Doctoral Thesis

Investigating the efficacy of Cognitive Bias Modification for Interpretation and the Maudsley Review Training Programme on social anxiety and reasoning biases in individuals with persecutory delusions: a single case series.

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Abstract

The Threat Anticipation Model (Freeman, 2007) implicates social anxiety and reasoning biases in the formation and maintenance of persecutory delusions. Computerised packages, such as Cognitive Bias Modification for Interpretation (CBM-I) have been shown to improve social anxiety in psychosis (Turner et al., 2011). Similarly, the Maudsley Review Training Programme (MRTP) has improved reasoning biases associated with delusions (Waller et al., 2011). This study examined the use of both of these treatment packages in people with persecutory delusions. It was hypothesised that CBM-I would reduce social anxiety, but not reasoning biases and that the MRTP would reduce reasoning biases, but not social anxiety. It was also hypothesised that both packages would reduce paranoia. A single case series design with twelve participants from Early Intervention and Recovery services in Norfolk was used. Measures of social anxiety, paranoia and reasoning biases were taken during baseline, package and one-month follow up. Data were analysed according to Kazdin's (2010) criteria and were inspected for clinical and reliable change. Complimentary analyses were also performed using Simulation Modeling Analysis (Borckardt, 2006) and inferential statistics. Results indicated mixed support for the first hypothesis and moderate support for all other study hypotheses. Paranoia reduced in line with reductions in social anxiety and/or reasoning biases in eight cases. In two cases, no improvement in social anxiety or reasoning biases corresponded with lack of improvement in paranoia. The remaining two cases contradicted any relationship between improved social anxiety, reasoning biases and paranoia. These findings support the Threat Anticipation Model (Freeman, 2007), suggesting that social anxiety and reasoning biases are distinct mechanisms in the formation of paranoia that have unique aetiology and treatment responses. Computerised therapy may help people who are unwilling to engage with services and reduce cost of provision.

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<center>**Introduction**</center>

1.1 Overview

This thesis will focus on investigating whether Cognitive Bias Modification for Interpretation (CBM-I) and the Maudsley Review Training Programme (MRTP) affect social anxiety and reasoning biases in a differential manner within a sample of individuals with persecutory delusions. This chapter will begin with a brief introduction to psychosis and the potential advantages of targeting single symptoms in psychosis. A psychological understanding of persecutory delusions will be described using three influential models, each of which will be briefly evaluated. The literature regarding cognitive behavioural treatments for persecutory delusions will be reviewed. Finally, the rationale for this thesis will be outlined.

1.2 Introduction to psychosis and focus on persecutory delusions

Psychosis is an umbrella term for various clinical presentations, mainly characterised by distorted thinking and perception. Psychosis comprises positive symptoms, such as hallucinations and delusions, and negative symptoms, e.g., anhedonia and alogia (ICD-10, WHO, 2010). This thesis will focus specifically on persecutory delusions, defined as firmly held threat beliefs that other people, groups or entities are deliberately causing psychological or physical harm, which are unfounded, resistant to change, preoccupying and distressing to the individual concerned (Freeman, 2007).

1.3 Definition and prevalence of persecutory delusions

Freeman and Garety (2000) proposed criteria which focus more on the form of the delusion, rather than specific themes. The criteria are: (a) belief that harm is presently being inflicted upon the individual, or that harm is imminent, and (b) belief that the persecutor has the intention to inflict harm on the individual. These criteria will be adopted for the purpose of the current study. What constitutes harm is also clarified: any harm – whether

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psychological (e.g., irritation or humiliation) or physical (e.g., poisoning or cutting out parts of organs) – should be considered persecutory in nature. Only beliefs about harm being inflicted are considered persecutory; thereby addressing the potential over inclusiveness of ideas of reference (e.g., government agencies monitoring phone calls, but without any intention to cause distress), as well as of persecution in research samples.

After ideas of reference, delusions of persecution are the second most common symptom encountered in psychosis (Andreasen et al. 1991; Freeman, 2007). In a study of 1,136 acutely hospitalised patients, 4.4% experienced at least one persecutory delusion, which represented 78.4% of the 328 people in that sample with a delusion (Appelbaum, Robbins & Roth, 1999). Sartorius et al. (1986) found that almost 50% of their international sample of individuals with signs of schizophrenia (N=1379) experienced persecutory delusions. Persecutory delusions can also be found among individuals with various diagnoses other than schizophrenia; 44% of a sample of 136 people with unipolar depressive psychosis experienced persecutory delusions (Frangos, Athanassenas, Tsitourides, Psilolignos & Katsanou, 1983). They are also prevalent in bipolar disorder, with one review estimating a frequency of 28% in the manic phase (Goodwin & Jamison, 1990).

The majority of current studies that have examined efficacy of cognitive therapies have done so using samples comprising a range of differing psychotic experiences, or delusions of varying subtypes (e.g., Freeman et al., 1998). Although useful, multi-symptom research does little to identify specific mechanisms of change or improvement because the symptom profiles of the psychoses are heterogeneous (Garety et al., 2008). It may be a reason why effect sizes of cognitive behavioural therapy (CBT) for psychosis are estimated at small to moderate (Wykes, Steel, Everitt & Tarrier, 2008; Jauhar, McKenna, Radua, Fung, Salvador & Laws, 2014). As a result, there has been a move towards a single-symptom approach to both research and clinical work (Garety et al., 2008), which should improve

clarity of what is being examined, increase confidence in the evidence, and enhance understanding of the specific components of therapy which are most effective.

Having explored the merits of clearly defining persecutory delusions, and single-symptom research in psychosis, the next section will examine cognitive models of threat beliefs. This thesis will focus on the Threat Anticipation Model (Freeman, 2007), which will inform the research questions and hypotheses.

1.4 Cognitive models of persecutory delusions

There are many cognitive models of persecutory delusions to explain their onset and maintenance. Most of them fall into two different perspectives; the first approaches persecutory delusions from the writings of Maher (1974), which are characterised by experiences that drive a search for meaning by the individual. The second perspective stems from motivational theory.

1.4.1 The Threat Anticipation Model (Freeman, Garety, Kuipers, Fowler, Bebbington, 2002; Freeman, 2007). The Threat Anticipation Model (Freeman, 2007) proposes that persecutory delusions arise due to an interaction between vulnerability and stress (Freeman et al., 2002; Freeman, 2007). Figure 1.1 outlines the Threat Anticipation Model (Freeman, 2007) of persecutory delusions. Persecutory ideation arises due to attempts to make sense out of internal or external experiences that are unusual, anomalous, or emotionally salient. Three pathways to formation and maintenance of persecutory beliefs are postulated: anomalous experiences, emotional processes and reasoning biases.

1.4.1.1 Affective processes – depression and negative schematic beliefs. Depression is known to be highly prevalent among people with psychosis (Buckley, Miller, Lehrer & Castle, 2009). However, cross-sectional data put depression at the core of persecutory delusions also; Freeman, Garety and Kuipers (2001) found that 80% of their sample of people with persecutory delusions also presented with significant severity levels of depression, with

a mean Beck Depression Inventory (BDI) score of 23. The role of depression is implicated in the Threat Anticipation Model (Freeman, 2007), but not in the same way as anxiety. First, the relationship between depression and paranoia is less clear (Freeman, 2007). Second, depression is considered to be influential in the development of specific themes of persecutory ideation, as well as having a causal role in onset and maintenance.

In summary, depression does seem to be an important component of persecutory ideation. Recent studies indicate that there may be processes similar to both depression and persecutory ideation or paranoia (Freeman, 2007). This is important to bear in mind when formulating and developing treatments for persecutory delusions which present with depression. Having briefly discussed the importance of depression, the next section will consider the role of anxiety in persecutory ideation.

1.4.1.2 Emotional processes – anxiety. Differing forms of anxiety (such as social anxiety, state anxiety, or worry of an interpersonal nature) are argued to be central in the formation and maintenance of persecutory beliefs. This is because the psychological processes underlying persecutory and anxious thoughts are both concerned with the anticipation of physical, social or psychological harm (Freeman et al., 2002). Anxiety may therefore breed paranoid thinking, which in turn plays a part in the formation and maintenance of persecutory ideation (Freeman, 2007). Social anxiety itself is defined as a fear of being negatively judged or scrutinised by others (Colman, 2006), which conceptually overlaps with clinical phenomena such as interpersonal sensitivities, worry and paranoia. The model hypothesises that the experience of social anxiety in itself is misinterpreted by the individual as objective evidence of threat. Similar to how avoidance and biased interpretation of social information drives and maintains social anxiety (Clark & Beck, 2010), avoidance and biased interpretation of social information maintain threat beliefs because they

makes the individual's social world more constricted, limiting the amount and diversity of potentially disconfirming information.

Research indicates that anxiety is strongly associated with paranoia and with persecutory delusions (e.g., Freeman & Garety, 1999; Startup, Freeman & Garety, 2007). Empirical evidence has indicated a causal and maintaining role for social anxiety in an urban setting in persecutory delusions (e.g., Ellett, Freeman & Garety, 2008). Attempts to identify differential cognitive and behavioural responses among individuals with persecutory delusions and individuals with social phobia were not found, suggesting overlap between the clinical phenomena (e.g., Newman-Taylor & Stopa, 2013). The authors note that individuals with persecutory delusions may present with cognitive and behavioural responses characteristic of social phobia, which lends further support to the idea of a hierarchy of paranoia (Freeman et al., 2005a) that first builds upon social evaluative concerns.

Large longitudinal cohort studies (e.g., Schutters et al., 2012), show that social anxiety cognitions predict later onset of paranoid symptoms. Research has found anxiety and interpersonal sensitivity to be significant predictor variables of unfounded persecutory thinking (e.g. Freeman et al., 2003, 2005b). Furthermore, differential predictor variables of social anxiety and paranoia were examined. The key variable that increased the risk for paranoia rather than social anxiety was presence of perceptual anomalies (Freeman, 2008). This means that emotional disturbance can lead to social anxiety, but the presence of anomalous experiences – experiences unique to psychosis – makes paranoia more likely. The following section will discuss the second focus of this study – reasoning biases.

Figure 1.1 the Threat Anticipation Model (Freeman, 2007)
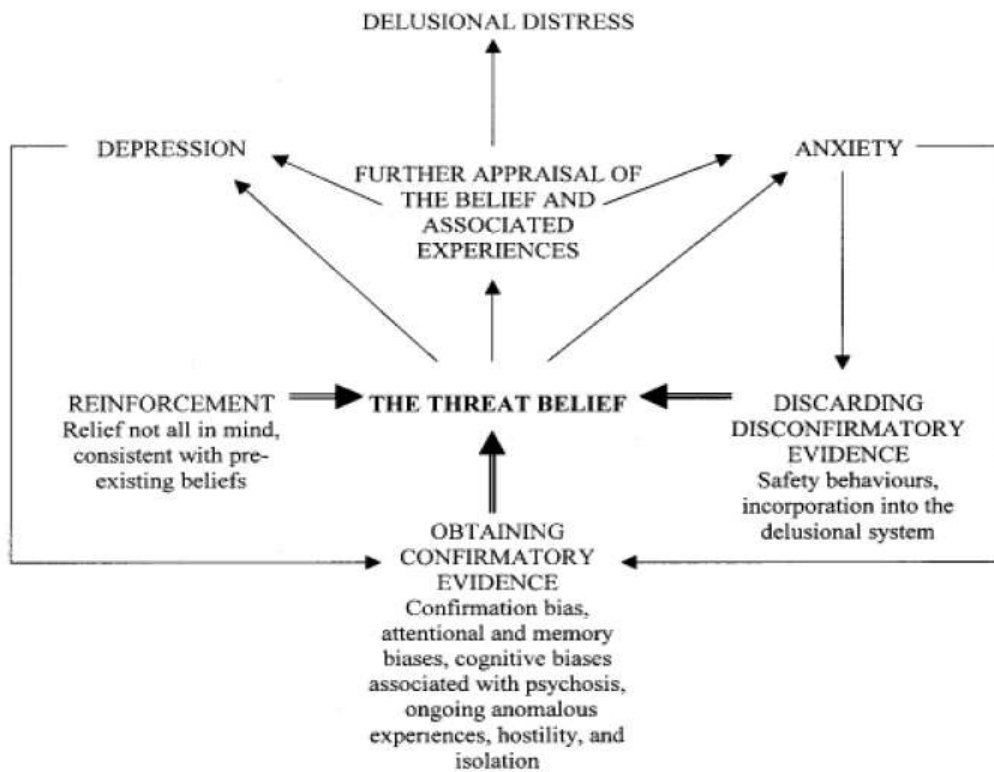
1.4.1.3 Reasoning biases. Although Maher (1974) argued that cognitive processes of people

with delusions are the same as those from non-clinical populations, authors of the Threat

Anticipation Model (Freeman, 2007) propose that delusions are formed and maintained by

reasoning biases, unique to individuals with psychosis (e.g., Freeman et al., 2007; Garety et

al., 2005). These biases lead the individual to selectively gather and attend to confirmatory

evidence and reject evidence that is contrary to the belief. Probabilistic reasoning has been

more extensively studied with respect to delusions (Garety, Hemsley & Wessely, 1991; So,

Garety, Peters & Kapur, 2010). To test reasoning according to Bayesian probability, a

content-neutral beads task was developed, which is described in detail in Section 2.2.3.5

(Garety, Hemsley & Wessely, 1991; Garety et al., 2005). Briefly, the participant is presented

with two jars, each filled with 100 beads of two different colours. The proportions of the

colours in each jar are usually either 85:15 (for the easier task) or 60:40 (for the hard task).

The participant is presented with one bead at a time from a randomly selected jar and is asked

to decide from which jar the beads have come. If a participant has decided which jar it is after two or fewer beads, then they have made a hasty decision, according to Bayesian probability (Garety et al., 1991). The tendency to make hasty decisions based on insufficient evidence (e.g., to decide which jar the beads were drawn from after seeing two or less beads) has been termed the jumping to conclusions (JTC) reasoning bias. Freeman (2007) reviewed the literature and found that in the ten such studies published at the time, all ten showed significantly hastier data gathering within the delusions groups, compared with non-clinical controls. JTC may also be related to strength of belief conviction (Garety et al., 2005).

Data on the relationship between JTC and persecutory delusions is less clear. However, several studies have found significant JTC biases in persecutory delusions samples, compared with matched non-clinical controls (Conway et al., 2002; Startup, 2004; Startup, Freeman & Garety, 2008), indicating that JTC may also be implicated in this particular clinical group.

Other types of reasoning biases proposed within the model include lack of belief flexibility, which is an inability to reflect on and alter one's own beliefs through the iterative process of generating and considering alternative explanations. This style of reasoning has been quantified in three different ways; (1) asking the participant if there is any possibility that they could be mistaken about their belief and noting their response; (2) presenting the individual with a hypothetical scenario that contradicts their belief, and recording their responses to it; and (3) asking the participant to consider any other possible alternative explanations for their experiences that have led them to form their belief, even if they think they are unlikely. The measures used for these biases include the Possibility of Being Mistaken (PM) and Reaction to Hypothetical Contradiction (RTHC) components of the Maudsley Assessment of Delusions (MADS; Wessely et al., 1993). The third construct is measured from the Explanations of Experiences assessment (Freeman et al., 2004). Belief

inflexibility, measured by these three constructs, has been found to be significantly elevated in samples of individuals with delusions and has been associated with increased delusional conviction (Garety et al., 2005; Freeman et al., 2004; So et al., 2012). The relationship between belief inflexibility and persecutory delusions is unclear at present. However, it seems likely that belief inflexibility is associated with persecutory delusions, given the fact that in one large study (So et al., 2012), 57.5% of a sample of 273 individuals with delusions reported persecutory delusions in particular, and belief inflexibility was found to be significantly inversely correlated with level of conviction of the overall sample.

1.4.1.4 Anomalous experiences. Anomalous experiences are explained as a dysfunction in cognitive processes that situate and disambiguate internal perceptual processes as originating from and remaining within the individual's mind. In other words, anomalous experiences occur from inner-outer confusion (Fowler, 2000; Frith, 1992). Using the example of auditory hallucinations, thoughts that originate from the mind of the individual are experienced as auditory perceptions that seem external. Passivity phenomena, ideas of reference and other psychotic experiences may also be explained by inner-outer confusion.

Some empirical findings support the above hypotheses (e.g., Green & Kinsbourne, 1990) however; a detailed review is beyond the scope of this section. Data linking anomalous experiences to persecutory delusions specifically is limited, due to methodological problems (Freeman, 2007). Anomalous experiences have been shown to differentially predict paranoia and not social anxiety (Freeman et al., 2005b). Data on delusions in general indicate onset of beliefs due to anomalous experiences such as hallucinations (e.g., Garety & Hemsley, 1994). Compton, Potts, Wan & Ionescu (2012) examined the temporal relationship between delusions and hallucinations in first episode psychosis. They divided their sample into four groups; (1) delusions only (n = 29, 18.2%), (2) delusions present at least one month before hallucinations (n = 31, 19.5%), (3) hallucinations present at least one month before

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delusions (n = 26, 16.4%) and (4) delusions and hallucinations that emerged within the same month (n = 73, 45.9%). Only a very small proportion of the sample experienced hallucinations without delusions. The delusions only group also consistently exhibited less positive symptom severity and impairment.

1.4.1.5 Summary of the Threat Anticipation Model (Freeman, 2007). According to the Threat Anticipation Model (Freeman, 2007), persecutory delusions arise due to the interaction between anomalous experiences, emotional disturbance and reasoning biases. Some data suggest the possibility of a differential aetiology of persecutory delusions as compared to other types of delusion. For example, Garety et al. (2013) found that negative self-evaluation, depression and anxiety predicted a significantly increased chance of persecutory delusions, whereas grandiose delusions were predicted by lower levels of all three variables. Grandiosity was also significantly better predicted by higher levels of positive self and positive other evaluations. Although JTC and belief inflexibility were elevated in both groups, both styles of reasoning were significantly more pronounced in the group with grandiose delusions. These findings support the processes implicated in the Threat Anticipation Model (Freeman, 2007).

Mechanisms within the model include the role of depression, negative schematic beliefs, and anomalous experiences, but this study will focus on social anxiety and reasoning biases specifically. Similar experimental manipulations of anxiety within non-clinical groups have also found support for the model. Lincoln, Lange, Burau, Exner, and Moritz (2009) used a sample of 90 non-clinical participants who were randomly allocated to an anxiety-inducing manipulation, or control task. They found that paranoia and JTC were elevated within the anxiety provoking condition, that higher baseline vulnerability to psychosis predicted a more paranoid reaction to the anxiety provoking condition, and that the relationship between anxiety and paranoia was mediated by the JTC reasoning bias.

In conclusion, research is now focusing on detailed aetiological processes of persecutory ideation. Initial data support the mechanisms postulated within the Threat Anticipation Model (Freeman, 2007).

1.4.2 Cognitive models based on motivational theory. Alternative models such as the attributional bias and defence of self-esteem model of persecutory delusions (Bentall, 1994; Bentall, Kinderman & Kaney, 1994; Kinderman & Bentall, 1997a) and Trower and Chadwick's (1995) model of paranoia have also been developed. The attributional bias model (Bentall, 1994) suggests that persecutory delusions are a defence of self esteem, therefore it is hypothesised that people with persecutory delusions display an externalising bias, compared with non-clinical controls. Freeman (2007) conducted a review of the relevant studies at the time and reported that three of the studies support this claim (Fear, Sharp & Healy, 1996; Krstev, Jackson & Maude, 1999; Lyon, Kaney & Bentall, 1994), while two studies do not (Kinderman, Kaney, Morley & Bentall, 1992; Martin & Penn, 2002). One possible reason for these mixed findings is difference in methodology across studies; including a mixture of between-group and within group cross-sectional designs, populations that were poorly defined (e.g., the sample reported by Krstev et al., 1999, comprised first episode psychosis with no operational criteria for any type of delusion), as well as variation in sample size. Treatment identified from Bentall's (1994) cognitive model involves specific forms of attribution therapy. Although external attribution bias for negative events is a potentially important theoretical and clinical hypothesis, it differs from the Threat Anticipation Model (Freeman, 2007) by not being given a central role in the formation and maintenance of persecutory ideation, rather as a dimensional feature of it (Freeman, 2007).

Trower and Chadwick's (1995) model of persecutory delusions suggests that paranoia may be broadly categorised into two different types; 'Bad Me' paranoia, where the content of the delusion implicates some deserved punishment of the individual and 'Poor Me,' paranoia,

which implicates persecution that is not warranted. Clinical aspects focus on addressing depressive beliefs in therapy, prior to paranoid beliefs, for those who present with 'Bad Me' paranoia. They assert that people with 'Bad Me' paranoia will benefit from therapy due to alleviation of negative beliefs about the self. Conversely, individuals who present with 'Poor Me' paranoia will be more difficult to engage, due to higher levels of narcissism and grandiosity, and will be more resistant to accepting help.

However, there have been few studies to test these hypotheses. One study investigated the clinical characteristics of a sample of 53 individuals sub classified into 'Poor Me,' 'Bad Me,' or neither category, finding that the 'Bad Me' group had lower self-esteem, more negative self-evaluative beliefs, lower negative evaluative beliefs about others and higher depression and anxiety (Chadwick, Trower, Juusti-Butler & Maguire, 2005). These findings may indicate that there are two distinct types of paranoia. Further research into possible typologies of paranoia could prove clinically and theoretically useful.

The second line of evidence that Trower and Chadwick (1995) cited originates from a cognitive model of auditory hallucinations (Chadwick & Birchwood, 1994) and the attributions given to them based on dimensions such as power, identity and purpose. However, this may not be a valid way of conceptualising persecutory delusions since the phenomenology of auditory hallucinations may not be directly the same as that of persecutory ideation.

Although potentially useful, these models are mentioned here for context because they do suggest some interesting theoretical and clinical hypotheses, and there is some evidence for them. Neither of these models identifies anxiety or reasoning biases as significant mechanisms in the formation and maintenance of paranoia, therefore, this thesis will focus on the Threat Anticipation Model (Freeman, 2007).

1.5 Summary and conclusion

In conclusion, clarity on the definition of persecutory delusions as well as their theoretical basis is essential for research and clinical practice to make advances. As discussed above, psychological models of persecutory beliefs have been developed to identify treatment targets and test these empirically. Prominent treatment targets suggested from the Threat Anticipation Model (Freeman et al., 2002; Freeman, 2007) are interpersonal-related anxiety and reasoning biases. These models of persecutory beliefs have opened up further research avenues with which treatments can be developed and evaluated. However, due to such attempts being made only relatively recently, it would be useful to investigate if cognitive packages targeted specifically at persecutory delusions are effective, and if so, if any common treatment approaches or targets can be identified as being most effective. The next section will give a systematic review of the literature focusing on this issue.

1.6 Systematic review of the efficacy of cognitive behavioural therapies in treating persecutory delusions

1.6.1 Overview. This section gives a systematic review of the literature to evaluate the efficacy of cognitive behavioural therapy for persecutory delusions. The review will consider the methodological profile of relevant studies. It will highlight the need to replicate findings of key studies and to determine specific mechanisms of change, as well as common elements or therapeutic targets that work best. The research and clinical implications of this will be discussed, with an emphasis on further developing the field.

1.6.2 Search strategy. A literature search was performed separately on the Embase, Medline and PsycINFO databases on 6th May 2014. Although the review focuses on persecutory delusions within the context of psychosis, earlier searches incorporating different terms relating to psychosis (e.g., schizophren* OR psychosis OR schizoaffective...etc.) failed to detect key papers (e.g., Foster, Startup, Potts & Freeman, 2010). Therefore, the search

used two groups of terms; one group of terms for various cognitive behavioural therapies and the other a group of differing terms relating to persecutory delusions. Search terms were nested together, rather than entered as phrases, which maximised sensitivity. The following terms were used: (cognitive AND behavio* AND therapy) OR CBT OR (cognitive AND therapy) OR (metacognitive AND therapy) OR (metacognitive AND training) OR (reasoning AND training) OR (cognitive AND bias AND modification) OR (acceptance AND commitment AND therapy) OR (dialectic AND behavio* AND therapy) OR (DBT) OR (dialectical AND behavio* AND therapy) AND (persecut* AND delusion*) OR persecut* OR (paranoi* AND delusion*) OR paranoi*. Titles, abstracts and occasionally methodology sections were scrutinised manually to reveal CBT based packages that specifically reported persecutory delusions. As evident from the search parameters, various CBT based packages were searched for, including 2nd and 3rd wave therapies. The ancestry method was also used to identify studies the initial search missed.

1.6.3 Inclusion criteria. *A priori* limits were set to human studies, published in the English language. Peer reviewed journals were not set as search parameters prior to the search, but non peer-reviewed articles were excluded during manual screening. No other parameters were set. The search revealed 509 results on Embase, 154 on Medline and 315 on PsycINFO. Studies were only selected on the basis of persecutory delusions being reported in the title or abstract. Studies reporting paranoid delusions alone were further scrutinised to determine suitability for inclusion. This is because paranoid delusions and persecutory delusions are often referred to interchangeably in the literature (Key et al., 2003). This may result in studies that purport to examine one specific element of psychotic experience actually including varying types, such as delusions of reference as well as persecutory delusions, in their respective samples. In some cases, it was not clear if the delusion could be classified as paranoid or persecutory. In keeping with Freeman and Garety's (2000) criteria of (a) harm

occurring, or will be occurring to the individual in question, and (b) a persecutor having intention to inflict harm, some studies were omitted, (e.g., Serruya & Grant, 2009; Key et al., 2003). This is because some of the delusional themes were of being under surveillance, with no actual harm – psychological or physical – intended (or none reported).

One study reported a randomised controlled trial of paranoia-focused CBT for a sample of individuals with persecutory delusions (Landa et al., 2012), but was excluded because only conference proceedings were published and no written material other than the abstract was available. During various searches for more material, a previous abstract that briefly described the RCT was discovered (Landa et al., 2011), so this was included. Attempts to contact the authors to determine if more information was published were unsuccessful. All duplicates were excluded in the initial screening phase. In total, 14 studies were selected from Embase, one from PsycINFO, one from Medline, and one as described above. A review of the studies' reference lists revealed one further study (Kuipers et al., 1998). Although this was not an RCT specifically targeting persecutory delusions, it is the first RCT of CBT to specifically report persecutory delusions, and so effects of CBT can be examined. This study was included in a selective review of CBT for persecutory delusions (Garety, Bentall & Freeman, 2008). Three studies were then excluded from the full-text articles assessed for eligibility, as described above (Landa et al., 2012; Serruya & Grant, 2009; Key et al., 2003). Figure 1.2 below provides a PRISMA diagram (Moher et al., 2009) indicating how the literature was selected. Table 1.1 below presents the selected studies in chronological order.

Figure 1.2 PRISMA diagram of systematic literature review

Identification

Records identified through database searching
(n = 978)

Additional records identified through other sources
(n = 2)

Records after duplicates removed
(n = 793)

Screening

Records screened
(n = 793)

Records excluded
(n = 775)

Eligibility

Full-text articles assessed for eligibility
(n = 18)

Full-text articles excluded, with reasons
(n = 3)

Studies included
(n = 15)

Included
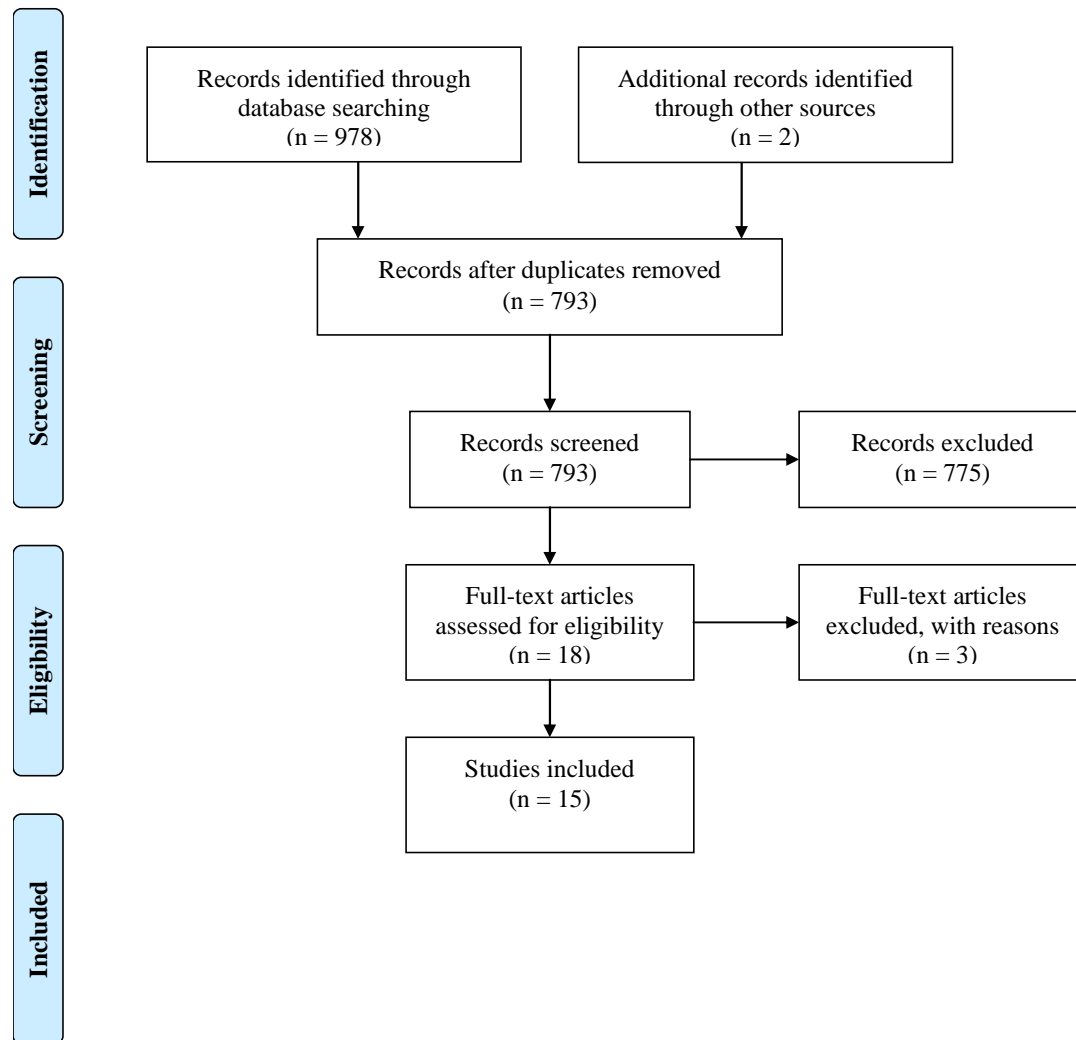
Table 1.1
Studies reporting on the efficacy of differing cognitive behavioural therapies for persecutory delusions, displayed in chronological order.

Author	Study design	N/ Sex	Mean age (SD)	Diagnosis	Delusion description(s)	Therapy – no of sessions	Outcome measures	Outcomes (1st baseline - last follow up, or mean change, if applicable)
Chadwick and Trower (1995)	Multiple-baseline single case	1 M	31	Schizophrenia	(a) Being punished by members of the public (b) Being physically punished by God for blasphemy	12 sessions Cognitive Therapy	1. BDI 2. Idiographic conviction % rating of belief (a) 3. Idiographic conviction % rating of belief (b)	1. BDI: 24 – 9 2. Conviction in belief a: 100% - 5% 3. Conviction in belief b: 40% - 0%
Kinderman and Bentall (1997b)	Case report	1 M	33	Paranoid schizophrenia	Conspiracy to pressure him into joining a drug cartel	21 sessions Attribution Therapy	1. BDI 2. Idiographic paranoid anxiety, depression and self-esteem ratings (/10) 3. FPS 4. IPSAQ	1. BDI: 30 – 8 2. Paranoid anxiety: 7/10 – 1/10, depression† self-esteem† 3. FPS: 78 – 40 4. IPSAQ +5 - +2
Kuipers et al. (1997)	RCT	38 M 22 F	40 Range: 18-65	Psychosis	Various persecutory delusions	Mean of 19 sessions CBT for psychosis	1. BPRS 2. MADS: conviction and distress 3. BDI 4. BAI	1. BPRS: reduction** 2. non-significant reduction in conviction and distress 3. BDI: non-sig. difference 4. BAI: non-sig. difference

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Table 1.1 (continued)

Author	Study design	N/ Sex	Mean age (SD)	Diagnosis	Delusion description(s)	Therapy – no of sessions	Outcome measures	Outcomes (1st baseline- last follow up, or mean change, if applicable)
Morrison 2004	Case Study	1 M	30	Delusional disorder	Being under surveillance by a group who wished him harm	12 sessions Imagery-based CBT	PSYRATS Delusions: 1. Conviction 2. Preoccupation 3. Distress	PSYRATS Delusions: 1.Conviction: 100% - 0% 2.Preoccupation: 75% - 0% 3.Distress 75% - 0%
Pinninti and Datto (2006)	Case report	1 F	80	Paranoid schizophrenia	Being poisoned by the blood tests required for clozapine monitoring	† sessions CBT	Medication adherence	Initial withdrawal of clozapine due to refusal of blood draws – Acceptance of blood draws and clozapine adherence.
Hagen and Nordahl (2008)	Case study	1 M	25	Paranoid schizophrenia	Being tortured by members of the anti-narcotic squad through radio beams	42 sessions Behavioural experiments	Idiographic ratings of: 1. Anxiety (/8) 2. Depression (/8) 3. Conviction (/8)	1. Anxiety: 8/8 – 0/8 2. Depression 8/8 – 0/8 3. Conviction 8/8 – 0/8
Foster, Startup, Potts and Freeman (2010)	RCT	14 M 10 F	CBT: 40 (10) TAU: 39.1 (9.2)	Schizophrenia, schizoaffective disorder, delusional disorder	Various persecutory delusions according to Freeman and Garety's (2000) criteria	4 sessions CBT worry intervention	1. PSWQ 2. PSYRATS-B: frequency / duration 3. PSYRATS-B: distress 4. GPTS	1. Reduction in PSWQ* 2. Non-significant reduction in PSYRATS frequency/duration 3. Reduction in distress* 4.Non-significant reduction in GPTS

Table 1.1 (continued)

Author	Study design	N/ Sex	Mean age (SD)	Diagnosis	Delusion description(s)	Therapy – no of sessions	Outcome measures	Outcomes (1st baseline- last follow up, or mean change, if applicable)
Kuller and Bjorgvinsson (2010)	Case Study	1 M	33	Paranoid schizophrenia	Being under surveillance by the mafia, who intend to kill him.	30 sessions CBT	Idiographic measures of 1. Conviction (/100) 2. Preoccupatiom (/100)	1. Conviction: 98 – 20 2. Preoccupation: 90 – 5
Hatzipetrou and Tian Po Oei (2010)	Case study	1 M	53	Paranoid schizophrenia	No description reported	11 sessions CBT	1. DASS: Depression, 2. DASS: Anxiety 3. DASS: Stress 4. BDI-II 5. BAI	1. DASS Depression: 25 – 18 2. DASS Anxiety: 25 – 20 3. DASS Stress: 28 – 21 4. BDI-II: 36 – 24 5. BAI: 33 – 22
Coentre and Power (2011)	Case report	1 F	32	Psychosis, PTSD	Men in white are following her and are coming to get her	† sessions CBT	Self-report qualitative descriptions of symptoms	Psychotic symptoms resolved, according to self-report and clinician opinion.
Myers, Startup and Freeman (2011)	Pilot Trial	9 F 6 M	45.5 (11.3)	Insomnia and Schizophrenia, psychosis, schizoaffective disorder, or delusional disorder	Various persecutory delusions according to Freeman and Garety's (2000) criteria	4 sessions CBT-I	1. ISI 2. PSQ 3. GPTS 4. PSYRATS-B 5. DASS Anxiety 6. DASS Depression 7. CAPS	1. ISI reduced** 2. PSQ reduced** 3. GPTS reduced** 4. PSYRATS reduced** 5. DASS Anxiety: reduced** 6. DASS Depression: reduced** 7. CAPS reduced*

Table 1.1 (continued)

Author	Study design	N/ Sex	Mean age (SD)	Diagnosis	Delusion description(s)	Therapy – no of sessions	Outcome measures	Outcomes (1st baseline- last follow up, or mean change, if applicable)
Bloy, Oliver and Morris (2011)	Case study	1 M	32	Psychosis	Others are plotting and conspiring against him	27 sessions of ACT	1. CORE-OM 2. PSYRATS-B 3. CES-D 4. HoNOS	1. CORE-OM: 0.88 - 0.68 2. PSYRATS-B: 8 – 7 3. CES-D: 30 – 22 4. HoNOS: 19 – 2
Landa et al. (2011)	RCT	24	Range: 18-65	DSM-IV Schizophrenia or Schizo - affective disorder	Persecutory delusions: specifics not reported	30 sessions Group and Individual P-CBT	1. Persecution Severity Score on PANSS 2. Cognitive Biases, specific measure not reported	1. Significant reduction in Persecution Severity† 2. Reduction in cognitive biases†
Hepworth, Startup and Freeman (2011)	ABA baseline case series	8 M 4 F	40.3 (11.9)	Schizophrenia or delusional disorder	Persecutory delusions according to Freeman & Garety's (2000) criteria	3 sessions EPMA	1. PSYRATS-B 2. DASS: Anxiety 3. DASS: Depression 4. PSWQ 5.RSQ	1. PSYRATS-B reduction** 2. DASS: Anxiety reduction 3. DASS: Depression* 4. PSWQ: reduction* 5.RSQ: reduction
Ellett (2013)	Case series	2 M	34, 49	Delusional disorder	Persecutory delusions according to Freeman & Garety's (2000) criteria	6 sessions mindfulness	1. Conviction 2. Distress 3. Impact 4. Preoccupation 5. SMQ 6. HADS	Reduction in all ratings of psychopathology and increase in mindfulness ratings. Positive behaviour change also.

