would be needed so that each non-psychosis diagnostic category had sufficient power. In the first instance, it is perhaps most pertinent to investigate whether the CBTv model applies to people who hear distressing voices in the context of a borderline personality disorder (BPD) diagnosis, as there is considerable scepticism as to the validity of this experience (Adams & Sanders, 2011; Berrios & Denning, 1996; Yee et al., 2005), as well as an elevated risk of suicide and self-harm (Slotema et al., 2016).

Although more research is needed into the nature of voices from a transdiagnostic perspective, the literature is yet to identify how voices interact with other mental health symptoms. Hearing voices could be an externalised form of another mental health symptom that is more closely associated with the person's diagnosis. For example, in the context of PTSD, hearing voices could be an auditory ‘flashback’ or intrusive memory (Morrison, Frame,

& Larkin, 2003). In this instance, the distressing voices could be better ‘treated’ using traditional PTSD interventions rather than psychological interventions for voices. To answer this question, measures of voice-related distress could be added as secondary outcomes in trials of psychological interventions other than CBTv with patients who hear voices outside the context of psychosis. If patients report little to no benefit on this outcome post-therapy then this will support the need for further research into the effectiveness of CBTv for people distressed by voices without psychosis.

Conversely, it may be possible that CBTv could improve the other mental health symptoms that are more closely associated with the person’s diagnosis e.g. reduce self-harm or improve emotional stability in those with BPD. Again, to answer this question would require trials of CBTv with a transdiagnostic population that include diagnosis-related outcome measures. Moving forward, there is a more pressing need to ask patients who hear distressing voices without a psychosis diagnosis what their treatment priority would be. Although voices may be distressing, they may not be the person’s primary source of distress. In this instance, and in line with broader CBT principles, psychological interventions should be offered to support people achieve their personal goals – whether these be related to voices or not.

#### ***11.1.4 Addressing the Issue of Access:***

As mentioned previously, the long term aim of this research programme is to increase access to psychological therapies for people who hear distressing voices. But, at this point in time, we cannot be sure that implementing guided self-help CBTv in clinical practice will achieve this aim. The primary and secondary outcome measures included in the trial were geared towards estimating effectiveness and assessing feasibility, not uptake and implementation. By cutting the contact time needed to deliver CBT to this client group in half, it is likely that guided self-help CBTv is more feasible to implement than the NICE (2014) recommended form of CBTp. However, reducing the duration of therapy may not be enough to substantially improve access. This is reflected in our consultations with mental health practitioners who still reported concerns as to the feasibility of implementing and delivering a brief, guided self-help CBTv intervention. In the pilot RCT, the intervention was delivered by Clinical Psychologists, with extensive training in how to deliver CBTp. Clinical Psychologists make up only a small proportion of the clinical mental health workforce (Page & Stritzke, 2015). It is possible, that even if all of the Clinical Psychologists working within the NHS were delivering guided self-help CBTv, that demand would still outweigh supply. Therefore, to truly address the issue of access a larger workforce may need to be trained to deliver this intervention.

One option is to train frontline mental health practitioners, who make up the majority of the workforce (Health Education England, 2016), in how to deliver guided self-help CBTv. There is some evidence that frontline mental health practitioners can deliver CBT-based interventions to people with psychosis symptoms (Guo et al., 2017; Turkington et al., 2014; Waller, Garety, Jolley, Fornells-Ambrojo, Kuipers, Onwumere, Woodall, Emsley, et al., 2013). Significant pre-post improvements have been found on measures of depression, delusions, negative symptoms, and levels of activity (Waller, Garety, Jolley, Fornells-Ambrojo, Kuipers, Onwumere, Woodall, Emsley, et al., 2013) – but these results are unable to control for spontaneous recovery over time. Significant between-group improvements were found on insight, depression and functioning – but these effects were not present at all time points, and all types of analysis (i.e. either per-protocol or intention to treat) (Guo et al., 2017). The study by Turkington et al. (2014) did not find any significant pre-post effects. Although there seem to be no issues with risk, the evidence for the effectiveness of CBTp delivered by frontline mental health practitioners is somewhat unconvincing and inconsistent.

The notion of frontline mental health practitioners delivering guided self-help CBTv becomes even less appealing when we consider its feasibility. All of the organisational barriers that we know prevent therapists from delivering CBTp (Ince et al., 2015), are also likely to be an issue for these clinicians. Frontline mental health clinicians will have to balance the demands of their other clinical work with delivering therapy (Jolley et al., 2012; Waller, Garety, Jolley, Fornells-Ambrojo, Kuipers, Onwumere, Woodall, & Craig, 2013). Moreover, working within a medically-orientated mental health service is unlikely to provide a working environment that encourages clinicians to prioritise therapy delivery (Berry & Haddock, 2008). This alignment with the medical model may also make it difficult for mental health practitioners to work psychologically and therefore deliver CBT (Jolley et al., 2012). Perhaps an alternative workforce needs to be identified.

Psychological Wellbeing Practitioners (PWPs) are employed within Increasing Access to Psychological Therapies (IAPT) services to deliver low intensity CBT to people with so-called common mental health problems (i.e. anxiety and depression) (Clark, 2011). PWPs are trained on the principles of CBT, and their application to depression and anxiety using CBT self-resources. One possible innovation to address this issue of access is to replicate the IAPT model within secondary care, and train PWPs to deliver guided CBT to people with psychosis. PWPs have a good understanding of CBT, and cost mental health services less to employ compared to Clinical Psychologists/High Intensity Therapists. Instead of frontline mental health practitioners, perhaps PWPs could be a viable workforce to deliver guided self-help CBTv, and increase therapy access. The initial IAPT pilot site for psychosis was not able to offer any low intensity therapies because of an absence of evidence (Jolley et al., 2015). There



is a real need for research to explore the efficacy of PWP-delivered low intensity CBT for psychosis symptoms, such as guided self-help CBTv.

Guided self-help CBTv delivered by non-expert therapists may help to increase access. But prior to conducting this research we will need to consider the concerns that both clinicians and people distressed by voices have in relation to this. The results of the consultations with both clinicians and people who hear voices both highlighted a common belief that this intervention would only be effective in the hands of an expert therapist. Treatment outcome expectancies, on the part of both clinicians (Berry & Greenwood, 2015; Byrne et al., 2008) and patients (Westra, Dozois, & Marcus, 2007), can act as a self-fulfilling prophecy. That is, if they believe the intervention is unlikely to help then the patient is unlikely to experience any significant benefit. Therefore, there may be a need to establish the credibility of the non-expert therapists before the commencement of therapy.

Once an appropriate workforce has been identified, and the evidence suggests they can effectively and feasibly deliver guided self-help CBTv, we need to consider what outcome measures can capture any improvements in access. These implementation-based outcome measures have largely been neglected in the wider CBTp literature. This has led to the current impasse in mental health services, whereby all of the NICE (2014) recommended psychological interventions are impractical to deliver in the current health economic climate (Ince et al., 2015; Roberts, 2015). Including audits of uptake pre- and post-implementation as part of a cluster RCT would give an objective assessment of changes to implementation rates. Mental health sites would be randomised to either receive training in how to deliver guided self-help CBTv or not. Using the uptake audits, we would then test the hypothesis that the site who received the guided self-help CBTv training would have offered and delivered therapy to more patients distressed by hearing voices than the site that did not have the training. These audits would also need to be conducted at follow-up time points to establish whether the implementation of guided self-help CBTv can be maintained.

#### ***11.1.5 The Long-Term Effects of Guided Self-Help CBTv:***

Although the results from the pilot RCT are promising, we do not know if any of these benefits were maintained because (for practical reasons) we were unable to collect follow-up data. To our knowledge, there are no other trials of guided self-help CBT for people distressed by hearing voices. Without this previous research, it is difficult to make any firm predictions as to whether any effects will persist past the end of therapy. RCTs of guided self-help CBT for common mental health problems (anxiety and depression) have found significant and sustained benefits on key clinical outcomes (Bailer et al., 2004; Furmark et al., 2009) – but the generalisability of these findings to people distressed by hearing voices is questionable.

Participants in the pilot RCT were encouraged to continue using their self-help materials after therapy had ended. If participants followed this advice we would hope that any gains made would be largely maintained but this question requires addressing in our next trial.

Future trials of guided self-help CBTv will hopefully be sufficiently resourced to assess whether any benefits are maintained after the end of therapy, and whether this effect is moderated by whether participants continue to use their self-help materials. Follow-up assessments would also provide a timeline with which to assess the economic impact of guided self-help CBTv. For CBTp more broadly, the evidence suggests that although there are increased treatment costs associated with delivering CBTp (approximately £1184 per patient), this is returned via a reduction in inpatient service use (equal to £2277). Per patient, the overall saving is estimated to be £989 (Andrew, Knapp, Mccrone, Parsonage, & Trachtenberg, 2012). Mental health services have limited funding (Roberts, 2015), making it difficult for new services to be commissioned. Therefore, it is important for guided self-help CBTv to not only be clinically effective, but also cost-effective for health services (e.g. reduce the number of hospital days). Owing to its brevity, guided self-help CBTv will cost less to deliver compared to CBTp – this cost could be reduced even further if future studies evidence this intervention can be effectively delivered by less-qualified practitioners (e.g. PWP). If the results of a non-inferiority RCT comparing CBTp to guided self-help CBTv found the clinical effects were equivalent, then this can only increase the attractiveness of guided self-help CBTv to health service commissioners.

The need for these effects to remain at follow-up time points is based largely on the assumption that guided self-help CBTv is a standalone intervention. But perhaps this intervention is better placed within a broader therapy package. That is, guided self-help CBTv could produce initial gains that need to be reinforced or boosted by further intervention. One option is to situate guided self-help CBTv as a therapy module within a high intensity therapy programme. The Feeling Safe Programme for persecutory delusions (Freeman et al., 2016) is an example of this: brief CBT-based interventions for sleep (Freeman, Waite, Startup, Myers, Lister, McInerney, Harvey, et al., 2015a), worry (Freeman, Dunn, Startup, Pugh, Cordwell, Mander, Černis, et al., 2015) and self-confidence (Freeman et al., 2014) are combined to create a therapy package that will hopefully produce long-lasting benefits for patients. However, this approach is unlikely to improve access to psychological therapies because of the prolonged duration of therapy and its delivery by expert therapists. Alternatively, guided self-help CBTv could be offered as part of a stepped care model – whereby briefer interventions are offered first, with the higher intensity therapies being offered only to those still in distress (Clark et al., 2009). We know from IAPT services for common mental health problems that stepped care can increase access (Improving Access to Psychological Therapies (IAPT), 2012), but more

research is needed to establish where, if at all, guided self-help CBTv is best situated in clinical practice.

#### ***11.1.6 The Placebo Effect:***

The pilot RCT used a wait-list control group, instead of an active control, meaning we are unable to rule out the possibility that the results of the pilot RCT reflect a placebo effect. Some researchers believe any improvements reported by patients post-CBT are more likely a product of non-specific therapy effects rather than the CBT model (Lambert, 2005). Non-specific effects are any components of the therapy that are not theory driven e.g. the therapist's compassion and kindness, or giving the patient space to talk (Messer & Wampold, 2006). This assertion is based on evidence that most of the clinical benefit acquired during therapy, is attained within the first few sessions, before any of the cognitive techniques have been introduced (Ilardi & Craighead, 1994, 1999). This critique of CBT is less relevant to guided self-help CBTv as, due to the brevity of the intervention, cognitive-behavioural principles are introduced from the first session. But this does not rule out the possibility that similar effects could have been achieved without the CBT components. Although using an active control group may have addressed this limitation, using a treatment-as-usual (TAU) control group is commonplace for the initial study of a novel intervention, and has advantages when assessing feasibility (Relton, Torgerson, O'Cathain, & Nicholl, 2010).

Subsequent studies of guided self-help CBTv should use an active control, but selecting the control intervention depends on what aspects of the study need to be controlled for. One option is to make the duration of therapy as the independent variable, as part of a non-inferiority RCT. Guided self-help CBTv would then be compared to the current gold standard intervention available in the field – in this case it would be at least 16 sessions of NICE (2014) recommended CBTp. Alternatively, the independent variable could be the content of therapy. In this instance, guided self-help CBTv would be compared to another psychological intervention that does not target the CBTv model (Chadwick & Birchwood, 1994) mechanisms as part of an RCT i.e. a non-specific psychological therapy. Both of the active controls suggested here should control for the placebo effect.

After consideration of the current needs of mental health services, perhaps option one (the non-inferiority trial) would be the most clinically useful study. With the extensive past research verifying the CBTv model (both experimentally and in a therapeutic context) (Beck-Sander, Birchwood, & Chadwick, 1997; Birchwood & Chadwick, 1997; Birchwood et al., 2014; Chadwick & Birchwood, 1994, 1995; Chadwick, Lees, & Birchwood, 2000; Chadwick, Sambrooke, Rasch, & Davies, 2000; Close & Garety, 1998; Hacker, Birchwood, Tudway, Meaden, & Amphlett, 2008), we could be relatively confident that an intervention based on the

CBTv model would be more effective at reducing voice-related distress compared to a non-specific psychological intervention. Whereas, the effect of therapy duration on treatment outcomes for people with psychosis has received far less research attention.

## **11.2 Strengths:**

There are a number of strengths with the research outlined in this thesis.

### ***11.2.1 Increasing Access to CBTp:***

One strength of this thesis is that it aims to address a ‘real world’ problem. Just under half of the participants recruited to the pilot RCT had a psychosis diagnosis. People with psychosis have very few treatment options made available to them, with most receiving an entirely pharmacological treatment package (Schizophrenia Commission, 2012). This is problematic when we consider medication is not helpful for everyone experiencing psychosis (Valmaggia, van der Gaag, Tarrier, Pijnenborg, & Slooff, 2005), and many do not adhere because of the unpleasant side effects (Lambert et al., 2004). Although there is much evidence in support of CBT for psychosis (CBTp) (Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012; Jauhar et al., 2014; Pilling et al., 2002; Wykes et al., 2007; Zimmermann et al., 2005), far less consideration has been given to how these interventions can be implemented into cash-strapped mental health services (Roberts, 2015). By contrast, guided self-help CBTv was designed with pragmatics in mind. By reducing the number of sessions used to deliver this intervention (8 sessions, compared to the minimum 16 sessions recommended by NICE (2014), at least double the number of patients can receive therapy using the same amount of resource. Although we hope guided self-help CBTv will improve access rates, the actual impact on effectiveness and accessibility is still to be determined.

### ***11.2.2 Methodological Rigour:***

A second strength of this thesis is the effort to ensure each study was of high methodological quality. Each study was first designed and outlined in a research protocol. The study procedures were standardised (i.e. kept the same), and analysis plans were developed a priori. For example, the literature search for the meta-analysis (chapter 6) was systematic and followed PRISMA guidelines; and each of the focus groups conducted with people who hear voices (chapter 8) was guided by the same discussion guide. Each protocol was independently peer-reviewed during the ethics submission process. To evaluate the potential of guided self-help CBTv we used a (pilot) randomised controlled design (RCT), which is ranked as the highest quality study design to explore the effectiveness of an intervention by NICE (2006) and Cochrane (2016). For the pilot RCT, assessments were conducted by a member of the research team who was blind to the participants’ group allocation – a key indicator of trial quality (Jadad

et al., 1996). As discussed in chapter 5, efforts were made to minimise bias for all studies in accordance with the Cochrane Risk of Bias Tool (Higgins & Green, 2011). These methodological decisions were made to reduce potential bias. The consequence of this is that we can be more confident in attributing our findings to the study manipulation, rather than any extraneous variables.

### ***11.2.3 Stakeholder Involvement:***

Another strength is that the relevant stakeholders have had a high level of involvement in all aspects of this thesis. Specifically, people who hear voices, local Hearing Voices Network support groups, and practicing mental health clinicians have helped to ensure each research question is relevant, and the study design is sensitive to the needs of each group. Public and patient involvement (PPI) in research can provide a new perspective that can give insight into how participants may perceive the study (Crawford et al., 2002). Both people who hear voices and mental health practitioners were instrumental in developing the therapy protocol for guided self-help CBTv (Hazell, Hayward, Cavanagh, Jones, et al., 2016): (1) the lived experience focus groups were responsible for the development of an accompanied workbook, and the order of the therapy modules; and (2) the mental health practitioners helped identify what outcome measures were important to include, and the potential barriers to engagement that we could then troubleshoot. The input from these stakeholders has been invaluable.

### ***11.2.4 Programmatic Research:***

A further strength of this thesis is that the programme of research will not end with the completion of this thesis. This PhD will be an important first step to addressing the issue of access. The research team is currently planning the next step in this research programme.

## **11.3 Theoretical Implications:**

The first session of guided self-help CBTv was designed to be a condensed form of coping strategy enhancement (CSE), based on a functional analytic approach to voice hearing (Tarrier et al., 1993; Tarrier et al., 1990). The aim of this session, and CSE, is to encourage the patient to explore strategies they find more or less helpful in managing their distressing voices. CSE is typically delivered over 10 sessions, compared to just the one session offered here. To evaluate the effectiveness of this first session we collected data on patient's perception of their ability to cope with voices using visual analogue scale (VAS) – but this data is yet to be analysed. It is hoped this one session was sufficient to improve coping with voices; but it is possible that this one session was ineffective. This same criticism could also be directed at the other therapy modules, as each is a condensed form of a longer-term intervention. But both the mechanism and clinical outcome data suggest we were able to target the hypothesised constructs associated

with the ‘Me’, ‘My Voices’, and, to a lesser extent, the ‘My Relationships’ module. Although this first session of guided self-help CBTv might not produce effects that are equivalent to the full course of CSE (pre-post  $d=1.27$ ; Tarrier et al., 1993), it may serve to engage patients in the therapy. Session one is the first time that the patient will meet their therapist. This first session on coping may provide an opportunity for the patient to become comfortable with their therapist and talking about their voices.

There are several constructs theoretically associated with voice-related distress. These constructs have been operationalised as therapeutic targets, and were used to structure guided self-help CBTv into three core modules: (1) Me – targeting beliefs about the self, (2) My Voices – targeting beliefs about voices, and (3) My Relationships – targeting relating patterns. Firstly, patients were invited to evaluate the accuracy of a negative belief about themselves and strengthen more positive ones, because studies have found people who hear distressing voices tend to have strong negative beliefs about themselves, and very few positive ones (Fielding-Smith et al., 2015b). Secondly, patients were invited to question the unhelpful beliefs that they have about their voices, in line with the CBT model of distressing voices (Chadwick & Birchwood, 1994). People who are distressed by hearing voices tend to believe their voice is omnipotent (all powerful), omniscient (all knowing), and malevolent (Chadwick & Birchwood, 1995). Finally, patients were invited to consider more assertive ways of relating in the context of a negative relationship they have with either another person or their voice. This module was included as a result of the association between negative relating and voice-related distress (Hayward, 2003; Sorrell, Hayward, & Meddings, 2010). In addition to a reduction in voice-related distress, we also found a reduction on all of the aforementioned therapeutic targets in the pilot RCT. It is therefore likely that our results provide support for the cognitive model of voices, and this mechanistic approach to CBTv. However, some of these effects were much larger than others (i.e. a large improvement on voice-related omnipotence beliefs, and only a small effect on negative relating), and we did not have sufficient statistical power to confirm whether these mechanisms explained the changes in voice-related distress. Consequently, future studies of guided self-help CBTv should include mediation analysis to test the role of these proposed CBTv mechanisms.