Note – standard deviations of mean ages are presented in parentheses. † = missing/unreported data. BDI = Beck Depression Inventory; Beck and Steer (1987). FPS = Fenigstein and Vanable's Paranoia Scale (1992). IPSAQ = Internal, Personal and Situational Attributions Questionnaire; Kinderman and Bentall (1996). BPRS = Brief Psychiatric Rating Scale; Overall and Gorham (1962). MADS = Maudsley Assessment of Delusions Scale; Buchanan, Reed & Wessley (1993). BAI = Beck Anxiety Inventory; Beck, Epstein, Brown, & Steer (1988). PSYRATS-B = Psychotic Symptoms Rating Scales,

Delusions Subscale; Haddock, McCarron, Tarrier and Faragher (1999). PSWQ = Penn State Worry Questionnaire; Meyer, Miller, Metzger and Borkovec (1990). GPTS = Green et al. Paranoid Thought Scales; Green et al. (2008). DASS42 = Depression, Anxiety and Stress Scales; Lovibond and Lovibond (1995). BDI-II = Beck Depression Inventory – 2nd Edition; Beck, Steer & Brown (1996). PTSD = post-traumatic stress disorder. CBT-I = CBT for Insomnia. ISI = Insomnia Severity Index; Bastien, Vallieres & Morin (2001). PSQ = Pittsburgh Sleep Quality Index; Buysse, Reynolds, Monk, Berman & Kupferet (1988). CAPS = Cardiff Anomalous Perception Scale; Bell, Halligan & Ellis (2006). ACT = Acceptance and Commitment Therapy. CORE-OM = Clinical Outcomes in Routine Evaluation – Outcome Measure; Evans et al. (2000). CES-D = Center for Epidemiologic Studies – Depression Scale; Ross and Mirowski (1983). HoNOS = Health of the Nation Outcome Scales; Wing et al. (1998). P-CBT = Paranoia-Focused CBT. PANSS = Positive and Negative Syndrome Scale; Kay, Fiszbein & Opler (1987). EPMA = Emotional Processing and Metacognitive Awareness. RSQ = Response Style Questionnaire; Nolen-Hoeksema & Morrow (1991). SMQ = Southampton Mindfulness Questionnaire; Chadwick et al. (2008). * $p \leq$ .05. ** $p \leq$ .01.

1.6.4 Evaluation of case studies. Chadwick and Trower (1995) described Bill, with whom they used cognitive therapy, to target both of his persecutory beliefs sequentially. Using a multiple-baseline design made the results more reliable than single case studies, as it established that observed change could be attributed with more confidence to the treatment, rather than extraneous influences. The idiographic conviction rating in belief (a) was stable throughout baseline and intervention phase until session 5, when it fell from approximately 95% to 50%. Conviction in belief (b) was more erratic, but indicated a decline overall. Use of follow up assessments at one, two and three months further strengthened the study. However, presenting an isolated case contributes little to the evidence base (Kazdin, 2010). It is interesting that depression, not anxiety, was assessed – according to the Threat Anticipation Model (Freeman, 2007), there may have been a very important treatment target that was missed.

Kinderman and Bentall (1997) presented BI, with whom they used attribution therapy, in order to allow BI to re-attribute negative life experiences to situational causes rather than persecutory delusions. As described in table 1, they took multiple observations of idiographic measures of paranoid anxiety, low mood and self-esteem over two therapy phases, before and after introducing instructions to practice alternative situational explanations for ambiguous events. As well as a visual graph, they also conducted one-way ANOVA indicating significant declines in paranoid anxiety ($F (1, 47) = 24.08$, $p <.0005$), low mood ($F (1, 47) = 10.11$, $p <.005$) and poor self-esteem ($F (1, 47) = 12.04$, $p <.005$). Improvements on paranoid anxiety were maintained at one - five month follow up. A lack of multiple baseline assessments confused the differential effects of the two different therapies (Kazdin, 2010).

Morrison (2004) reported Joe, with whom CBT with imagery was used. Although use of standardised assessment tools (PSYRATS) could be considered more robust than idiographic measures, there was no extended baseline period. Also, the study could have benefitted from more controlled applications of verbal, imaginal and behavioural intervention

strategies (Barker, Pistrang & Elliott, 2011). Table 1 indicates improvement in delusional conviction, preoccupation and distress.

Pinninti and Datto (2006) briefly described a case where CBT was used to assist with Clozapine monitoring. The individual rapidly developed delusions of being poisoned by the blood tests necessary to continue Clozapine therapy and withdrew from treatment. CBT was initiated and focused on this delusion. Following improvement, Clozapine was re-instated and maintained. Other than medication compliance, no other measures were reported in this letter to the editor, making further interpretation of the efficacy of CBT in this case impossible.

Hagen and Nordahl (2008) presented Tony, who was treated with 42 sessions of behavioural experiments. A rich account of the various behavioural experiments was given. All measures were idiographic and no stable baseline of difficulties was established (Kazdin, 2010). Although all domains improved, follow up was only a week following the therapy, which cannot determine longer term gains.

Kuller and Bjorgvinsson (2010) reported on Michael, treated with CBT. A detailed history and case conceptualisation is given, e.g., after 10 sessions, Michael was able to trust his wife again, and moved back home with his family. This can be useful information from a clinical perspective. However, no extended baseline assessment was conducted, weakening the methodology (Kazdin, 2010). There was also no official follow-up.

Hatzipetrou and Tian Po Oei (2010) described 11 sessions of CBT with MH, who experienced persecutory delusions and visual and auditory hallucinations. Although improvements were documented, no elements specifically related to delusions were assessed, e.g., conviction, etc. The authors did not include a description of the belief, and the therapy focused more on hallucinations. Lack of extended baseline or follow-up also weakened their methodology (Kazdin, 2010).

Coentre and Power (2011) presented a case of psychosis and PTSD, treated with an unknown number of CBT sessions. Although clear persecutory ideation was described, no standardised measures were reported, leaving only clinician opinion, which reported psychotic symptoms being 'resolved,' and persistent PTSD symptoms. This article was much more focused on the challenges of diagnosis rather than the efficacy of CBT. This was more of a clinical case presentation rather than a piece of research with methodological rigour.

Bloy et al. (2011) reported on Brian, who believed that he was being filmed by the secret service and was the subject of a malevolent conspiracy. He was treated with 27 sessions of ACT, which, although a 3rd wave CBT therapy, is quite different in its underlying approach. As with other studies, a rich account of Brian's history and comprehensive case conceptualisation was given. As indicated in Table 1, Brian improved on all outcomes, and these measures were appropriate for delusional experiences. One strength of this study was calculation of reliable change indexes. Interestingly, all outcomes except for the PSYRATS B demonstrated reliable reduction. These outcomes fit well with the ACT model, as symptom reduction is not the aim: increasing ability to cope with and limiting distress resulting from symptoms is the focus. A 6 month follow-up was conducted, but outcome measures were not taken. HoNOS ratings were performed by independent evaluators, which is another advantage.

Ellett (2013) described two participants who undertook mindfulness exercises for persecutory beliefs. Description of the beliefs allowed clear comparison with Freeman and Garety's (2000) criteria. This study was succinctly reported, but contained all of the information needed to evaluate its strength. Therapy followed previously published guidance, increasing uniformity of delivery. Although outcomes were independently verified, clinical supervision of therapy delivery would have increased the study's merit (Barker et al., 2011). The design addressed the research question well but a longer baseline was needed to establish

whether symptoms were on a natural path to recovery or not – Kazdin (2010) suggests a minimum of five observations.

1.6.5 Evaluation of group Studies. The RCT conducted by Kuipers et al. (1997), although not designed specifically for persecutory delusions, still comprises one of the best sources of evidence of the efficacy of CBT. Randomisation to treatment and control conditions limited bias and also provided fair basis for comparison. Although a CONSORT diagram (Altman et al., 2001) was not given, a full account of the recruitment and selection process was provided, increasing confidence in the sampling methods used. Power calculations indicated their sample size was such that inferences could be made about the population from which the sample was derived. Although assessors were not blinded to condition (a common difficulty in psychology research), all assessments were carried out by independent researchers. Peer and therapy supervision was also reported, along with efforts to maintain uniform provision of therapy - manualised therapy facilitated this (Fowler, Garety & Kuipers, 1995). Detailed numbers of therapy sessions conducted with all clients was reported, which is an advantage. Similarly, strategies to maximise engagement and minimise drop out were also outlined. This controlled against participants being excluded from analyses due to insufficient engagement, which can be the result of more severe levels of distress or symptoms. Maximising engagement strengthened the method as this more closely mirrored clinical practice.

In terms of data analysis, missing data and data transformations were reported and appropriate. Where participants were lost to second assessment, subsequent intention to treat analyses were conducted using the carry forward method to impute missing values. This represents a particular strength, given that this RCT was one of the first of its kinds at the time. Assessments were conducted at initial, three, six and nine month intervals, with a follow-up assessment at 18 months after entry. The length of follow-up assessment was a further strength. Use of two-way analysis of variance (ANOVA) with both explanatory

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factors being treatment centre (London, Norwich or Cambridge) and treatment group (CBT vs. TAU) was an appropriate way of analysing the data. Number needed to treat analysis might have been another advantage, had it been employed (Barker et al., 2011).

Measures were appropriate for the research questions concerned – in the case of this review, significant improvement in the BPRS suspiciousness item indicated improvement in persecutory ideation and ideas of reference. Unusual thought content (delusional ideas) and hallucinations also significantly improved. The change was greatest on these three variables, indicating that efficacy of CBT for persecutory and delusional ideation was effective. No other clinical or occupational variable improved significantly (apart from total BPRS scores), including other individual BPRS items, such as delusional conviction and distress. Even considering its modest efficacy and the fact that generic CBT for psychosis was used rather than specific interventions targeting persecutory ideation, this study still represents some of the most robust evidence for efficacy of CBT.

Foster et al. (2010) reported on the first published RCT to specifically target persecutory delusions. Increased theoretical understanding of formation and maintenance of persecutory ideation has led to identification of more specific putative causative processes, resulting in development of novel treatment targets; in this case interpersonal worry. They were also interested in finding if changes in worry were related to changes in paranoia, as there are theoretical grounds for this. Inclusion criteria were psychosis spectrum disorder and presence of persecutory ideation according to Freeman and Garety's (2000) criteria, which increaseed confidence in the sampling methods used. They also stipulated a clinically significant level of worry: 45+ on the PSWQ.

A CONSORT diagram was provided, outlining the recruitment process and losses to follow-up, which further improved transparency and confidence in non-biased recruitment and data analysis. Block randomisation to treatment and control conditions, performed by an independent researcher limited selection bias. Both treatment and control conditions were

described, but manualising the worry intervention might have improved uniform delivery of therapy across all participants. Therapy supervision was given to the author who delivered it. There was no monitoring of therapy adherence or competence however, which is a weakness. High levels of engagement with therapy were reported: all individuals completed all 4 sessions.

A *priori* power calculation indicated a sample size of 24 (12 in each arm) to achieve a clinically important effect size of 0.9 in the analysis of PSWQ scores, at 90% power and 5% (2-sided) significance. Outcome measures in Table 1 are appropriate to the research question: delusional dimensions as well as paranoia, worry and persecutory ideation are all important variables. The outcomes were modeled using multilevel linear regression as the data were longitudinal and this method is robust against missing data (Van Der Leeden, 1998).

Kendall's *tau* was calculated to investigate possible relationships between reduction in worry and reduction in persecutory thoughts. This method is robust against outliers and ties in the data. Adjusting for baseline differences indicated that W-CBT reduced worry by ten points at two month follow-up in comparison to TAU – a significant difference. Similarly, PSYRATS delusional distress scores were reduced by 1.7 points in comparison to TAU at two month follow-up. Reliable and/or clinical change were not reported, which may have benefitted the study (Kazdin, 2010), although given that the reliable change index calculated by others (e.g., Bole et al., 2011) for the PSYRATS-B subscale is 5.41, it is very unlikely that reliable change could be evidenced based on the reported data. Finally, non-significant reductions in paranoia when compared to TAU were positively correlated with reductions in persecutory ideation, measured by the PSYRATS, at two month follow-up.

Although a good pilot study, it would have been greatly improved if the sample size had been increased (Barker et al., 2011); this may have added increased power to detect significant changes in paranoia. There were also differences between the groups, the intervention group initially having higher levels of worry and paranoia. Another follow-up

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after 2 months would have improved understanding of longer term therapeutic gains Kazdin, 2010).

Myers et al. (2011) reported a pilot trial of CBT-I for persecutory delusions, given that insomnia has been theoretically and empirically identified as a strong putative causal and maintaining factor for paranoia and persecutory ideation (Freeman, 2007). Using an open, uncontrolled trial methodology was appropriate for pilot research, but ideally a small scale RCT would have increased confidence in the findings. Power calculations identified a total of eleven participants needed to have 80% power to detect an effect size of 0.96 for a reduction in insomnia, using a single group t-test with a 0.5 two-sided significance level. Fifteen individuals were recruited to allow for loss to follow-up. A diagnosis of psychosis spectrum disorder and presence of persecutory delusions as defined by Freeman and Garety (2000) clarified the sample. Flow-charting recruitment and selection improved transparency and limited selection bias. The components of therapy were briefly discussed, but there was no treatment manual developed, and although the therapist was supervised, adherence and competence was not formally assessed.

The design was amended after eight participants had been through the process. An extra baseline assessment of all outcome measures was added one or two weeks before the pre-treatment assessment, to assess stability of symptoms. This strengthened the methodology, indicating that the symptoms were not on a path of natural recovery. In terms of data analysis, there were no missing data. Changes in outcomes across time (pre and post-treatment, one month follow-up) were assessed using repeated measures ANOVA, which is appropriate, although reporting properties of assumptions of the data would have increased confidence in the appropriateness of the analyses. Pairwise comparisons identified differences in assessment times and effect sizes were calculated using Cohen's d (Cohen, 1988) – this multiple statistical testing is a disadvantage (Barker et al., 2011), although confidence was enhanced due to all measures showing similar changes.

As indicated in Table 1, all outcomes were significantly reduced at one month follow-up. Although delusional content was never targeted, improving sleep reduced persecutory ideation. There were also moderate to large effect sizes for reduction of anxiety, depression and anomalous experiences. This study represents a well designed and carried out pilot test, with some disadvantages, such as lack of control group and randomisation, short length of follow-up assessment, and small sample size (Barker et al., 2011).

Landa et al. (2011) reported a small scale RCT of group P-CBT for 24 adults experiencing drug-refractory persecutory delusions. Groups were randomised to P-CBT plus TAU, or TAU alone. Therapy consisted of one group and one individual session weekly for 15 weeks, participants were assessed by blind assessors at baseline, post-treatment and six month follow up. Differential treatment effects were examined using linear mixed effects modeling, indicating significant reductions in PANSS Persecution Severity (main outcome). It is unclear as to whether these analysis methods were appropriate, as no other information was given, e.g., power calculations. No other details of the study were reported in this abstract, and so judgments cannot be made as to how well it was carried out. The study does provide preliminary efficacy of P-CBT for persecutory delusions.

Hepworth et al. (2011) reported a case series using an ABA design. Two baseline assessments were conducted, allowing comparison of baseline differences between both time points. They report that symptoms were improving during the baseline period, which limits confidence in the findings (see table 1.1; Barker et al., 2011), but does improve transparency and methodology. The intervention itself involved three sessions of writing about their experiences of persecutory beliefs in a narrative style, to promote access to the emotional experience. Further verbal descriptions of the material were encouraged but in a reflective rather than evaluative manner, to promote exposure to anxiety and hence habituation. Following this, the narrative was broken down to identify thoughts, feelings, images and memories, to promote metacognitive awareness. Participants were then encouraged to

observe the malleability of thoughts, to promote acceptance. Finally, Gestalt and diffusion techniques were used where experiences were particularly powerful and distressing.

This study has some limitations. No CONSORT diagram was provided to show how participants were recruited (Altman et al., 2001). No randomisation to treatment was conducted. All assessments were carried out unblinded also (Barker et al., 2011). As indicated in Table 1, paired *t* tests were conducted to determine symptomatic change. However, no formal power calculation was reported, and so it is unclear if a sample size of 12 participants with repeated measures can provide enough data for adequately powered analysis (Field, 2005). With this in mind, the authors report reliable change estimates for the PSYRATS-B, indicating that ten participants showed reliable improvement in total scores following the intervention phase, one showed no change, and one reported a reliable increase in delusion symptoms.

1.6.6 Discussion. Although the literature reviewed is varied and from different theoretical viewpoints, there is preliminary support that CBT based interventions are efficacious for persecutory delusions. Before the theoretical and clinical implications of these studies are discussed, the overall limitations shall be briefly outlined.

1.6.6.1 Methodological issues regarding the studies reviewed. Single-case research has been shown to be useful for pilot testing of novel therapies and developing rich phenomenological accounts of how hypothesised mechanisms interact to drive intention, behaviour and belief systems (Kazdin, 2010). It also provides insight into individual mechanisms of change, which may then be tested using group designs. The single case design can also be used to identify gaps in research and refine clinical theories or models. Although the case studies reported give rich accounts of the problems and how they were maintained and treated, their usefulness is limited. They cannot make claims as to efficacy of a therapy using isolated or small sample designs – they can only test them out in a preliminary fashion (Kazdin, 2010). Regarding multiple baseline single case series methodology, a convincing

demonstration of intervention efficacy requires change that does not occur across settings, behaviour or individuals until the intervention is introduced; change that does occur across outcomes simultaneously is therefore difficult to interpret from a research viewpoint, even if it may be desirable from a clinical perspective (Nock, Michel & Photos, 2007). In terms of data analysis, there is ongoing debate as to the most appropriate method for analysing time-series data; different authors promoting visual inspection (e.g., Kazdin, 2010) and inferential statistical testing (e.g., Zhan & Ottenbacher, 2001). Both approaches suffer disadvantages: visual inspection has been criticised for being too subjective, with different analysts reaching different conclusions (Kazdin, 2010), whereas inferential statistics for small sample sizes are invalid because they are underpowered to detect real change.

As indicated, evaluating the efficacy of CBT for persecutory delusions is majorly hampered by a lack of well-designed RCTs. Given that persecutory delusions are such a common experience in psychosis, the various trials that have examined efficacy of CBT for psychosis would have encountered and treated many individuals with persecutory ideation. This is unfortunate; a lack of clarity in defining, identifying and reporting persecutory delusions in this research has led to heterogeneity of the research samples. This hampers exact analysis of effects, leading to a situation where firm conclusions cannot yet be drawn.

More recent efforts to gain clarity on the problem are proving beneficial, with some small trials reporting preliminary progress. The quality of these trials is improving which increases confidence in their findings. However, there are always improvements that can be made. Longer follow-up assessment periods would inform length of therapeutic gains Barker et al., 2011). Arguably, once of the most crucial reasons for a follow-up assessment is that CBT based interventions help clients to maintain their own therapeutic gains. Evidence indicates that CBT for psychosis is superior for maintenance of gains when compared to other more general supportive work, e.g., befriending (Garety, Fowler & Kuipers, 2000).

Although very difficult to achieve and easily undone, blind assessment is possible and studies that successfully employ it are at an advantage, as unblinded assessment has been found to be a particular source of bias (Tarrier & Wykes, 2004). Manualisation of therapy, clear reporting of supervision and formal assessment of quality and adherence will add further clarity as to what the 'active ingredients' of the therapy are. This also promotes further development of treatments, to make them safer, more tolerable and effective.

In summary, there are some key methodological strengths across the above sample of studies. The variety of case studies provides a rich account of various therapeutic targets, according to presentation, which inform individual clinical work. The above case studies also identify novel treatment targets and provide detailed information on individual mechanisms of change. The small numbers of RCTs provide data on the effectiveness of specific forms of CBT for persecutory delusions that target specific areas of psychopathology, e.g., clinical levels of worry and insomnia.

However, there are key methodological weaknesses in the above sample of studies also. Many of the case studies did not employ baseline lengths of sufficient duration to establish stability of symptoms. The group designs suffer from this limitation also; one measure of symptoms at one time-point does not facilitate group statistical comparison, which is important in determining whether or not significant symptomatic differences existed prior to package. One study that did address this difficulty was that of Myers et al (2011).

1.6.6.2 Theoretical and clinical implications. Broadly speaking, the research to date supports the Threat Anticipation Model (Freeman, 2007). Specific mechanisms of formation and maintenance of persecutory ideation include anxiety, such as worry and disturbances in functioning, e.g., insomnia. These have been used successfully as proxy therapeutic targets, which have had beneficial effects on persecutory delusions and paranoia. Out of the 15 studies reviewed, nine of them report variants of anxiety as specific therapeutic goals. Considering some studies came from differing theoretical viewpoints, as well as others not

reporting any specifics about therapeutic targets; this in itself can be considered to be good consensus that anxiety is an important mechanism of persecutory ideation.

Some therapeutic components common to the studies include generic CBT principles, such as engagement, working collaboratively, normalisation, exploring meaning and appraisals of psychotic experiences, working with negative affect and relapse prevention. Another common theme was not directly challenging delusional content. This seems to be an important consideration when working clinically: Brehm (1966) termed 'psychological reactance' the process whereby direct challenging of a delusional belief may only serve to further reinforce it. Other common components included reviewing the evidence, practicing generating alternative explanations for experiences and reality-testing. These techniques could be thought of as attempts to improve belief inflexibility, as described by the Threat Anticipation Model (Freeman, 2007). However, no studies to date have targeted specific reasoning biases, such as JTC, within the context of persecutory delusions. Whether or not this will result in clinical improvement remains to be determined, however, future studies now have very specific targets with which to test out therapies to see if they have a positive impact.

Finally, the studies also show the positive benefits of applying attribution theory to a clinical setting (e.g., Kinderman & Bentall, 1997b). This suggests that the Threat Anticipation Model (Freeman, 2007) may benefit from also considering the process of misattributions in persecutory ideation.

1.6.7 Conclusion. In summary, although the quality of the evidence of CBT for persecutory delusions is improving, it is still premature to draw firm conclusions about efficacy. However, some forms of CBT that focus on convergent therapeutic targets (e.g., anxiety) do seem to benefit individuals with persecutory delusions. Clearer definition of the problem and consensus among researchers as to the definition will greatly assist a more uniform approach to sampling methods. Structured, clearly specified interventions set at

theoretically and empirically identified treatment targets will bring clarity to mechanisms of change. Single-case research that is designed well should provide rich information about potential benefits and pitfalls of these therapies. Appropriately designed group research that is well powered to detect key processes of change will enable findings to be generalised to the population, and should help shape policy of care and treatment.

When considered together, the main drawback from the above sample of studies is that there are not enough of them to give a clear indication as to the efficacy of any of the forms of CBT for persecutory delusions used. There is a clear need for further research as outlined above before the question 'are CBT interventions efficacious for persecutory delusions?' can be answered one way or the other.

1.7 Rationale for the current study

The Threat Anticipation Model (Freeman, 2007) identifies specific treatment targets for persecutory delusions. In particular, social anxiety or worry of an interpersonal nature, anomalous experiences, and reasoning biases are implicated in the formation and maintenance of paranoia and persecutory ideation.

With this in mind, together with the recent empirical evidence discussed, treatments to reduce social anxiety are now indicated in the study of persecutory delusions. To identify suitable treatments for social anxiety, the anxiety literature should be consulted. If there are psychological mechanisms common to individuals with anxiety disorders as well as individuals with psychotic disorders, then treatments shown to be efficacious for one group may also be so for the other. There is much evidence indicating that socially anxious individuals selectively attend more to socially threatening words in experimental situations using tasks such as the dot-probe task (e.g., Pishyar et al., 2004) and the stroop test (e.g., Matthews & MacLeod, 1985). These studies indicate that socially anxious individuals demonstrate a negative attention bias, which is in keeping with the Threat Anticipation Model (Freeman, 2007) of persecutory ideation. Studies also indicate that individuals with clinical

and non-clinical levels of social anxiety demonstrate a more negative interpretation bias when processing and interpreting ambiguous social information; i.e., they interpret ambiguous situations as negative and threatening (e.g., Stopa & Clarke, 2000; Mathews & Mackintosh, 2000). This bias would seem to have particular clinical relevance for individuals with social anxiety as well as paranoia, given the overlap between the two, since most social situations are ambiguous and are therefore open to interpretation.

1.7.1 Targeting social anxiety: cognitive bias modification for interpretation (CBM-I). Building on these findings, recent research has focused on whether or not these interpretative biases can be modified to help the individual process social information in a less negative and threatening way. One treatment is known as Cognitive Bias Modification for interpretation (CBM-I; Mathews & Mackintosh, 2000). This is based on the premise that repeatedly exposing the individual to socially ambiguous stimuli and then promoting positive and non-threatening interpretation of that information will modify the pre-existing negative interpretation bias towards a more positive one. This is usually done through text-based computer training programmes that deliver repeated scenarios in specific ways. How CBM-I is conducted will be described in further detail in section 2.3.1 below.

Many previous studies have shown a relationship between negative interpretation bias and varying levels of severity of anxiety, ranging from non-clinical high trait anxiety (e.g., MacLeod & Cohen, 1993) to clinical levels of social anxiety (e.g., Mobini, Reynolds & Mackintosh, 2013). A recent meta-analysis of studies using CBM-I within clinical and non-clinical samples indicates small but significant effect sizes on anxiety in both post-test ($g = 0.13$, 95% CI = [0.05, 0.22]) and stressor ($g = 0.28$, 95% CI = [0.16, 0.41] types of study protocol (Hallion & Ruscio, 2011).

Therefore, this study will not seek to replicate previous studies by determining whether or not interpretation biases change as a result of CBM-I. Any change in social

anxiety symptoms attributed to CBM-I will be assumed to have happened due to underlying change in interpretation biases.

At present, the link between social anxiety, paranoia and persecutory delusions is reasonably well established. However, no experimental studies have used CBM-I to target social anxiety within the context of persecutory delusions. Two studies published to date have examined the feasibility of CBM-I to treat both social and state anxiety within the context of psychosis. Steel, Wykes, Ruddle, Smith, Shah and Holmes (2010) reported a non-significant reduction in state anxiety following a single session of CBM-I in a group of 21 individuals diagnosed with schizophrenia. Turner et al. (2011) piloted a CBM-I task particularly for social anxiety in psychosis using a case series of six individuals experiencing first episode psychosis, resulting in more positive interpretation of social situations and improvement in social anxiety after a single session. However, neither study investigated levels of paranoia. Given the proposed link between social anxiety and paranoia in the genesis of persecutory ideation, it would seem theoretically worthwhile to investigate any indirect effects CBM-I may also have on paranoia, as well as social anxiety. Preliminary empirical findings suggest a possible link between reducing interpersonal anxiety, such as worry and a corresponding reduction in paranoia, as previously discussed (Foster et al, 2010).

However, given that the Threat Anticipation Model (Freeman, 2007) highlights at least three important mechanisms (social anxiety or worry, anomalous experiences and reasoning biases), reducing social anxiety alone may not be enough to produce appreciable reductions in persecutory thinking. Targeting reasoning biases may also reduce paranoia; promote increased data gathering in uncertain situations and increase belief flexibility, which may result in increased processing of disconfirming information. Computerised treatment packages targeting reasoning biases have been developed for delusions generally, and may now be indicated for persecutory delusions.

1.7.2 Targeting reasoning biases: the Maudsley Review Training Programme (MRTP; Waller, Freeman, Jolley, Dunn & Garety, 2011). As previously discussed, the Threat Anticipation Model (Freeman, 2007) also implicates reasoning biases in the formation and maintenance of persecutory delusions. Selective gathering of confirmatory evidence and dismissal of disconfirmatory evidence are hypothesised to lead to the rapid acceptance of beliefs, even if there is limited evidence to support them. Computerised reasoning packages have been developed and piloted to reduce the reasoning biases of JTC, promote increased belief flexibility, and reduce delusional conviction rates. These have generally been delivered also as computer packages, which involve training slides, video vignettes and other exercises that individuals can engage with. For example, Waller et al. (2011) used the MRTP among 13 people with delusions with high conviction, demonstrating a significant improvement in reasoning (belief flexibility, and a non significant reduction in JTC) after a single session. A more detailed description of the MRTP is given in section 2.3.2. Similarly, preliminary results from a recent randomised controlled trial using the same programme indicate an improvement in reasoning (significant reduction in JTC and improvement in belief flexibility) over the 3 time points measured, following 3 sessions (Waller, H. personal communication, June 2012).

Although the exact nature of the relationship between reasoning biases and paranoia is less clear (Freeman et al., 2005a), research does suggest some association between paranoia and the JTC bias in particular (e.g., Moritz, Van Quaquebeke & Lincoln, 2012; Garety et al., 2013). Therefore, similar to social anxiety, investigating the effect of improving reasoning biases on levels of paranoia would also be theoretically and clinically important.

1.7.3 The rationale for hypothesising differential effects of CBM-I and the MRTP on social anxiety and reasoning biases. As discussed above, negative interpretative biases contribute to social anxiety, and targeting these biases using CBM-I has led to modest improvements in anxiety. Reasoning biases are involved in persecutory delusion formation

and maintenance through biased data gathering and lack of belief flexibility, and targeting these biases with the MRTP has led to improvements in reasoning.

The Threat Anticipation Model (Freeman, 2007) proposes that both social anxiety and reasoning biases play different yet complementary roles in the formation and maintenance of paranoia and therefore persecutory delusions. To date, no studies have examined the differential effects of CBM-I on social anxiety and the MRTP on reasoning biases within the same group. This comprises the first research question. Since social anxiety and reasoning biases are hypothesised to interact and therefore develop and maintain paranoia, the second research question asks whether targeting social anxiety and reasoning biases will have any subsequent effect on levels of paranoia. These will be the aims of the current study.

1.7.4 Research hypotheses. Based on the rationale above, the following hypotheses will be tested:

1. In comparison to baseline, five sessions of CBM-I will reduce levels of social anxiety, but will not improve reasoning in a sample of individuals with persecutory delusions.

2. In comparison to baseline, five sessions of CBM-I will correspondingly reduce levels of severity of paranoia in a sample of individuals with persecutory delusions.

3. In comparison to baseline, five sessions of the Maudsley Review Training Programme (MRTP) will improve reasoning, but will not improve anxiety in a sample of individuals with persecutory delusions.

4. In comparison to baseline, five sessions of MRTP will result in a corresponding reduction in paranoia in a sample of individuals with persecutory delusions.

The next chapter will outline the design and methodology used to test the above hypotheses.

<center>**Methods**</center>

2.1 Participants

Participants were approached from Early Intervention and Adult Recovery services based in King's Lynn. Inclusion criteria were males and females aged between 18-65 years with a primary diagnosis of schizophrenia spectrum disorder and presence of persecutory delusions, based on Freeman and Garety's (2000) criteria. Both criteria were (a) belief that harm is occurring, or that harm will occur to the individual and (b) belief that the persecutor has intention to inflict harm on the individual. Conviction level in persecutory belief needed to be at 50% or higher at time of assessment, as assessed by The Psychotic Symptoms Rating Scales – Delusions subscale (PSYRATS-B; Haddock, McCarron, Tarrier & Faragher, 1999). Participants needed to be deemed to have capacity to give informed consent by their care coordinator or responsible clinician.

Exclusion criteria included a primary diagnosis of substance or alcohol dependency, organic syndrome or learning disability, insufficient command of English to engage in the tasks, or receiving psychological input at the same time as the study (for ethical reasons and to reduce potential differential effects of other interventions on outcome measures).

Although no formal power calculation was needed, some consideration of sample size was required. Kazdin (2010) does not describe any formal means of calculating how many participants are adequate for a single case series for standard hypothesis testing. Therefore, other non-statistical considerations were addressed, such as: what would be a feasible number of participants, given the constraints of time and resources? What would provide a good enough balance of participants, to be able to be randomised to four different conditions and to provide enough data to adequately test the differential hypotheses? Although no sample sizes are recommended, Gerring (2007) does describe single case series studies with a sample of five participants to test standard hypotheses. Since there are no other papers or books (to the

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author's knowledge) that recommend appropriate sample sizes, it was decided that doubling the minimum of five and adding two (for potential attrition, etc.) would be a sensible sample size for the current study. Therefore, 12 participants were sought after. All 12 participants were recruited, with no missing data and none lost to follow-up. The sample comprised eight males and four females with a mean age of 39.4 (SD = 14.5) and an age range of 19-61. Table 3.2 in the results section gives full demographic and clinical information on all participants.

2.2. Design

The study employed a multiple baseline single case series ABC crossover design (Kazdin, 2010), with a total of 12 participants allocated to one of four conditions using block randomisation. Block randomisation was conducted by the author's primary supervisor and the allocation slips kept in sealed envelopes so that the author did not know to which condition the participant would be assigned until after the participant had consented on to the study. The four conditions comprised two differing baseline lengths of two or three weeks and counterbalanced order of treatment blocks. Counterbalancing of packages assisted with control of carry-over effects and enhanced confidence in attributing any symptomatic improvement to the treatment, rather than extraneous influences (Kazdin, 2010). Multiple baseline periods and two baseline assessments established that symptoms were not on a natural path to recovery (Nock et al., 2007). Each package block was approximately two weeks, bearing in mind flexibility of research appointments for participants. Figure 2.1 illustrates the design and treatment allocation.

Figure 2.1 Outline of four conditions to which participants were randomised

Participants N=3	14 Days	CBM-I	Reasoning	Follow up	
Participants N=3	14 Days	Reasoning	CBM-I	Follow up	
Participants N=3	21 Days		Reasoning	CBM-I	Follow up
Participants N=3	21 Days		CBM-I	Reasoning	Follow up

2.2.1 Measures. Measures included semi-structured interviews, standardised questionnaires and idiographic ratings. Initially, basic demographic information was recorded including age, sex, and length of difficulties, medication use and estimated premorbid IQ.

2.2.1.1 The National Adult Reading Test (NART; Nelson, 1982). The NART is a commonly used indicator of premorbid IQ, based on the finding that ability to pronounce irregular words is a cognitive skill that is left relatively unimpaired following onset of conditions such as dementia or psychosis (McGurn et al., 2004). McGurn et al. (2004) found that the correlations between age 11 IQ and NART scores at age 80 were moderate, both for individuals who had developed dementia ($r = .63$, $p < 0.001$) and for those who had not ($r = .60$, $p < 0.001$), indicating that the NART is a good proxy measure of premorbid intelligence. These data were collected for use as general demographic information about participants and are reported along with the other demographic data in the results section. A copy of the NART is included in Appendix 4.

2.2.1.2 The PSYRATS-B (Haddock et al., 1999). The PSYRATS-B was used to screen for presence of persecutory ideation, which was then used to determine agreement with Freeman and Garety's (2000) criteria for persecutory delusions. This semi-structured interview assesses severity of delusions in several different domains; preoccupation with delusions, conviction, distress and disruption to life caused by beliefs. Drake, Haddock, Tarrier, Bentall and Lewis (2007) report an intra-class correlation coefficient for the

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PSYRATS-D subscale of .70, indicating good test-retest reliability. Kendall's *tau* for each subscale score minus that item ranged from .17 to .41, indicating overall adequate internal consistency. Drake et al. (2007) also report a Spearman coefficient of .80, indicating good sensitivity to change in relation to the Delusions subscale of the Positive and Negative Syndrome Scale (PANSS; Kay et al., 1987), which is a very well established measure of positive symptoms. A copy of the PSYRATS-D is included in Appendix 4.

2.2.1.3 The Social Interaction Anxiety Scale (SIAS; Mattick & Clarke, 1998). This measure assesses levels of social anxiety, including cognitive, affective and behavioural reactions to situations that involve social interaction. Out of a total of 60 points, scores of 34 or above indicate clinically significant social phobia, while scores of 43 or above indicate clinical levels of social anxiety that impact on the individual's life greatly. Mattick and Clarke (1998) report high internal consistency ($\alpha = .94$), while others have demonstrated good test-retest reliability (range from .86 to .92; Heimberg, Mueller, Holt, Hope & Liebowitz, 1992). Factor analysis has revealed good construct validity, indicating that the SIAS measures social anxiety well with good convergent and discriminant validity also being demonstrated (Orsillo, 2001). The SIAS is increasingly being used in research studies as well as in clinical work with people who experience psychosis, e.g., Turner et al. (2011). A copy of the SIAS is included in Appendix 4.

2.2.1.4 The Green et al., Paranoid Thoughts Scale (GPTS; Green et al., 2007). The GPTS is a 32-item scale with two constructs measuring (1) ideas of reference and (2) overt persecution, which combined make a robust measure for paranoia. Reliability was found to be very high ($\alpha = .90$) and factor analysis demonstrated good measurement of ideas of reference and persecution. Concurrent and convergent validity were estimated by correlating scores from the GPTS with existing measures of paranoia, namely the Paranoia Scale (PS; Fenigstein & Vanable, 1992) and the Peters et al., Delusions Inventory (PDI; Peters, Joseph & Garety, 1999). This indicated good validity of the GPTS when compared with the PDI

(Spearman's ρ = 0.39, p = 0.01) and the PS (ρ = 0.81, p = 0.01, Green et al., 2007).

Sensitivity to change in relation to the PSYRATS was demonstrated by significant positive

correlations with GPTS scores over time. A copy of the GPTS is included in Appendix 4.