The promising results found across a wide range of clinical outcomes in the pilot RCT of guided self-help CBTv provides tentative support for the symptom specific approach: that is, psychological therapies can be effective when designed to target a single symptom rather than a broader diagnostic label (Bentall et al., 1988). However, as the pilot was not adequately powered, a definitive trial is needed to determine whether guided self-help CBTv is effective and therefore supports the symptom-specific approach. If the definitive trial results also find guided self-help CBTv to be effective with large effects, then this could have implications for

the way CBT is currently practiced. Traditionally, CBT begins with an individualised collaborative formulation and assessment, with time set aside to build the therapeutic alliance (Beck & Haigh, 2014). In guided self-help CBTv the patient is provided with a formulation template to formulate their (unique) experiences (Chadwick & Birchwood, 1994), and the therapeutic relationship is developed as the therapy progresses. Perhaps, by adopting a symptom specific approach, the therapist is given license to forsake these non-specific elements of therapy in exchange for directly addressing the presenting problem. The low therapy dropout rates and high patient satisfaction scores suggest that this more direct approach is acceptable to patients. As mentioned previously, a definitive trial is now needed to establish whether guided self-help CBTv is effective, and can add to the body of evidence in favour of the symptom specific approach.

The effect sizes on the relating outcome measures, both social and voice relating, were all in favour of guided self-help CBTv, but were more modest in size (small to medium effects) and all the 95% confidence intervals crossed zero, compared to the other therapy mechanisms that tended to be larger with 95% confidence intervals that largely did not cross zero. A possible explanation for this difference on relating outcomes is that perhaps more than two therapy sessions are required to significantly improve negative relating. Relating therapy is typically delivered over 16 sessions with a Clinical Psychologist (Hayward, Strauss, & Bogen-Johnston, 2014). When delivered in this format, a recent pilot RCT suggested that relating therapy can produce large, significant effects on voice-related distress, and relating variables (Hayward, Jones, Bogen-Johnston, Thomas, & Strauss, 2016). Offering more therapy sessions therefore to cover the relating principles in more depth may increase the relating effect sizes, but it would also increase the duration of therapy. The potential benefit that could be garnered from increasing the duration of the relating module does not appear to outweigh the pragmatic benefits of guided self-help CBTv being so brief. On the other hand, a case could be made for dropping the relating module. However, we would need to clarify what effect this would have on the primary outcome, as well as measures of both beliefs about voices and relating outcomes. The relating module may have contributed to the large reduction on omnipotence beliefs about voices for instance – by believing the voice is/is not powerful this creates a relational dyad (i.e. where one agent is powerful and the other is submissive). Therefore, learning to be more assertive may reduce the belief that voice/s are more powerful. To clarify this, we would need to compare the effects of guided self-help CBTv with and without the relating module.

#### **11.4 Clinical Implications:**

The clinical implications of this thesis are somewhat limited at present because the aims of the RCT were to estimate effectiveness and assess feasibility in preparation for a definitive

trial. But what has emerged from the pilot RCT is that using self-help materials with patients distressed by hearing voices, irrespective of diagnosis, appears to be safe (no related adverse events), and acceptable (low dropout rates, and high patient satisfaction). The more modest clinical impact of this thesis is that the 28 participants who took part in the pilot RCT had the opportunity to receive a psychological intervention that they would not have done so otherwise. This research programme may have further clinical implications in the future, but more research is needed first.

More broadly, the findings from this thesis suggest that clinicians, and patients themselves, may be underestimating what people distressed by hearing voices are capable of. The results from our consultations with both parties revealed a number of anticipated barriers to engagement with guided self-help CBTv. For example, both clinicians and the lived experience group reported concerns that people distressed by hearing voices do not have the cognitive skills or motivation to engage with self-help materials. We did not collect any quantitative data on patient engagement with the self-help materials. While other studies have also found self-help materials to be helpful for people with psychosis symptoms, again little is known about levels of engagement (Scott, Webb, & Rowse, 2015). However, looking at the outcomes of the pilot RCT, it appears that barriers clinicians and patients predicted were either not realised, or that if they were, they did not prevent participants from finding benefit from the therapy.

Considering these barriers to engagement further, the lived experience consultants may have been pessimistic about their ability to engage in this intervention because of the common co-occurrence of a negative self-concept and hearing distressing voices (Fielding-Smith et al., 2015). These negative beliefs about the self are targeted at the start of guided self-help CBTv within the 'Me' module: negative beliefs about the self are identified and challenged, and alternative, more positive beliefs are strengthened. This part of the intervention could have indirectly improved engagement by improving the participants' self-concept.

The barriers to engagement put forward by mental health practitioners are in line with previous research. Clinicians can be sceptical about the value and appropriateness of psychological therapies for people experiencing psychosis symptoms (Caldwell & Jorm, 2001; Coffey & Hewitt, 2008; Prytys et al., 2011). If these beliefs are founded, then they may serve a protective function by preventing their client from a potentially damaging experience of failure when they receive an intervention that is unlikely to be helpful. However, the results from this thesis, and other trials of CBTv (Van der Gaag et al., 2014), suggest that this scepticism is unjustified. This could lead to patients being denied potentially beneficial treatments, as clinicians do not make the necessary referrals. In the same way that unhelpful beliefs can be challenged within CBT through confronting more and more evidence that contradicts the belief



(Beck, 1976), hopefully through the publication of more studies, like our pilot RCT, clinicians will become more open to the idea that psychological therapies can be beneficial for people who hear distressing voices.

### **11.5 Priorities:**

The results from this thesis warrant continued investigation. As the aim of each study was largely related to assessing feasibility, the logical next step is to assess the effectiveness of guided self-help CBTv using an RCT that has sufficient power to detect statistically significant differences. In line with intervention development recommendations (Craig et al., 2008), this larger, effectiveness trial should ideally replicate the study design of the pilot trial. However, as discussed previously, guided self-help CBTv is unlikely to significantly improve access if it can only be delivered by accredited therapists. Funding for CBT-related research is difficult to secure at present. It is therefore all the more important to ensure any research in this area can answer the questions that are most pertinent and useful to mental health services. Consequently, it may be more impactful if the next step in this research program is actually to explore the effectiveness of guided self-help CBTv when delivered by non-accredited therapists who may be more widely available, and more cost-effective, compared to an active control. In addition to clinical outcomes, measures of cost effectiveness and access should be included.

Moreover, in contrast to the pilot RCT, it seems most appropriate to continue this research programme with people who hear voices in the context of a psychosis diagnosis. Guided self-help CBTv may be effective for people who hear distressing voices in the context of other mental health problems. But there is still so much to learn about the nature and impact of this experience. As discussed earlier, we need to ascertain whether voices are a treatment priority for people without a psychosis diagnosis, and then investigate how similar voices are across diagnoses. More foundation work is needed before we can consider a transdiagnostic definitive trial of CBTv for people distressed by voices.

#### **11.5.1 Current Plans:**

We have already begun to take this next step. We are currently developing a grant application to evaluate the effectiveness of guided self-help CBTv delivered by non-therapists in an internal pilot RCT. Evaluating this idea on a small scale initially is more ethical than going straight to a large RCT, as we cannot guarantee that the intervention will be effective (Lenth, 2001). We plan to monitor for any adverse events, observe any changes in symptoms, and evaluate both the clinician and patient experience. The outcome of this trial will determine what the next research priority should be.

## **11.6 Conclusion:**

Guided self-help CBTv has been developed not only for, but with, people who hear distressing voices. From the outset, we have been mindful to develop an intervention that is not only effective at reducing voice-related distress, but is also feasible to implement into mental health services. The results of the guided self-help CBTv development studies, and the pilot RCT, demonstrate the promise and support for this intervention. This thesis is the first step in a wider research programme. The next step is already underway with the development of a grant application for an internal pilot of guided self-help CBTv delivered by non-therapists. If funded, the findings from this project will indicate whether guided self-help CBTv can be effectively, and practically, delivered by these practitioners; as well as raising awareness of the issue of access, and the current capacity of mental health services. This programme of research will continue to give equal priority to effectiveness and pragmatics.

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## 13 Appendix.

### 13.1 Equations used in chapter 6.

*Equation One*

$$d = \frac{M_t - M_c}{S_{pooled}}$$

*Equation Two*

$$S_{pooled} = \sqrt{\frac{s_1^2(n_1 - 1) + s_2^2(n_2 - 1)}{n_1 + n_2 - 2}}$$

*Equation Three*

$$w = \frac{1}{v}$$

Where:

$$v = \frac{n_1 + n_2}{n_1 n_2} + \frac{d^2}{2(n_1 + n_2)}$$

### 13.2 Supplementary material for chapter 6.

Moderator	<i>N</i>	<i>n</i>	<i>d</i>	<i>b</i>	95% Confidence Intervals for <i>b</i>		$\beta$	<i>z</i>	<i>p</i>	<i>R</i> <sup>2</sup> (%)
Contact hours	9	300	-0.23	0.02	-0.02	0.07	0.17	1.00	.32	2.92
Number of sessions	9	300	-0.23	0.04	-0.01	0.06	0.25	1.45	.15	6.19

Table I. Meta-analysis regression analogue using post-intervention between-group effect sizes on psychosis symptom outcomes, with therapist contact hours and number of sessions as predictors.