2.2.1.5 The 85:15 and 60:40 Beads Tasks (Garety et al., 2005; Dudley, John, Young & Over, 1997). These tasks both represent the 'easy' and 'difficult' versions of a Bayesian

probabilistic reasoning task that has been extensively used among individuals with delusions,

to measure the JTC reasoning bias. During this 'easy' task, individuals are presented with

two jars each containing 100 coloured beads. There are 85 beads of one colour (e.g., black)

and 15 beads of another (e.g., yellow) in one jar, while the other jar contains beads in opposite

proportions (i.e., 15 black and 85 yellow). The jars are removed from view. Upon request

from the participant, beads are presented, one at a time, from one of the jars in a

predetermined order. Although predetermined, the participants are informed that the jars and

order of beads have been selected randomly every time the task is given. Participants can

view as many beads as they want until they are certain from which jar the beads are drawn. In

a harder version of the task, a colour ratio of 60:40 instead of 85:15 may be used (Dudley et

al., 1997). Freeman (2007) reviewed the literature and found that in the ten studies looking at

discriminatory performance on the different versions of the beads tasks, all ten showed

significantly hastier data gathering within the delusions groups. JTC seems to also be related

to strength of belief conviction (Garety et al., 2005). The relationship between JTC and

persecutory delusions is less clear, most likely because the majority of studies rarely focus on

delusion subtypes. However, initial data indicate that the JTC bias has been found to also be

significantly pronounced among individuals with persecutory delusions when compared with

matched non-clinical controls (Conway et al., 2002; Startup, 2004; Startup, Freeman &

Garety, 2008). Data were grouped by category of whether participants JTC or not – this was

operationalised as a decision based on two or fewer beads drawn.

2.2.1.6 Possibility of being Mistaken (PBM) and Reaction to Hypothetical Contradiction (RTHC) items from the Maudsley Assessment of Delusions Schedule (MADS; Wessely et al., 1993). These measures have been extensively used in delusions research (Garety et al., 2005). These components of the MADS are delivered as a semi-structured interview. PBM is measured by recounting the evidence that the participant has cited for their belief and by then asking the participant 'Is there any possibility that you might be mistaken?' in relation to their primary belief. A Yes/No response is recorded, providing categorical data. Wessely et al. (1993) report good inter-rater reliability for this component (k = .91). RTHC involves presentation of a hypothetical scenario (the participant is informed it is hypothetical, in order to encourage engagement with the scenario) that is at clear odds with the content of the delusion. Their reaction to this scenario is coded as follows: 1. Ignores/Rejects Scenario, 2. Accommodates Scenario into Delusion, 3. Delusional Conviction is lowered, 4. Delusion is dismissed. In this case, one and two indicate belief inflexibility, three and four indicate belief flexibility, thus providing either ordinal or categorical data for this measure. Wessely et al. (1993) report good inter-rater reliability for this component (k = .90). Copies of these measures are included in Appendix 4.

2.2.1.7 Explanations of Experiences Assessment (EoE; Freeman et al., 2004). This is an item also taken from the MADS (Wessely et al., 1993), which presents a description of the delusional belief, and asks, citing the identified evidence for this belief, if any other explanations for these experiences could be possible, even if the participant considers the alternative to be very unlikely. The numbers of explanations that are qualitatively different from the primary explanatory delusion are counted, therefore giving continuous scores to be used in analysis. Freeman et al. (2004) report an inability to calculate a simple reliability statistic and so examined each of the changes over three months separately for the 25 individuals that were given repeat administration of the EOE interview, concluding that good stability was demonstrated overall. In terms of validity, individuals who had alternatives

(83%) were more likely than those who did not (43%) to have greater awareness that they experienced false beliefs, as assessed by the Assessment of Insight in Psychosis (Amador, Strauss, Yale, Gorman, & Endicott, 1993), t (95) = 3.16, p < .01. Therefore, this indicates that the EoE shows some validity, in that it is consistent with another established measure of insight (Freeman et al., 2004). A copy of the EoE interview schedule is included in Appendix 4.

2.2.1.8 Idiographic ratings of anxiety, conviction and paranoia. In order to establish levels of anxiety, delusional conviction and paranoia that are stable and not on a natural path to recovery, it was necessary to take multiple measures on a daily basis. Idiographic self-ratings of anxiety, delusional conviction and paranoia were completed once daily. Participants were asked to provide a rating from 0-100% to measure social anxiety severity. To assist participants with giving these ratings, anchor points were provided; 0% = not at all anxious, 25% = somewhat anxious 50% = moderately anxious, 75% = very anxious, 100% = extremely anxious. Similar anchor points were also given to assist with 0-100% ratings levels of delusional conviction and paranoia (Appendix 5).

2.2.1.9 Anecdotal qualitative observations from participants. As part of every session, any noteworthy qualitative feedback from participants was recorded. This typically included any helpful aspects of either programme they had remembered, or how they felt they were responding to the study programmes. These qualitative data were not subjected to any formal analysis; the author's primary supervisor read through drafts of the results section to ensure that comments included were appropriate and were for informational purposes to enhance understanding of the quantitative results of each case.

2.3 Experimental manipulations

2.3.1 Text-based CBM-I for social anxiety in psychosis, Turner et al. (2011). The aim of CBM-I is to train individuals to appraise an ambiguous social situation in a more

positive or neutral way. It is the bias modification which is hypothesised to result in symptom reduction (Mathews & Mackintosh, 2000). The training materials used in the current study were based on the original text based paradigm and were identical to those developed by Turner et al. (2011). Prior to beginning each session, participants were asked to engage in a brief visual exercise, in order to promote visual imagination of the text-based materials, which previous research has shown to be more effective than verbal processing alone (e.g., Holmes, Matthews, Dalgleish & Mackintosh, 2006). This exercise is based on the study by Holmes et al. (2006). Participants were asked to close their eyes while they imagined cutting a lemon (holding the lemon, shining a light on it and looking at its skin, cutting it with a knife and squeezing it) then rating how vividly they could imagine the images on a 5 point likert scale (1 = not at all vivid, 5 = extremely vivid). This exercise provides a useful means of assessing the degree to which participants can use imagery as well as explaining what was being asked of them during the following task.

Following administration of the brief visual exercise, participants were presented with a written set of instructions and 100 scenarios (see Appendix 6), given in blocks of 10, with optional brief rests after each block. Each scenario was 3 lines in length, and was emotionally ambiguous until the last word, which was presented as fragmented, and resolves the scenario in a positive way. To progress through the text-based stimuli at their own pace, participants pressed the 'advance key' (programmed to be the down arrow key). The scenario concluded once the participant entered the correct letter. At the end of each scenario, a comprehension question was presented to ensure the participant had interpreted and understood the scenario in the intended way. Feedback on whether the participant's response was 'correct' or 'incorrect' was given. Each session lasted approximately 60 minutes.

An example of one scenario is: "A friend suggests that the two of you join an evening class on creative writing. The thought of other people looking at your efforts makes you feel [word presented with missing letters: enth----st-c]. [Correct word: enthusiastic]. [Missing

letter: u]. Would you expect to feel uncomfortable if others look at your work? [Correct response: No]." No other data (e.g., response time, interpretation bias pre/post measurement) from the CBM-I task will be recorded. As described in the introduction, interpretation bias will be assumed to have changed, if levels of social anxiety have decreased from baseline, following CBM-I.

2.3.2 The Maudsley Review Training Programme; the MRTP – Waller et al. (2011). Adapted from earlier work by Ross, Freeman, Dunn and Garety (2011), this package aims primarily to reduce frequency of JTC, improve ability to generate alternative explanations of experiences and ultimately to reduce delusional conviction, without directly challenging any of the delusional content itself. The training package was delivered in task format; each task was delivered by computer and then discussed with the participant. A synopsis of the five tasks follows, a screenshot of some of the slides in the MRTP is provided in Appendix 10.

Task 1: 'What's the Picture?'   This task introduces the idea that it can be difficult to come to an informed decision without all of the evidence. Six pictures are revealed in sections, one at a time; the participant is given the option to decide what picture it is (from a list of six possibilities displayed at the beginning), or to request another piece to be added to it. The task is designed so that all options are potentially correct to begin with, and only by requesting more information will the correct option become clearer. This teaches participants to look for more evidence before making a decision.

Task 2: 'Illusions.' This introduces the idea that things are not always as they first seem and that sometimes we only see part of the story, which can lead us to jump to conclusions and make mistakes. A series of optical illusions are presented, which helps to illustrate this.

Task 3: 'First impressions.' This task gives three real life examples in video vignettes of scenarios. Participants are asked to rate what they believe is going on at early stages of the

scenarios, which illustrates how we can all make incorrect assumptions, if we do not slow down and gather all the necessary evidence.

Task 4: 'Looking for other possible explanations.' This introduces the idea of thinking flexibly about alternative explanations before reaching a conclusion. Three video vignettes are shown, each with the option of positive, neutral or paranoid interpretation. Participants are encouraged at various points to use the interactive software to interpret the scenario as they see fit, with a discussion after the end of each vignette, depending on their interpretation.

Task 5: 'JTC summary.' This final task allows review of the key learning points throughout the tasks. Participants are shown four video scenarios, involving characters who jump to conclusions. They are encouraged to identify who the characters that jump to conclusions will be. Finally, they are asked about how the characters might have avoided the situations they got themselves into, by not jumping to conclusions.

The tasks do not involve any material directly related to the participant's delusional content, but are based on everyday scenarios such that it is anticipated or hoped that the participant might be able to generalise the ideas to their own experiences. The format is video and task-based, which is interactive, and encourages active participation. Each session lasted about 60 minutes.

2.3.3 Equipment. The 85:15 and 60:40 versions of the Beads Task (Garety et al., 2005, Dudley et al., 1997) were developed on Microsoft PowerPoint. The CBM-I materials were programmed and presented using E-Prime Software (Version 2.0, Psychology Software Tools, Inc 2010). The MRTP materials were developed on Microsoft PowerPoint and then transferred to a Real BASIC programme to incorporate the interactive elements (Waller et al., 2011). The programmes were run on a personal laptop using Windows 7 Home Premium (© Microsoft Corporation, 2009). The testing sessions were carried out in locations convenient

and comfortable for the research participants, i.e., either on NHS premises, or in their own homes.

2.4 Procedure

   2.4.1 Ethical approval, consent and randomisation. Ethical approval was granted by the NRES Committee East of England on 14th June, 2013 (Ref: 13/EE/0134; see Appendix 11). Research and Development approval for Norfolk and Suffolk NHS Foundation Trust was given on 26th July, 2013 (see Appendix 12 for the Letter of Access).

   Potential participants were first approached by their care coordinators or case managers within Early Intervention and Recovery services in West Norfolk. Following discussion with the researcher to determine eligibility for the study, case managers approached potential participants with the Participant Information Sheet (Appendix 1), in order to briefly explain what the project entailed and to ascertain if they would be interested in taking part. If so, case managers passed on contact information (home address and telephone number) to the researcher who would send them the Participant Information Sheet with a cover letter (Appendix 2), indicating that they would be contacted via telephone to arrange a screening meeting.

   At the screening meeting the PSYRATS-B semi-structured interview was conducted. This information was used to determine whether the study was suitable for the participant. Those who did not meet inclusion criteria were informed verbally and thanked for their time. Those who were eligible and still interested in taking part were asked to sign a consent form (Appendix 3). Following consent, basic demographic information was documented (such as age, sex, length of difficulties, estimated premorbid IQ and medication use) and participants were randomly allocated to one of the four groups as outlined in figure 2.1 above. Block randomisation was conducted by the researcher's supervisor. The researcher was blinded to allocation of condition, using sealed envelopes, until after the participant had consented to

take part. Figure 2.2 below provides a flow diagram of study participants. The five

participants who were not suitable were so because they had no specific beliefs that they were

being harmed on purpose. They were referred for screening by their care co-ordinators in

Early Intervention services because they experienced paranoia. However, after screening, it

transpired that they experienced generalised paranoia, but no persecutory delusions.

Figure 2.2 Recruitment flowchart
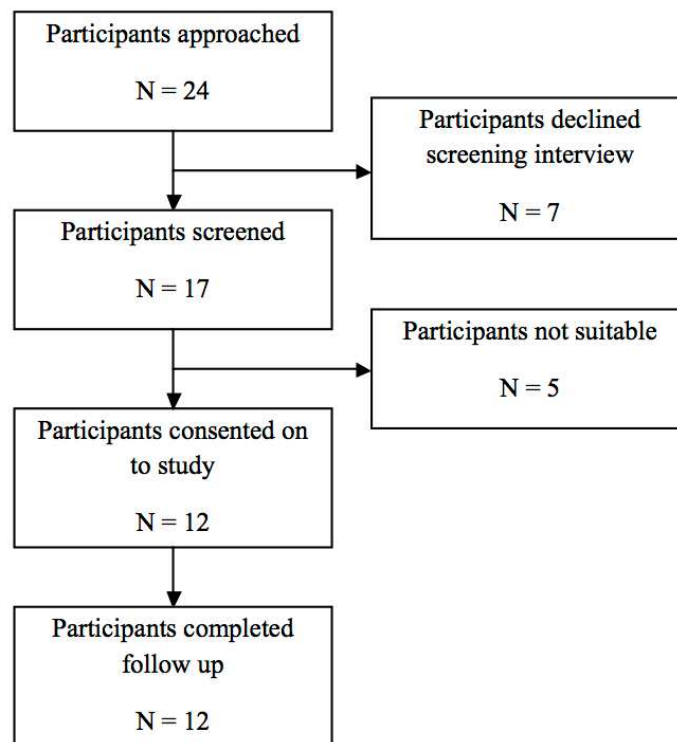
2.4.2 **Assessment.** Following consent and randomisation, participants completed the

following measures with the researcher in a baseline assessment (Appendix 4):

1. The NART (Nelson, 1982).

2. The SIAS (Mattick & Clarke, 1998).

3. The GPTS (Green et al., 2007).

4. The 85:15 and 60:40 Beads Tasks (Garety et al., 2005; Dudley et al., 1997).

5. PBM and RTHC items from the MADS, (Wessely et al., 1993).

6. The EoE (Freeman et al., 2004).

7. Idiographic ratings of anxiety, conviction and paranoia.

2.4.3 **Baseline period.** Upon completion of the initial research assessment,

participants began their two or three week baseline period, during which they rated their level

of social anxiety, conviction in their main delusion, and severity of paranoia once daily, using

a booklet of the three idiographic ratings described above (Appendix 5). Text message reminders were sent by the researcher if requested by the participant.

Upon completion of the baseline period, the research assessment was conducted again, and the first session of the computerised therapy was given. Participants completed the three idiographic measures of conviction, paranoia and social anxiety at the end of each session. Both blocks of computerised treatment were five sessions long, delivered over two weeks at a rate of approximately one session every two or three days. Following completion of the first block of computerised package, the participants completed the research assessment again. The second block of computerised treatment then began two or three days after completion of the first. As before, the three idiographic measures were completed at the end of each session. Upon completion of the second block of computerised package, participants completed the research assessment and then entered the follow-up phase.

During follow-up, participants did not need to do anything, but were encouraged to record or note any questions, comments or thoughts that they would like to bring up at the follow-up meeting. After one month, the follow-up meeting was conducted, where all of the above measures were re-administered, except for the NART. Participants were also debriefed during this session. Figure 2.3 provides a flow diagram of the procedure.

Figure 2.3 Participant flow diagram

```
                    ┌─────────────────────────────┐
                    │   1. Screening meeting.     │
                    └─────────────────────────────┘
                              │
                              │     ┌──────────────────────────────────┐
                              ├────►│ 2. If study not suitable,         │
                              │     │ participants are thanked for      │
                              │     │ their time and exit the study.    │
                              │     └──────────────────────────────────┘
                              ▼
          ┌───────────────────────────────────────────────┐
          │ 3. Participants give consent and complete      │
          │ first interview. They enter baseline phase     │
          │ and complete daily idiographic measures.       │
          └───────────────────────────────────────────────┘
                              ▼
  ┌─────────────────────────────────────────────────────────────────────┐
  │ 4. When baseline finishes, participants begin the first intervention  │
  │ phase; five sessions over approximately two weeks.  After the final   │
  │ session, the standardised measures (except for PSYRATS) are           │
  │ re-administered.                                                      │
  └─────────────────────────────────────────────────────────────────────┘
                              ▼
  ┌─────────────────────────────────────────────────────────────────────┐
  │ 5. Participants begin intervention block two, and complete the        │
  │ standardised measures as previously described.                        │
  └─────────────────────────────────────────────────────────────────────┘
                              ▼
                    ┌─────────────────────────────┐
                    │ 6. Participants enter one   │
                    │ month follow up.            │
                    └─────────────────────────────┘
                              ▼
  ┌─────────────────────────────────────────────────────────────────────┐
  │ 7. At follow up assessment, participants are administered             │
  │ standardised measures (including PSYRATS), except the NART.           │
  └─────────────────────────────────────────────────────────────────────┘
                              ▼
  ┌─────────────────────────────────────────────────────────────────────┐
  │ 8. Participants are thanked for their time, given the monetary token  │
  │ of appreciation and then exit the study.                              │
  └─────────────────────────────────────────────────────────────────────┘
```

2.5 Data analysis plan

Data were recorded on original anonymous paper files and later entered on to a Microsoft Excel spreadsheet. This spreadsheet was checked several times for accuracy of data entry. Data on conviction for participant 11 had to be retrospectively re-rated by the participant during both package phases, as it transpired during the follow up assessment that participant 11 had been rating how much they believed the delusion was happening at that time, rather than how much they believed the delusion was true. Participant 3 declined to do

the NART, because the voices were calling them derogatory names at the time. Other than these instances, there were no other known missing or incorrect data.

2.5.1 Hypothesis one: In comparison to baseline, five sessions of CBM-I will reduce levels of social anxiety, but will not improve reasoning. To test this hypothesis, the idiographic data on social anxiety were visually inspected and Kendall's *tau* was calculated (Kazdin, 2010). Data were plotted graphically according to participant on social anxiety measures over time. A standardised measure of social anxiety, the SIAS, was also used and the five measurements were plotted underneath the idiographic data. Reliable and clinical changes were examined between both baseline assessments, at the end of each package phase, and at four week follow-up. Further information on reliable and clinical change and how they were calculated is given in the results chapter.

The reasoning component of this differential hypothesis was tested using the beads tasks. Reliable change could not be calculated due to insufficient published data, but a cut off score of 3+ draws indicated not JTC. These data were tabulated across the five time points along with the categorical data derived from the PM, continuous data from the EoE and ordinal data from the RTHC. Using these two graphs and one table, the differential effects of CBM-I on social anxiety and reasoning were investigated.

2.5.2 Hypothesis two: In comparison to baseline, five sessions of CBM-I will correspondingly reduce levels of severity of paranoia. As above, this hypothesis was tested using visual inspection of the idiographic paranoia data; Kendall's *tau* was also calculated to assess stability of baseline (Kazdin, 2010). GPTS scores were plotted across phases and aligned underneath the idiographic ratings. There are no clinical cut-offs published for the GPTS, (Green et al., 2007). However, based on criterion b by Jacobson and Truax (1991), the clinical cut-off was calculated to be 86.2. The reliable change index for the GPTS was calculated using the same guidance to be 18.69. These calculations are given in more detail in the results section.

Conviction was included in the analyses with the GPTS scores because it is a dimensional measure of paranoia (Haddock et al, 1999; Freeman, 2007), indicating how firmly held the persecutory belief is and how susceptible to change the belief may be. The idiographic data were visually inspected to determine which package had an effect on conviction, if any. Kendall's *tau* was also calculated to assess stability of baseline. An improvement in paranoia occurred if a participant improved in GPTS scores and/or conviction.

2.5.3 Hypothesis three: In comparison to baseline, five sessions of the Maudsley Review Training Programme (MRTP) will improve reasoning, but will not improve anxiety. As with the first hypothesis, this hypothesis was tested by visual inspection and Kendall's *tau* calculation of the idiographic data on social anxiety (Kazdin, 2010). Idiographic social anxiety and SIAS data were plotted graphically according to each participant over time, visually inspected and examined for clinical and/or reliable change.

The reasoning component of this differential hypothesis was tested using the tabulated reasoning measures as described above. Improvements in these reasoning measures that were stable (i.e., were not present during baseline and were maintained at follow up) were attributed to the relevant package.

2.5.4 Hypothesis four: In comparison to baseline, five sessions of MRTP will result in a corresponding reduction in paranoia. As described, this hypothesis was tested using visual inspection and Kendall's *tau* calculation of the idiographic paranoia and conviction data (Kazdin, 2010). GPTS data were examined for clinical and/or reliable change.

2.5.5 Statistical analysis. Although Kazdin (2010) advocates the use of visual inspection alone, others argue that statistical analyses of time series data are more appropriate (e.g., Zhan & Ottenbacher, 2001). A recent large scale study reviewed the validity of both

visual inspection and statistical analyses, concluding that both should be used in conjunction with one another (Harrington, 2013).

A programme running Simulation Modeling Analysis (SMA; Borckhardt, 2006) uses bootstrapping to reliably analyse short streams (N < 30) of time series, autocorrelated data. SMA was used along with visual inspection to analyse the conviction data. SMA analysis was only used with conviction data because there was no standardised measure to accompany conviction change, which could also be inspected visually, as with the social anxiety and paranoia data. Even though it is likely that the conviction data are not normally distributed, Borckardt (2006) recommends use of Pearson's *r* rather than Spearman's ρ to determine significant change in slope and level of phases, because it is more reliable within the model used.

Conviction data from each treatment phase were both compared with baseline, because the package could not analyse three variables using correlation. This assumes no carry-over effects, which is a limitation, but the analyses should be considered in conjunction with the visual inspection. Use of statistical analysis makes it easier to determine differential effects on conviction, which was measured with idiographic ratings alone.

To complement interpretation of the visual analyses of social anxiety, paranoia and reasoning biases, underpowered statistical tests of significance were used, and where appropriate, effect sizes generated. Data on all participants were merged together to increase power, but again this assumes no carry-over effects, which is a limitation, but is preferable to tests with N = 6.

Due to the fact that multiple comparisons would limit the confidence of the findings, it was decided to test three variables; the second baseline assessment and measures taken from the CBM-I and the MRTP packages. These tests were reported within the relevant sections on hypotheses at the end of the results chapter. Because these tests are underpowered, the

results should be interpreted with caution. However, if the visual analyses correspond with

the statistical test results, it may improve confidence in the findings.

Results

3.1 Overview

This chapter outlines the results of the data analysis plan. Self-reported idiographic measures of social anxiety, paranoia and belief conviction were collected at assessment points then graphed in terms of number of days of involvement in the study and visually inspected using Kazdin's (2010) criteria. Social anxiety and paranoia measures were assessed for reliable and clinically significant change at various time points: within the baseline period itself, following each package phase and at follow up. Reasoning data were tabulated and monitored for change across phases. Statistical analyses were also computed to complement the visual inspection. Data were initially grouped together according to each participant, with a summary of the results per hypothesis at the end. Effect sizes of both packages on social anxiety and paranoia were calculated.

3.2. Data presentation and analysis

3.2.1 Visual inspection. Kendall's *tau* (Kendall, 1970) establishes whether scores over baseline are stable enough to make a good basis for comparison with the other phases. Kazdin's (2010) four criteria for visual inspection are outlined in Table 3.1.

Table 3.1

Criteria for data evaluation in single-case series designs

Characteristic	Definition
Change in mean	Change in mean scores from phase to phase, in the expected direction
Shift in level	Change in score from the last day of one phase and the first day of the next. An abrupt shift facilitates interpretation.
Change in slope	Whether the direction of the slope changes between phases; slopes can be classified as (1) stable, (2) accelerating or (3) decelerating
Latency of change	The speed with which change occurs when the conditions are changed; briefer latency of change implies an effect

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Idiographic data were examined according to Table 3.1 above across phases; from left to right. This means that change was assessed in one phase based on comparison with the preceding phase. When assessing latency of change, change in idiographic rating between phases was established by comparing the final rating in the preceding phase with the ratings in the following phase. The first rating that was different was noted and the number of days that lapsed in between that change was calculated, and reported in the relevant tables.

When all four criteria are met, effects can be easily attributed to the relevant package (Kazdin, 2010). However, all four criteria need not be met to infer an effect, and the criteria can vary, making the process more subjective (Kazdin, 2010). Reliable and clinical change was assessed slightly differently. Scores on the SIAS and GPTS were examined by first determining whether there was a significant reduction between both baseline assessments. Reduction in the second baseline assessment, relative to the first, made it more difficult to attribute change to the relevant package because the baseline itself was not stable. Mean baseline scores minus the RCI were then compared with all phases, to determine whether there was a significant reduction in each phase.

Clinical and/or reliable reductions compared to baseline were reported for each phase, including follow up. Due to the fact that two package phases were used to test differential hypotheses, it was decided that the package that first resulted in a significant effect would support the relevant hypothesis. This was to separate out potential interaction effects of both packages. For example, if there were no significant reductions in social anxiety during baseline or MRTP phases, but there were during the CBM-I and follow-up phases, hypothesis one (CBM-I would improve social anxiety, but not reasoning biases) would be supported. Regarding reasoning biases, it was decided that if an improvement in any one of the five measures of reasoning biases was stable across the remaining phases, the improvement would be attributed to the relevant package. For example, if a participant JTC during baseline and then stopped JTC following phase one (MRTP), and also stopped JTC throughout other

phases (i.e., CBM-I and follow-up), then this would be interpreted as an improvement in reasoning biases, following the MRTP package.

3.2.2 Calculation of clinical and reliable change indices. The guidance by Jacobson and Truax (1991) was used to calculate clinical and reliable change indices.

3.2.2.1 Clinical change. Jacobson and Truax (1991) recommend three different ways of calculating appropriate cut scores to denote clinical levels of symptoms when these cut scores have not been published. When clinical and non-clinical norms are available and do not overlap with each other, criterion b is recommended (Jacobson & Truax, 1991); this is where the post-treatment score should fall within two standard deviations of the normative group mean. Jacobson and Truax (1991) argue that this criterion leads to fairly stringent levels of clinically significant change. For paranoia assessed by the GPTS using psychometric data from Green et al. (2007), this was calculated as:

$$b = \text{(non-clinical mean)} + 2*\text{(SD of non clinical group)}$$

$$b = 48.8 + 37.4 = 86.2.$$

Therefore, GPTS scores above 86 during baseline that reduced to below 86 during package phases were considered clinically significant. This is out of a possible range of 32 - 160.

According to Mattick and Clarke (1998), SIAS scores above 34 during baseline that reduced to below 34 during package phases were also considered clinically significant.

3.2.2.2 Reliable change. The reliable change index (RCI) was calculated using the following formula (Jacobson & Truax 1991):

$$1.96*SD1*\sqrt{2}*\sqrt{(1-r)}$$

Where SD1 = standard deviation of the sample and r = test re-test reliability coefficient.

Using the standard deviation and reliability coefficient reported by Mattick and Clarke (1998), the RCI for the SIAS was calculated to be:

$$1.96*16.4*\sqrt{2}*\sqrt{(1-.92)} = 12.86.$$

Data from Green et al. (2007) yielded $1.96*18.7*\sqrt{2}*\sqrt{(1-.87)} = 18.69$. Reductions greater than or equal to 13 points on the SIAS and 19 points on the GPTS were considered statistically significant.

3.2.3 Participant information. Table 3.2 gives the clinical and demographic characteristics of the sample. Table 3.3 outlines the threat belief of each participant and conviction obtained during screening interview.

Table 3.2

Clinical and demographic characteristics of participants

Characteristic	Value	Range
Mean age (SD)	39.4 (14.5)	19-61
Gender		
Male	8	
Female	4	
Mean estimated NART IQ (SD)	109.7 (5.9)*	100-116
Ethnicity		
White British	12	
Diagnosis		
Paranoid schizophrenia	5	
Non-organic psychosis	3	
Schizoaffective disorder	3	
Delusional disorder	1	
Mean length of difficulties in years (SD)	10.29 (7.59)	1-23
Patient status		
Outpatient	12	
Recruited from Early Intervention	3	
Recruited from Recovery Services	9	
Participants taking antipsychotics	11	
Mean daily chlorpromazine equivalents (SD)	420.8 (285.6)	0 – 1000mg daily
Initial percentage delusional conviction (SD)	85 (15)	50-100%
Baseline PSYRATS total scores (SD)	19.67 (1.83)	16-22
Follow-up PSYRATS total scores (SD)	11.5 (5.81)	0-19

Note: *Participant 3 declined to do the NART. All other data are complete. Chlorpromazine equivalents were calculated according to Woods (2003 & 2011) and Atkins, Burgess, Bottomley and Riccio (1997); PSYRATS – Psychotic Symptoms Rating Scale.

Table 3.3

The content of the study participants' delusions and initial conviction

Participant Number	Description of delusions	Initial Conviction
1	"The travellers are upsetting me, filming me, watching everything I do in order to upset me and stress me as much as they can; eventually they will beat me to death."	100%
2	"If I go out by myself, I will be taken and imprisoned by a group of people and I will never see my family again."	75%
3	"People down the bottom of the garden, neighbours and MI5 are constantly sending me pains by laser because they hate me."	75%
4	"My neighbours spy on me, they say nasty things about me and they torment me, it's like fun for them and hell for me."	80%
5	"If I am outside, I will be attacked by a member of the public at any minute."	100%
6	"They put a microchip in my head to keep me under constant surveillance to mess with my life."	100%
7	"When outside, I will be attacked or murdered any minute."	80%
8	"I get interfered with by spirits daily, in order for them to aggravate and annoy me."	75%
9	"Members of the public want to hurt me by getting into my mind."	50%
10	"The travellers want to get revenge on me by badly beating me. This could happen any minute."	90%
11	"The secret service has placed cameras in my house, watching and listening to me because they want to upset me and kill me."	90%
12	"Much of my family, friends and everyone are involved in a game to try to confuse me and upset me."	100%

3.3 Participant 1

Participant 1 is a 19 year old male, with one year duration of difficulties, recruited from Early Intervention Services.

3.3.1 Social anxiety data.

Figure 3.1 Participant 1 idiographic and standardised social anxiety scores
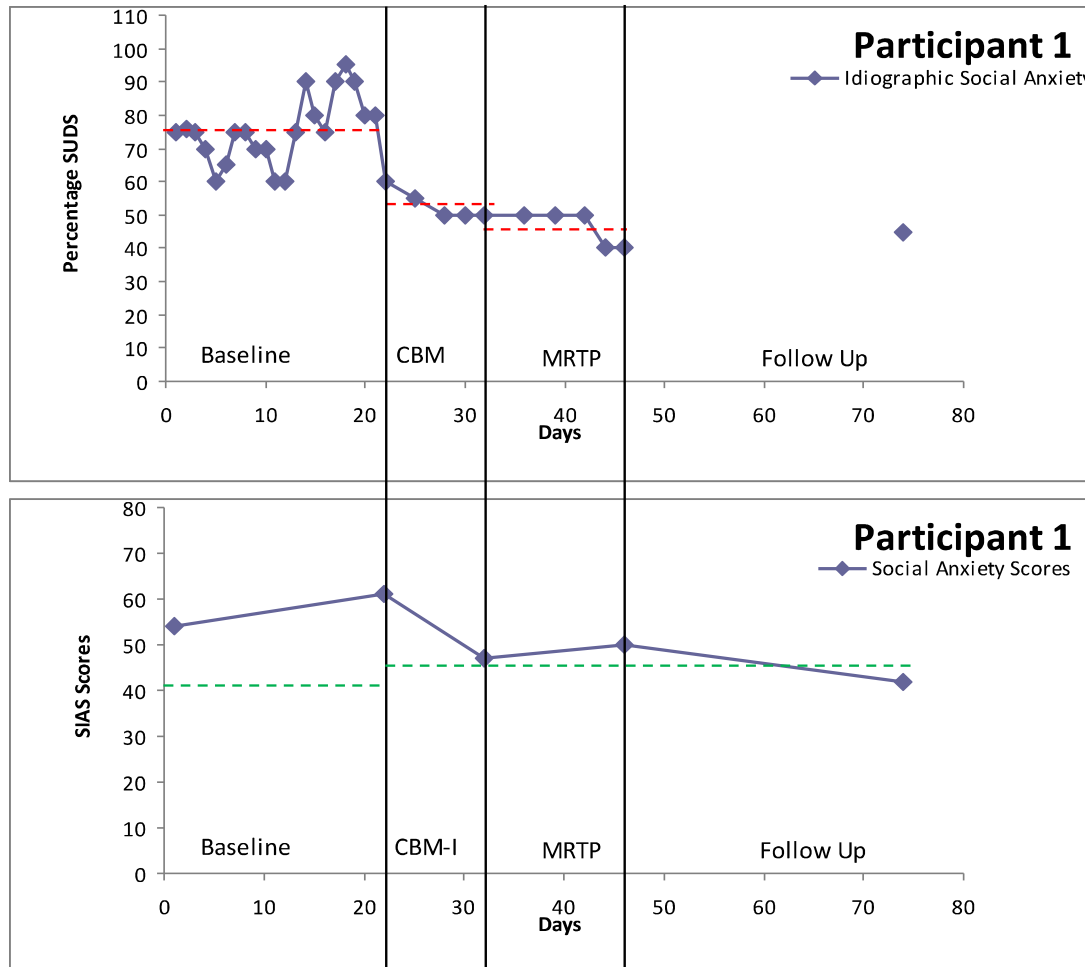
Note: – – – – – = mean idiographic ratings, – – – – – = reliable change threshold.

Baseline idiographic social anxiety worsened (*tau* = .362, *p* < .05), which facilitates interpretation, as the slope was arcing in the opposite direction to that during the treatment phases, indicating an effect. Table 3.4 provides the results from visual inspection of figure 3.1, which reads from left to right, e.g., 'reduced' in the MRTP column means that a further reduction in mean idiographic social anxiety occurred relative to the CBM-I phase.
Considered together, the results show no reliable effect on social anxiety, although there is

some indication that idiographic ratings reduced following the introduction of CBM-I.

Reliable reduction in SIAS scores occurred at follow-up.

Table 3.4

Results of visual inspection of social anxiety data in figure 3.1

Social anxiety	Baseline	CBM-I	MRTP	Follow Up
Mean Idiographic Ratings	76	Reduced	Reduced	
Shift in level		Abrupt	NC	NC
Slope	Accelerating	Decelerating	Stable	
Latency of change between phases		1	12	NC
SIAS Clinical Reduction	N	N	N	N
SIAS Reliable Reduction	N	N	N	Y

Note: NC – No Change, Latency of idiographic rating change between phases is expressed as number of days, N – No, Y – Yes, SIAS reliable change threshold during package phases was calculated by subtracting the RCI from mean time-point one and two ratings.

3.3.2 Conviction data.

Figure 3.2 Participant 1 idiographic conviction scores
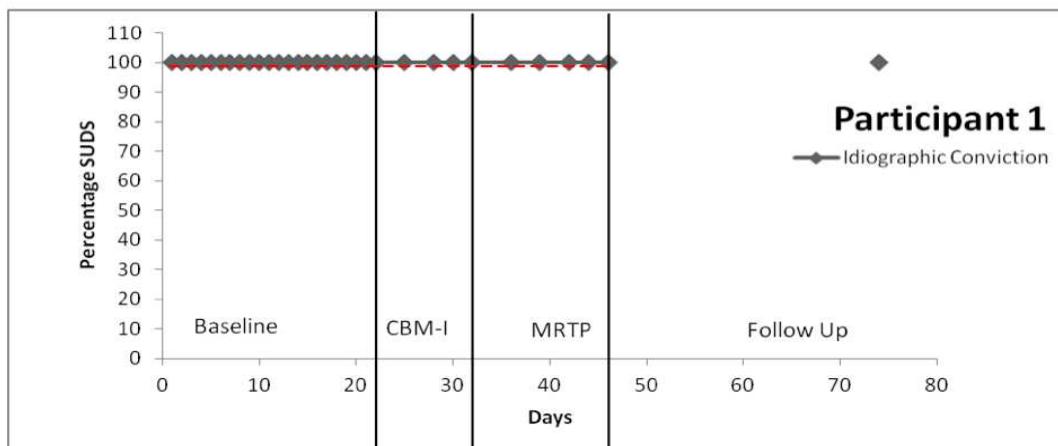
Note: - - - - - = mean idiographic ratings.

Table 3.5 outlines the visual inspection of the conviction data. Conviction remained at 100% throughout the full duration of the study.

3.3.3 Paranoia Data.

Figure 3.3 Participant 1 idiographic and standardised paranoia scores
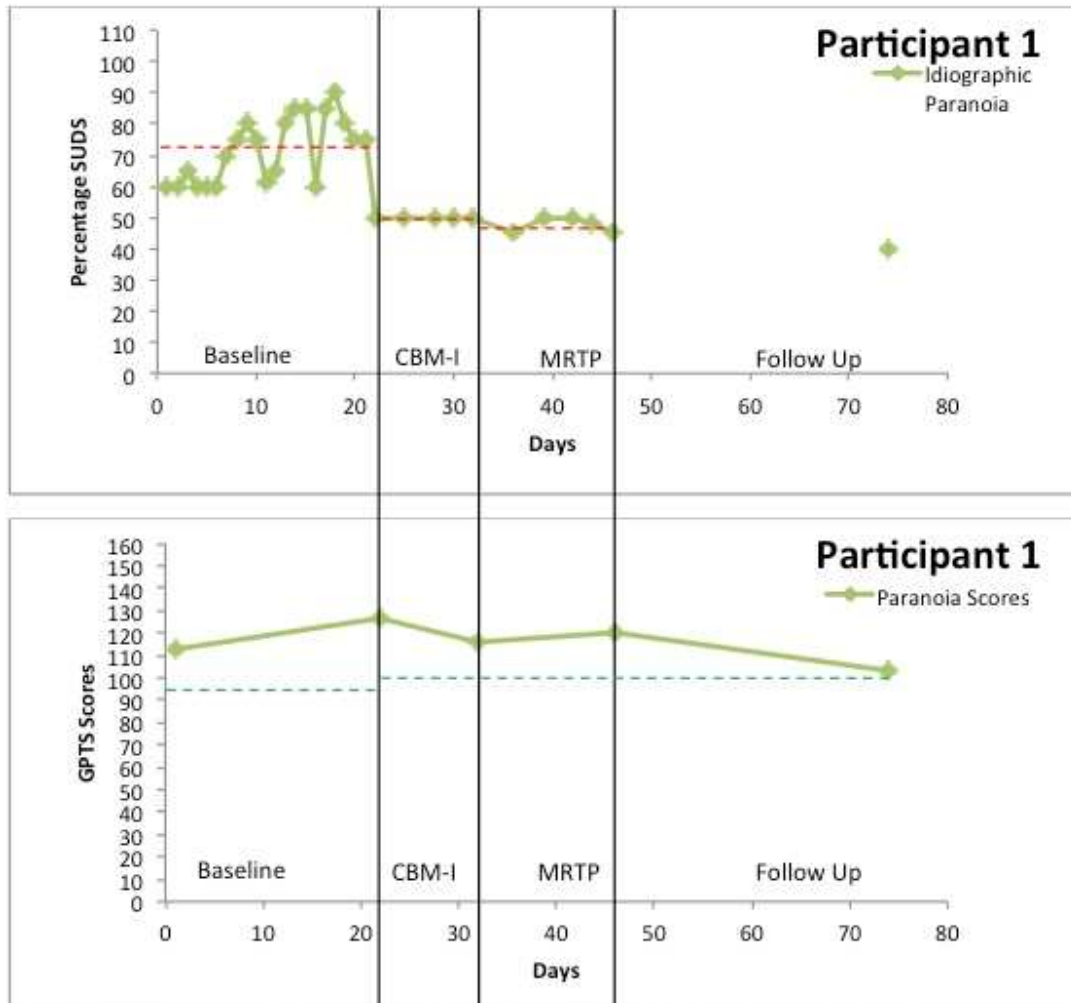
Note: ----- = mean idiographic ratings,   ----- = reliable change threshold.

Baseline idiographic paranoia worsened (*tau* = .512, *p* < .01), which facilitates interpretation due to magnitude of symptoms increasing prior to package. Table 3.5 provides the results from visual inspection of figure 3.2, indicating no effect on conviction or paranoia. However, there is some indication that idiographic ratings of paranoia reduced following the introduction of CBM-I.

Table 3.5

Results of visual inspection of paranoia and conviction data in figures 3.2 and 3.3

Paranoia	Baseline	CBM-I	MRTP	Follow Up
Mean Idiographic Ratings	72	Reduced	Reduced	
Shift in level		Abrupt	NC	NC
Slope	Accelerating	Stable	Stable	
Latency of change		1	4	28
GPTS Clinical Reduction	N	N	N	N
GPTS Reliable Reduction	N	N	N	N
Mean conviction	100	100	100	
Shift in level		NC	NC	NC
Slope	Stable	Stable	Stable	
Latency of change		NC	NC	NC

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes, GPTS reliable change threshold during package phases was calculated by subtracting the RCI from mean time-point one and two ratings.

3.3.4 Reasoning data.

Table 3.6

Standardised measures for participant 1

Measure	B1	B2	CBM-I	MRTP	Follow Up
85:15 Beads Task	X	X	X	X	X
60:40 Beads Task	X	X	X	X	X
EoE	0	0	0	0	0
PBM	No	No	No	No	No
RTHC	2	2	2	2	2

Note: X – not Jumping to Conclusions, EoE – Explanations of Experiences, PBM – Possibility of being mistaken, RTHC – Reaction to Hypothetical Contradiction; 2 – accommodated contradiction into delusion.

As indicated in table 3.6, participant 1 did not JTC on either of the beads tasks during any of the time points. Scores on the EoE, PBM and RTHC assessments indicate a lack of belief flexibility at all time points that did not change following either package phase. These results show no effect on reasoning biases.

3.3.5 Participant summary. Idiographic ratings of social anxiety reduced with introduction of CBM-I and were maintained. SIAS scores did not reliably reduce until follow-up, indicating no specific effects of either package. Although idiographic paranoia decreased, there was no reliable or clinical change in scores on the GPTS and conviction and reasoning biases remained stably high. Idiographic and standardised ratings of social anxiety seemed to follow the same trajectory. Idiographic ratings of paranoia improved, but GPTS did not. Regarding qualitative feedback on the packages, participant 1 felt that the CBM-I package was very helpful, noting that they practiced more positive interpretation of ambiguous social information after the sessions, e.g., when they heard fellow residents mention their name and laugh, they thought maybe the residents were talking about something funny they had said, rather than making fun of them. Participant 1 also reported the MRTP to be helpful, saying they tried to put into practice to slow down and think through situations, even if their first explanation for what had happened was their delusional one. Overall, it seemed that there was little effect of either package, possibly because participant 1 had a more severe overall presentation. Similar lack of response in more severe psychotic symptoms has been indicated in the literature (e.g., a meta-analysis by Cormac, Jones & Campbell, 2002).

3.4 Participant 2

Participant 2 is a 20 year old female, with five years duration of difficulties, recruited from Early Intervention Services.

3.4.1 Social anxiety data.

Figure 3.4 Participant 2 idiographic and standardised social anxiety scores
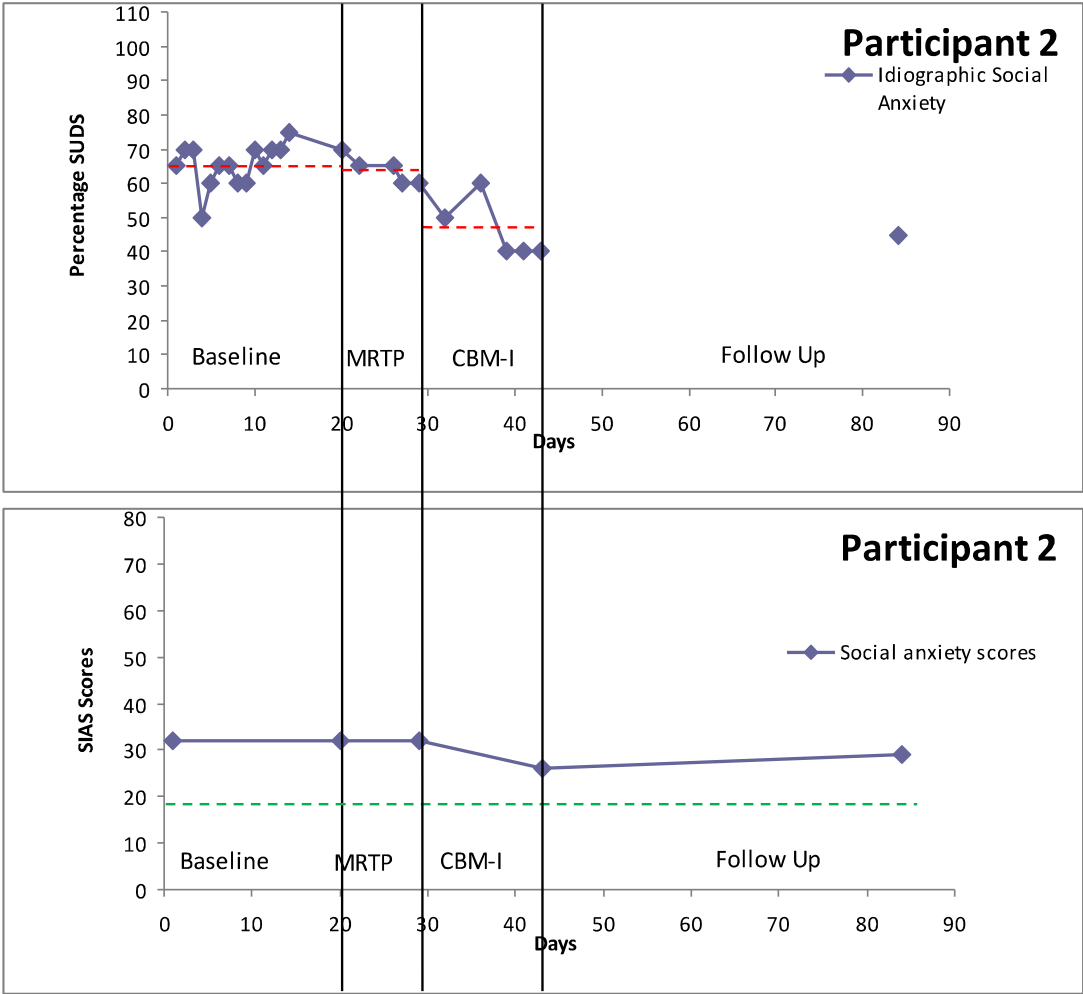
Note: ----- = mean idiographic ratings,   ----- = reliable change threshold.

Baseline idiographic social anxiety was stable (*tau* = .321, *p* = .136). Table 3.7 provides the results from visual inspection of figure 3.4, indicating no effect on social anxiety, although there is some indication that idiographic ratings of social anxiety reduce following the introduction of the CBM-I package.

Table 3.7

Results of visual inspection of social anxiety data in figure 3.4

Social anxiety	Baseline	MRTP	CBM-I	Follow Up
Mean Idiographic Ratings	65	NC	Reduced	
Shift in level		NC	Gradual decrease	NC
Slope	Stable	Stable	Decelerating	
Latency of change between phases		6	3	41
SIAS Clinical Reduction	N	N	N	N
SIAS Reliable Reduction	N	N	N	N

Note: NC – No Change, N – No, Y – Yes.

3.4.2 Conviction data.

Figure 3.5 Participant 2 idiographic conviction scores
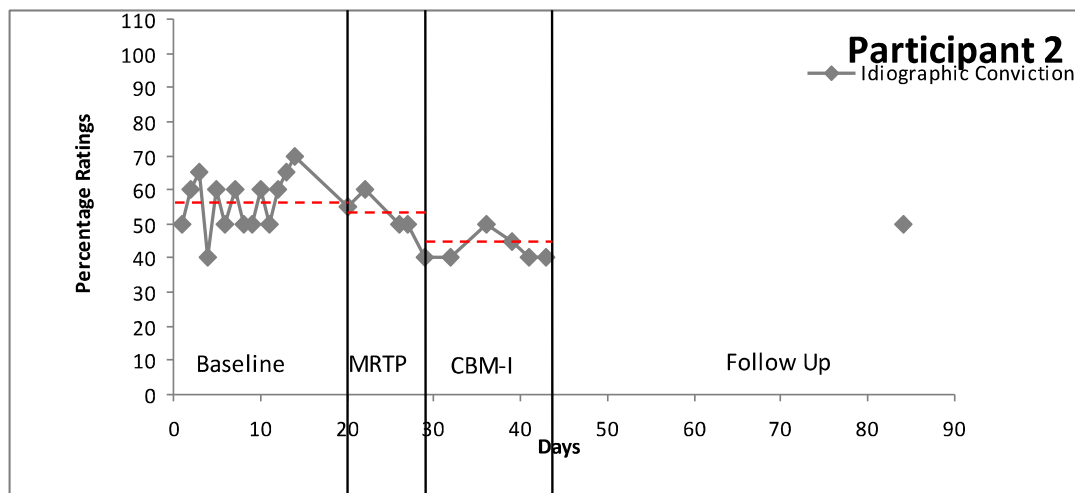
Note: - - - - - = mean idiographic ratings.

Baseline appeared stable (*tau* = .301, *p* = .165). Table 3.8 provides the results from

visual inspection of figure 3.5.

3.4.3 Paranoia Data.

Figure 3.6 Participant 2 idiographic and standardised paranoia ratings
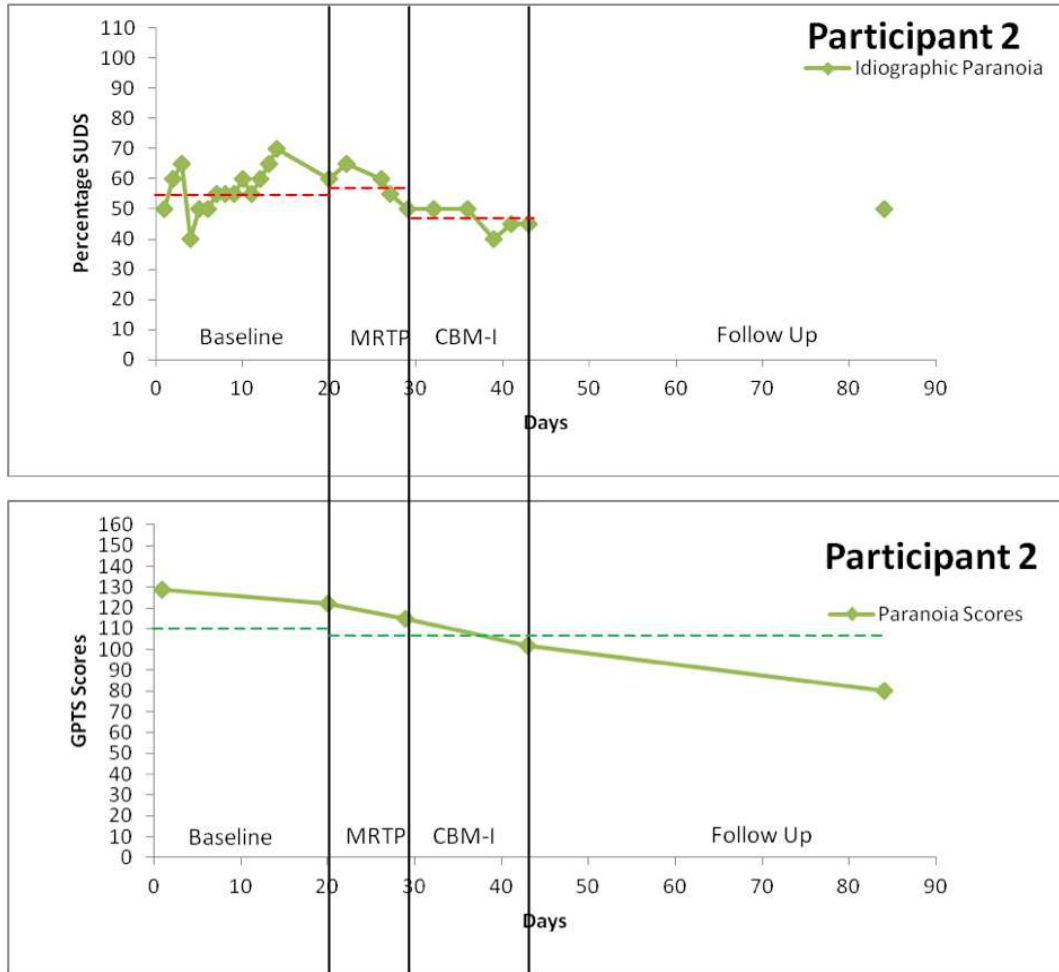
Note: ----- = mean idiographic ratings, ----- = reliable change threshold.

Baseline idiographic paranoia worsened (*tau* = .499, *p* < .05). Table 3.8 provides the results from visual inspection of figures 3.5 and 3.6, indicating that CBM-I improved paranoia, as measured by idiographic ratings and GPTS scores. Visual analysis indicated that CBM-I improved conviction, which was maintained at follow up. SMA concurred with these results: no change in level (*r* = -0.301, *p* = 0.194) or slope (*r* = 0.188, *p* = 0.422) of conviction occurred between baseline and MRTP phases, however a significant reduction in level of conviction (*r* = -0.641, *p* <.01) not slope (*r* = -0.067, *p* = 0.781) occurred between baseline and CBM-I phases.

Table 3.8

Results of visual inspection of paranoia and conviction data in figures 3.5 and 3.6

Paranoia	Baseline	MRTP	CBM-I	Follow Up
Mean Idiographic Ratings	56	Stable	Reduced	
Shift in level		Abrupt	NC	NC
Slope	Accelerating	Decelerating	Stable	
Latency of change between phases		6	10	41
GPTS Clinical Reduction	N	N	N	Y
GPTS Reliable Reduction	N	N	Y	Y
Mean Conviction Ratings	56	Reduced	Reduced	
Shift in level		Abrupt	NC	Increased
Slope	Stable	Decreasing	Stable	
Latency of change between phases		6	7	41

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes.

3.4.4 Reasoning data.

Table 3.9

Standardised measures for participant 2

Measure	B1	B2	MRTP	CBM-I	Follow Up
85:15 Beads Task	X	X	X	X	X
60:40 Beads Task	X	X	X	X	X
EoE	0	0	1	1	1
PBM	Yes	Yes	Yes	Yes	Yes
RTHC	1	1	1	1	1

Note: X – not Jumping to Conclusions, EoE – Explanations of Experiences, PBM – Possibility of being mistaken, RTHC – Reaction to Hypothetical Contradiction; 1 – reduced delusional conviction.

As indicated in table 3.9, participant 2 did not JTC on either of the beads tasks during any of the time points. Scores on the EoE assessment indicate an improvement in generating alternative explanations of experiences following the MRTP phase. PBM and RTHC assessments indicate presence of belief flexibility at all time points that did not change following each phase. This indicates improved reasoning biases following the MRTP, although participant 2 already had better flexibility of thinking and lower conviction than others.

3.4.5 Participant 2 summary. Idiographic ratings of social anxiety reduced with introduction of the MRTP and were further reduced following CBM-I. SIAS scores were not reliably reduced, indicating no effect. Idiographic conviction reduced following CBM-I, which was maintained. Idiographic paranoia decreased after MRTP, which further decreased following CBM-I. This corresponded with a reliable and clinical reduction in GPTS scores following CBM-I. Although participant 2 had less severity in terms of reasoning biases, the MRTP did improve this. Idiographic and standardised ratings of social anxiety and paranoia seemed to follow a similar trajectory. Participant 2 also reported finding the CBM-I training helpful when out socially, although they reported it being tedious to complete. The MRTP was also reported to be helpful, in training participant 2 to generate alternative explanations for things that related to the delusional content, e.g. attributing hearing voices outside saying 'they're going to get you,' to being stressed/the psychosis rather than the delusional explanation. Overall, it seemed that there was more of an effect during the package phases, possibly because participant 2 had a less severe overall presentation.

3.5 Participant 3

Participant 3 is a 31 year old male, with 16 years duration of difficulties, recruited from Recovery Services.

3.5.1 Social anxiety data.

Figure 3.7 Participant 3 idiographic and standardised social anxiety scores
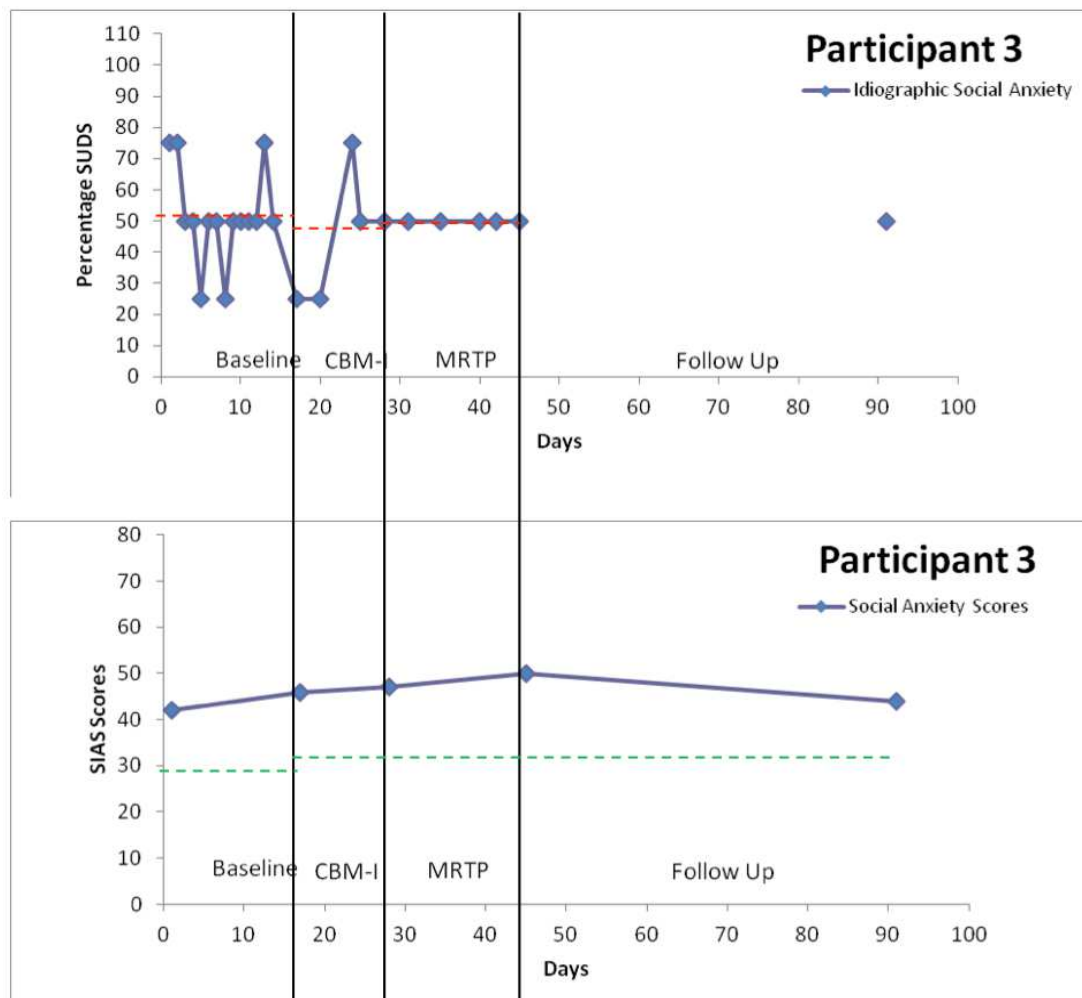
Note: - - - - - = mean idiographic ratings, - - - - - = reliable change threshold.

Baseline idiographic social anxiety was unstable yet not significantly increasing or decreasing (*tau* = -.103, *p* = .649). Table 3.10 provides the results from visual inspection of figure 3.7, indicating no effect on social anxiety.

Table 3.10

Results of visual inspection of social anxiety data in figure 3.7

Social anxiety	Baseline	CBM-I	MRTP	Follow Up
Mean Idiographic Ratings	52	Reduced	Increased	
Shift in level		Abrupt decrease	NC	NC
Slope	Stable	Stable	Stable	
Latency of change between phases		3	NC	NC
SIAS Clinical Reduction	N	N	N	N
SIAS Reliable Reduction	N	N	N	N

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes.

3.5.2 Conviction data.

Figure 3.8 Participant 3 idiographic conviction scores
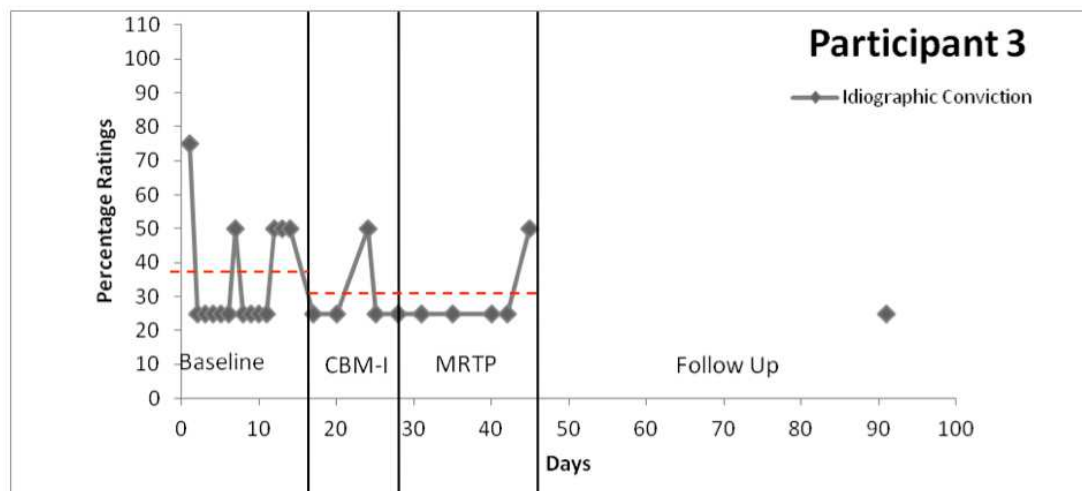
Note: - - - - - = mean idiographic ratings.

Baseline idiographic conviction ratings did not appear to be stable, but there was no significant trend (*tau* = .225, *p* = .326). Table 3.11 provides the results from visual inspection of figure 3.8.

3.5.3 Paranoia Data.

Figure 3.9 Participant three idiographic and standardised paranoia scores

Note: ----- = mean idiographic ratings, ----- = reliable change threshold.
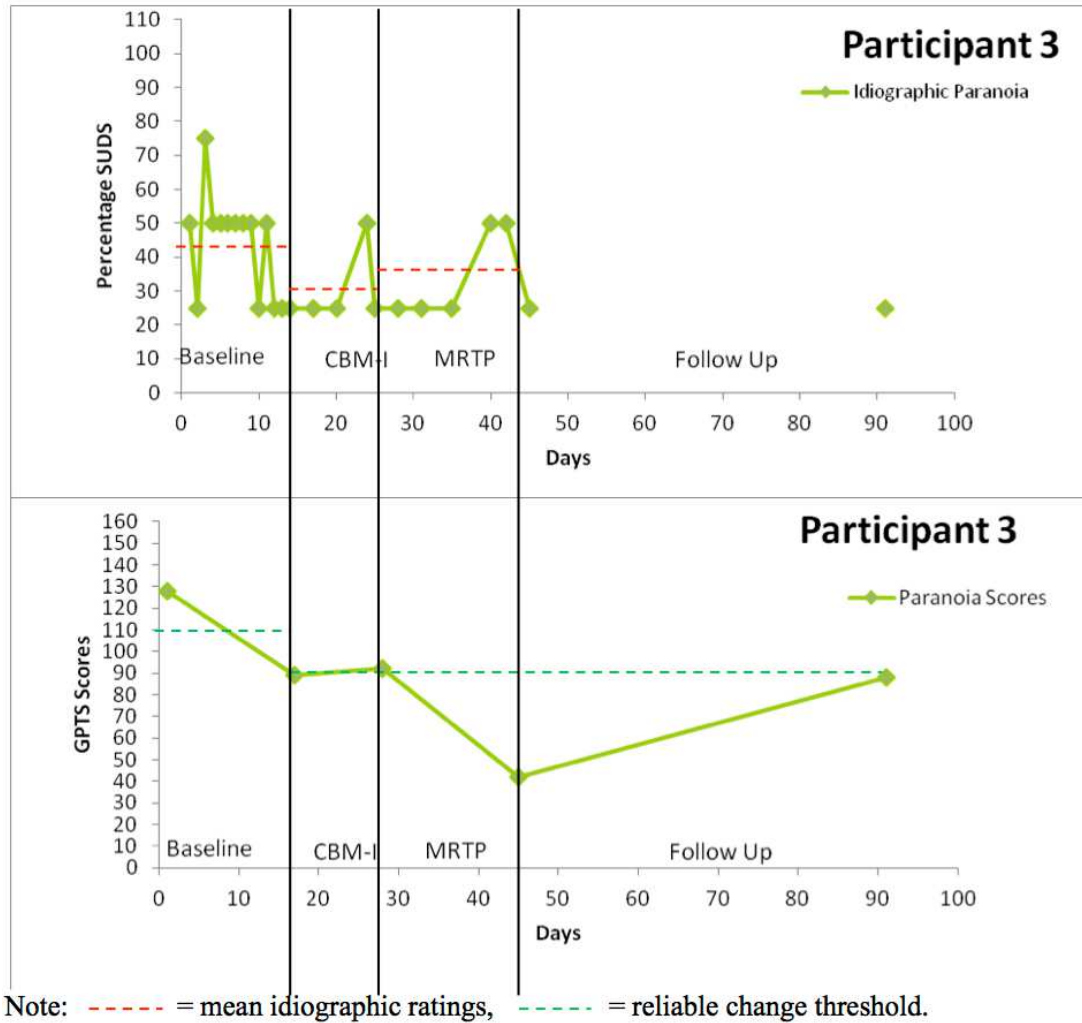
Baseline idiographic paranoia decreased over time, making interpretation more difficult as this suggests a change in symptoms before any package was introduced ($tau = -.475, p < .05$). Table 3.11 provides the results from visual inspection of figures 3.8 and 3.9, indicating no clear effect on conviction. SMA agreed with this finding, indicating no change in level ($r = -0.173, p = 0.4774$) or slope ($r = -0.018, p = 0.94$) of conviction between baseline and CBM-I phases. Similarly, there was no change in level ($r = -0.173, p = 0.508$) or slope ($r = -0.062, p = 0.815$) of conviction between baseline and MRTP phases. Regarding paranoia in table 3.11, even though the baseline is not stable, the magnitude of change would suggest a reduction in paranoia following the MRTP that is maintained at follow up.

Table 3.11

Results of visual inspection of paranoia and conviction data in figures 3.8 and 3.9

Paranoia	Baseline	CBM-I	MRTP	Follow Up
Mean Idiographic Ratings	43	Reduced	Increased	
Shift in level		NC	NC	NC
Slope	Decelerating	Stable	Stable	
Latency of change between phases		10	12	NC
GPTS Clinical Reduction	N	N	Y	N
GPTS Reliable Reduction	Y	N	Y	Y
Mean Conviction Ratings	36	Reduced	NC	
Shift in level		Abrupt	NC	NC
Slope	Stable	Stable	Stable	
Latency of change between phases		3	17	36

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes.

3.5.4 Reasoning data

Table 3.12

Standardised measures for participant 3

Measure	B1	B2	CBM-I	MRTP	Follow Up
85:15 Beads Task	J	J	J	X	X
60:40 Beads Task	J	J	J	X	X
EoE	0	1	1	2	2
PBM	Yes	Yes	Yes	Yes	Yes
RTHC	3	1	2	1	0

Note: X – not Jumping to Conclusions, J – JTC, EoE – Explanations of Experiences, PBM – Possibility of being mistaken, RTHC – Reaction to Hypothetical Contradiction; 3 –

rejected/dismissed contradiction, 2 – accommodated contradiction into delusion, 1 – reduced delusional conviction, 0 – dismissed delusion.

Table 3.12 indicates that participant 3 did JTC on both beads tasks during both time-point one and two assessments and the CBM-I phase. Participant 3 did not JTC on either task following the MRTP phase. This continued at follow up. Scores on the EoE assessment indicate improved belief flexibility at the second time-point, with a further improvement following the MRTP phase, maintained at follow up. PBM scores did not change throughout. RTHC assessments indicate an improvement in belief flexibility at second time-point, which remained the same throughout both package phases. Participant 3 eventually dismissed the belief at follow up. These results indicate that the MRTP, not the CBM-I package, improved reasoning biases.

3.5.5 Participant 3 summary. Participant 3 fluctuated in idiographic ratings of anxiety and paranoia, but there was some indication of a decrease following introduction of CBM-I, which was maintained with following the MRTP. SIAS scores remained in the clinical range throughout. GPTS scores reduced during time-point one and two, maintained following CBM-I and further decreased after the MRTP. However, they increased to clinical and non-reliable levels at follow-up. This suggests that the MRTP did reduce paranoia, which remains reliably reduced at follow up. Initial conviction satisfied study inclusion criteria of above 50% but mean baseline conviction fell below this. There was no effect on conviction. Reasoning biases improved after the MRTP. Therefore, reasoning biases were influenced by the MRTP, as was paranoia, which supports the idea that reasoning biases are implicated in paranoia. There seemed to be some discrepancy between idiographic and standardised ratings of social anxiety and paranoia. Unfortunately, participant 3 reported getting little help from either package. Overall, it seemed that there was only a minor effect of either package, possibly because participant 3 had a more severe overall presentation.

3.6 Participant 4

Participant 4 is a 47 year old female, with 14 years duration of difficulties, recruited from Recovery Services.

3.6.1 Social anxiety data.

Figure 3.10 Participant 4 idiographic and standardised social anxiety scores
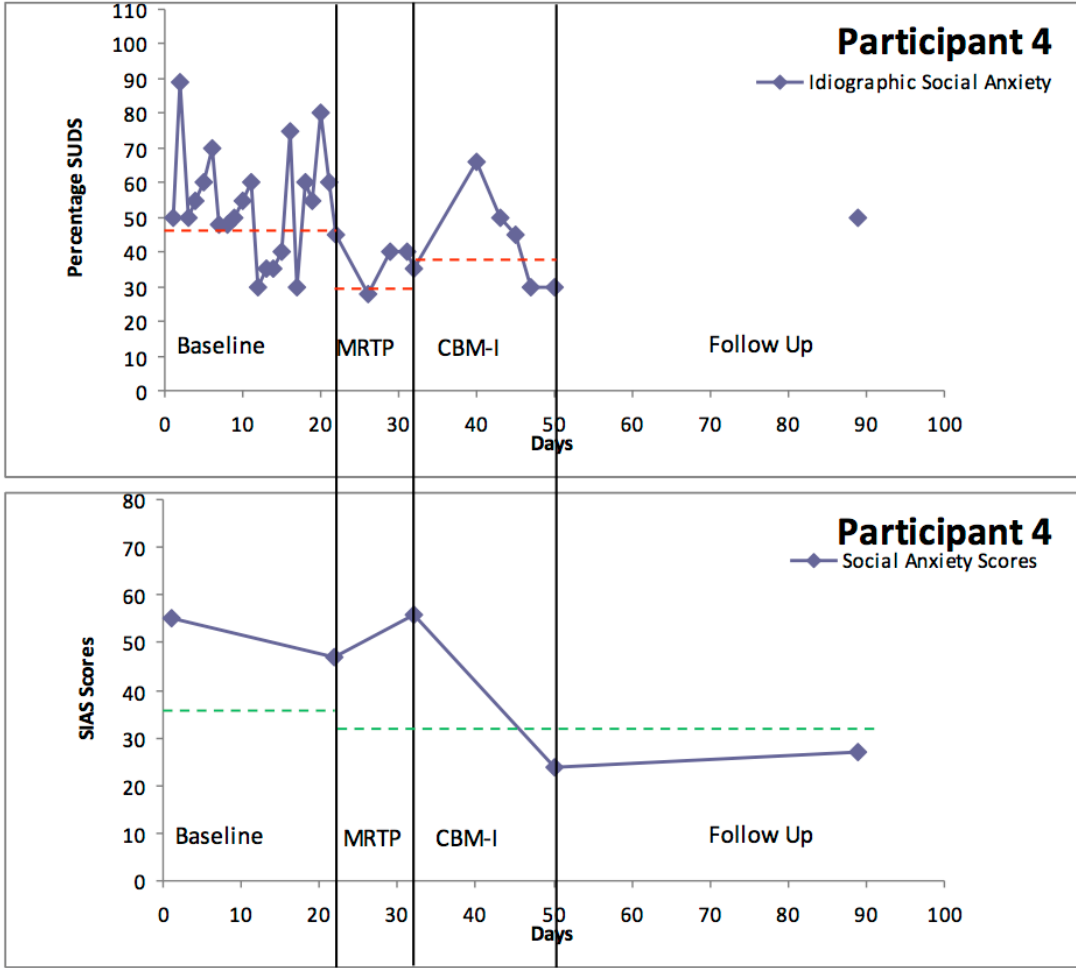
Note: - - - - - = mean idiographic ratings,   - - - - - = reliable change threshold.

Baseline idiographic social anxiety appeared unstable, but without significant change in symptoms ($tau = -.015$, $p = .927$). Table 3.13 provides the results from visual inspection of figure 3.10, which indicates that CBM-I improved social anxiety.

Table 3.13

Results of visual inspection of social anxiety data in figure 3.10

Social anxiety	Baseline	MRTP	CBM-I	Follow Up
Mean Idiographic Ratings	54	Reduced	Increased	
Shift in level		Abrupt	NC	Increase
Slope	Stable	Decelerating	Stable	
Latency of change between phases		1	8	39
SIAS Clinical Reduction	N	N	Y	Y
SIAS Reliable Reduction	N	N	Y	Y

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes.

3.6.2 Conviction data.

Figure 3.11 Participant 4 idiographic conviction scores
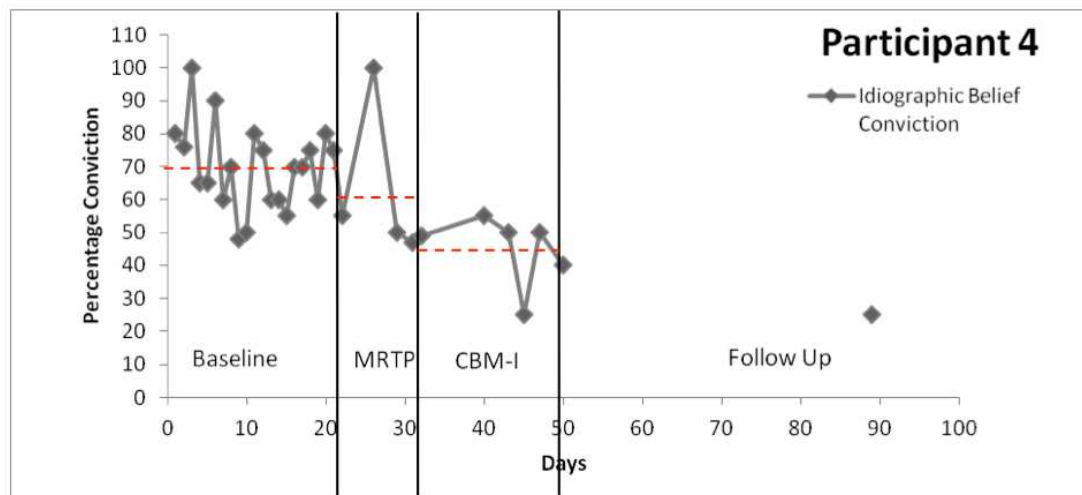
Note: - - - - - = mean idiographic ratings.

Baseline idiographic conviction was not stable, but there was no significant direction in trend (*tau* = -.109 *p* = .502). Table 3.14 provides the results from visual inspection of figure 3.11. Conviction ratings appear to reduce following introduction of the CBM-I package.