*Note:* A negative effect size favors low intensity CBTp over the control condition. *N* = number of studies; *n* = number of participants; *d* = Cohen's *d* effect size; *z* = *z* score; *p* = exact *p* value. \*  $p < .05$ , \*\* $p < .01$ , \*\*\* $p < .001$ .

Format	<i>N</i>	<i>n</i>	Between Group Q	<i>d</i>	95% Confidence Interval for <i>d</i>		Within Group Q	<i>z</i>	<i>p</i>
			0.01						.93
Individual	4	205		-0.23	-0.42	-0.03	6.58	-2.29*	.02
Group	5	95		-0.24	-0.54	0.06	27.41***	-1.58	.11

Table II. Meta-analysis ANOVA analogue on post-intervention between-group effect sizes on psychosis symptom outcomes, comparing low intensity CBTp when delivered in group and individual formats.

*Note:* A negative effect size favors low intensity CBTp over the control condition. *N* = number of studies; *n* = number of participants; *d* = Cohen's *d* effect size; *z* = *z* score; *p* = exact *p* value. \*  $p < .05$ , \*\* $p < .01$ , \*\*\* $p < .001$ .

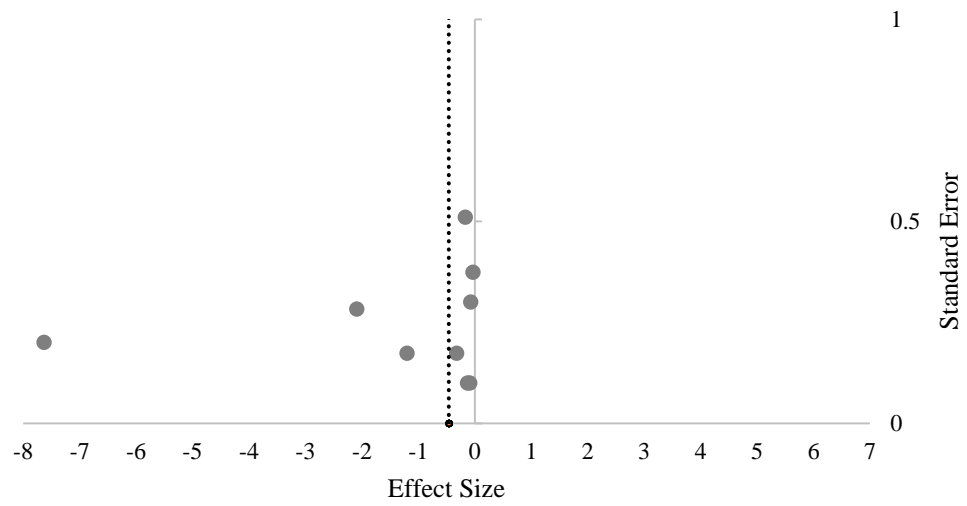


Figure I. Funnel plot of the post-intervention between-group effect sizes for psychosis symptom outcomes.

*Note:* the trend line reflects the mean effect size.



### 13.3 Research Ethics Committee (REC) approval for chapters 7 and 8.



University of Sussex

Certificate of Approval	
<b>Reference Number:</b>	ER/CH283/4
<b>Title Of Project:</b>	Staff Survey: Attitudes towards guided self-help CBT for distressing voices
<b>Principal Investigator (PI):</b>	Clara Strauss
<b>Student:</b>	Cassie Hazell
<b>Collaborators:</b>	
<b>Duration Of Approval:</b>	6 months
<b>Expected Start Date:</b>	09-Feb-2014
<b>Date Of Approval:</b>	29-Mar-2014
<b>Approval Expiry Date:</b>	01-Oct-2014
<b>Approved By:</b>	Richard de Visser
<b>Name of Authorised Signatory:</b>	Richard de Visser
<b>Date:</b>	29-Mar-2014

\*NB. If the actual project start date is delayed beyond 12 months of the expected start date, this Certificate of Approval will lapse and the project will need to be reviewed again to take account of changed circumstances such as legislation, sponsor requirements and University procedures.

**Please note and follow the requirements for approved submissions:**

Amendments to protocol

- \* Any changes or amendments to approved protocols must be submitted to the C-REC for authorisation prior to implementation.

Feedback regarding the status and conduct of approved projects

- \* Any incidents with ethical implications that occur during the implementation of the project must be reported immediately to the Chair of the C-REC.

Feedback regarding any adverse and unexpected events

- \* Any adverse (undesirable and unintended) and unexpected events that occur during the implementation of the project must be reported to the Chair of the Social Sciences C-REC. In the event of a serious adverse event, research must be stopped immediately and the Chair alerted within 24 hours of the occurrence.

For Life Sciences and Psychology projects

- \* The principal investigator is required to provide a brief annual written statement to the committee, indicating the status and conduct of the approved project. These reports will be reviewed at the annual meeting of the committee. A statement by the PI to the C-REC indicating the status and conduct of the approved project will be required on the Approval Expiration Date as stated above.

### 13.4 Normalisation Process Theory Questionnaire used in chapter 7.

Select the answer that best fits your opinion for each statement.

1	2	3	4	5	6	7
Strongly Agree	Agree	Somewhat Agree	Neither Agree nor Disagree	Somewhat Disagree	Disagree	Strongly Disagree

A	Randomized controlled trials e.g. comparing the treatment to a control group, is a good way to evaluate the effectiveness of guided self-help CBT for distressing voices	1	2	3	4	5	6	7
B	Guided self help CBT for distressing voices is an appropriate treatment option	1	2	3	4	5	6	7
C	Qualitative measures e.g. interviews after the intervention, are a good way to evaluate the effectiveness of guided self help CBT for distressing voices	1	2	3	4	5	6	7
D	Guided self help CBT for distressing voices would be effective for those with long standing symptoms	1	2	3	4	5	6	7
E	I would be willing to be involved in the development of guided self help CBT for those with distressing voices	1	2	3	4	5	6	7
F	I would be willing to refer a client who hears distressing voices to receive guided self help CBT as part of a research project	1	2	3	4	5	6	7
G	I would be happy to refer a client who hears distressing voices to receive guided self help CBT	1	2	3	4	5	6	7
H	It is a waste of resources to trial guided self help CBT for those who hear distressing voices	1	2	3	4	5	6	7
I	I would be willing to be involved in research that is trialing guided self help CBT for distressing voices	1	2	3	4	5	6	7
J	Attending a separate supervision for those who deliver guided self help CBT for stressing voices would not be practical for me	1	2	3	4	5	6	7
K	Self help materials e.g. books, would be effective for those that hear distressing voices	1	2	3	4	5	6	7
L	People who hear distressing voices would not be able to engage in guided self help CBT	1	2	3	4	5	6	7

M	It is not possible to implement guided self help CBT, within existing mental health services	1	2	3	4	5	6	7
N	It would be possible to free up time to deliver guided self help CBT for distressing voices	1	2	3	4	5	6	7
O	It would be possible to find the time to attend a two day training course on how to deliver guided self help CBT for distressing voices	1	2	3	4	5	6	7
P	Majority of my clients who hear distressing voices would like to receive guided self help CBT	1	2	3	4	5	6	7
Q	I would not be prepared to receive training to deliver guided self help CBT for distressing voices	1	2	3	4	5	6	7
R	I would be willing to deliver guided self help CBT for distressing voices as part of my job	1	2	3	4	5	6	7
S	Measures of other clinical symptoms e.g. anxiety and depression, are a good way to evaluate the effectiveness of guided self help CBT for distressing voices	1	2	3	4	5	6	7
T	Measures of symptom severity e.g. psychosis measures, are a good way to evaluate the effectiveness of guided self help CBT for distressing voices	1	2	3	4	5	6	7

Select the answer that best fits your opinion for each statement.

1	2	3	4	5	6	7
Strongly Agree	Agree	Somewhat Agree	Neither Agree nor Disagree	Somewhat Disagree	Disagree	Strongly Disagree

A	Those who hear distressing voices should be able to receive the same treatment options as those with common mental health problems	1	2	3	4	5	6	7
B	CBT can be effective for those who hear distressing voices if it is delivered by a non-therapist e.g. psychological wellbeing practitioner	1	2	3	4	5	6	7
C	I believe my colleagues would be willing to be involved in trials for guided self-help CBT for distressing voices	1	2	3	4	5	6	7

D	It would be possible to identify clients that are suitable to receive guided self-help CBT for distressing voices	1	2	3	4	5	6	7
E	Measures of quality of life e.g. engagement in meaningful activity, are a good way to evaluate the effectiveness of guided self-help CBT for distressing voices	1	2	3	4	5	6	7
F	Research is a good method of testing a new intervention	1	2	3	4	5	6	7
G	The resources needed to trial guided self-help CBT for distressing voices are available	1	2	3	4	5	6	7
H	Having a client who hears distressing voices receiving guided self-help CBT would make my workload unmanageable	1	2	3	4	5	6	7
I	My team would be able to aid in the implementation of guided self-help CBT for distressing voices	1	2	3	4	5	6	7
J	I would be willing to attend a course on the therapeutic principles of guided self-help CBT for those who hear distressing voices	1	2	3	4	5	6	7
K	Measures of acceptability e.g. client satisfaction, is a good way to evaluate the effectiveness of guided self-help CBT for distressing voices	1	2	3	4	5	6	7
L	Being trained to deliver guided self-help CBT for distressing voices would make my job harder	1	2	3	4	5	6	7
M	Guided self-help CBT for distressing voices sounds like a good idea	1	2	3	4	5	6	7
N	Guided self-help CBT for those who hear distressing voices would be unsafe	1	2	3	4	5	6	7
O	Symptom specific treatment, like guided self-help CBT for distressing voices, are a good approach to treatment	1	2	3	4	5	6	7
P	Having 6-8 sessions of guided self-help CBT for those with distressing voices would be feasible to implement as a treatment option	1	2	3	4	5	6	7
Q	Following clients up after a period of several months to administer clinical measures is a good way to evaluate the effectiveness of guided self-help CBT for distressing voices	1	2	3	4	5	6	7
R	I would be willing to have training to be able to deliver guided self-help CBT for distressing voices	1	2	3	4	5	6	7
S	Guided self-help CBT for those who hear distressing voices will be very effective	1	2	3	4	5	6	7

T	Measures of the distress experience from hearing voices is a good way to evaluate the effectiveness of guided self-help CBT for distressing voices	1	2	3	4	5	6	7
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### 13.5 Research Ethics Committee (REC) approval for chapter 8.