3.6.3 Paranoia Data.

Figure 3.12 Participant 4 idiographic and standardised paranoia scores
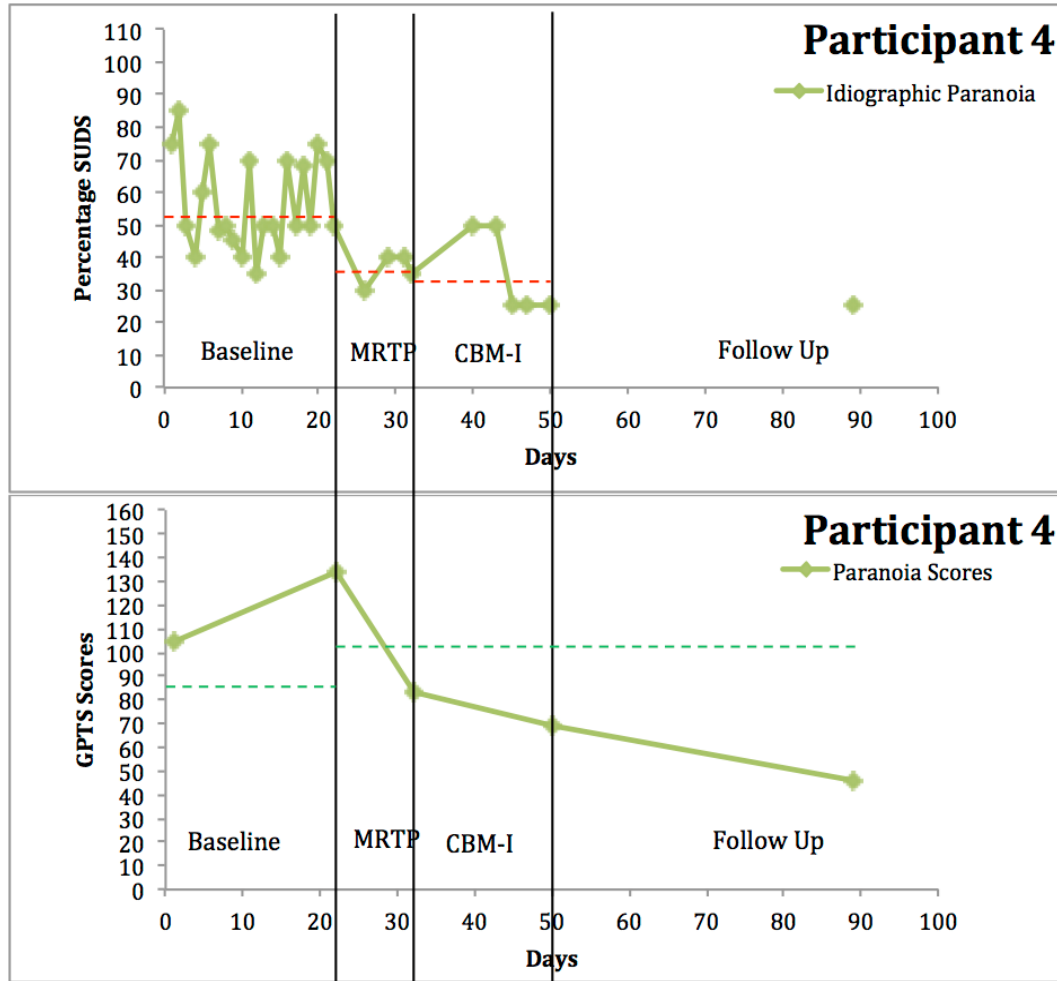
Note: - - - - - = mean idiographic ratings,   - - - - - = reliable change threshold.

Baseline idiographic paranoia did not appear stable from visual inspection, but change was not shown to be significant over the baseline phase ($tau = 0$, $p = 1$). Table 3.14 provides the results from visual inspection of figures 3.11 and 3.12, indicating a reduction in conviction following the MRTP that is further reduced after CBM-I. SMA indicated no change in level ($r = -0.254$, $p = 0.207$) or slope ($r = -0.238$, $p = 0.224$) of conviction between baseline and MRTP phases. Comparison between baseline and CBM-I phases revealed a significant reduction in level ($r = -0.641$, $p < .01$) but not slope ($r = -0.437$, $p = 0.117$) of conviction. This indicates that CBM-I, not the MRTP significantly improved conviction. Visual inspection results in table 3.14 indicate that the MRTP improved paranoia as measured by idiographic ratings and GPTS scores.

Table 3.14

Results of visual inspection of paranoia and conviction data in figures 3.11 and 3.12

Paranoia	Baseline	MRTP	CBM-I	Follow Up
Mean Idiographic Ratings	57	Reduced	Reduced	
Shift in level		Abrupt	NC	NC
Slope	Stable	Stable	Decelerating	
Latency of change between phases		1	8	NC
GPTS Clinical Reduction	N	Y	Y	Y
GPTS Reliable Reduction	N	Y	Y	Y
Mean Conviction ratings	70	Reduced	Reduced	
Shift in level		Abrupt	NC	Abrupt
Slope	Stable	Stable	Decelerating	
Latency of change between phases		1	8	39

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes.

3.6.4 Reasoning data.

Table 3.15

Standardised measures for participant 4

Measure	B1	B2	MRTP	CBM-I	Follow Up
85:15 Beads Task	X	X	X	X	X
60:40 Beads Task	X	X	X	X	X
EoE	0	0	2	2	2
PBM	No	No	Yes	Yes	Yes
RTHC	3	2	1	1	1

Note: X – not Jumping to Conclusions, EoE – Explanations of Experiences, PBM – Possibility of being mistaken, RTHC – Reaction to Hypothetical Contradiction; 3 –

rejected/dismissed contradiction, 2 – accommodated contradiction into delusion, 1 – reduced delusional conviction.

Table 3.14 indicates that participant 4 did not JTC on any of the beads tasks during all phases. Scores on the EoE assessment indicate improved belief flexibility following the MRTP phase, which was maintained throughout CBM-I and follow up. PBM scores improved following the MRTP phase. RTHC assessments indicate improved belief flexibility after the MRTP phase, which was maintained throughout. This indicates that the MRTP improved reasoning biases.

3.6.5 Participant 4 summary. There was fluctuation in idiographic measures of social anxiety and paranoia to start off with which reduced with the introduction of the MRTP and was maintained. Clinical and reliable reduction in SIAS scores occurred only after introduction of CBM-I. A clinical and reliable reduction in GPTS scores occurred after introduction of the MRTP, and was maintained. There was a reduction in conviction by the end of MRTP package, which became significant following CBM-I. Improvement in reasoning biases (EoE, PBM, RTHC) occurred following introduction of the MRTP which was maintained across phases. There was marked discrepancy between idiographic and standardised ratings of social anxiety; however, the same paranoia measures seemed to follow a similar trajectory to one another. Participant 4 reported finding it challenging to practice the ideas presented by both packages, although they tried very hard to make this happen. Participant 4 reported seeing the potential for the packages to help a good deal. With this in mind, participant 4 worked very hard to challenge their views in relation to other people and particularly the neighbours (who were the persecutors), to the point where participant 4 reported not dismissing the belief fully, but being much less distressed by it. Even though participant 4's presentation could be thought of as more severe than others, there seemed to be a strong response to both package packages in this case.

3.7 Participant 5

Participant 5 is a 53 year old male, with 20 years duration of difficulties, recruited from Recovery Services.

3.7.1 Social anxiety data.

Figure 3.13 Participant 5 idiographic and standardised social anxiety scores
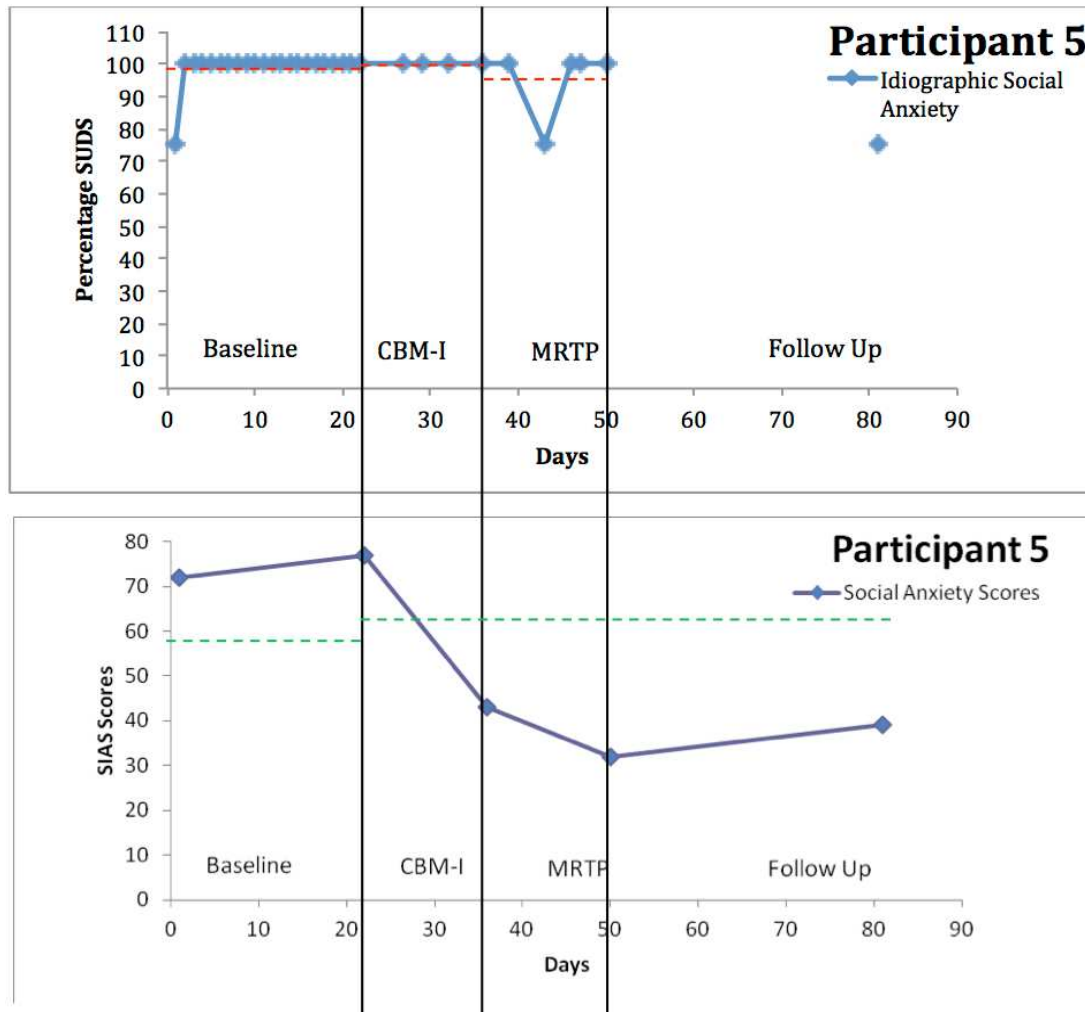
Note: – – – – = mean idiographic ratings,   – – – – = reliable change threshold.

Baseline idiographic social anxiety was stable (*tau* = .309, *p* = .099). Table 3.16 provides the results from visual inspection of figure 3.13, indicating that CBM-I improved social anxiety.

Table 3.16

Results of visual inspection of social anxiety data in figure 3.13

Social anxiety	Baseline	CBM-I	MRTP	Follow Up
Mean Idiographic Ratings	99	Slight increase	Slight reduction	
Shift in level		NC	NC	NC
Slope	Stable	Stable	Stable	Stable
Latency of change between phases		NC	7	31
SIAS Clinical Reduction	N	N	Y	N
SIAS Reliable Reduction	N	Y	Y	Y

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes.

3.7.2 Conviction data.

Figure 3.14 Participant 5 idiographic conviction scores
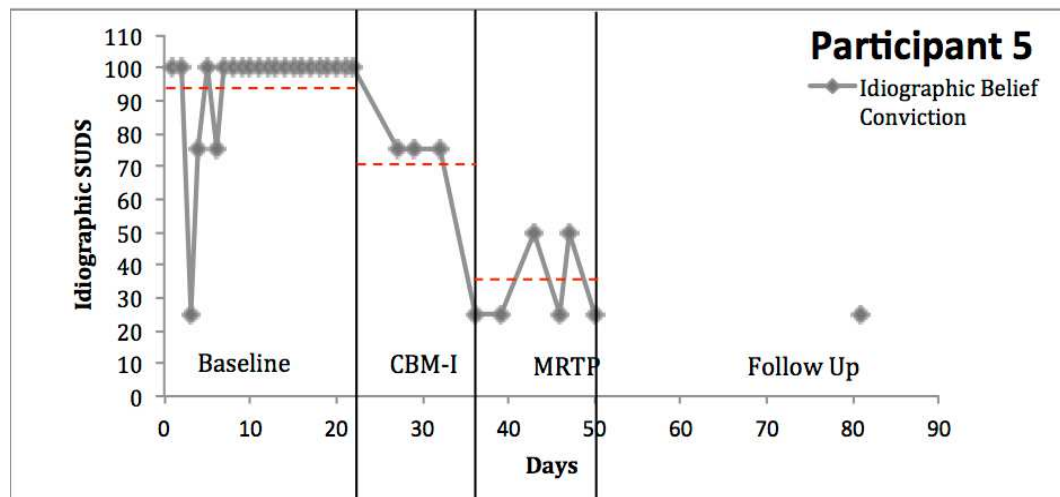
Note: - - - - - = mean idiographic ratings

Baseline conviction appeared stable visually, but testing indicated a significant increase over time (*tau* = .387, *p* < .05). Table 3.17 provides the results from visual inspection of figure 3.14, suggesting that conviction did reduce over the study period.

3.7.3 Paranoia Data.

Figure 3.15 Participant 5 idiographic and standardised paranoia scores
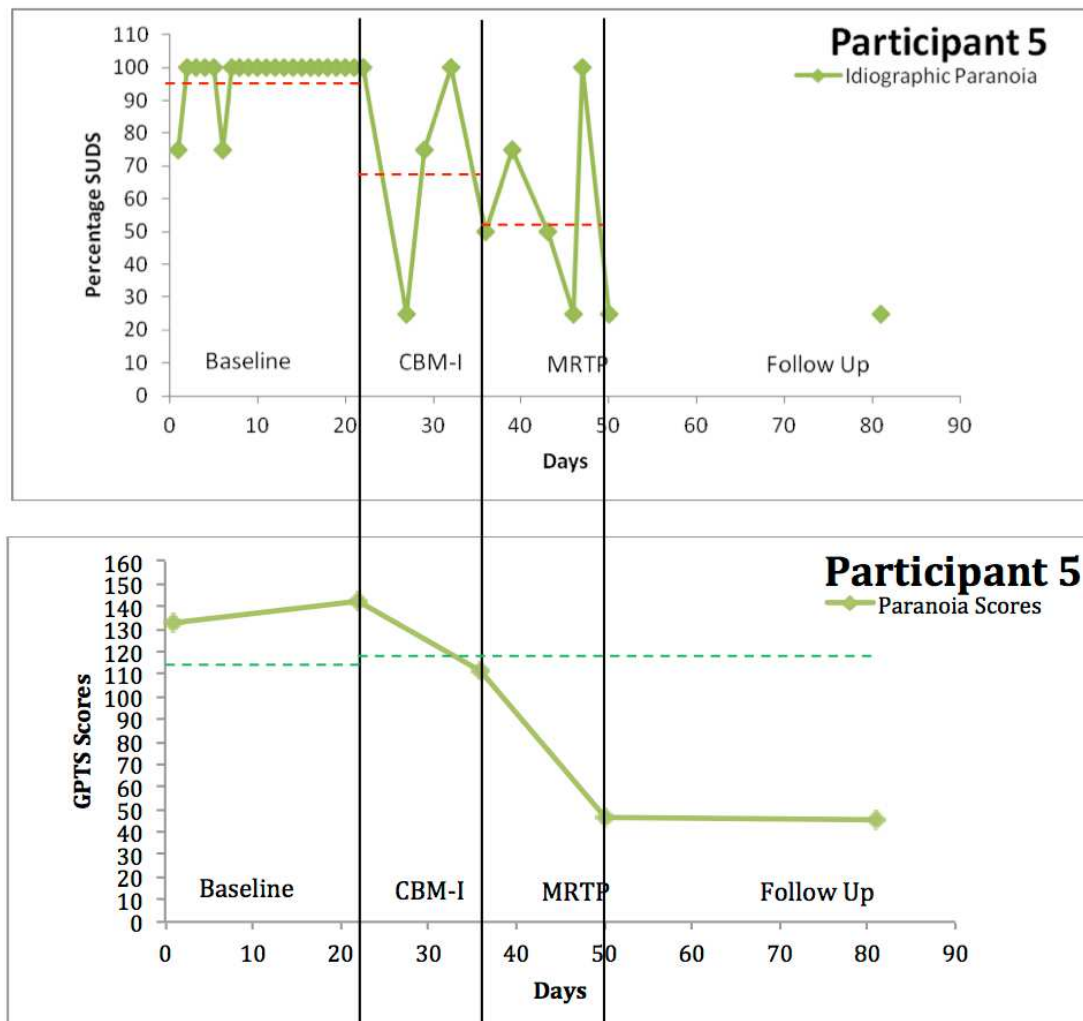
Note: ----- = mean idiographic ratings, ----- = reliable change threshold.

Baseline idiographic paranoia was stable (tau = .336, p = .072). Table 3.17 provides the results from visual inspection of figures 3.14 and 3.15, indicating a cumulative effect of both packages on conviction. SMA agreed with this, indicating no change in level (r = -0.451, p = 0.067) or slope (r = 0.079, p = 0.76) of conviction between baseline and CBM-I phases. Comparison between baseline and MRTP phases indicated a reduction in level (r = -0.820, p < 0.001) but not slope (r = -0.216, p = 0.533) of conviction. Table 3.17 also indicated that CBM-I improved GPTS scores which were maintained throughout.

Table 3.17

Results of visual inspection of paranoia and conviction data in figures 3.14 and 3.15

Paranoia	Baseline	CBM-I	MRTP	Follow Up
Mean Idiographic Ratings	98	Reduced	Reduced	
Shift in level		NC	Abrupt Increase	NC
Slope	Stable	Unstable	Unstable	
Latency of change between phases		6	3	NC
GPTS Clinical Reduction	N	N	Y	Y
GPTS Reliable Reduction	N	Y	Y	Y
Mean Conviction Ratings	94	Reduced	Reduced	
Shift in level		NC	NC	NC
Slope	Accelerating	Decelerating	Stable	
Latency of change between phases		6	7	NC

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes.

3.7.4 Reasoning data

Table 3.18

Standardised measures for participant 5

Measure	B1	B2	CBM-I	MRTP	Follow Up
85:15 Beads Task	X	X	X	X	X
60:40 Beads Task	J	X	X	X	X
EoE	0	0	0	1	1
PBM	Yes	Yes	Yes	Yes	Yes
RTHC	1	1	1	0	0

Note: X – not Jumping to Conclusions, J – JTC, EoE – Explanations of Experiences, PBM – Possibility of being mistaken, RTHC – Reaction to Hypothetical Contradiction; 1 – reduced delusional conviction, 0 – dismissed delusion.

Table 3.18 shows that participant 5 did not JTC on either of the beads tasks during all phases, with the exception of JTC once on the first time-point. Scores on the EoE assessment indicate an improvement in belief flexibility following the MRTP phase, which continued at follow up. PBM scores did not change throughout. RTHC assessments indicate improved belief flexibility following the MRTP phase, where participant 5 dismissed the belief. This continued at follow up. These results indicate that the MRTP improved reasoning biases.

3.7.5 Participant 5 summary. There were no changes in idiographic ratings of social anxiety, but reliable change in SIAS scores occurred following CBM-I, which was maintained (and became clinically significant) after introduction of MRTP package. Reduction in idiographic ratings of paranoia following CBM-I followed further reduction during the MRTP package. Reliable and clinical change in GPTS scores occurred following introduction of CBM-I which was maintained (and became clinically significant) following MRTP package. Reduction in conviction occurred following CBM-I and a further significant reduction was observed following the MRTP. Improvement in reasoning biases (EoE, RTHC) occurred only after the MRTP, which was given after CBM-I, suggesting a specific effect of the MRTP on reasoning biases. There was marked discrepancy between idiographic and standardised ratings of social anxiety; however, the same paranoia measures seemed to follow a similar trajectory to one another. Participant 5 reported finding both packages helpful; to the point that delusional conviction fell significantly following CBM-I. This could be due to the nature of the belief being that they would be killed if they went outside. It could be that reduction in negative interpretative biases had a knock-on effect on social anxiety and paranoia simultaneously. Even though participant 5's presentation could be thought of as more severe comparatively (with high initial social anxiety, paranoia and conviction), there seemed to be a strong response to both package packages in this case.

3.8 Participant 6

Participant 6 was a 30 year old male, with 6 years duration of difficulties, recruited from Recovery Services.

3.8.1 Social anxiety data.

Figure 3.16 Participant 6 idiographic and standardised social anxiety scores
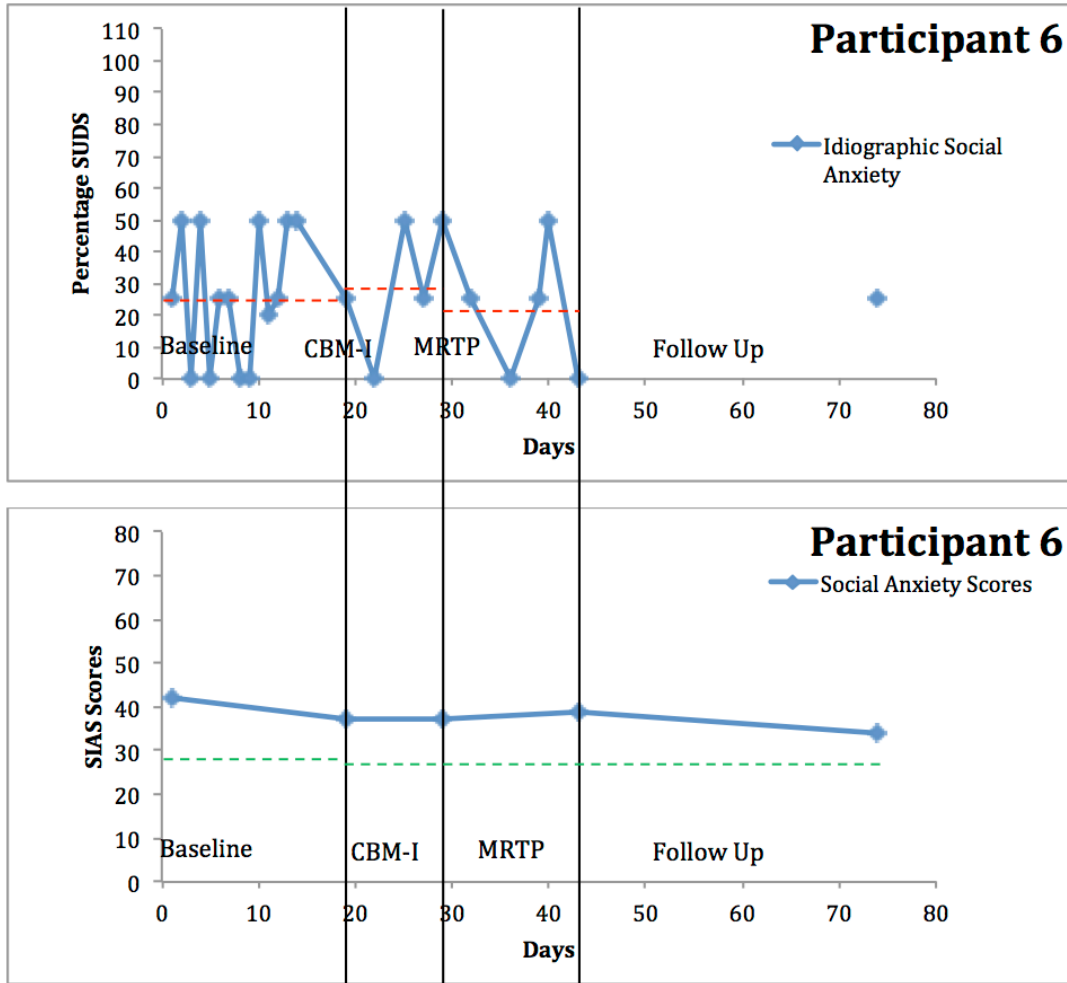
Note: - - - - - = mean idiographic ratings, - - - - - = reliable change threshold.

Baseline social anxiety did not appear stable following visual inspection, but there was no significant change (*tau* = .164, *p* =.453). Table 3.19 provides the results from visual inspection of figure 3.16, indicating no effect on social anxiety.

Table 3.19

Results of visual inspection of social anxiety data in figure 3.16

Social anxiety	Baseline	CBM-I	MRTP	Follow Up
Mean Idiographic Ratings	26	Increased	Decreased	
Shift in level		Abrupt	Abrupt	Abrupt
Slope	Stable	Accelerating	Unstable	
Latency of change between phases		5	3	31
SIAS Clinical Reduction	N	N	N	N
SIAS Reliable Reduction	N	N	N	N

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes.

3.8.2 Conviction data.

Figure 3.17 Participant 6 idiographic conviction scores
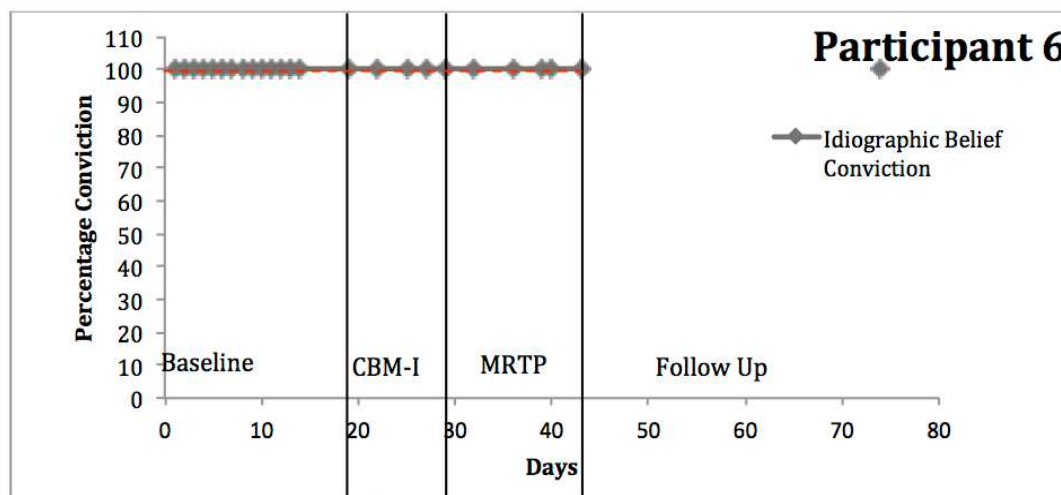
Note: - - - - - = mean idiographic ratings.

The results of visual inspection of conviction data are in table 3.20. Conviction remained at

100% throughout the study period.

3.8.3 Paranoia Data.

Figure 3.18 Participant 6 idiographic and standardised paranoia scores
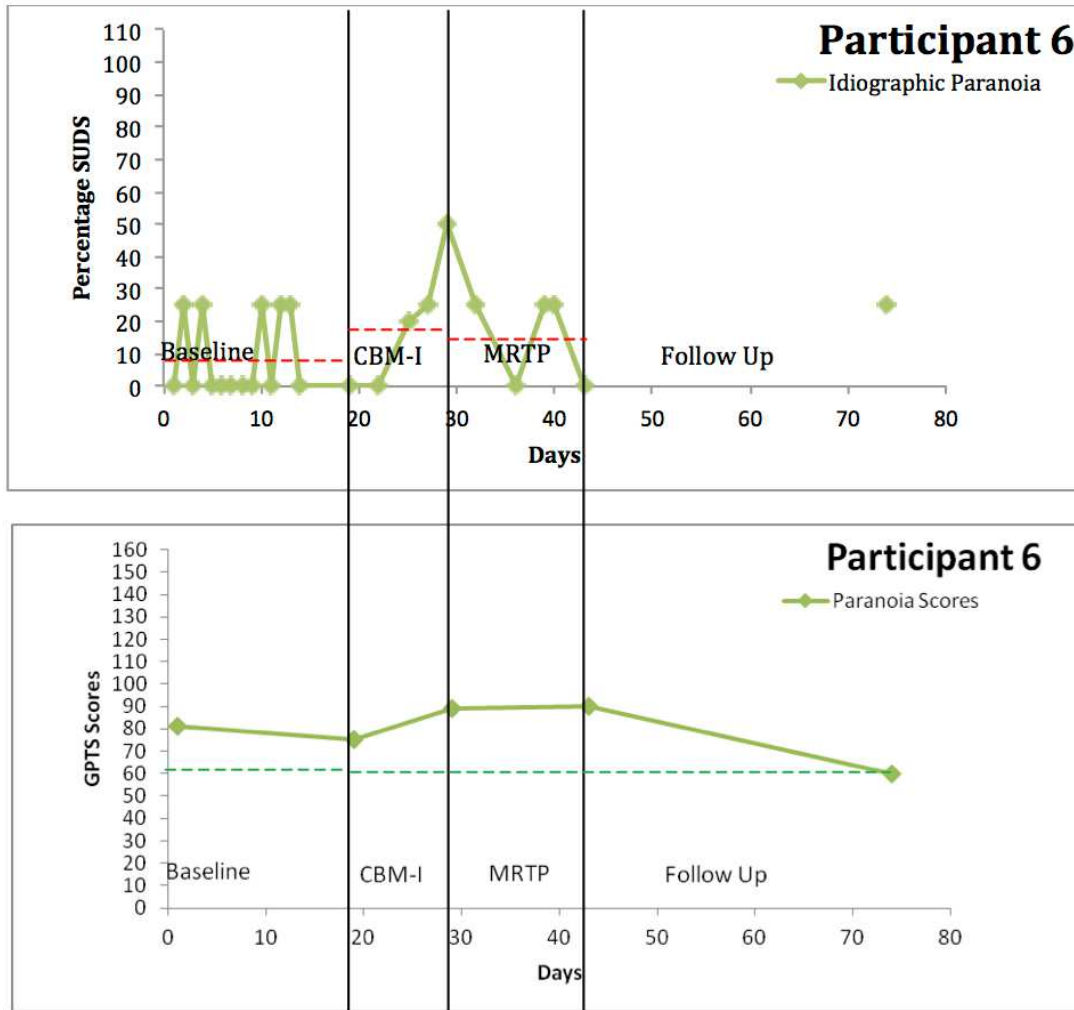
Note: ----- = mean idiographic ratings, ----- = reliable change threshold.

Baseline idiographic paranoia was stable (*tau* = .109, *p* = .641). Table 3.20 provides the results from visual inspection of figures 3.17 and 3.18, indicating no effect on conviction or paranoia.

Table 3.20

Results of visual inspection of paranoia and conviction data in figures 3.17 and 3.18

Paranoia	Baseline	CBM-I	MRTP	Follow Up
Mean Idiographic Ratings	9	Increased	Reduced	Increased
Shift in level		NC	Abrupt	Abrupt Increase
Slope	Stable	Accelerating	Decelerating	
Latency of change between phases		11	3	31
GPTS Clinical Reduction	N	N	N	N
GPTS Reliable Reduction	N	N	N	N
Mean conviction	100	100	100	
Shift in level		NC	NC	NC
Slope	Stable	Stable	Stable	
Latency of change		NC	NC	NC

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes.

3.7.4 Reasoning data

Table 3.21

Standardised measures for participant 6

Measure	B1	B2	CBM-I	MRTP	Follow Up
85:15 Beads Task	X	X	X	X	X
60:40 Beads Task	X	X	X	X	X
EoE	0	0	0	0	0
PBM	No	Yes	No	Yes	Yes
RTHC	3	3	3	3	3

Note: X – not Jumping to Conclusions, EoE – Explanations of Experiences, PBM – Possibility of being mistaken, RTHC – Reaction to Hypothetical Contradiction; 3 – rejected/dismissed contradiction.

Table 3.21 shows that participant 6 did not JTC on either of the beads tasks during all phases. Scores on the EoE assessment indicate a lack of belief flexibility, which continued across all conditions. PBM scores changed during time-point one and two, again after the CBM-I phase, and again following the MRTP phase. RTHC assessments indicate a lack of belief flexibility such that participant 6 completely rejected the scenario every time. These results indicate no effect of the packages on reasoning biases.

3.8.5 Participant 6 summary. Idiographic ratings of social anxiety fluctuated throughout the study and were quite low ratings in comparison to other participants. No change in SIAS scores indicated no effect on social anxiety. Idiographic paranoia was also low to start off with, increasing slightly following introduction of package and then fluctuated over duration of study. GPTS scores were also lower than other participants to begin with and were under the clinical cut-off. No reliable change indicated lack of any effect on paranoia. Conviction remained at 100% throughout study, and there were no effects of either package on reasoning biases. Although idiographic and standardised measures of social anxiety and paranoia followed similar trajectories, the idiographic ratings did not reflect the severity of the standardised measures. Participant 6 reported not finding either package to be of any help. They felt that the CBM-I paradigm was 'obvious' and 'childish' in its aims, and they reported feeling a little patronised by it. Even though participant 6's presentation could be thought of as less severe than others, there seemed to be no response to either package packages in this case.

3.9 Participant 7

Participant 7 is a 41 year old male, with 13 years duration of difficulties, recruited from Recovery Services.

3.9.1 Social anxiety data.

Figure 3.19 Participant 7 idiographic and standardised social anxiety scores
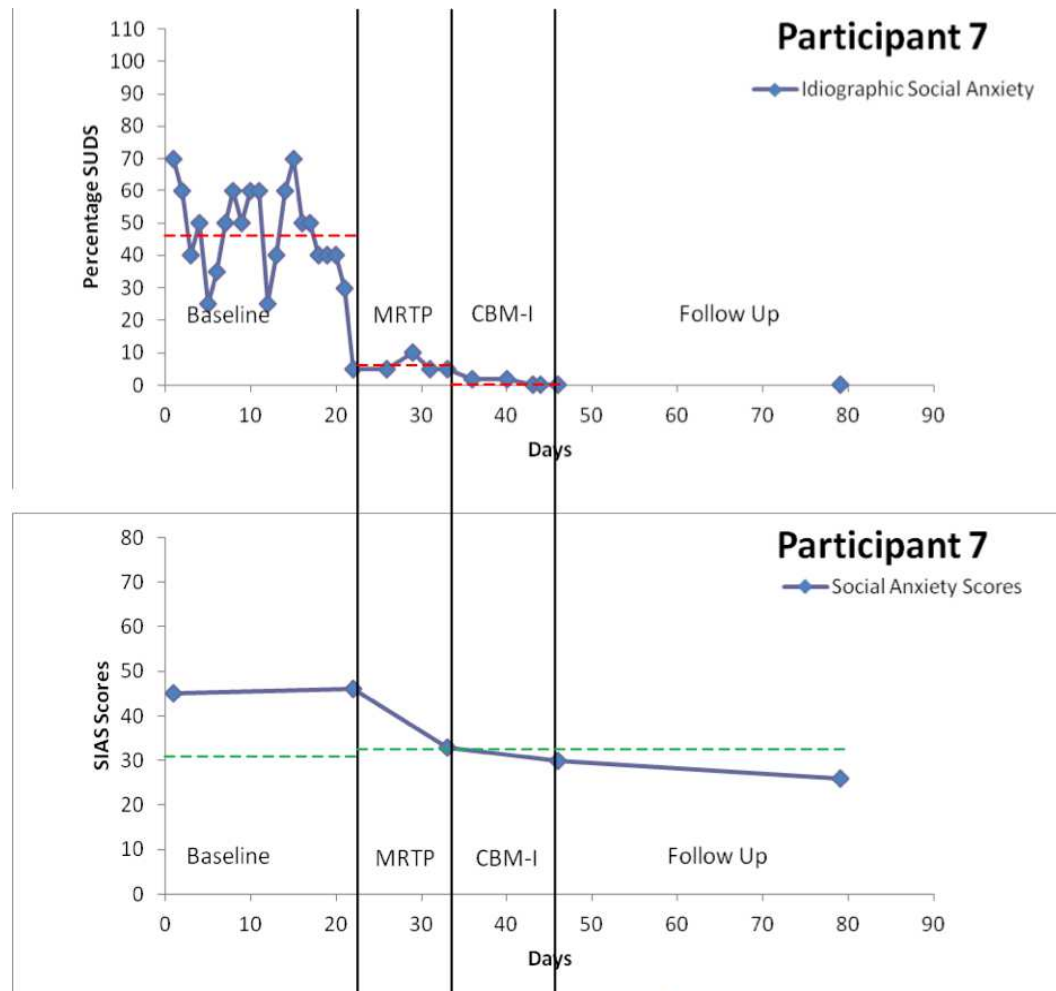
Note: ----- = mean idiographic ratings, ----- = reliable change threshold.

Baseline idiographic social anxiety did not appear stable from visual inspection, but was not shown to be significantly changing over the baseline phase (*tau* = -0.197, *p* = 0.25). Table 3.22 provides the results from visual inspection of figure 3.19, indicating that the MRTP improved social anxiety.

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Table 3.22

Results of visual inspection of social anxiety data in figure 3.19

Social anxiety	Baseline	MRTP	CBM-I	Follow Up
Mean Idiographic Ratings	48	Reduced	Reduced	
Shift in level		Abrupt	NC	NC
Slope	Stable	Stable	Stable	
Latency of change between phases		1	3	NC
SIAS Clinical Reduction	N	Y	Y	Y
SIAS Reliable Reduction	N	Y	Y	Y

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes.

3.9.2 Conviction data.

Figure 3.20 Participant 7 idiographic conviction scores
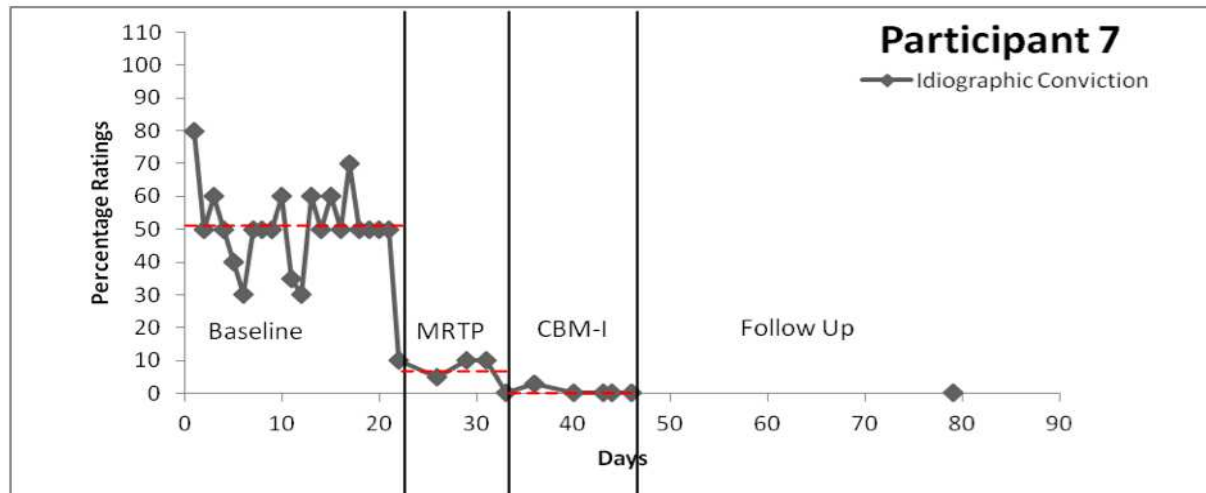
Note: - - - - - = mean idiographic ratings.

Baseline idiographic conviction appeared stable following visual inspection and was also shown not to significantly change over the baseline period (*tau* = -0.01, *p* = 0.97). Table 3.23 provides the results from visual inspection of figure 3.20 and suggests that conviction reduced following the introduction of the MRTP package.

3.9.3 Paranoia Data.

Figure 3.21 participant 7 idiographic and standardised paranoia scores
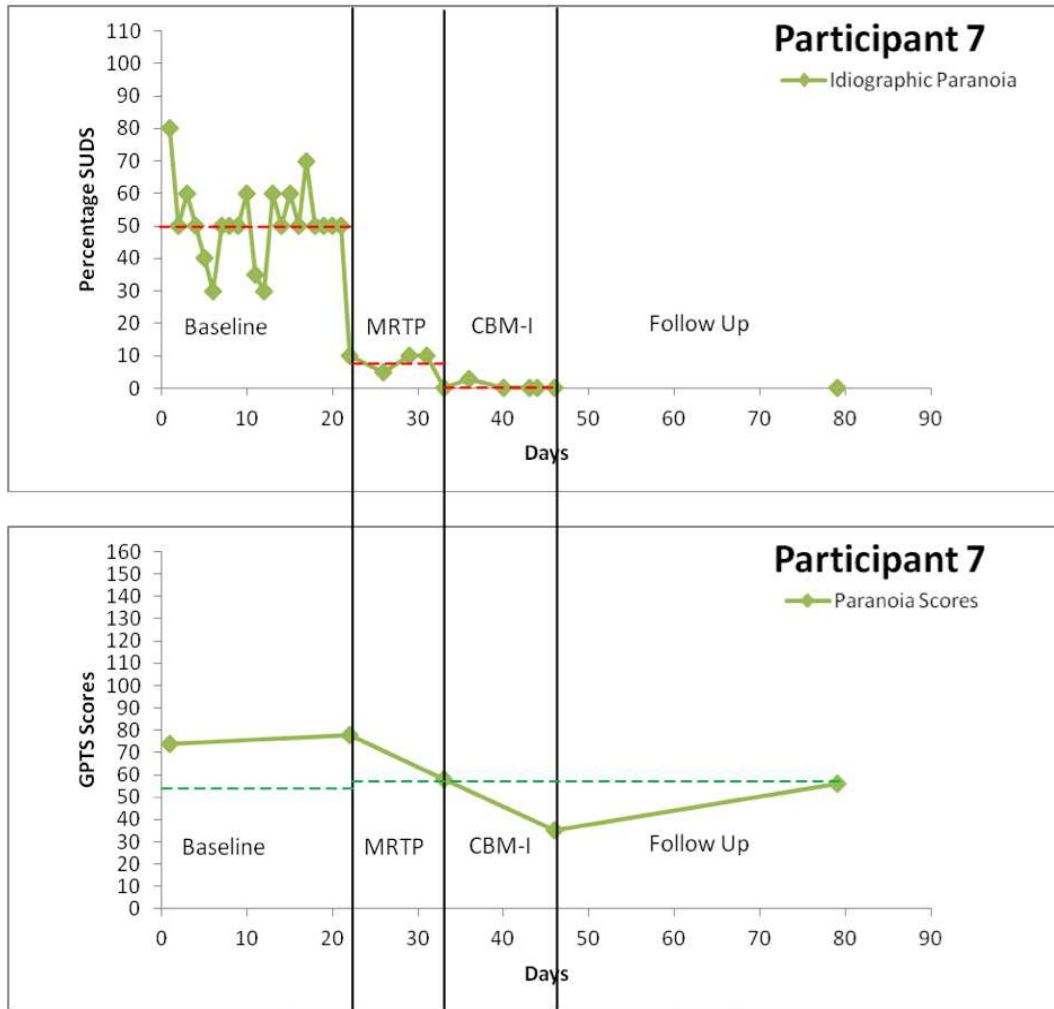
Note: ----- = mean idiographic ratings, ----- = reliable change threshold.

Baseline idiographic paranoia did not appear stable from visual inspection but was not found to significantly change over the baseline phase ($tau = -0.127$, $p = 0.483$). Table 3.23 provides the results from visual inspection of figures 3.20 and 3.21, indicating that the MRTP and CBM-I had cumulative effects on conviction. The results of SMA agreed with this, indicating a significant change in level ($r = -0.856$, $p < 0.001$) but not slope ($r = -0.444$, $p = 0.237$) of conviction between baseline and MRTP phases and significant reduction in level ($r = -0.887$, $p < 0.001$) not slope ($r = -0.460$, $p = 0.259$) of conviction when comparing baseline with CBM-I. Table 3.23 also indicated that CBM-I improved GPTS scores that maintained at follow up.

Table 3.23

Results of visual inspection of paranoia and conviction data in figures 3.20 and 3.21

Paranoia	Baseline	MRTP	CBM-I	Follow Up
Mean Idiographic Ratings	50	Reduced	Reduced	
Shift in level		Abrupt	Abrupt	NC
Slope	Stable	Stable	Stable	
Latency of change between phases		1	3	NC
GPTS Clinical Reduction	*	*	*	*
GPTS Reliable Reduction	N	N	Y	Y
Mean Conviction Ratings	51	Reduced	Reduced	
Shift in level		Abrupt	Abrupt	NC
Slope	Stable	Decelerating	Stable	
Latency of change between phases		1	3	33

Note: NC – No Change, Latency of change between phases is expressed as number of days, * - Scored below clinical cut off at time-points one/two, N – No, Y – Yes

3.9.4 Reasoning data

Table 3.24

Standardised measures for participant 7

Measure	B1	B2	MRTP	CBM-I	Follow Up
85:15 Beads Task	J	J	X	X	X
60:40 Beads Task	J	J	X	X	X
EoE	0	0	1	2	2
PBM	Yes	Yes	Yes	Yes	Yes
RTHC	1	1	0	0	0

Note: X – not Jumping to Conclusions, J – JTC, EoE – Explanations of Experiences, PBM – Possibility of being mistaken, RTHC – Reaction to Hypothetical Contradiction; 1 – reduced delusional conviction, 0 – dismissed delusion.

As indicated in Table 3.24, participant 7 JTC on both of the beads tasks during both time-points one and two, but not following the MRTP phase. Scores on the EoE assessment indicate improved belief flexibility following the MRTP phase and a further improvement following the CBM-I phase, which is maintained at follow up. PBM scores remain unchanged. RTHC assessments indicate improved belief flexibility following the MRTP phase, which is maintained thereafter. These results indicate that the MRTP improved reasoning biases.

3.9.5 Participant 7 summary. There was some fluctuation in idiographic anxiety and paranoia at baseline, and a reduction in idiographic social anxiety and paranoia following the start of the MRTP package which was maintained with the CBM-I package and at follow-up. A reliable and clinically significant reduction in SIAS scores occurred following the MRTP which was maintained with CBM-I and at follow-up. Reduction in GPTS scores occurred following the MRTP but this only became reliable following CBM-I package and was maintained at follow up. Participant 7 was below the clinical cut off for paranoia throughout. Conviction analyses indicated cumulative effects of both the MRTP and CBM-I. The MRTP improved reasoning biases. Idiographic and standardised ratings of social anxiety and paranoia measures seemed to follow a similar trajectory to one another. Qualitatively, Participant 7 reported finding the MRTP very helpful and CBM-I less so (it was described by the participant as "boring"). The MRTP was felt to be so helpful that their delusion was dismissed completely by the end of the study. Participant 7 was the only person for whom the MRTP significantly improved social anxiety. Participant 7's presentation could be thought of as less severe than others, which may partly explain the positive response to both package packages in this case.

3.10 Participant 8

Participant 8 is a 48 year old male, with 8 years duration of difficulties, recruited from Recovery Services.

3.10.1 Social anxiety data.

Figure 3.22 Participant 8 idiographic and standardised social anxiety scores
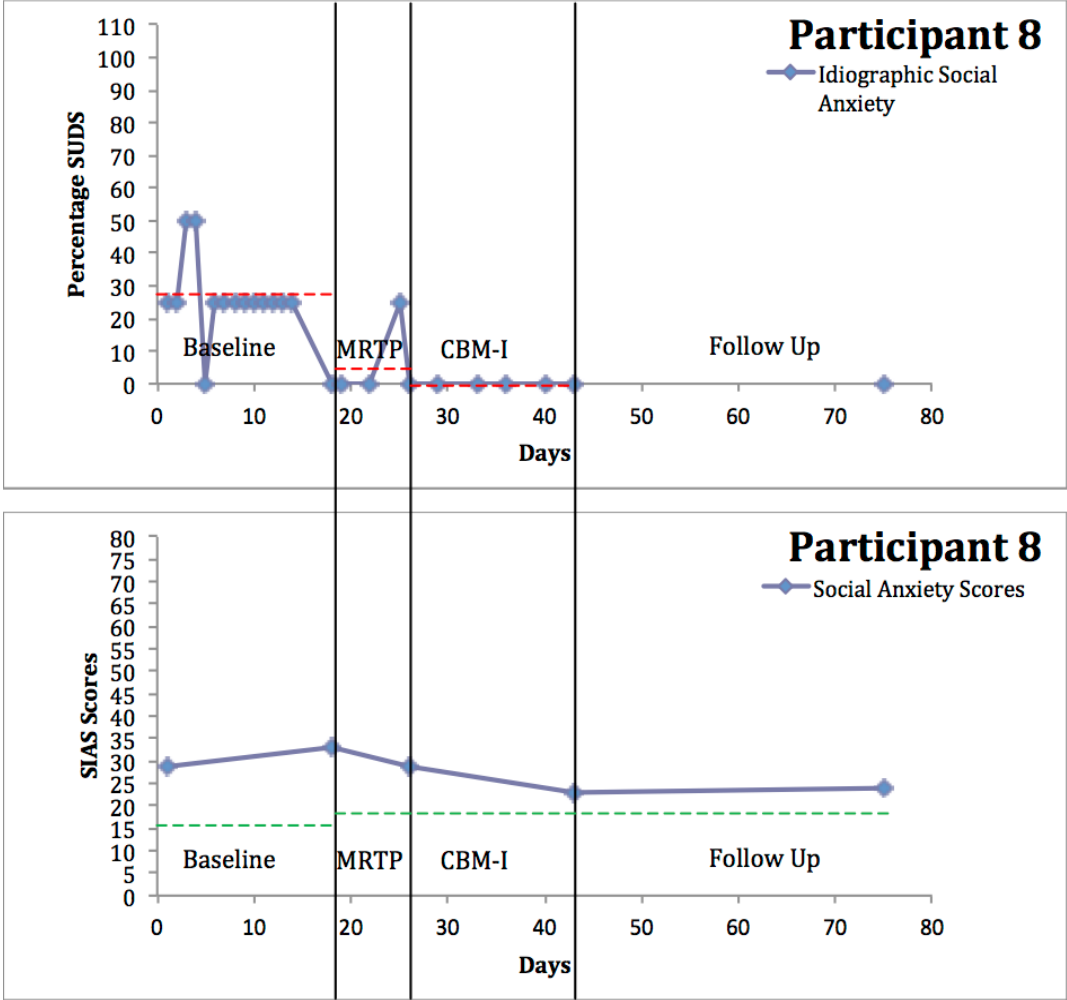
Note: - - - - - = mean idiographic ratings, - - - - - = reliable change threshold.

Baseline idiographic social anxiety was stable ($tau = -0.159$, $p = 0.536$). Table 3.25 provides the results from visual inspection of figure 3.22, indicating some reduction in social anxiety, although this was not significant or reliable. However, participant 8 scored below the clinical cut-off for social anxiety from the start of the study.

Table 3.25

Results of visual inspection of social anxiety data in figure 3.22

Social anxiety	Baseline	MRTP	CBM-I	Follow Up
Mean Idiographic Ratings	27	Reduced	Reduced	
Shift in level		Abrupt	NC	NC
Slope	Stable	Stable	Stable	
Latency of change between phases		4	NC	NC
SIAS Clinical Reduction	*	*	*	*
SIAS Reliable Reduction	N	N	N	N

Note: NC – No Change, Latency of change between phases is expressed as number of days, *
- Already below clinical cut off, N – No

3.10.2 Conviction data.

Figure 3.23 participant 8 idiographic conviction scores
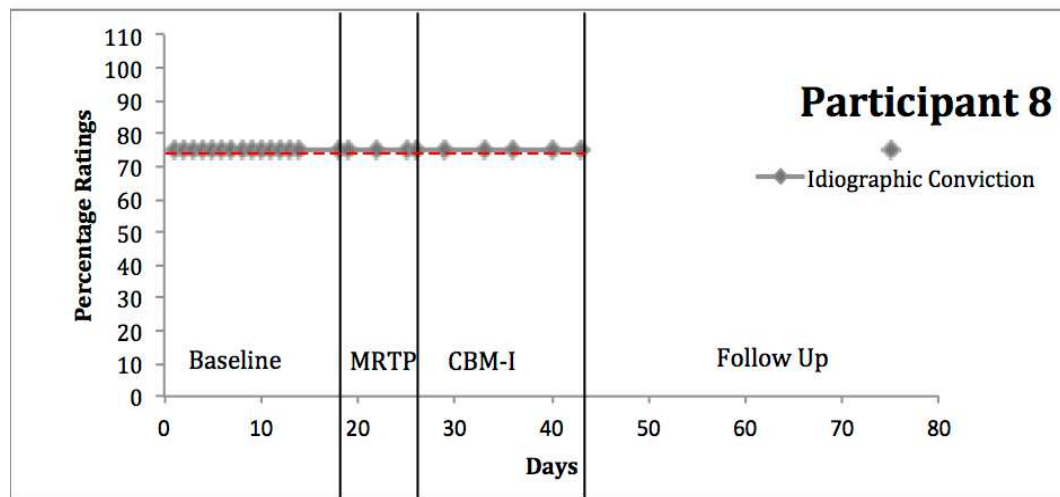
Note: ----- = mean idiographic ratings.

Visual examination of figure 3.23 is displayed in table 3.26. Conviction remained high

throughout the duration of the study.

3.10.3 Paranoia Data.

Figure 3.24 participant 8 idiographic and standardised paranoia scores
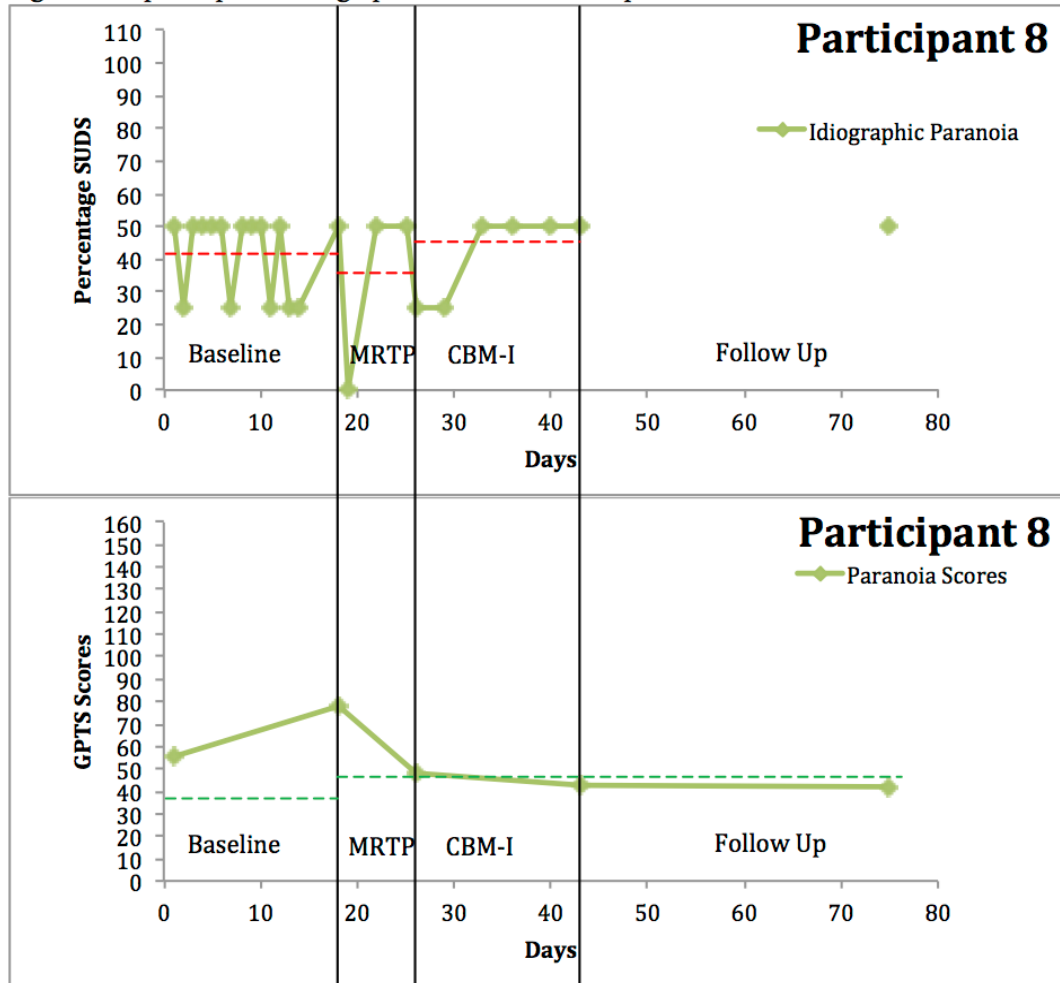
Note: - - - - - = mean idiographic ratings, - - - - - = reliable change threshold.

Baseline idiographic paranoia was stable (*tau* = -0.297, *p* = 0.23). Table 3.26 provides the results from visual inspection of figures 3.23 and 3.24, indicating no effect on conviction and that the MRTP improved GPTS scores, which was maintained throughout the CBM-I package phase and at follow up.

Table 3.26

Results of visual inspection of conviction and paranoia data in figures 3.23 and 3.24

Paranoia	Baseline	MRTP	CBM-I	Follow Up
Mean Idiographic Ratings	41	Reduced	Increased	
Shift in level		Abrupt Increase	Abrupt Decrease	NC
Slope	Stable	Unstable	Accelerating	
Latency of change between phases		4	3	NC
GPTS Clinical Reduction	*	*	*	*
GPTS Reliable Reduction	N	Y	Y	Y
Mean conviction	75	75	75	
Shift in level		NC	NC	NC
Slope	Stable	Stable	Stable	
Latency of change		NC	NC	NC

Note: NC – No Change, Latency of change between phases is expressed as number of days, * - Scored below clinical cut off, N – No, Y – Yes.

3.10.4 Reasoning data

Table 3.27

Standardised measures for participant 8

Measure	B1	B2	MRTP	CBM-I	Follow Up
85:15 Beads Task	J	J	X	X	X
60:40 Beads Task	J	J	X	X	X
EoE	1	1	2	1	1
PBM	No	No	Yes	No	No
RTHC	2	2	2	2	2

Note: X – not Jumping to Conclusions, J – JTC, EoE – Explanations of Experiences, PBM – Possibility of being mistaken, RTHC – Reaction to Hypothetical Contradiction; 2 – accommodated contradiction into delusion.

Table 3.27 shows that participant 8 JTC on both of the beads tasks during both time-points one and two. This improved following the MRTP phase and throughout. Scores on the EoE assessment indicate an improvement in belief flexibility following the MRTP phase, that returned to baseline level following the CBM-I phase and at follow up. PBM scores improved only following the MRTP phase and also revert back to baseline level following CBM-I and at follow up. RTHC assessments indicate lack of belief flexibility throughout. These results indicate that the MRTP improved reasoning biases.

3.10.5 Participant 8 summary. Reduction in idiographic ratings of anxiety occurred following the MRTP which was maintained (and potentially further reduced) following CBM-I. There were no reliable changes in SIAS scores, but participant 8 scored below the clinical cut off at time-point one and two. Idiographic ratings of paranoia fluctuated throughout the study, but these were not as high as other participants. A reliable reduction in GPTS scores occurred after the MRTP and was maintained throughout, but participant 8 scored below the clinical cut off for paranoia at time-point one and two. Conviction remained at 75% throughout. There was some indication of improvement in reasoning biases (JTC, EoE, PBM) following MRTP but only improvement in the JTC task maintained with CBM-I and at follow up. This indicates that the MRTP improved reasoning biases and paranoia. There was marked discrepancy between idiographic and standardised ratings of social anxiety; however, the idiographic and GPTS measures seemed to follow a similar trajectory to one another. Participant 8 reported not finding either package to be particularly helpful. Participant 8's less severe presentation (comparatively) may partly explain the positive effects of both packages.

3.11 Participant 9

Participant 9 is a 55 year old male, with 23 years duration of difficulties, recruited from Recovery Services.

3.11.1 Social anxiety data.

Figure 3.25 Participant 9 idiographic and standardised social anxiety scores

Note: ----- = mean idiographic ratings, ----- = reliable change threshold.
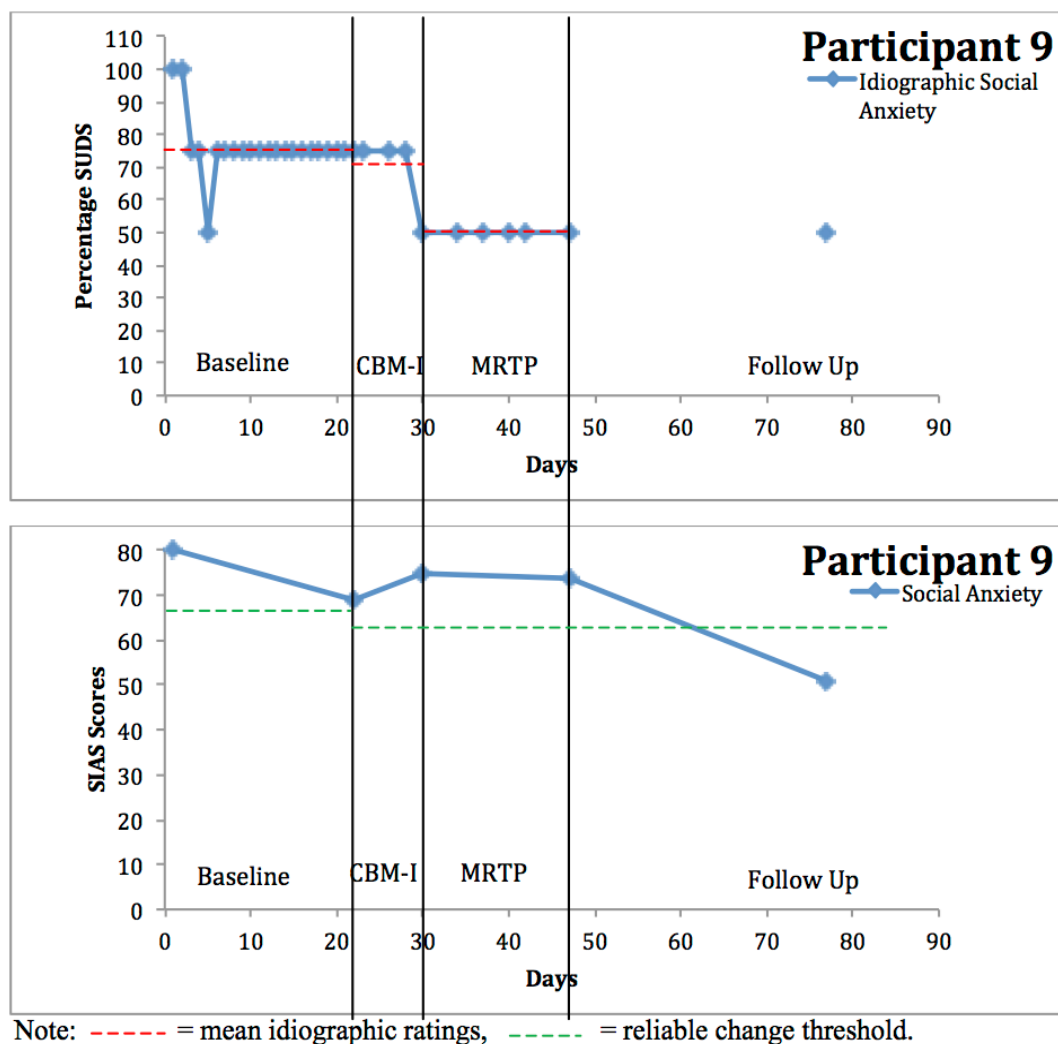
Baseline idiographic social anxiety was stable ($tau = -0.221$, $p = 0.249$). Table 3.28 provides the results from visual inspection of figure 3.25, indicating a reduction in idiographic ratings and a significant reduction in SIAS scores by the end of the study.

Table 3.28

Results of visual inspection of social anxiety data in figure 3.25

Social anxiety	Baseline	CBM-I	MRTP	Follow Up
Mean Idiographic Ratings	76	Reduced	Reduced	
Shift in level		NC	NC	NC
Slope	Stable	Stable	Stable	
Latency of change between phases		9	NC	NC
SIAS Clinical Reduction	N	N	N	N
SIAS Reliable Reduction	N	N	N	Y

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes.

3.11.2 Conviction data.

Figure 3.26 Participant 9 idiographic conviction scores across all conditions
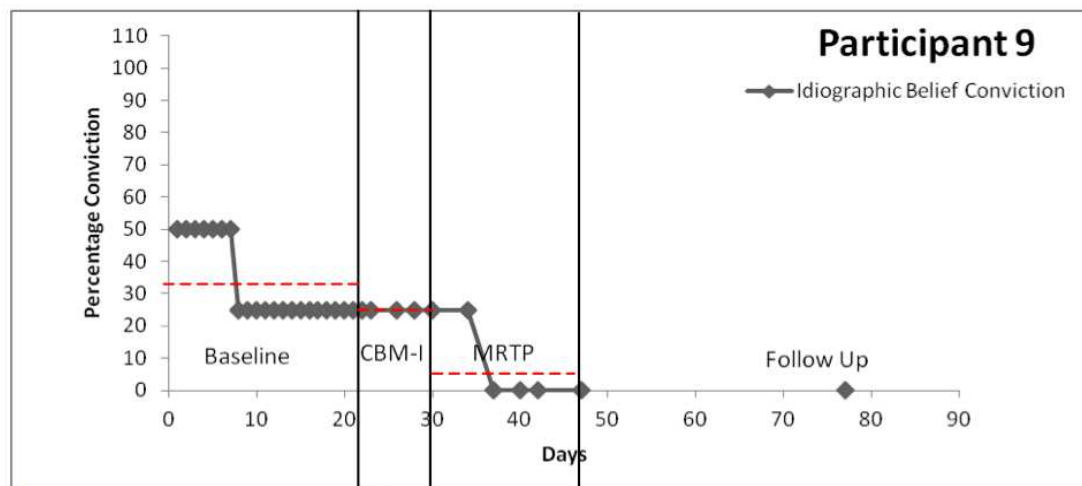
Note: ----- = mean idiographic ratings.

Baseline conviction improved, making interpretation more difficult due to the direction of conviction being the same as that of the package phases, which makes it more difficult to ascertain if any reduction in conviction can be attributed to either package (*tau* = -0.683, *p* < .001). Table 3.29 provides the results from visual inspection of figure 3.26.

3.11.3 Paranoia Data.

Figure 3.27 Participant 9 idiographic and standardised paranoia scores across all conditions
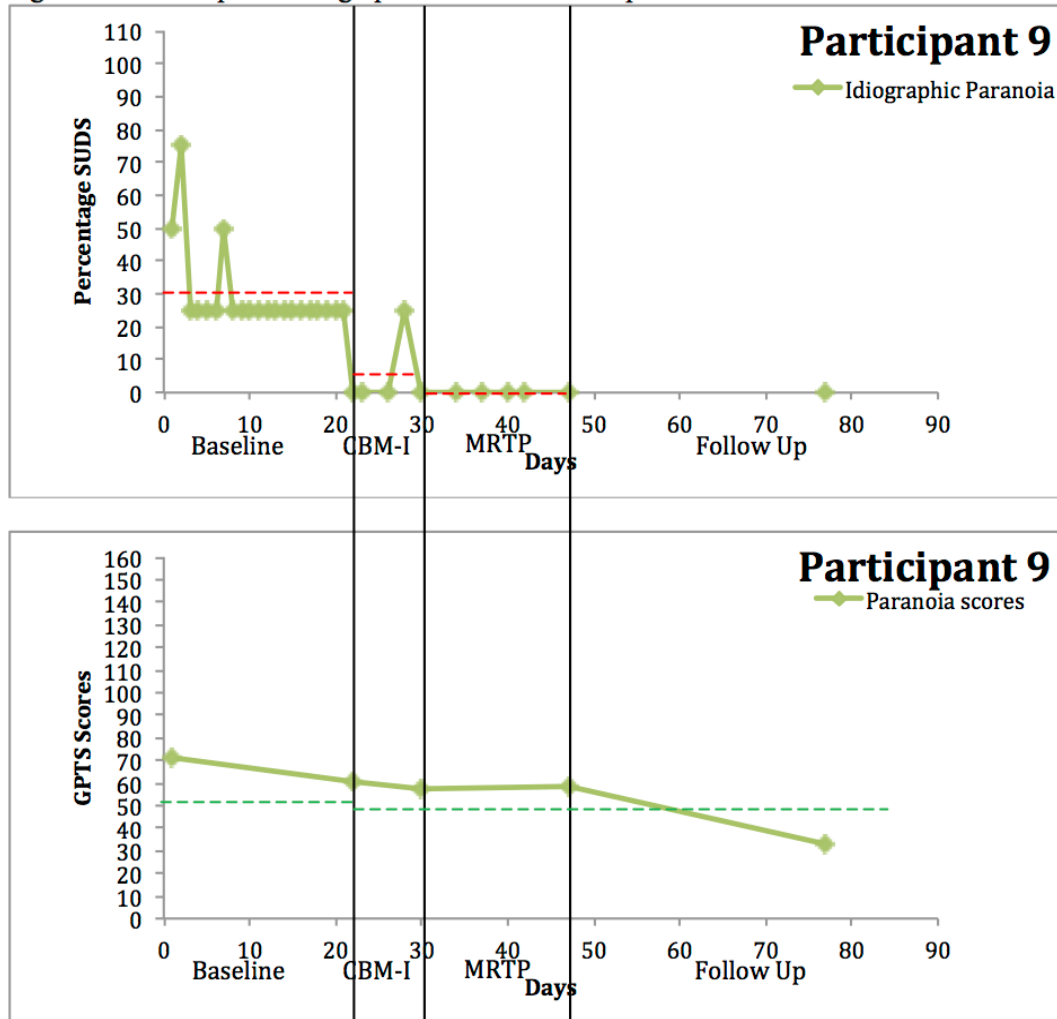
Note: ----- = mean idiographic ratings, ----- = reliable change threshold.

Baseline idiographic paranoia was improving (*tau* = 0.424, *p* < 0.05). Table 3.29 provides the results from visual inspection of figures 3.26 and 3.27, indicating that the MRTP significantly reduced conviction but already within the context of some improvement. The SMA results were in agreement with this observation, indicating no significant change in level (*r* = -0.296, p = 0.5768) but a significant reduction in slope (*r* = -0.820, p < 0.05) between baseline and CBM-I phases. A significant change in level (*r* = -0.778, *p* < 0.05) and slope (*r* = -0.830, *p* < 0.05) of conviction was found between baseline and MRTP phases. The results in table 3.29 also indicate no clear effect of either package on paranoia, although there was a reliable reduction at follow up.

Table 3.29

Results of visual inspection of paranoia and conviction data in figures 3.26 and 3.27

Paranoia	Baseline	CBM	MRTP	Follow Up
Mean Idiographic Ratings	30	Reduced	Reduced	
Shift in level		Abrupt	NC	NC
Slope	Decelerating	Stable	Stable	
Latency of change between phases		1	NC	NC
GPTS Clinical Reduction	*	*	*	*
GPTS Reliable Reduction	N	N	N	Y
Mean Conviction Ratings	33	Reduced	Reduced	
Shift in level		NC	NC	NC
Slope	Decelerating	Stable	Decelerating	
Latency of change between phases		NC	7	NC

Note: NC – No Change, Latency of change between phases is expressed as number of days, * - scores below clinical cut off, N – No, Y – Yes.

3.11.4 Reasoning data

Table 3.30

Standardised measures for participant 9

Measure	B1	B2	CBM-I	MRTP	Follow Up
85:15 Beads Task	J	X	X	X	X
60:40 Beads Task	X	X	X	X	X
EoE	0	0	0	1	2
PBM	Y	Y	Y	Y	Y
RTHC	1	1	1	0	0

Note: X – not Jumping to Conclusions, J – JTC, EoE – Explanations of Experiences, Y – Yes, N – No, PBM – Possibility of being mistaken, RTHC – Reaction to Hypothetical Contradiction; 1 – reduced delusional conviction, 0 – dismissed delusion.

Table 3.30 shows that participant 9 JTC once at time-point one, and did not JTC on either beads task during all remaining phases. Scores on the EoE assessment indicate lack of belief flexibility, which improved following MRTP and follow up phases. PBM scores were stable across phases. RTHC assessments indicate belief flexibility that improved following the MRTP and follow up phases, such that participant 9 dismissed the delusion. These results indicate that the MRTP improved reasoning biases.

3.11.5 Participant 9 summary. A reduction in idiographic ratings of social anxiety occurred following CBM-I, with a further reduction following the MRTP. There was no reliable reduction in SIAS scores following either package but a reliable change had occurred at follow up. Some reduction in idiographic ratings of paranoia followed CBM-I and were maintained throughout, however, there was some improvement during baseline. GPTS scores were also below the clinical range throughout the study. No reliable change in GPTS scores occurred following either package but there was a gradual decreasing slope in GPTS scores over the duration of study that ended up with reliable reduction at follow up. Conviction also improved during baseline and was maintained during CBM-I, with an additional reduction following the MRTP. There was some improvement in reasoning biases only following MRTP (EoE, RTHC) but participant 9 already showed flexibility at time-point one and two (PBM) and JTC improved between both time-points. Idiographic and standardised measures of social anxiety largely agree with one another and follow a similar trajectory. Idiographic and GPTS scores also follow a similar trajectory, but the severity of both scores is not matched, i.e., idiographic measures don't reflect the same severity as the GPTS. Participant 9 reported finding both packages very helpful and gave several examples of how they had put into practice the training tips from the MRTP. Participant 9's comparatively less severe presentation may partly explain the positive response to both package packages. However, it is difficult to ascertain specific effects of either package due to the gradually improving profile of scores over the duration of the study.

3.12 Participant 10

Participant 10 is a 61 year old male, with 1.5 years duration of difficulties, recruited from Recovery Services.