## Health Research Authority

### NRES Committee South East Coast - Surrey

Bristol Research Ethics Committee Centre

Whitefriars

Level 3, Block B

Lewins Mead

Bristol

BS1 2NT

Telephone: 0117 342 1380

10 December 2014

Miss Cassie Hazell  
University of Sussex  
Falmer  
Pevensey 1  
1C1  
BN19QJ

Dear Miss Hazell

<b>Study title:</b>	<b>The customer is always right: Lived experience perspectives on guided self-help CBT for distressing voices.</b>
<b>REC reference:</b>	<b>14/LO/1880</b>
<b>IRAS project ID:</b>	<b>160459</b>

Thank you for your letter of 01 December 2014, 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 Acting 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 favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Miss Gemma Oakes, [nrescommittee.secoast-surrey@nhs.net](mailto:nrescommittee.secoast-surrey@nhs.net). Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

#### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

## 13.6 Supplementary material for chapter 8.

### Study 1:

#### *The Self-Help Book:*

It is perhaps unsurprising that as participants were given a copy of the ‘Overcoming Distressing Voices’ self-help book (Hayward, Strauss & Kingdon, 2012) that will form the basis of this intervention, that one of the themes extracted identifies the participants opinions on the book. All of the participants had read at least one chapter from the book before attending the focus group.

#### *Positive feedback:*

Most participants provided some positive feedback about the self-help book. One of the most prominent strengths of the book was the use of case studies to illustrate theories. Many of the participants felt that the case studies closely echoed their own experience of voices.

Jillian: ‘Yeah referring back to this [the book], um I think that I can relate to all of what’s in here um which is quite amazing reading it.’

Bobby: ‘It is really sort of um, it characterised my schizophrenia really down to a tee. And comments in there by Ruth and Martin [characters in the book] and their own personal experiences so I can relate to it. I haven’t actually read it all. I read it a couple of weeks ago. Um, no it’s good. It’s quite therapeutic.’

Being able to relate to the book helped both Jillian and Bobby to feel less alone. Both commented on how surprised they were to find such strong similarities between their experiences and that described in the book. The perceived ‘realness’ of the case studies appeared to increase confidence in the credibility of the book, and the advice it suggested. In addition to the case studies, the language used within the book encouraged the participants to read the book. The language used was perceived as accessible and easy to understand.

Sam: ‘Yeah it was easy for me to read. I thought the language, and it was quite compassionately written I think, quite kindly written.’

Jonathan: ‘I found while reading it. It’s just very easy to read. And it’s just, and it’s accessible. Some of the things like tables and diagrams I thought whoa I won’t be able to grasp it well and it was easy as well suppose. It’s easy to follow.’

Jonathan talks about feelings apprehensive about reading the book after scanning through the pages. The use of diagrams and tables he felt were initially off-putting but this apprehension soon dissipated after he began reading. Jonathan’s ability to understand the book

seemed to give him a sense of achievement, and could (regardless of the books content) have a therapeutic effect.

*Negative feedback:*

Although the feedback from participants was largely positive, there were a number of critical comments offered. Some of these ideas are in direct conflict with the positive comments discussed above.

Jonathan: 'I struggle to in bring my case into the literature. So I would really have to think and think and think so it's not as straight forward for me really. It's helped me to identify only to a certain degree really. So, yeah.'

Tim: 'It was very different from the experiences given. Um I couldn't, yeah. I could relate to them as separate people. But I couldn't fit my own experience into that category, into that category.'

Hearing voices and mental health more generally is a personal experience that can be influenced by many individual differences. The diverse nature of hearing voices meant that both Tim and Jonathan felt that the case studies did not present their experience. Arguably it is not possible to produce a brief and accessible case study that everyone who hear voices could relate to. However being able to have a personal connection with the self-help book seemed to be important to the participants. Consequently we must consider other means of personalising the self-help book that doesn't use case studies.

Related to this issue, is the criticism from some participants that the book (including the case studies) was too simplistic. In addition to being a personal experience, hearing voices can also be complex.

Joe: 'It takes a very basic level of um sort of voice hearing and it can be a lot more complex than that. I think the book, I think it's quite hard for any book to get one person's sort of view on voice hearing, their experiences.'

This criticism is at odds with the positive comments that praised the self-help book for being easy to understand. Increasing the book's complexity may help some people to identify with and relate to the material. However this is likely to exclude those that are unable to comprehend information at that level of complexity. The difference in opinion between these sub-themes shows how difficult it is to produce self-help materials that are suitable for everyone.

*Self-reflection:*



Reading the self-help book prompted some of the participants to review their own experience of hearing voices in light of what they were reading.

Sam: 'I think its gentle enough. I think it's, like, it's not difficult reading, it's not frightening reading. Well I didn't think. You know facing other people, seeing that other people go through similar experiences is very enlightening it makes you feel part of something – you're not on your own.'

Jonathan: 'I think the way it worked for me I started having some sort of intuitions, the voices saying this and that and it expanded, and it confirmed my suspicions. I have been in the services for quite a long while and not being able to talk really about voices and the book confirms my intuitions and that was the greatest thing really.'

Pippa: 'Yeah because mine is an outrage really of my inner creators and invasion of privacy, although it's all happening in my mind; and I have to say that other times I feel differently. So when I looked at the table [in the book] I was really able to say ok that's my situation and once you know what your situation is it's easier to address.'

The participants within this study were not instructed to try to treat themselves using the book – they were instructed to read the book with the view to consulting on a new intervention idea. Despite this, it seems that some of the participants engaged in some self-reflection as a result of reading the self-help book. This kind of self-evaluation is one of the key skills needed within CBT in order to identify and challenge unhelpful beliefs. It is promising of the future of this therapy that a number of the participants engaged in this process spontaneously.

### ***Therapy Protocol:***

In addition to reviewing the self-help book, the participant were asked to consider how it could be used within a guided self-help therapy. The participants picked out a number of topics that they felt were important should be discussed within the intervention. Each subtheme discussed here describes a topic that the participants identified.

#### ***Self:***

Although the self-help book has a primary aim of reducing the distress associated with hearing voices, participants talked about the self-esteem chapters of the book most often. Considering beliefs about the self and self-esteem was seen as important by all participants. The participants across all three focus groups agreed that the self should be discussed first within the intervention.

Tim: 'Self-esteem is important because if your self-esteem is really low then you're less likely to be able to challenge your voices because um I think you give them more power. You

see them as bigger than yourself um and you won't kind of be able to have enough self-esteem to even want to challenge them, you just go along with letting them beat you around.'

Nikki: 'We can have a day where we do 90% productive, a good day where we have just gone about our business and it's all been fine, but the 10% that I do that I feel like I can criticise myself for I will. So I will forget about the 90% that happened that actually I was loving and kind towards people and I was good with my family or whatever. I will forget up about that and I will beat myself up about the 10% all the time I will go no but you did that bit sh\*t just that little bit of the day and I think challenging that is really interesting and the core belief stuff is really interesting.'

The quote from Jimmy below creates a hierarchical image of recovery. This hierarchy prioritises the self before voices. He felt the need to create a strong core from which to challenge the voices that were identified as a product of the self. Jimmy's response suggests that it would not be possible to reduce the distress associated with voices until he has addressed and unhelpful beliefs about the self.

Jimmy: 'I agree that um beliefs about self should come first because that gives a sort of basis for everything else so um you can't um sort of um, when we are talking about voices you are obviously talking about the way you are reacting to those voices and so yeah it so you have got to talk about yourself first.'

#### *Voices:*

None of the participants discussed their voices in a positive light – all participants attributed negative emotions to the experience of hearing voices. Many of the participants appeared to understand the aim of CBTv is to reduce the distress associated with voices, and not reduce voice frequency. Many participants understood how this change could result in positive outcomes.

Jimmy: 'I think the challenging beliefs in the power that the voices have. You know when they are really loud and when they are really insistent I think that what they are saying is true and um and that they can make me do things that if I could challenge that in that moment then that would be you know that would completely change everything really.'

Jonathan: 'I think the voices themselves are not as bad as the thing they can do with you in terms of how you respond. I mean it could be self-neglect or some other things. I always think that if I only heard the voices then it would fine but it's the other problems like how I respond to them.'

In contrast to some participants views that the self-help book could be too narrow and simplistic, some of the participants liked the symptom-specific approach. For those participants who reported cognitive difficulties (see below), having a specific therapy aim helped to minimise distraction and increase transparency. Participants liked the idea of knowing what they would be asked to talk about within the intervention, and what aspects of their mental health they were trying to improve. Within a briefer form of therapy, like guided self-help CBTv, taking a symptom specific approach can ensure that the limited time is used most efficiently.