3.12.1 Social anxiety data.

Figure 3.28 Participant 10 idiographic and standardised social anxiety scores
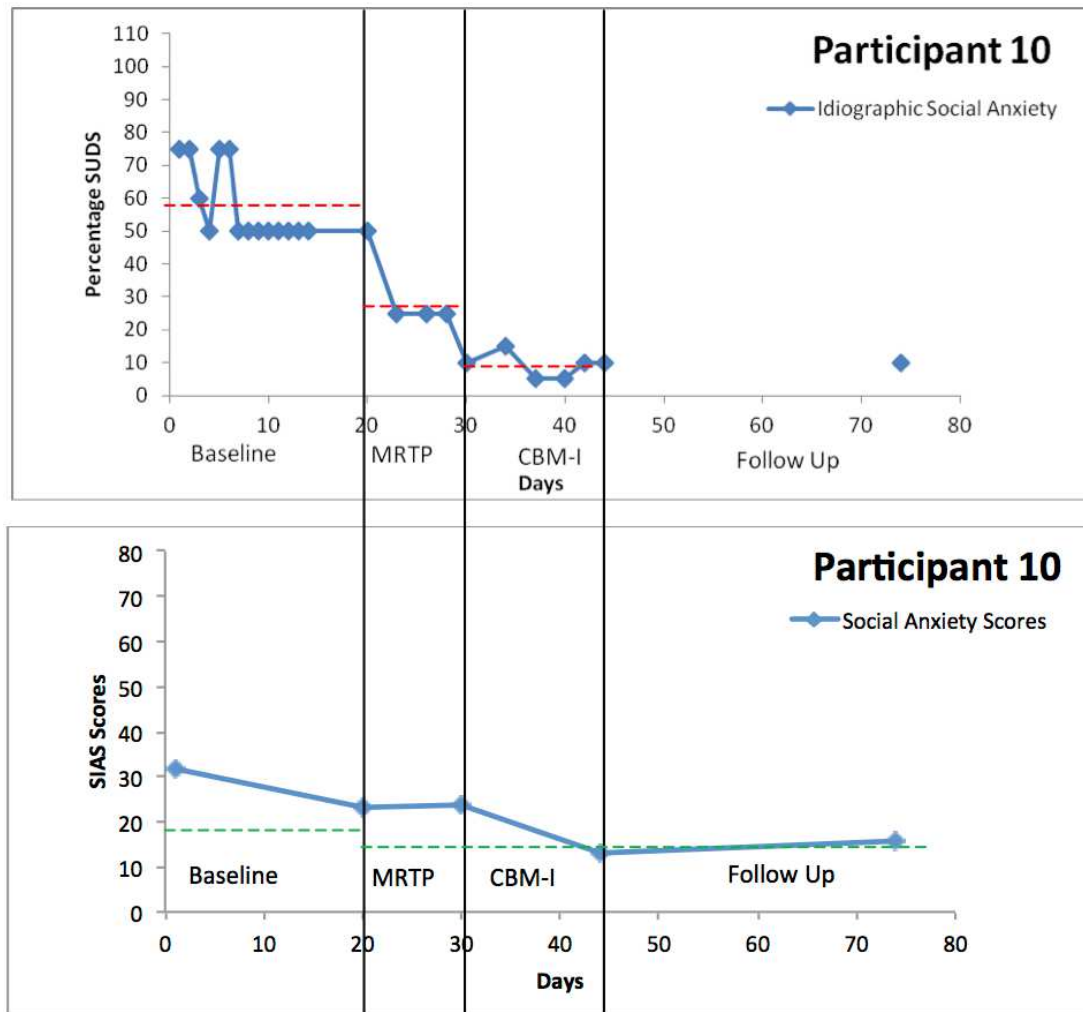
Note: ----- = mean idiographic ratings, ----- = reliable change threshold.

Baseline idiographic social anxiety was improving (tau = -0.614, $p < 0.01$). Table 3.31 provides the results from visual inspection of figure 3.28, indicating that CBM-I improved social anxiety but this became non-reliable at follow-up, although the reduction was maintained to some degree.

Table 3.31

Results of visual inspection of social anxiety data in figure 3.28

Social anxiety	Baseline	MRTP	CBM-I	Follow Up
Mean Idiographic Ratings	58	Reduced	Reduced	
Shift in level		NC	NC	NC
Slope	Decelerating	Decelerating	Stable	
Latency of change between phases		7	3	NC
SIAS Clinical Reduction	*	*	*	*
SIAS Reliable Reduction	N	N	Y	N

Note: NC – No Change, Latency of change between phases is expressed as number of days, *
- Scores within non-clinical range, N – No, Y – Yes.

3.12.2 Conviction data.

Figure 3.29 participant 10 idiographic conviction scores
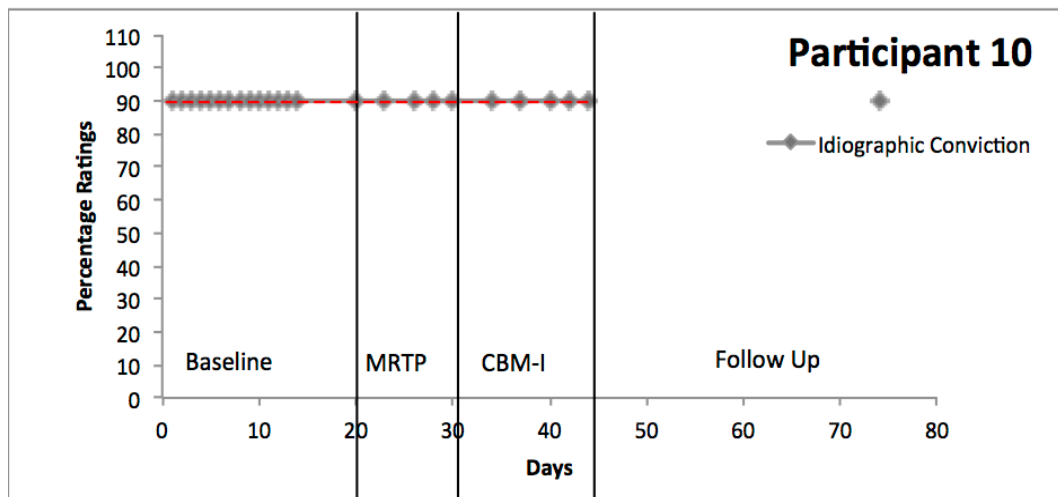
Note: ----- = mean idiographic ratings

Visual examination of figure 3.29 is in table 3.32. Conviction remained high over the

duration of the study.

3.12.3 Paranoia Data.

Figure 3.30 participant 10 idiographic and standardised paranoia scores
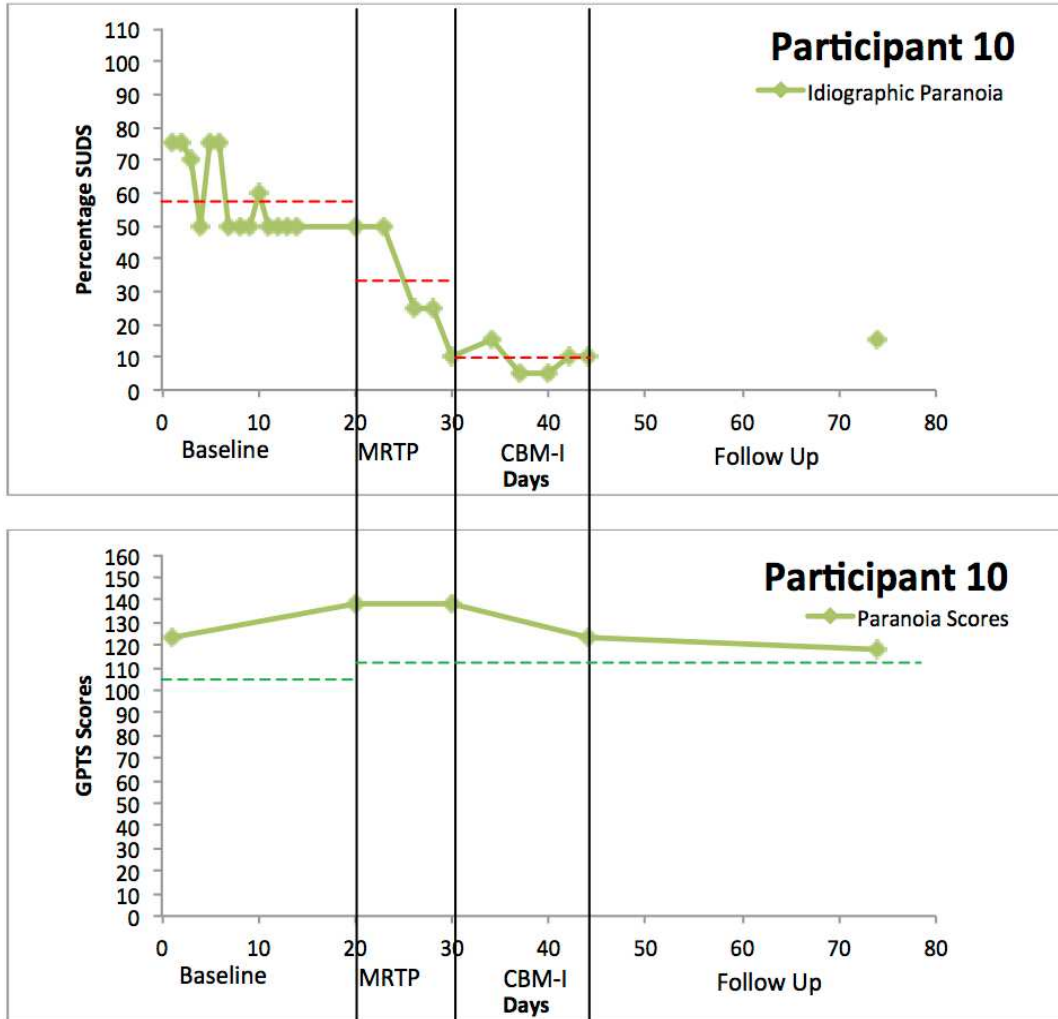
Note: ----- = mean idiographic ratings, ----- = reliable change threshold.

Baseline idiographic paranoia improved (*tau* = -.569, *p* < 0.05). Table 3.32 provides the results from visual inspection of figures 3.29 and 3.30, indicating no effect of either package on conviction or paranoia.

Table 3.32

Results of visual inspection of conviction and paranoia data in figures 3.29 and 3.30

Paranoia	Baseline	MRTP	CBM-I	Follow Up
Mean Idiographic Ratings	59	Reduced	Reduced	
Shift in level		NC	NC	NC
Slope	Decelerating	Decelerating	Stable	
Latency of change between phases		12	4	30
GPTS Clinical Reduction	N	N	N	N
GPTS Reliable Reduction	N	N	N	N
Mean conviction	90	90	90	
Shift in level		NC	NC	NC
Slope	Stable	Stable	Stable	
Latency of change		NC	NC	NC

Note: NC – No Change, N – No, Y – Yes.

3.12.4 Reasoning data

Table 3.33

Standardised measures for participant 10

Measure	B1	B2	MRTP	CBM-I	Follow Up
85:15 Beads Task	X	X	X	X	X
60:40 Beads Task	X	X	X	X	X
EoE	0	0	2	1	2
PBM	No	No	Yes	Yes	Yes
RTHC	2	2	1	1	1

Note: X – not Jumping to Conclusions, J – JTC, EoE – Explanations of Experiences, PBM – Possibility of being mistaken, RTHC – Reaction to Hypothetical Contradiction; 2 – accommodated contradiction into delusion, 1 – reduced delusional conviction.

Table 3.33 shows that participant 10 did not JTC on either of the beads tasks during all assessments. Scores on the EoE indicate improved belief flexibility following the MRTP phase, which was maintained at follow up. PBM scores improved following the MRTP phase and were maintained at CBM-I and follow up. RTHC assessments indicate belief flexibility that improved following the MRTP phase and was maintained. These results indicate that the MRTP improved reasoning biases.

3.12.5 Participant 10 summary. Idiographic ratings of social anxiety and paranoia improved during baseline and were further improved following the MRTP, which was maintained throughout. Reliable reduction in SIAS scores only occurred following CBM-I, but was not maintained at follow up. SIAS scores remained below the clinical cut-off throughout. There were no changes in GPTS scores or conviction rates throughout the study (conviction remained at 90%). Improvements in reasoning biases occurred following the MRTP (EoE, PBM, RTHC), and were maintained during CBM –I and at follow up. Although idiographic and standardised measures of social anxiety follow a similar trajectory, they do not match on severity, as the idiographic data indicate more severe levels of social anxiety than the SIAS scores. Idiographic and standardised paranoia scores are very disparate and do not follow the same trajectory; the GPTS scores reflect more severe paranoia than the idiographic ratings would suggest. Participant 10 was not experiencing clinical levels of social anxiety when entering the study, which may partly explain the positive response to CBM-I. Similarly, participant 10's more severe clinical GPTS scores did not respond significantly, even though idiographic measures of paranoia did. Participant 10 reported finding the packages somewhat helpful and worked hard to practice some of the training tips, but found this difficult to translate into clinical gains, particularly in terms of paranoia.

3.13 Participant 11

Participant 11 is a 46 year old female, with 15 years duration of difficulties, recruited from Recovery Services.

3.13.1 Social anxiety data.

Figure 3.31 Participant 11 idiographic and standardised social anxiety scores
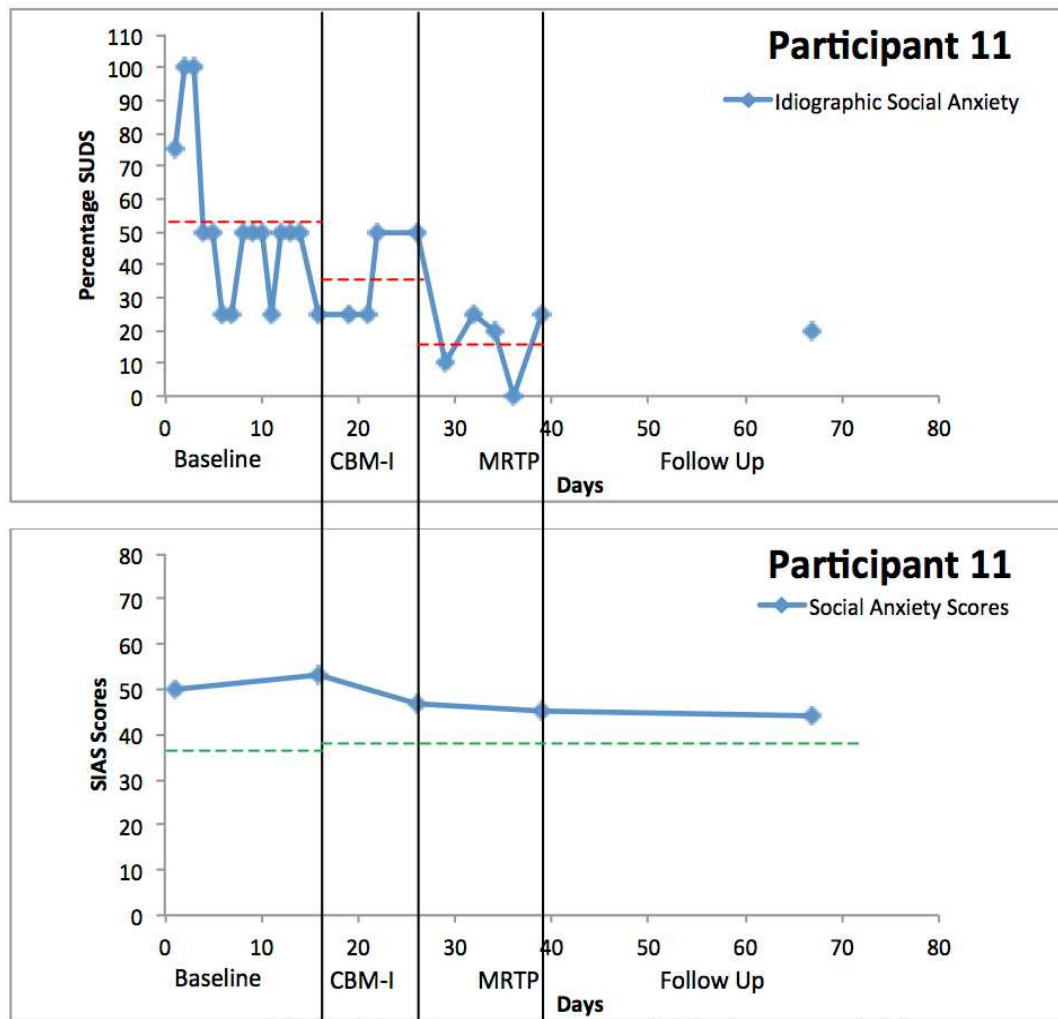
Note: - - - - - = mean idiographic ratings,   - - - - - = reliable change threshold.

Baseline idiographic social anxiety ratings appeared to improve, but this was not found to be significant (*tau* = -0.341, *p* = 0.14). Table 3.34 provides the results from visual inspection of figure 3.31, indicating no effect on social anxiety.

Table 3.34

Results of visual inspection of social anxiety data in figure 3.31

Social anxiety	Baseline	CBM-I	MRTP	Follow Up
Mean Idiographic Ratings	54	Increased	Reduced	
Shift in level		Abrupt	Abrupt	NC
Slope	Stable	Stable	Decelerating	
Latency of change between phases		2	3	28
SIAS Clinical Reduction	N	N	N	N
SIAS Reliable Reduction	N	N	N	N

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes.

3.13.2 Conviction data.

Figure 3.32 Participant 11 idiographic conviction scores
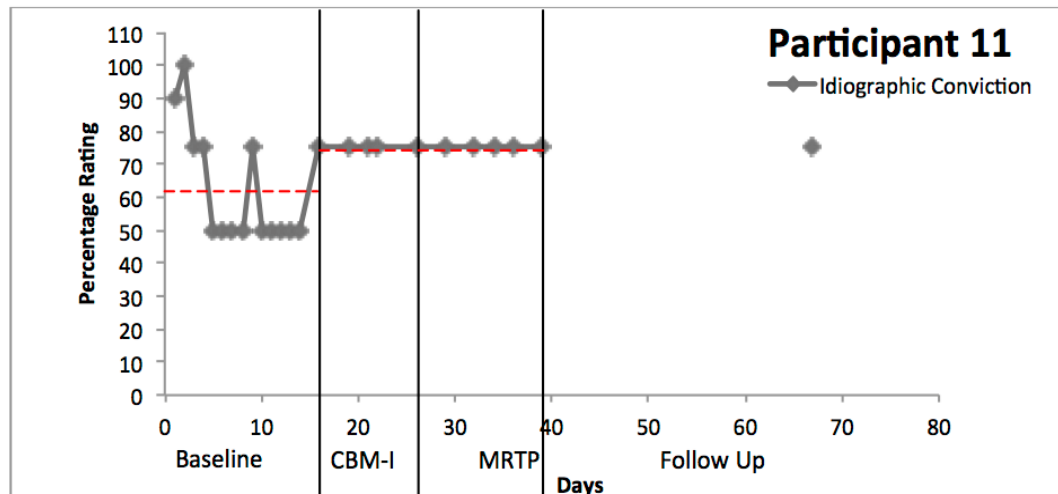
Note: ----- = mean idiographic ratings.

Baseline idiographic conviction scores significantly improved over the baseline phase (*tau* = -0.611, *p* <.01). Table 3.35 provides the results from visual inspection of figure 3.32 and suggest no effect of either package on conviction.

3.13.3 Paranoia Data.

Figure 3.33 Participant 11 idiographic and standardised paranoia scores

Note: - - - - - = mean idiographic ratings, - - - - - = reliable change threshold.

Baseline idiographic paranoia was found to significantly improve over the baseline phase (tau = -0.641, p <.01). Table 3.35 provides the results from visual inspection of figures 3.32 and 3.33, indicating no effect on conviction, which was supported by SMA, indicating identical statistics when comparing baseline with the MRTP and CBM-I phases; no significant change in level (r = 0.371, p = 0.401) or slope (r = -0.396, p = 0.368) of conviction. Table 3.35 also indicated a reliable reduction of CBM-I on paranoia that clinically reduced following the MRTP, but which was not maintained at follow up.

Table 3.35

Results of visual inspection of paranoia and conviction data in figures 3.32 and 3.33

Paranoia	Baseline	CBM-I	MRTP	Follow Up
Mean Idiographic Ratings	55	Reduced	Reduced	
Shift in level		NC	Abrupt	NC
Slope	Decelerating	Stable	Decelerating	
Latency of change between phases		NC	3	NC
GPTS Clinical Reduction	N	N	Y	N - increased
GPTS Reliable Reduction	N	Y	Y	N
Mean Conviction Ratings	62	Increased	NC	
Shift in level		Abrupt Increase	NC	NC
Slope	Decelerating	Stable	Stable	
Latency of change between phases		2	NC	NC

Note: NC – No Change, N – No, Y – Yes.

3.13.4 Reasoning data

Table 3.36

Standardised measures for participant 11

Measure	B1	B2	CBM-I	MRTP	Follow Up
85:15 Beads Task	X	X	X	X	X
60:40 Beads Task	X	X	X	X	X
EoE	0	0	0	0	0
PBM	No	No	No	No	No
RTHC	3	1	2	2	2

Note: X – not Jumping to Conclusions, EoE – Explanations of Experiences, PBM – Possibility of being mistaken, RTHC – Reaction to Hypothetical Contradiction; 3 – rejected/dismissed contradiction, 2 – accommodated contradiction into delusion, 1 – reduced conviction

Table 3.36 shows that participant 11 did not JTC on either of the beads tasks during all phases. Scores on the EoE and PBM assessments indicate lack of belief flexibility across all conditions. RTHC assessments indicate improved belief flexibility at second time-point, which reverts to lack of belief flexibility across all other phases. These results indicate no effect on reasoning biases.

3.13.5 Participant 11 summary. There was some fluctuation in baseline idiographic anxiety and paranoia that appeared to be improving spontaneously. There was some improvement following CBM-I and additional reduction following MRTP, maintained at follow up. No reliable or clinically significant change in SIAS scores occurred following either package participant 11 remained stably high throughout. Reliable reduction in GPTS scores occurred following CBM-I with clinically significant change occurring following MRTP. However, scores had increased back to time-point one and two levels at follow up. There was a slight increase in conviction during package phase – this was due to the realisation at follow up assessment that participant 11 was rating how much they believed the delusion was happening presently, rather than rating how much did they believe it at all. When queried, participant 11 decided to go back over the idiographic ratings and re-rate; because it was felt the previous conviction ratings were lower and not accurate. During the course of the study, participant 11 believed that the secret service had withdrawn their surveillance equipment and had stopped the persecution for the time being. No effect of either package on reasoning biases was noted. There was also marked discrepancy between idiographic and standardised ratings of social anxiety and paranoia. Participant 11 reported finding limited benefit from both packages. Participant 11's comparatively more severe presentation may partly explain the lack of maintained response to both package packages. Participant 11 had their Flupentixol Decanoate depot reduced from 120mg to 100mg fortnightly during week two of the package phase. This may indicate that their symptoms

were improving, as participant 11 had spent over two months in a psychiatric ward and had been consented on to the study five weeks post discharge.

3.14 Participant 12

Participant 12 is a 22 year old female, with one year duration of difficulties, recruited from Early Package Services.

3.14.1 Social anxiety data.

Figure 3.34 Participant 12 idiographic and standardised social anxiety scores
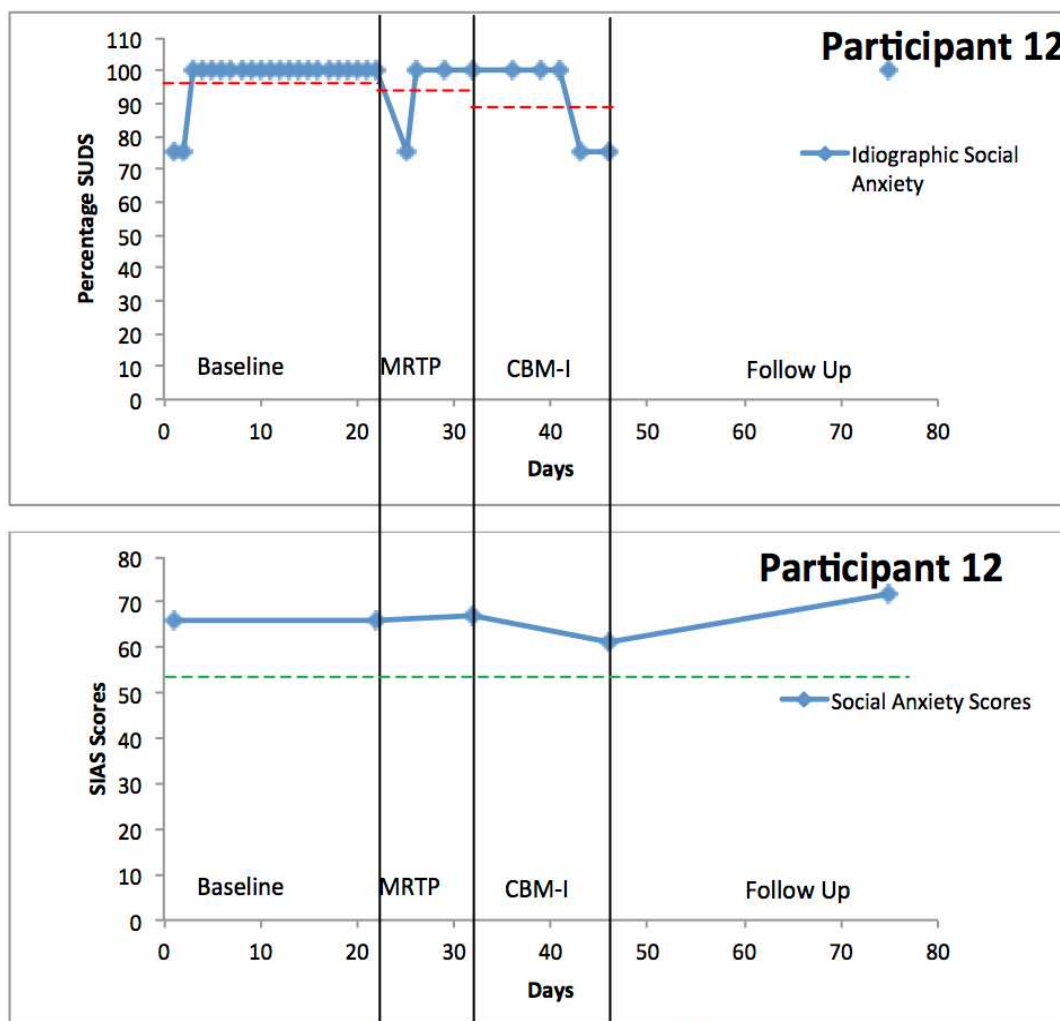
Note: ----- = mean idiographic ratings,   ----- = reliable change threshold.

Baseline idiographic social anxiety looked stable following visual inspection but was shown to significantly worsen over the baseline phase ($tau = 0.425$, $p < .05$). Table 3.37 provides the results from visual inspection of figure 3.34, indicating no effect of either package on social anxiety.

Table 3.37

Results of visual inspection of social anxiety data in figure 3.34

Social anxiety	Baseline	MRTP	CBM-I	Follow Up
Mean Idiographic Ratings	98	Reduced	Reduced	
Shift in level		NC	NC	Abrupt Increase
Slope	Accelerating	Stable	Stable	
Latency of change between phases		4	11	29
SIAS Clinical Reduction	N	N	N	N
SIAS Reliable Reduction	N	N	N	N

Note: NC – No Change, Latency of change between phases is expressed as number of days, N – No, Y – Yes.

3.14.2 Conviction data.

Figure 3.35 participant 12 idiographic conviction scores

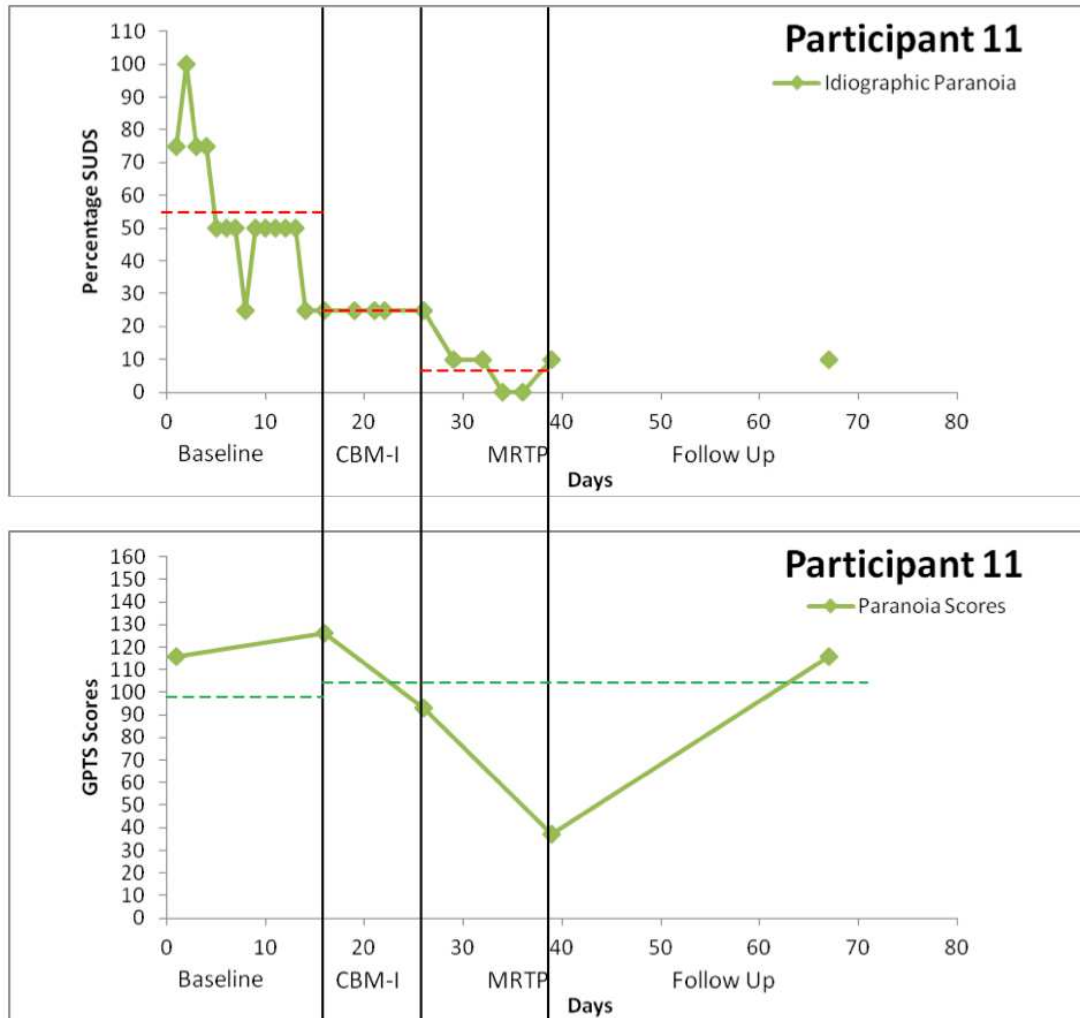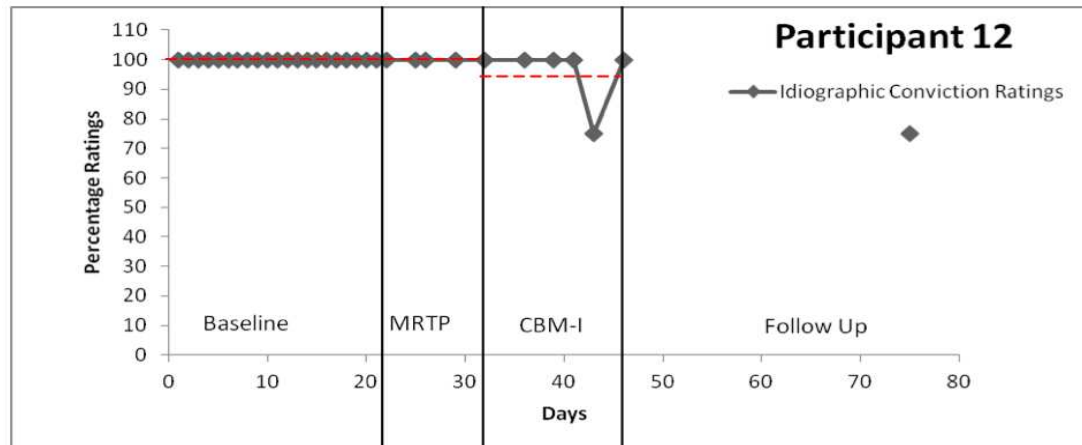

Note: - - - - - = mean idiographic ratings

Baseline conviction was stable (*tau* = 1, *p* = 1). Table 3.38 provides the results from visual inspection of figure 3.35, suggesting a small reduction in conviction following the CBM-I package phase.

3.12.3 Paranoia Data.

Figure 3.36 participant 12 idiographic and standardised paranoia scores
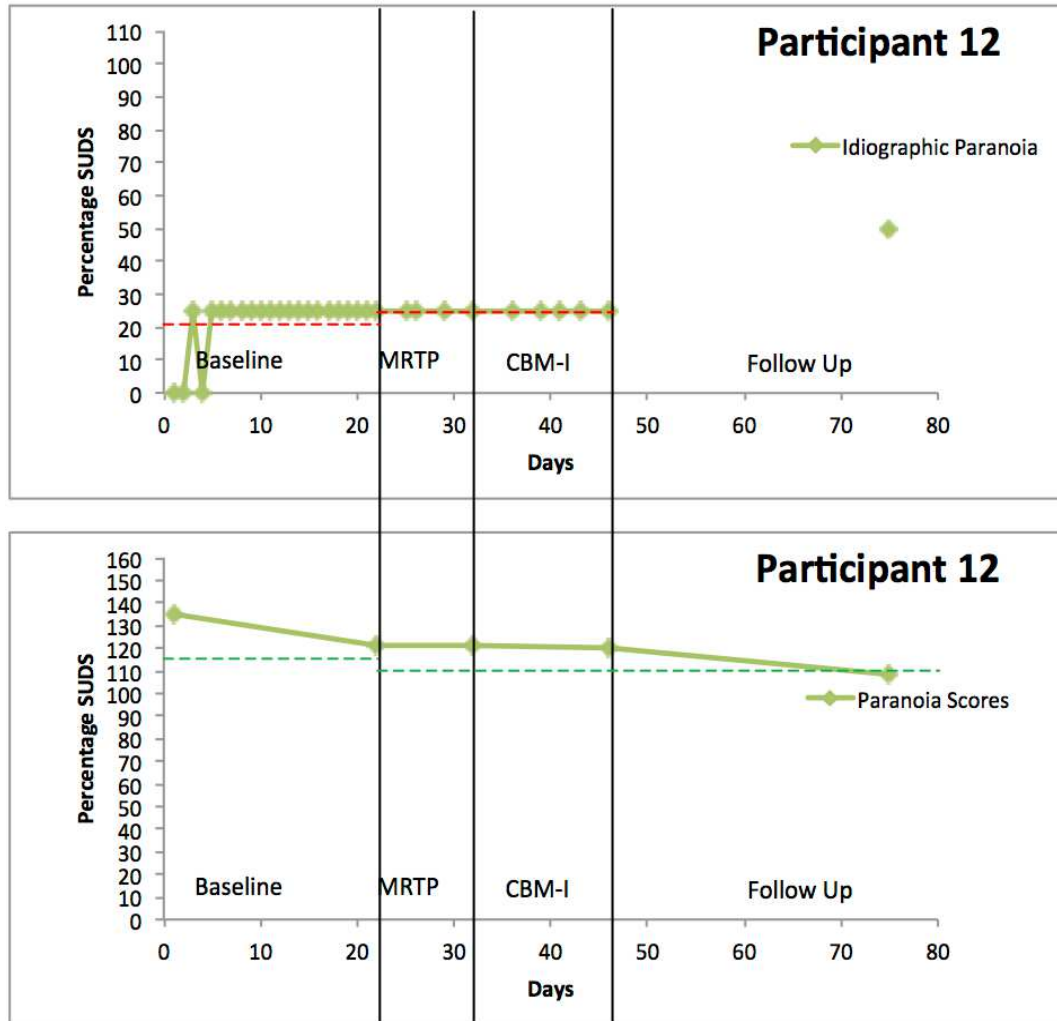
Note: ----- = mean idiographic ratings, ----- = reliable change threshold.

Baseline idiographic paranoia appeared stable following visual inspection but was shown to significantly worsen over the baseline phase (*tau* = 0.488, *p* < .01). Table 3.38 provides the results from visual inspection of figures 3.29 and 3.30, indicating no significant effect on conviction. However, SMA results differed from this analysis slightly. SMA analysis could not be performed as all values within baseline and MRTP phases were identical. However, significant change in level (*r* = -0.410, p = 0.0344) not slope (*r* = -0.173, p = 0.3972) of conviction was found between baseline and CBM-I phases, which does indicate an effect of CBM-I on conviction. Table 3.38 also indicated that a reliable reduction in GPTS scores was only present at follow up.

Table 3.38

Results of visual inspection of paranoia and conviction data in figures 3.35 and 3.36

Paranoia	Baseline	MRTP	CBM-I	Follow Up
Mean Idiographic Ratings	21	Increase	NC	
Shift in level		NC	NC	Abrupt Increase
Slope	Accelerating	Stable	Stable	
Latency of change between phases		NC	NC	29
GPTS Clinical Reduction	N	N	N	N
GPTS Reliable Reduction	N	N	N	Y
Mean Conviction Ratings	100	NC	Decreased	
Shift in level		NC	NC	Abrupt
Slope	Stable	Stable	Stable	Stable
Latency of change between phases		NC	11	29

Note: NC – No Change, N – No, Y – Yes.

3.14.4 Reasoning data

Table 3.39

Standardised measures for participant 12

Measure	B1	B2	MRTP	CBM-I	Follow Up
85:15 Beads Task	J	J	J	J	J
60:40 Beads Task	J	J	J	J	J
EoE	0	0	2	1	1
PBM	N	N	Y	N	N
RTHC	3	2	1	1	1

Note: J – JTC, EoE – Explanations of Experiences, PBM – Possibility of being mistaken, RTHC – Reaction to Hypothetical Contradiction; 3 – rejected/dismissed contradiction, 2 – accommodated contradiction into delusion, 1 – reduced delusional conviction.

Table 3.39 shows that participant 12 did JTC on both tasks at all assessments. Scores on the EoE indicate improved belief flexibility following the MRTP phase, which declined but remained improved at follow up. PBM scores improved following the MRTP phase but were not maintained at CBM-I and follow up. RTHC assessments indicate belief flexibility that improved following the MRTP phase and was maintained. These results indicate that the MRTP improved reasoning biases.

3.14.5 Participant 12 summary. Idiographic anxiety and paranoia remained stable visually, but were shown to worsen over time according to *tau* calculations with very slight reductions in both package phases. No reliable or clinically significant change in SIAS scores occurred following either package (social anxiety remained stably high). No reliable or clinically significant change occurred in GPTS scores following either package (paranoia remained stably high), with a reliable decrease at follow up. Conviction ratings remained stably high with a suggestion of a very slight decrease following CBM-I. Reasoning biases improved following the MRTP package (EoE, PBM, RTHC) but only EoE remained following CBM-I. JTC occurred throughout. Although idiographic and standardised measures of social anxiety seemed to follow the same trajectory, there was marked discrepancy between idiographic and standardised measures of paranoia. Participant 12 reported limited benefit from both packages, and struggled to leave the house, even to go to the shops. Participant 12's comparatively more severe presentation may partly explain the lack of response to either package packages. Participant 12 changed from Risperidone 10mg daily to Olanzapine 20mg daily during the baseline period, because those involved in their care felt that the symptoms were worsening.