Tim: '[Therapy] felt a lot more useful if I know I'm there just to focus on a specific topic around voice hearing and not all the other things that might be going on for me.'

Jimmy: 'As Tim says it has just such a huge impact on your life because it's there all the time, and um yeah so I think it's [symptom specific approach] a really good idea.'

#### *Relationships:*

The self-help book looks at both the voices and the self within both a traditional CBT and relational framework. The relating approach was a new concept to most of the participants. Some of the participants agreed with the concept of a voice-hearer relationship. Even if it was not mentioned explicitly, many of the participants discussed their voices using relational language.

Pippa: 'This [the book] helps you, well it helped me, to realise that it takes a little work to regain your faith in other people and then in you. It's all down to the way you reply to them [voices], even verbally, so if you improve your relationship with your voices you will then improve your relationship with the outside world.'

Ed: 'Well one thing positive one thing [about the book] is having a relationship with them [voices] because it is a relationship. It's not going to suddenly go away so the whole denying it and stuff... so I think having a relationship with them, and maybe not talking to them, but giving them as you were saying some leeway like an actual amount of time for them to do what they want.'

Ed in particular connected with the idea of having a relationship with his voices. Having this relational understanding resulted in the development of coping strategies that respected the voice as an equal member of the relationship. His response above illustrates one way that Ed manages his voices – by giving the voices an allotted amount of time to take control has helped him to negotiate some protected time that he can have for himself without the voices.

### *Coping strategies:*

Coping strategies was the final topic from the self-help book identified by the participants. Finding ways to cope with voices was prioritised by many of the participants. The participants discussed the coping strategies they have found helpful, and how these relate to the ones suggested within the book.

Sam: 'It's just finding as many coping mechanisms as you possibly can, um which I think should be more detailed in here [the book], um because that's what we need you know.'

Catherine: 'I mean there were times when I didn't turn it around. I have learned coping mechanisms. I will say 'oh yes I can' which has given me a bit of strength.'

Catherine's response illustrates that developing helpful coping strategies is a process of learning and experimentation. Where participants talked about coping strategies, they were discussed in relation to a trial-and-error process, whereby different strategies were tried and evaluated until helpful ones were found. Also having one coping strategy was considered insufficient – instead it was important to have as many as possible for different situations and voices.

### ***The Therapist:***

#### *Personal qualities:*

See main paper.

#### *Therapist skills:*

See main paper.

#### *Confidentiality in therapy:*

See main paper.

### ***Pragmatics of Therapy:***

With regard to this theme, more so than any others discussed thus far, there was little consensus amongst the participants. This theme covers all aspects of the intervention that does not relate to the therapy content.

#### *Therapy structure:*

Some of the participants wanted to have some contact with their therapist between therapy sessions.

Jillian: 'I have just had an occupational therapist um and she used to um give me a text just to ask me how I am and for me to let her know that I am ok. So I think that's a really good thing.'

Lee: 'To have the option to be able to phone someone up. Just to have that option that you can phone this number and they will get back to you within a day or two if you want to discuss something specifically or you're really mixed up about something.'

Whereas other participants felt that contact in-between sessions would be unhelpful.

Tim: 'I find that [a phone call] a little bit intrusive. Because who knows where I will be when that call comes um and I might feel a bit like I'm being chased up and I have to think of a response, whereas if it's a text message it's up to me what I do with that.'

Sam: 'I would be on the phone nattering away to my therapist for no good reason it would be a waste of their time I just want it to be completely focussed for that one hour a week... the boundaries of the relationship become crossed and you're like 'oh why am I ringing up my therapist?' Oh because I want a chat and a cup of tea.'

Again, when asked whether they would prefer guided self-help CBTv to be delivered on a one-to-one basis or as part of a group, some of the participants expressed a preference for individual therapy.

Jimmy: 'Because you are like talking about your own beliefs in yourself and your own voices, because it is a very personal therapy, personal subjects, I think it would work better on a one to one basis um because obviously everybody in the group is going to have a very different experiences and beliefs. And um I don't know if you would sort of maybe waste time sort of listening to, sounds awful wasting time, but you would spend a lot of time listening to the individual differences and you wouldn't have the time to focus on how you're going to challenge, or what your own beliefs are in fact, so yeah it would work better on your own.'

Jackie: 'I would prefer to do it one to one because then you can talk more. People won't pressure you to talk about things that you don't want to talk about.'

Nikki: 'I think there's some things that are very private that you wouldn't necessarily say in a group, so I wouldn't think it would get to the core issues for me because I wouldn't share it in a group. I think privately would help.'

In contrast, some participants valued the social aspect of a group-based intervention.

Joe: "For you to get the most out of it, you know in groups, it's good because you get other people experiences and you hear about it."

The differences in opinions reported here show how difficult it can be to design an intervention that is standardised and suitable for all. It is important for research quality and implementation that interventions like guided self-help CBTv are guided by a structured protocol. However to maximise patient benefit and experience, there needs to be a degree of flexibility to accommodate these differences in opinion, wherever it is possible.

*Timing:*

The participants discussed when they felt would be a good time to engage in guided self-help CBTv. For some of the participants this sense of ‘readiness’ was discussed as following a linear trend – comparing those who have just started hearing voices, to those who have heard them for a number of years. Other participants believed that feeling ready to engage in the intervention followed more of a fluctuating trajectory that was influenced by how ‘well’ they felt.

Tim: “You need to have a certain level of wellness in order to engage with the book.”

Joe: “I know that when I have been ill there is a lot more going on and I think it really depends on how, where you are in your illness. I know that if I had read this book a few years ago, I wouldn't be able to use the stuff. It wouldn't really compute with you or anything like that. I wouldn't be able to sort of um, use it as a self-help book. But obviously further down the line its better, easier to use.”

The participants largely agreed that trying to engage in guided self-help CBTv while unwell would not be appropriate or helpful. Being in a more ‘stable’ state seemed to be important in deciding a good time to intervene. It is important to note that the participants did not feel that intervening at a time of mental ill-health would be unsafe. As described by Joe, intervening at that time would just be unlikely to produce any benefit.

There was some disagreement when considering whether guided self-help CBTv would work as part of an early intervention care package. Some participants felt that the intervention could help to address the initial feelings of confusion when a person starts hearing voices by increasing their understanding.

Sam: ‘I mean these sorts of books [self-help book] should be available in schools as well because like if a kid starts hearing voices, that’s when I started hearing voices as a kid, I thought I didn't even know that was something that could happen to anyone. I didn't even know that even existed. I didn't even realise that was a thing so you know.’

Mia: I think for me, something like that would have been good when it started, when I started to hear voices and to feel down, because I didn't understand what it all was and when I

started hearing voices there wasn't any um sort of real help. So I think something like that would be quite good, if you could catch someone who just like an early sort of intervention.'

Jeremy: It's [the book] nice because you can pick out so many different coping mechanisms and strategies and stuff that I wouldn't personally think about myself, so that's why I think that book would be good for what I call 'starter outers'.'

In contrast other participants felt that it would be important to have an understanding of you voices before you can engage in an intervention like guided self-help CBT. This understanding is something that comes with time.

Jimmy: "It's [the voices] all too confusing early on and there's all too much going on and you don't really, you're not stable enough um to um properly think about or talk about your voices. From my experience, I didn't want to talk about it because I was really embarrassed about it and to be forced into that position it would be quite damaging I think, um so I think early on you are definitely, it could either be a waste of time or it could be damaging I would say."

Joe: "Helping people early on with it would be helpful but I think the whole process of trying to challenge everything would be too difficult. Well I know it was when I was that ill and stuff."

Pippa: "You know I think some therapy is important when voices first start, but because they start with derogatory and insulting content, and you have to give somebody who is just experiencing this for a brief period of time, a therapy about themselves and how they see themselves it might appear to them either a little off topic or that your blaming them and agreeing with the voices about them being weak you know um and vulnerable... if I was in a therapy where I was told to challenge core beliefs right at the very beginning it might be too difficult."

Starting to hear voices was frequently associated with a sense of chaos and efforts to make sense of the experience. Whereas some participants felt that guided self-help CBTv could be helpful during this sense-making process, others felt that this was something that needed to be done independently.

Jonathan: 'It would need to be people who are ready for it. I don't know what time it is, I know when I would be ready.'

Sam: 'I think you have to be at a certain level, a certain place to be able to engage with therapy in the first place, you know, wanting some changes and in a place where you are there.'

Although there is little consensus as to when guided self-help CBTv should be offered, all of the participants acknowledged the importance of timing and intervening at the ‘right time’. As discussed previously, hearing voices is a personal experience. It therefore seems reasonable to assume that the ‘right time’ to intervene is also a personal decision.

***The Presenting Problem:***

*Voices:*

See main paper.

*Cognitive processes:*

See main paper.

***Networks:***

The themes discussed thus far are all related to the development of guided self-help CBTv – this theme is not. However it was a theme that emerged across all of the focus groups. Participants spoke about the various relationships that they have, and unfortunately these were largely discussed as negative.

*Clinical relationships:*

Many of the participants discussed the mental health treatment they were currently receiving and the relationship they have with the practitioners. Participants were largely dissatisfied with these relationships. The most common issues reported were not being listened to, not being understood, and not having their needs met.

Sam: ‘It said [in the book] if you’re feeling as if life is not worth living you should seek professional help from your GP or mental health practitioner or A&E. From my experience I had tried, well I have wanted to commit suicide a few times, and I have never received any help. I have contacted A&E, I have contacted my mental health worker, and they have done absolutely jack sh\*t about it.’

Lee: ‘They [services] give everyone antipsychotics every day and that's it.’

Catherine: ‘You go and see your psychiatrist and it’s what twenty minutes? And he will say ‘how are you feeling?’ And you’ll tell him, and he’ll say ‘Well you know Catherine, we all get this and we all get that.’ No we don't all suffer with hearing voices, and getting told to do stuff we don't want to do. So it’s like they’re not listening to what you’re going through and it, you know, throws you off init.’



The participants became very emotional when talking about these clinical relationships. The stories shared demonstrated a sense of disempowerment and helplessness. The participants spoke of asking for help and not receiving it. This sub-theme strongly suggests that the participants were unhappy with mental health care they were currently receiving.

*Nonclinical relationships:*

Similarly the participants discussed their relationships with friends and family under the same negative veil. The same points of disgruntlement experienced within the clinical relationships appear to be mirrored within these nonclinical relationships.

Catherine: 'A few years back when I started getting voices people didn't understand it in my family, um especially my sisters, who I fell out with. You know they had no, they have never suffered with depression or anything like that, so to them it was like 'oh you're ill you know'. Your ill and its like 'snap out of it' and you can't.'

Ed: 'Like my family are in denial still, so I will tell them something that's been going on and they think it's nothing, its fine. And that's one thing, that's every time I'm having a really good patch I fall back, because of the fact that my family are still not supportive about it and they think I'm doing something. So that's one thing that I think. Your family is your main stronghold so I think if you get them to also help it will be a lot easier process.'

Jillian: 'I explained to my brother, um I told my brother that I was diagnosed with schizophrenia and he joked about it. And he said, you know, he thought it was a person with um Jekyll and Hyde, with two split personalities. And I said to him, I said you are so wrong. I said what you need to do is you need to go and get a book on schizophrenia, and then you will begin to understand me better as a person.'

The participants reported feeling like their family did not understand their experiences, and often tried to dismiss it (as reported by both Ed and Catherine). The word most frequently used by participants when discussing their relationships is 'understand'. The participants are not asking for anyone to change their voices or make them disappear – they are looking for someone who can actively listen to their experiences and offer understanding. The responses within these sub-themes supports the findings within the 'therapist' theme, and demonstrates the importance of building a strong therapeutic relationship.

*Stigma:*

Within all of the focus groups, there were points where the participants shared their own experience of hearing voices. Voices were always discussed as being negative. However this distress was more than an emotional reaction to hearing voices, but also involved feelings of

shame and fear of judgement. This sub-theme was most apparent when discussing the front cover of the self-help book.

Nikki: 'Privacy is important to me and this cover is quite loud. On a bus, it's hardly coffee shop reading. It's like 'oh there you go that's what I'm reading today' and it's you could be anybody, like a professional looking into something. I just felt a little uncomfortable with the cover. I would want something more anonymous if I was going to take it out and read it. Just something a little more discrete because if I tell people I have mental health issues that's my business and sometimes I do and sometimes I don't, but if a book starts a conversation that's uncomfortable for me then I would find that a little, it sort of blows your anonymity a little bit.'

Lee: 'I um I was thinking about that on the bus yesterday and I was thinking because I was on a packed bus with it [the book] and I thought if anyone asks me I will tell them I am a psychologist.'

Catherine: 'I would say if you are on a bus and if you're out in public and people are not aware, you can get some nasty comments or discrimination.'

The participant felt that reading the self-help book (which says 'Overcoming Distressing Voices' on the cover) in public would put them at risk of experiencing stigma. Lee was so aware of this that he had even considered what his excuse would be if someone questioned him about it – and this response would be to deny that he hears voices. Some of the participants reported even feeling uncomfortable reading the book around family and friends in their own home. As well as being distressing for the participants, feeling unable to read the book because of stigma could impeded therapy engagement. Consideration needs to be given to help patients engage in guided self-help CBTv in a way that does not make them feel ashamed.

#### *Group dynamics:*

This sub-theme differs from the other 'network' sub-themes discussed thus far. Relationships have so far been associated with negative beliefs and feelings. However this sub-theme describes the process of a positive network in vivo. Across all of the focus groups the participants treated each other with respect, gave each other space to speak, and fully attended to the person who was speaking. In one of the focus groups this mutual respect and support went a step further. Participants took the time to explicitly validate each other's experiences, as well as sharing advice and ideas for coping strategies that they had found helpful.

Jillian: '[To another participant] I think it's quite amazing. I think you're quite special to have experienced voices for such a long period of time and still be here. I think that's amazing, so well done you, that's pretty amazing.'

Ed: 'Yeah other coping strategies. One of mine, one thing they tell me to do is cut myself and I had a big problem with self-harm and that sort of stuff.'

Jeremy: 'Yeah I went through that and all.'

Ed: 'So I found one way of doing it is not to deny, like 'no I'm not going to cut myself'. It's to get a pen and actually do it with a pen just drawing lines on your skin instead. So it's psychological in the fact that they [the voices] get something from it because you have done it but at the same time you haven't caused harm to yourself.'

Jillian: 'Yeah I think that's genius.'

Jeremy: 'I don't know if anyone else has tried it, but I was told about it. If you're out in public and you're telling your voices to 'bugger off' just put your mobile phone to your ear.'

This sub-theme potentially provides evidence for the non-specific effects of group therapy, and support groups. Being in a non-judgemental space with other people who also hear voices seemed to provide some therapeutic effect. Previously the participants spoke about wanting to feel understood (see 'clinical relationships' and 'nonclinical relationships'). Although the experience of hearing voices is personal, because of this shared experience, the participants were able to empathise with each other much more quickly and on a much deeper level compared to someone who did not hear voices.

### ***Therapy Flaws:***

This final theme describes the criticisms that some of the participants had of guided self-help CBTv protocol. This theme demonstrates that the participants in the focus groups were not 'yes men', and instead felt able to share both positive and critical opinions.

### ***Theory:***

Guided self-help CBTv is based upon the cognitive behavioural understanding of voices. CBT hypothesises that it is not the event itself that causes distress (in this case hearing voices), it is the beliefs that the person has about the event that cause the distress (e.g. believing that the voices are malevolent). After reading the self-help book most of the participants understood the concept of CBT, but not all were convinced by it.

Abe: "It says that 'hearing voices in itself is not a problem' but I can't agree with that because hearing voices itself is a problem. Even if the voices aren't being nasty or not saying anything to you, I have a terrible job trying to listen to two people at one time. Yeah so hearing the voice, even if it's not being scary or disruptive, it's a matter of I don't want it to speak to me. I just want to concentrate."

Abe did not agree that hearing voices itself was not a problem because of the voice's effect on his ability to concentrate. The book also explores the application of the CBT model to beliefs about the self; it states that people who hear voices often have negative beliefs about themselves, but that these are rarely true. Sam and Jonathan did not agree with this part of the book. These objections to the CBT model could be explored and evaluated within therapy sessions. Alternatively these comments may evidence the importance of individualising interventions to the beliefs and needs of the patient, as a 'one size fits all' approach may not be appropriate.

Sam: "What happens if you don't believe you have a self? I mean it's quite difficult. What happens if you don't think you actually have a personality? You don't have anything? You feel empty? I mean it's quite difficult to kind of find something inside of yourself that's yours, when you're just completely bombarded with voices, I mean what is you? When you start challenging, asking what you think about yourself, maybe you don't think anything about yourself anymore"

Jonathan: "There was something that I picked out, was um about negative core beliefs. I only read one chapter recently, and it was 'the important thing to remember about negative core beliefs is in fact they're rarely true', and then it gave some examples of some negative core beliefs, and one of them was 'I am weak, I am vulnerable' but that could be true about someone."

The self-help book also explores the notion that people are in a relationship with their voice, and that voice-related distress is often associated with a negative hearer-voice relating pattern. The self-help book suggests way that people can relate to their voices in a more assertive way. Some of the participants did not identify with the notion of being in a relationship with their voices.

Nikki: "For me I kind of see, I don't, the relationship with voices and giving the voices an entity, other than something you would have a relationship with, I didn't really identify with but that's very personal nark for me about what was going on in the book. Because I don't give the voices an entity. When I hear auditory hallucinations or sounds or voices or things, I don't give them an entity or a relationship or a personality or anything because I see it as my own brain working too hard so I very much accept that it's just my brain."

Sam: "I have never felt that they have any sort of reference to anything whatsoever and they are just my mind playing tricks on me, and that um it happens most when I'm tired, when I'm overthinking about something um and medication, yeah, slows my brain and helps me calm down a bit."

Abe: "I just have one more thing to say about the book. Not always, but in lots of the book they say we all have a two way conversation with the voice. I actually don't. I can shout, scream, speak at the voice and they will speak at me, but we don't have a conversation, a one-to-one conversation."

Again these objections to the fundamental theory underpinning the intervention is something that could be explored within a therapy session, or suggest that the relating approach is not suitable for everyone who hears voices.

*Missing elements:*

While some of the participants disagreed with the theory of the book, some thought that there were key parts of their voice hearing experiences that the book did not cover.

Joe: "This just concentrates on voices, but usually there is a lot more symptoms that come along when. I know that when I have been ill there is a lot more going on."

Sam: "Say if you believe you're reading other people's thoughts, that might, that's not hearing voices but it's another sort of type of delusion that it can have, maybe, a relationship with maybe hearing voices."

In contrast to the responses from participants within the 'positive feedback' subtheme, some of the participants did not like the symptom specific approach. Both Joe and Sam felt for guided self-help CBTv to be effective for them it needed to give space to discuss other aspects of mental health such as unusual beliefs (delusions), paranoia, depression or anxiety. Other participants felt that the self-help book and therapy protocol did not acknowledge that there were other ways to understand the experience of hearing voices. Although this intervention is based on the CBT model, several of the participants reported that they would have appreciated the acknowledgement of alternative approaches.

Sam: "I'm not sure if this will be relevant, but I did think that they mentioned, sort of apart from the cognitive behavioural techniques, other ways in which you can deal with distressing voices. Like healthy eating, taking vitamins, like holistic therapies. Um you know all sorts of things that are quite beneficial to mental health but I don't know if that's going to be relevant, if they wanted to put a chapter in there about other ways to help mental health."

Jillian: "I find it quite interesting that the only responses discussed are those that are emotional and behavioural what about logical and intellectual response as well as biological and physiological? So it's not only just the mental side. Having um schizophrenia effects everything that you do. It effects your body, it effects how you eat, you know sleeping, um

emotionally, intellectually, um and I thought that perhaps that should have been mentioned more.”

Ed: “I think all areas. Not just the medical. You have everything else as well. It would allow people to have a choice on what their experiencing and what they feel like they would be better to go and do.”

This was the most commonly reported criticism of guided self-help CBTv.

### ***Final Remarks:***

At the end of each of the focus groups, participants were asked if they would want to receive this therapy if it was to be offered to them. All but one participant (95% of the sample) said that they would be interested in receiving this therapy. The one participant who did not want guided self-help CBTv was Sam. Sam said they felt they needed a more emotion-focussed therapy, rather than one that focussed on cognitions.

Sam: “The thing is, the fact that it's a cognitive thing wouldn't be helpful to me because I struggle with cognition in general. So it would have to be more of a feeling, it would have to be more emotional therapy rather than cognitive therapy for me yeah.”

### **Study 2 (clinicians):**

#### ***Positive Attitude towards Therapy:***

Many of the mental health clinicians that took part in the survey were very complimentary about guided self-help CBTv.

‘I can think of a number of clients who I think could engage and benefit from this.’

‘Brilliant! Self-help empowers clients, helps rebuild their self-esteem and take some control over something so distressing.’

‘I think this would be a good idea, especially in my area of rehabilitation and recovery. Most of our patients suffer from psychosis and a high proportion may be helped by this.’

This positive feedback generally fell under the following three sub-themes.

#### ***GSH in the context of IAPT:***

Majority of the staff who were in favour of guided self-help CBTv acknowledged that access to psychological therapies for this client group is currently poor within their service, and that this intervention could be a way to increase access.

‘The provision of CBT within this Trust is awful.’

‘Access to CBTp is a real problem for patients.’

‘It could help increase access to therapy which is at the moment very poor.’

‘Seems like a good way to make a treatment available that people might not otherwise be able to access.’

The clinicians identified that having an intervention, like guided self-help CBTv that was brief could be one way to use current resources differently. The positive response from clinicians here suggests that many are open to the idea of briefer psychological therapies. Even more encouraging are the responses from several clinicians stating that they are hopeful guided self-help CBTv could be actually increase access in practice within the services they work.

‘I feel in my work and with the client group I currently work with it would be feasible.’

‘I think as a trust it would be fairly feasible to bring in these guides.’

‘Clinicians will make the time in order to implement this approach, even given the demands services are currently facing.’

#### *Staff willingness to be involved:*

Many clinicians supported their positive attitudes towards guided self-help CBTv with action. They reported their willingness to be involved at three different levels: (1) research, (2) attend training, and (3) intervention delivery.

##### Research:

‘My desire to be involved in this project is very high, the aim of the project is sound and patient focused.’

‘I would be interest [sic] to help in developing this.’

##### Training:

‘It will be useful for myself as a support worker so I am able to support those with these issues on a more professional level. [I] would be happy to go on training days to learn more about this.’

‘I would be happy to make the time to be trained to deliver it after research has tested its effectiveness.’

##### Intervention delivery:

‘I am already a Family Interventions in psychosis practitioner and I believe that being able to offer CBT as a guided self-help tool would be a valuable addition to the armoury we have to help our Service Users in their recovery.’

The commitment from some clinicians to act upon their favourable opinions is promising for the future of this intervention. Positive attitudes are encouraging, but for guided self-help CBTv to be successfully implemented this will require collective action from mental health clinicians.

#### ***Negative Attitude towards Therapy:***

While many clinicians were in support of guided self-help CBTv, there was also a significant proportion of the respondents whom did not agree or support this intervention idea. The negative attitudes expressed generally reflected either a dislike for the concept or disbelief that it would be effective.

‘I am very sorry not to be more encouraging but I see a number of problems with offering CBT for distressing voices using guided self-help in my work setting.’

‘No [I would not be willing to be involved] as this would worsen symptoms and increase risk.’

‘Not keen on this [guided self-help CBT for distressing voices].’

The most prominent criticisms of the intervention are described within the following two sub-themes.

#### ***Not a stand-alone treatment:***

Related to the issue of effectiveness, some clinicians felt that guided self-help CBTv would not work as an intervention in its own right, and would need to part of a larger care package.

‘I do not feel that it would be appropriate as a blanket intervention in all other teams.’

‘It could be a co-treatment.’

Within primary care guided self-help CBT is a stand-alone therapy delivered within IAPT services. It seems that some staff do not seem to think this could be the case when applying this intervention to those who hear distressing voices. Although the notion of guided self-help CBT being delivered to those who hear distressing voices as part of a larger care package is not necessarily a bad one, it could mean that the issue of access would not be addressed through its implementation. Although resource would be saved by delivering this



brief therapy, this would be counteracted in the additional resources needed to supplement the interventions shortfall.

*GSH not an equal treatment option:*

Related to the above issue, is the concern expressed by some clinicians that this intervention would be used as a way of cheating patients out of the more resource-intensive interventions they should be entitled to.

‘I would be concerned that guided self-help is used in place of face to face therapy.’

‘I worry that it would be an opportunity to reduce staff time with the service user and save money.’

This subtheme implies that clinicians believe by reducing the amount of contact time involved in a psychological therapy this consequently makes it inferior. Furthermore the clinicians seem to be concerned about the motivations for developing this intervention. Instead of attempting to create an acceptable, effective, and feasible to implement intervention, some of the clinicians think guided self-help CBTv is a way to save money.

This theme highlights some of the reasons that clinicians would not support the implementation of guided self-help CBTv. Prior to any attempts at implementation it would be important to reassure clinicians as to the motivations for and the effectiveness of guided self-help- CBTv.

*Support for therapy with a caveat:*

For some of the clinicians, their opinions on guided self-help CBTv were more nuanced, and conditional on the caveats described in the sub-themes below.

*Importance of clinical training:*

Some of the clinicians believed that pure self-help would not be helpful for this client group and that they would need support from a mental health practitioner.

‘My experience of this group are that they will require a considerable degree of support to undertake this work.’

Interestingly, a number of the clinicians stated that this support needed to come from a clinician who was highly skilled, and trained in the delivery of psychological therapy. Some clinicians were concerned that if a clinician who was inexperienced delivered guided self-help CBTv there could be safety and risk issues.

‘The provision of Self-directed CBT in voices needs the support and backup of trained staff to ensure patient safety.’

‘I worry that an inexperienced practitioner would be more likely to blame the patient if the intervention was not going as planned, further stigmatising a massively stigmatised community.’

‘I believe that practitioners working with psychosis should be experienced mental health professionals with sufficient experience, training and skills in this area of work. I believe it to be a very specialised area requiring an advanced practitioner.’

These responses suggest that the clinicians perceive people who hear voices to be a more fragile and risky population to work with, compared to other mental health problems where guided self-help CBT is delivered by clinicians without therapist accreditation (e.g. in the treatment of depression and anxiety within IAPT services). Whether the concerns of clinicians translate into real world risks will require further research.

#### *Need for evidence:*

Clinicians also acknowledged that the development of guided self-help CBTv was at its early stages, and that there is currently little evidence to suggest it would be effective in clinical practice.

‘At the moment I don't think there's enough evidence that CBT self-help for distressing voices is helpful for people, but that's why I think it is good that you are doing a research study to find this out.’

‘I would be a bit wary about offering CBT self-help for distressing voices as part of routine clinical practice, as the evidence isn't really there, but if it's part of a research study I think that's fine and that's the point of research.’

Even though these staff members were unable to give support for this therapy, they did seem to support the idea of trialling this therapy within a research study. This theme shows that many clinicians want to work within evidence-based practice, and that they use this evidence to make decisions within their clinical work. The fact these clinicians did not dismiss the concept of this intervention implies that if guided self-help CBTv is found to be effective then they would be willing to support its implementation.

#### ***The Presenting Problem:***

##### *Symptoms:*

See main paper.

*Cognitive abilities:*

See main paper.

***Practical Barriers:***

*Lack of resources:*

See main paper.

*Conflict with service priorities:*

See main paper.

## 13.7 Research Ethics Committee (REC) approval for chapter 10.

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### NRES Committee North West - Lancaster

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15 July 2015

Miss C Hazell  
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Dear Miss Hazell

<b>Study title:</b>	<b>Guided self-help CBT intervention for Voices Evaluated (GiVE): external pilot randomised controlled trial using a wait-list control condition.</b>
<b>REC reference:</b>	<b>15/NW/0575</b>
<b>IRAS project ID:</b>	<b>151273</b>

Thank you for 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 Vice-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 favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Mrs Carol Ebenezzer, [nrescommittee.northwest-lancaster@nhs.net](mailto:nrescommittee.northwest-lancaster@nhs.net). Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

#### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

#### Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the