Following inspection of data for individual participants, the next section will collate data from all participants and relate this to the hypotheses posed in section 2.5.

3.15 Hypothesis one: In comparison to baseline, five sessions of CBM-I will reduce levels of social anxiety, but will not improve reasoning

Table 3.40 below collates the data on differential effects of CBM-I on social anxiety. Overall, it shows that social anxiety significantly improved following CBM-I in three out of twelve participants. CBM-I did not improve reasoning biases in any participants.

Table 3.40

Collated data on differential effects of CBM-I on social anxiety per participant

Participant	Baseline and 1st package	Reliable Reduction in Social Anxiety	Clinical Reduction in Social Anxiety	Improved Reasoning Biases	Hypothesis One Supported	Maintained at follow up
1	3 weeks CBM-I	N	N	N	N	N/A
2	2 weeks MRTP	N	N^	N	N	N/A
3	2 weeks CBM-I	N	N	N	N	N/A
4	3 weeks MRTP	Y	Y	N	Y	Y
5	3 weeks CBM-I	Y	N	N	Y	Y
6	2 weeks CBM-I	N	N	N	N	N/A
7	3 weeks MRTP	*	*	N	N	Y
8	2 weeks MRTP	N	N^	N	N	N/A
9	3 weeks CBM-I	N	N	N	N	N/A
10	2 weeks MRTP	Y	N^	N	Y	N
11	2 weeks CBM-I	N	N	N	N	N/A
12	3 weeks MRTP	N	N	N	N	N/A

Note: Y – Yes, N – No, ^ - Participant scored below clinical cut off to begin with * – Reduction occurred, but maintained following significant reduction from MRTP, N/A – not applicable

Using the Friedman test, social anxiety did not significantly change over the 2nd time-point or both package phases (χ^2 (2) = 5.522, p = .066). To test for potential differential effects, Wilcoxon tests were conducted using a Bonferroni correction for three multiple comparisons. This yielded

$$p = .05/3, p = .0167.$$

Effect sizes were computed by using the formula from Field (2005):

$$r = Z * \sqrt{N}$$

Where r = the effect size, Z = significance Z score computed for each T statistic and N = the total number of observations.

Mean ($\pm$ SD) social anxiety for time-point two, CBM-I and MRTP conditions were 49.17 (16.57), 39.42 (17.57) and 44.25 (15.68) respectively. Compared to time-point two, social anxiety significantly reduced following CBM-I ($T = 5$, $r = -0.51$, $p < .01$). There was no difference in social anxiety when comparing time-point two and MRTP phases ($T = 24.5$, $r = -0.15$, $p = .239$). Similarly, there was no difference in social anxiety between either treatment phase when taking the Bonferroni correction into account ($T = 64$, $r = -0.4$, $p = .026$). Mean ($\pm$ SD) social anxiety at follow up was 37.33 (14.93). Reduction in social anxiety was also maintained at follow up ($T = 4$, $r = -0.56$, $p < .005$). It appears that, in comparison to time-point two, the CBM-I phase significantly improved social anxiety, not the MRTP. It should be noted that this test was underpowered, so confidence in the findings is limited. However, the analysis does agree somewhat with the visual inspection that three of twelve participants (and a trend in participants 1, 2 & 8) showed reduction in social anxiety, while all twelve participants did not improve on reasoning biases. In two out of three cases (participants 4 & 5), reductions in social anxiety were maintained at follow up. In summary therefore, all that can be said about the effects of CBM-I on social anxiety with any degree of confidence is that the results are mixed and are therefore unclear. What must also be taken into account is the potential for cumulative effects of CBM-I on social anxiety but also potentially on unmeasured depression.

3.16 Hypothesis two: In comparison to baseline, five sessions of CBM-I will correspondingly reduce levels of severity of paranoia

Table 3.41 below collates the data on the effects of CBM-I on levels of paranoia. Overall, it shows that six out of twelve participants improved on measures of paranoia following the CBM-I package. In two of the three cases in which social anxiety improved following CBM-I (participants 4 & 5), there were corresponding reductions in paranoia. In one case (participant 10) a reduction in social anxiety occurred following CBM-I, with no corresponding reduction in paranoia.

Table 3.41

Collated data on effect of CBM-I on paranoia per participant

Participant	Baseline and 1st package	Reliable Reduction in Paranoia	Clinical Reduction in Paranoia	Reduction in conviction	Hypothesis Two Supported	Maintained at follow up
1	3 weeks CBM-I	N	N	N	N	N/A
2	2 weeks MRTP	Y	N	Y	Y	Y
3	2 weeks CBM-I	N	N	N	N	N/A
4	3 weeks MRTP	N	N	Y	Y	Y
5	3 weeks CBM-I	Y	N	N	Y	Y
6	2 weeks CBM-I	N	N*	N	N	N/A
7	3 weeks MRTP	Y	N*	Y	Y	Y
8	2 weeks MRTP	N	N*	N	N	N/A
9	3 weeks CBM-I	N	N*	N	N	N/A
10	2 weeks MRTP	N	N	N	N	N/A
11	2 weeks CBM-I	Y	N	N	Y	N
12	3 weeks MRTP	N	N	Y	Y	Y

Note: Y – Yes, N – No, * - Scored below clinical cut off at baseline, N/A – Not applicable

The Friedman test indicated that paranoia changed significantly over the course of both package packages ($\chi^2(2) = 9.913$, $p < .01$). This was followed up by Wilcoxon tests

using the Bonferroni correction for three multiple comparisons, yielding $p = .0167$. Mean ($\pm$ SD) paranoia scores for the time-point two, CBM-I and MRTP conditions were 107.58 (28.98), 87.58 (30.15) and 79.67 (36.2) respectively. Compared to time-point two, paranoia significantly reduced following CBM-I ($T = 7$, $r = -0.51$, $p < .01$). There were no differences in paranoia when both treatment phases were compared ($T = 45$, $r = -.10$, $p = 0.338$). Mean ($\pm$ SD) paranoia scores at follow up were 74.58 (31.3). Reduction in paranoia was also maintained at follow up ($T = 0$, $r = -0.62$, $p < .001$). It appears that, in comparison to time-point two, CBM-I significantly improved paranoia, with a moderate effect size. With regards to the visual inspection, it should be noted that an improvement in either conviction or GPTS scores constituted an improvement in paranoia, therefore support for hypothesis two. Although underpowered, these findings agree with the visual inspection results; six out of twelve participants showed significant improvement in either GPTS scores, conviction, or both.

3.17 Hypothesis three: In comparison to baseline, five sessions of the Maudsley Review Training Programme (MRTP) will improve reasoning, but will not improve anxiety

Table 3.42 below collates the data on differential effects of the MRTP on reasoning. Overall, this indicates improved reasoning biases in nine out of twelve participants (participants 2, 3, 4, 5, 7, 8, 9, 10 & 12) with one out of twelve participants improving in social anxiety from the MRTP (participant 7). This resulted in eight of twelve cases supporting hypothesis three.

Table 3.42

Collated data on differential effects of the MRTP on reasoning biases per participant

Participant	Baseline and 1st package	Reliable Reduction in Social Anxiety	Clinical Reduction in Social Anxiety	Improved Reasoning Biases	Hypothesis Three Supported	Maintained at follow up
1	3 weeks CBM-I	N	N	N	N	N/A
2	2 weeks MRTP	N	N*	Y	Y	Y
3	2 weeks CBM-I	N	N	Y	Y	Y
4	3 weeks MRTP	N	N	Y	Y	Y
5	3 weeks CBM-I	N	N	Y	Y	Y
6	2 weeks CBM-I	N	N	N	N	N/A
7	3 weeks MRTP	Y	Y	Y	N	Y
8	2 weeks MRTP	N	N*	Y	Y	Y
9	3 weeks CBM-I	N	N	Y	Y	Y
10	2 weeks MRTP	N	N*	Y	Y	Y
11	2 weeks CBM-I	N	N	N	N	N/A
12	3 weeks MRTP	N	N	Y	Y	Y

Note: Y – Yes, N – No, * - Scored below clinical cut off at time-point one or two, N/A – Not applicable

Taking the dichotomous data of the 85:15, 60:40 beads and PBM tasks together, Cochrane's Q was performed, which indicated significant change in reasoning biases across phases ($Q (2) = 13.636$, $p < .001$). To test for differential effects, McNemar's tests (suitable for binary, repeated measures data; UCLA, 2014) were conducted using the Bonferroni correction of $p = .0167$. Table 3.43 gives the frequency of JTC and the amount of times participants indicated there was no possibility that they could be mistaken.

Table 3.43

Frequency table for JTC and PBM data

Reasoning Bias	Time-point 2 Frequency	CBM-I Frequency	MRTP Frequency	Follow Up Frequency
*	4/12	2/12	1/12	1/12
^	4/12	2/12	1/12	1/12
†	6/12	5/12	2/12	4/12

Note: * - JTC on the 85:15 task, ^ - JTC on the 60:40 task, † - reporting no possibility of being mistaken about delusion on the PBM interview.

Compared to time-point two, reasoning biases significantly improved following the MRTP ($r = 0.54$, $p < .001$). There was no difference in reasoning biases between time-point two and the CBM-I phases ($p = .063$), neither was there a difference between MRTP and CBM-I phases when accounting for the correction ($p = .031$). The significant improvement comparing time-point two and the MRTP maintained at follow up ($r = 0.47$, $p < .005$). These results indicate that the MRTP, not CBM-I, improved performance on the 85:15, 60:40 beads tasks and the PBM task, with a moderate effect size.

The continuous data for the EoE assessment were subjected to Friedman's test, indicating significant differences between time-point two and both treatment phases ($\chi^2 (2) = 10.457$, $p < .005$). Mean ($\pm$ SD) numbers of alternative explanations at time-point two, CBM-I and MRTP conditions were 0.167 (0.389), 0.75 (0.754) and 1.167 (0.835), respectively. Post hoc Wilcoxon tests using the Bonferroni correction of $p = .0167$ indicated significant improvement in reasoning when comparing the MRTP to time-point two ($T = 51.5$, $r = -0.52$, $p < .01$). There was no significant difference in reasoning biases between time-point two and CBM-I phases when correcting for multiple comparisons ($T = 32$, $r = -0.43$, $p = .031$), or between CBM-I and MRTP phases ($T = 24$, $r = -0.39$, $p = .063$). Mean ($\pm$ SD) numbers of

alternative explanations at follow up were 1.167 (0.835). These improvements in EoE scores were maintained at follow up, compared to time-point two ($T = 51$, $r = -0.46$, $p = .01$). These results indicate that the MRTP improved performance on the EoE assessment, not CBM-I, with small – moderate effect sizes.

The ordinal data of the RTHC were tested using Friedman's test, indicating no significant differences in reasoning biases on this measure between phases (χ^2 (2) = 4.750, $p = .114$). Table 3.44 gives the frequency of the four different RTHC codes.

Table 3.44

Frequency table for RTHC codes

	Time-point 2	CBM-I	MRTP	Follow Up
Code	Frequency	Frequency	Frequency	Frequency
0	0/12	1/12	3/12	4/12
1	6/12	6/12	5/12	4/12
2	5/12	4/12	3/12	3/12
3	1/12	1/12	1/12	1/12

Note: 0 – dismissed delusion, 1 – reduced delusional conviction, 2 – accommodated contradiction into delusion, 3 – rejected/dismissed contradiction.

To investigate potential differential effects, Wilcoxon's test with the above Bonferroni correction of $p = .0167$ was used, indicating no significant difference in reasoning biases between time-point two and MRTP phases ($T = 4$, $r = -0.55$, $p = .063$). Similarly, there was no difference in reasoning biases between time-point two and CBM-I phases ($T = 7$, $r = -0.55$, $p = 0.344$), or between CBM-I and MRTP phases ($T = 0$, $r = -0.5$, $p = 0.125$). These results indicate that neither package had any effect on reasoning biases measured by the RTHC.

Again, although underpowered, these results do agree with the results from visual inspection that indicate that nine out of twelve participants improved in reasoning biases following the MRTP, while eight of those nine participants showed no improvement in social anxiety.

3.18 Hypothesis four: In comparison to baseline, five sessions of MRTP will result in a corresponding reduction in paranoia

Table 3.45 below collates the data on the effects of the MRTP on levels of paranoia. Overall, this shows that six out of twelve participants (participants 3, 4, 5, 7, 8 & 9) experienced an improvement in paranoia from the MRTP. All of these participants also demonstrated improvement in reasoning biases.

Table 3.45

Collated data on effects of the MRTP on paranoia per participant

Participant	Baseline and 1st package	Reliable Reduction in Paranoia	Clinical Reduction in Paranoia	Reduction in conviction	Hypothesis four Supported	Maintained at follow up
1	3 weeks CBM-I	N	N	N	N	N/A
2	2 weeks MRTP	N	N	N	N	N/A
3	2 weeks CBM-I	Y	Y*	N	Y	Y
4	3 weeks MRTP	Y	Y	N	Y	Y
5	3 weeks CBM-I	N	N	Y	Y	Y
6	2 weeks CBM-I	N	N	N	N	N/A
7	3 weeks MRTP	N	N	Y	Y	Y
8	2 weeks MRTP	Y	N	N	Y	Y
9	3 weeks CBM-I	N	N	Y	Y	Y
10	2 weeks MRTP	N	N	N	N	N/A
11	2 weeks CBM-I	N	Y^	N	N	N/A
12	3 weeks MRTP	N	N	N	N	N/A

Note: Y – Yes, N – No, * – clinical reduction was not maintained at follow up, ^ - Further clinical reduction followed after MRTP but paranoia scores had already reliably decreased following CBM-I, N/A – Not applicable

The Friedman test indicated that paranoia changed significantly over the course of both package packages ($\chi^2 (2) = 9.913$, $p < 0.01$). This was followed up by Wilcoxon tests using a Bonferroni correction for multiple comparisons, yielding $p = .0167$. Mean ($\pm$ SD) paranoia scores for the time-point two, CBM-I and MRTP conditions were 107.58 (28.98), 87.58 (30.15) and 79.67 (36.2) respectively. Compared to time-point two, paranoia significantly reduced with the MRTP ($T = 4$, $r = -0.49$, $p < .01$). There were no differences in paranoia when both treatment phases were compared ($T = 45$, $r = -.10$, $p = 0.338$). Mean ($\pm$ SD) paranoia scores at follow up were 74.58 (31.3). Reduction in paranoia was also maintained at follow up when compared to time-point two ($T = 0$, $r = -0.62$, $p < .001$). It

appears that, in comparison to time-point two, the MRTP significantly improved paranoia, with a moderate effect size.

With regards to the visual inspection, it should be noted that an improvement in either conviction or GPTS scores constituted an improvement in paranoia, therefore support for hypothesis four. Although underpowered, the statistical tests above agree with the visual and statistical testing of the GPTS and conviction data; six out of twelve participants reduced in GPTS scores, conviction, or both.

3.19 Relationship between social anxiety, reasoning biases and paranoia

Table 3.46 below outlines the relationship between improved social anxiety, improved reasoning biases and paranoia, regardless of the package responsible.

Table 3.46

Relationships between improved social anxiety, improved reasoning biases and paranoia

Participant	Baseline and 1st package	Improved Social Anxiety	Improved Reasoning Biases	Reduction in Paranoia	Relationship Supported
1	3 weeks CBM-I	N	N	N	Y
2	2 weeks MRTP	N	Y	Y	Y
3	2 weeks CBM-I	N	Y	Y	Y
4	3 weeks MRTP	Y	Y	Y	Y
5	3 weeks CBM-I	Y	Y	Y	Y
6	2 weeks CBM-I	N	N	N	Y
7	3 weeks MRTP	Y	Y	Y	Y
8	2 weeks MRTP	N	Y	Y	Y
9	3 weeks CBM-I	N	Y	Y	Y
10	2 weeks MRTP	Y	Y	N	N
11	2 weeks CBM-I	N	N	Y	N
12	3 weeks MRTP	N	Y	Y	Y

Note: Y – Yes, N – No

Table 3.46 above indicates that in eight out of twelve participants (participants 2, 3, 4, 5, 7, 8, 9 & 12) improved paranoia (measured by a reduction in GPTS and/or conviction, by either package) corresponded with improved social anxiety (by either package) and/or improved reasoning biases. In five out of twelve cases (participants 2, 3, 8, 9 & 12), improved paranoia corresponded with improved reasoning biases only. In three out of twelve cases (participants 4, 5 &7), improvements in both social anxiety and reasoning biases corresponded with improvements in paranoia. In two cases (participants 1 & 6), no improvement in social anxiety and reasoning biases corresponded with no improvement in paranoia. These are the only two cases in the series where neither package had any effect on any measures. In one case (participant 10), improvement in both social anxiety and reasoning

biases did not correspond with any reduction in paranoia. In one case (participant 11), no improvement in social anxiety and no improvement in reasoning biases corresponded with improvement in paranoia. Although these findings are quite mixed, overall they suggest that in ten out of twelve cases (participants 1, 2, 3, 4, 5, 6, 7, 8, 9 & 12), improvement (or lack thereof) in social anxiety and/or reasoning biases corresponded with improvement (or lack thereof) in paranoia. In two out of twelve cases (participants 10 & 11), no relationship between improvement in social anxiety and/or reasoning biases corresponding with improvement in paranoia was found.

Table 3.47 further clarifies the relationship between social anxiety, reasoning biases and paranoia according to which package evoked change. This indicates that CBM-I improved anxiety and correspondingly paranoia in two cases (participants 4 & 5). It also indicates that the MRTP improved reasoning biases and corresponding paranoia in six cases (participants 3, 4, 5, 7, 8 & 9). As indicated, there is overlap in participants 4 and 5, where the CBM-I and MRTP packages both improved conviction and GPTS scores.

Table 3.47

Relationships between improved social anxiety, improved reasoning biases and paranoia, according to package

Participant	CBM-I Improved Social Anxiety	CBM-I Reduced GPTS	CBM-I Reduced Conviction	MRTP Improved Reasoning Biases	MRTP Reduced GPTS	MRTP Reduced Conviction
1						
2		Y	Y	Y		
3				Y	Y	
4	Y		Y	Y	Y	
5	Y	Y		Y		Y
6						
7		Y	Y	Y		Y
8				Y	Y	
9				Y		Y
10	Y			Y		
11		Y				
12			Y	Y		

Note: Y – Yes

Table 3.48

Baseline variables that distinguish participants who benefitted from either or both packages

Participant	Mean Baseline Belief Conviction	Duration of Difficulties	Clinical Levels of Social Anxiety	Clinical Levels of Paranoia	Benefitted from CBM-I	Benefitted from MRTP
1	100	1	Y	Y	N	N
2	56	5	N	Y	Y	Y
3	36	16	Y	Y	N	Y
4	70	14	Y	Y	Y	Y
5	94	20	Y	Y	Y	Y
6	100	6	Y	N	N	N
7	51	13	Y	N	Y	Y
8	75	8	N	N	N	Y
9	33	23	N	N	N	Y
10	90	1.5	Y	Y	Y	Y
11	62	15	Y	Y	Y	N
12	100	1	Y	Y	N	Y

Table 3.48 above gives the participant baseline characteristics and response to either or both packages on any measure. As can be seen, participants 1 and 6 did not respond to either package. Overall, it would seem that mean baseline conviction does not play a significant role in response to either/both packages; although participants 1 and 6 had high average conviction (100%) throughout baseline and did not respond, other participants with high average conviction (e.g., participants 10, 8, 5 & 4) did. The same could be said for duration of difficulties, as some participants with very low duration of difficulties did not respond to either package (e.g., participant 1). From observing the table, it does not appear that time-point one and two levels of social anxiety and/or paranoia exert any effect on response to package either, although it is difficult to determine relationships without inferential statistics.

3.20 Chapter conclusion

This chapter details and displays the results of the current study in ascertaining the differential effects of both packages on social anxiety and reasoning biases as well as on paranoia. It may be worth noting here that the overall sample reflects three individuals from Early Intervention Services and nine from Recovery services. Although studies suggest that samples from Early Intervention and Recovery services are different, particularly in terms of chronicity and duration of difficulties (e.g., Singh, 2010), it is interesting to note here that the three participants from Early Intervention (participants 1, 2 & 12) comprised two individuals with a comparatively more severe presentation in terms of symptoms and treatment response (participants 1 & 12) and an individual with a comparatively less severe presentation overall. This indicates that the full sample may be considered in its entirety, without special consideration for participants from Early Intervention, as they did not seem to exert a differential influence over the presentation of the general sample.

Three out of twelve participants supported hypothesis one, i.e., that CBM-I would improve social anxiety, not reasoning biases. The statistical analyses also indicated a significant effect of CBM-I, not the MRTP, on social anxiety. Six out of twelve participants (participants 2, 4, 5, 7, 11 & 12) supported hypothesis two, that CBM-I would improve paranoia. This comprised four out of twelve reductions in GPTS scores, and four out of twelve reductions in conviction, with two cases of overlap. The underpowered statistical analyses also support this hypothesis.

Eight out of twelve participants supported hypothesis three; that the MRTP would improve reasoning biases, not social anxiety. In one case, (participant 7) the MRTP improved social anxiety and reasoning biases. The statistical analyses described above indicate significant improvement of the MRTP, not CBM-I, on reasoning biases, on all measures except the RTHC, which failed to reach significance.

Six out of twelve participants (3, 4, 5, 7, 8 & 9) supported hypothesis four; that the MRTP would reduce paranoia. This comprised three out of twelve reductions in GPTS scores (participants 3, 4 & 8) and three out of twelve reductions in conviction (participants 5, 7 & 9). Statistical analyses outlined above also indicate a significant overall effect of the MRTP on paranoia.

Finally, the patterns between improvement (and lack thereof) in social anxiety and/or reasoning biases and corresponding improvement (and lack thereof) in paranoia were investigated. A total of eight out of twelve participants demonstrated improvements in social anxiety and/or reasoning biases that also corresponded with improvements in paranoia. Two participants did not show any improvements in social anxiety, reasoning biases or paranoia. One participant reported improvements in social anxiety and reasoning biases but did not report any corresponding improvements in paranoia. One participant did not report improvements in social anxiety or reasoning biases but did report improvements in paranoia. These results are discussed in the next section.

Discussion

4.1 Chapter overview

This chapter reviews the aims of the study, and interprets and discusses the findings. The theoretical implications are discussed with an emphasis on the literature described in the introduction. How this study might inform clinical and service development within the NHS is also mentioned. Future research questions are identified based on this study. Limitations and advantages of the research are also outlined.

4.2 Aims

The main aims of this study were twofold: (1) Do CBM-I and the MRTP exert differential effects on social anxiety, and reasoning biases? (2) Do either/both packages also reduce paranoia? Following a review of the literature, social anxiety and reasoning biases were implicated in the formation and maintenance of persecutory delusions (Freeman, 2007) and may therefore be important therapeutic targets. However, the link between these mechanisms and the potential they may play in the development and persistence of delusional levels of paranoia are less clearly understood from the current evidence. This study aimed to clarify any relationship between these clinical constructs.

4.3 Summary of results

Single case series designs are useful from a clinical perspective, but the small sample sizes mean that generality of results must be conducted with caution (Kazdin, 2010). This is particularly true for the underpowered group analyses conducted, which undermines confidence in the findings. However, as Harrington (2013) suggests, visual inspection and clinical/reliable change should be used in conjunction with inferential statistical tests of single case series data. If these two independent and methodologically different analytical strategies

both converge on the same results, confidence in the findings and ability to generalise back to the population may increase. With this in mind, the hypotheses will now be discussed.

4.3.1 Hypothesis one: five sessions of CBM-I will reduce levels of social anxiety, but will not improve reasoning. In support of this hypothesis, three of twelve participants met reliable and/or clinical reduction in social anxiety (participants 4, 5 and 10). In one of these cases CBM-I occurred first (participant 5) and in two cases (participants 4 & 10) CBM-I occurred after the MRTP but it was only at the point that CBM-I was introduced that reductions in social anxiety occurred, suggesting a specific effect of CBM-I. Three participants trended towards significantly reduced social anxiety during the CBM-I package (participants 1, 2 & 8). Of the significant changes, two out of three participants' reduced social anxiety was maintained at follow up (with the exception of participant 10). There were no reliable and/or clinical changes in the remaining six participants. It should be noted that in some cases, (participants 2, 8 & 10) time-points one and/or two social anxiety scored below the clinical cut off of 34 to begin with. Having said this, time-points one and/or two scores were close to the clinical cut off, suggesting some degree of social anxiety.

All twelve participants showed no improvement in reasoning biases following CBM-I, suggesting effects of CBM-I that were specific to social anxiety, not reasoning biases. A change in only one quarter of participants provides only partial support for hypothesis one. The main reason why more participants did not support hypothesis one was because there was no reliable/clinical reduction in social anxiety: a reduction of at least 13/80 points on the SIAS. It is possible that the reason for this is due to the study design – larger effects must be present in each case for the analysis strategy to be able to attribute an effect to the treatment with confidence (Kazdin, 2010). Several participants approached reliable/clinical reductions in social anxiety, but did not meet reliable or clinical change criteria. Therefore, the statistical tests carried out may clarify whether or not this hypothesis is supported.

In addition to the individual differences, group analyses also supported hypothesis one. Although the Friedman test showed no significant change in social anxiety over the second time-point or package phases, post hoc Wilcoxon tests showed that, compared to time-point two, social anxiety significantly reduced following CBM-I. There was no difference in social anxiety when comparing time-point two and MRTP phases. Reduction in social anxiety was also maintained at follow up. However, social anxiety was still not reliably/clinically reduced in nine out of twelve participants. Taken together, these results indicate that CBM-I improved social anxiety but not reasoning biases, in three out of twelve participants, with a moderate effect size overall. The findings for this hypothesis are therefore mixed.

4.3.2 Hypothesis two: five sessions of CBM-I will correspondingly reduce levels of severity of paranoia, compared to baseline. In support of hypothesis two, six out of twelve participants showed clinical and/or reliable change in GPTS scores, reduced conviction, or both following the CBM-I package (participants 2, 4, 5, 7, 11, & 12). All participants, except participant 11, maintained their gains at follow up. Reduced paranoia due to CBM-I package corresponded with reduced social anxiety in two cases (participants 4 & 5, not participant 10). This means that in four cases paranoia reduced without corresponding reliable/clinical reduction in social anxiety.

In addition to the individual differences, group analyses also supported hypothesis two. The Friedman test indicated that paranoia changed significantly over the course of both package packages. This was followed up by Wilcoxon tests using the Bonferroni correction. Compared to time-point two, paranoia significantly reduced following CBM-I. There were no differences in paranoia when both treatment phases were compared. Reduction in paranoia was also maintained at follow up. It appears that, in comparison to time-point two, CBM-I significantly improved paranoia, with a moderate effect size.

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4.3.3 Hypothesis three: five sessions of the Maudsley Review Training Programme will improve reasoning, compared to baseline, but will not improve anxiety.

Following visual inspection, nine out of twelve participants improved in reasoning biases, although in one case (participant 7), the MRTP also improved social anxiety. Therefore, eight out of twelve participants' results supported hypothesis three (participants 2, 3, 4, 5, 8, 9, 10 & 12). All participants' improvements in reasoning biases were maintained at follow up.

Several group analyses were conducted, based on type of reasoning biases data. Cochrane's Q revealed significant change in reasoning biases across time-point two and package phases. To test for differential effects, McNemar's tests were conducted using the Bonferroni correction for multiple comparisons. Compared to time-point two, reasoning biases significantly improved following the MRTP. There was no difference in reasoning biases between time-point two and the CBM-I phases, neither was there a difference between MRTP and CBM-I phases when accounting for the correction. The significant improvement comparing time-point two and the MRTP maintained at follow up. Overall, it seems that the MRTP improved these reasoning biases with a moderate effect size, which was maintained at follow up.

Friedman's test indicated significant differences in EoE data between second time-point two and both treatment phases. Post hoc Wilcoxon tests using the Bonferroni correction indicated significant improvement in reasoning when comparing the MRTP to time-point two. There was no significant difference in reasoning biases between time-point two and CBM-I phases when correcting for multiple comparisons or between CBM-I and MRTP phases. These improvements in EoE scores maintained at follow up, compared to time-point two. These results indicate that the MRTP improved performance on the EoE assessment, with small – moderate effect sizes.

Friedman's test indicated no significant differences in RTHC data between phases. Post hoc Wilcoxon's tests with the Bonferroni correction also found no significant difference in reasoning biases between time-point two and MRTP phases, or between time-point two and CBM-I phases. These results indicate that neither package had any effect on reasoning biases measured by the RTHC.

Taken together, these results are suggestive of a moderate effect of the MRTP specific to reasoning biases, not social anxiety.

4.3.4 Hypothesis four: it is expected that five sessions of the Maudsley Review Training Programme will result in a corresponding reduction in paranoia, compared to baseline. Following visual inspection, six of twelve participants improved in GPTS scores, conviction or both (participants 3, 4, 5, 7, 8 & 9). All participants maintained their gains at follow up. All of these participants also had corresponding improved reasoning biases, attributed to the MRTP package. Three participants who reported improved reasoning biases did not report corresponding improvement in paranoia attributed to the MRTP (participants 2, 10 & 12). Two of these did experience improved paranoia following the CBM-I package however. Therefore, one participant (10) experienced improved reasoning biases but not paranoia. These relationships will be discussed in greater detail below.

In terms of group analyses, the Friedman test indicated that paranoia changed significantly over the course of both package packages. This was followed up by Wilcoxon tests using a Bonferroni correction. Compared to time-point two, paranoia significantly reduced with the MRTP. There were no differences in paranoia when both treatment phases were compared. Reduction in paranoia was also maintained at follow up. It appears that, in comparison to time-point two, the MRTP also significantly improved paranoia, with a moderate effect size.

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4.3.5 The relationship between baseline characteristics and response. Table 3.48 above describes time-point one and two and baseline clinical characteristics of each participant. However, as discussed above, there does not appear to be any strong relationship between levels of conviction, duration of difficulties, severity of social anxiety and/or paranoia and response to either package.

4.3.6 The relationship between social anxiety, reasoning biases and paranoia. This study was also interested in determining the relationship between these mechanisms of persecutory delusions. As outlined in table 3.47, eight out of twelve participants showed that an improvement in social anxiety and/or reasoning biases corresponded with improvement in paranoia (as measured by reduced GPTS scores and/or improved conviction). Specifically, improvement in social anxiety following CBM-I also corresponded with improvement in paranoia following CBM-I in two cases (participants 4 & 5), not in one (participant 10). Improvement in reasoning biases following the MRTP also corresponded with improvement in paranoia following the MRTP in five cases (participants 2, 3, 8, 9, & 12). In one case (participant 7), the CBM-I package improved GPTS scores and conviction, but not social anxiety. The MRTP improved social anxiety, reasoning biases and also improved conviction. In two cases (participants 1 & 6), did no improvements in either social anxiety or reasoning biases correspond with no improvement in paranoia, thus supporting the idea that these constructs may be linked. In one case (participant 10), there were improvements in both social anxiety and reasoning biases, but no corresponding improvement in paranoia. In another case (participant 11), the opposite occurred, where there were no improvements in either social anxiety or reasoning biases but paranoia improved. It is interesting that in some cases, there was overlap in improved GPTS scores and/or conviction, according to type of package (participants 4, 5 & 7). This also suggests that change in social anxiety and/or reasoning biases interact with change in paranoia, perhaps in a dynamic, rather than linear fashion. Overall, ten of twelve participants supported a relationship, two of twelve did not.

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It is also interesting to note that the underpowered inferential statistics indicated differential effects of CBM-I on social anxiety and the MRTP on reasoning, with a corresponding reduction in paranoia that was almost identical (both in terms of significance and effect size) to each package. This suggests that there is, to some extent, a relationship between these three clinical constructs, although it is difficult to clarify this any further.

These findings suggest that the Threat Anticipation Model (Freeman, 2007) has been largely supported, in that reduction in social anxiety and/or reasoning biases will result in a reduction in paranoia.

4.4 Theoretical implications

Although the findings should be interpreted with some caution, there are important theoretical implications based on this study.

4.4.1 Social anxiety. Although bias modification by CBM-I was not measured, the results support previous findings that social anxiety is at least to some extent maintained by negative interpretative biases of socially ambiguous information that promote fear of negative evaluation (Clark & Beck, 2010). Although not formally measured, previous research does suggest a link between interpretation bias and social anxiety symptoms and that CBM-I exerts moderate effect sizes in modifying these biases thereby reducing symptoms (Hallion & Ruscio, 2011). Similar effects of CBM-I have been found in the psychosis literature also (e.g., Turner et al., 2011). Therefore, we may be able to assume with reasonable confidence that similar mechanisms of change may have happened in the current study. In keeping with information processing models of social anxiety (e.g., Clark & Beck, 2010), the participants who reported better engagement with CBM-I did tend to get more clinical benefit from it (participants 1, 2, 4, 5 & 10), although in some instances this benefit only trended towards a reliable reduction. This may be due to increased engagement with the task material and greater likelihood to apply the positive interpretative modification to real-life scenarios, as

reported in the results chapter. Conversely, those participants who did not find the CBM-I task helpful (participants 3, 6, 8, 9, 11 & 12) were those who tended to have a more negative experience with it, e.g., it being patronising or repetitive, as well as being less likely to apply a more positive interpretation in real-life situations. Considered overall, the results show moderate yet limited support for information processing models of social anxiety.

The MRTP did not appear to significantly improve social anxiety, with the exception of one case (participant 7). This case is interesting, because improvement in social anxiety may have been secondary to decreased delusional conviction and paranoia, rather than direct effects on social anxiety alone. This makes sense when the content of the delusion is considered; a belief that they would be beaten or killed by a member of the public, were they to go outdoors. It also makes sense given that all measures (idiographic and standardised) improved dramatically following the first few sessions of the MRTP, which the participant was randomised to first receive. If this explanation is the case, then the Threat Anticipation Model (Freeman, 2007) would be supported, as relevant mechanisms of paranoia interact under change. However, the possibility that the MRTP may have directly acted on social anxiety can't be ruled out. This instance is difficult to tease apart with this design.

Other than in the above case, the MRTP did not have any significant effect on social anxiety, further supporting the idea that social anxiety and reasoning biases are qualitatively different, with different treatment profiles. The theoretical implications of this will be discussed further in the next section.

4.4.2 Interpretation biases and reasoning biases as distinct. Although reasoning biases have repeatedly been shown to be specific to psychosis (Garety et al., 2005; Freeman, 2007), the reason why they are specific has not been fully explained. The results of the current study may indicate that reasoning biases and social anxiety have unique aetiology, given their differential susceptibility to change. This fits with some of the initial literature on

reasoning biases, suggesting that they may be associated with neuropsychological problems, such as working memory (Broom et al., 2007; Garety et al., 2013). Difficulties with working memory have been shown to be more specific to psychosis, rather than social anxiety, and have even been proposed as a potential endophenotype of psychosis (e.g., Wood et al., 2003). Given this finding, the techniques used in the MRTP would be better suited to improve data gathering biases, since the package encourages general strategies, empirically shown to improve working memory, such as slowing down before making a decision, breaking down the decision making process into more manageable parts, use of visual aids, and frequent summarising, which all promote consolidation of material into longer term memory (McNamara & Scott, 2001). The results of the current study show a significant effect of the MRTP on improving reasoning biases within the sample – ten of twelve cases overall, with a moderate effect size.

Although theoretical models have explained the causal and maintaining role interpretation biases can play in social anxiety (e.g., Clark & Beck, 2010), the aetiology of reasoning biases in psychosis and persecutory delusions is less clearly known at present (Freeman, 2007). Also, there seem to be certain cognitive styles that overlap between psychosis and social anxiety, e.g., intolerance of uncertainty (Broome et al., 2007). Due to further research into the aetiology of data gathering biases in psychosis being needed, in-depth discussion on how they develop is beyond the scope of the present study.

4.4.3 Support for the Threat Anticipation Model (Freeman, 2007). The second research question was whether or not both packages would improve paranoia. The implication would be that improvements in social anxiety and/or reasoning biases would lead to improvements in persecutory delusions, paranoia and ideas of reference as measured by the full GPTS scores and conviction ratings. As already outlined in previous sections, support was found for hypothesised improvements in paranoia by both the CBM-I and MRTP packages. Furthermore, in eight out of twelve cases, support for improvements in social

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anxiety and/or reasoning biases corresponding with improved paranoia was found. In two cases, no improvement in either social anxiety, reasoning biases or paranoia was found, which does also support the model, as no change in either or both mechanisms corresponded with no change in paranoia. In two cases, the results contradicted any relationship between social anxiety, reasoning biases and paranoia. Considered together, the findings from the current study give moderate support to several hypotheses that the Threat Anticipation Model (Freeman, 2007) makes.

(1) Can it be shown that psychological factors are causal in paranoid thinking (Freeman, 2007)? One of the potential advantages of this study was the use of specific computerised treatments, aimed at discrete psychological styles of information processing, using an experimental prospective design. With the exception of one or two cases that could be argued to have been spontaneously improving (participants 2 & 3), the design of this study established with reasonable confidence that symptoms were not on a natural path to recovery. Therefore, experimental manipulation of psychological factors (such as interpretation and reasoning biases) corresponding with reduction in delusional conviction and persecutory ideation may lead to the conclusion that they are causally related.

(2) Do psychological factors interact in the development of paranoia (Freeman, 2007)? Overall improvement in social anxiety and/or reasoning biases with a corresponding reduction in paranoia suggests that these factors do interact in the development and maintenance of paranoia. Some individual findings supporting this hypothesis include the fact that there was some overlap of effects within individual cases, e.g., CBM-I and the MRTP both had significant effects on conviction for participant 7. While CBM-I reduced social anxiety and the MRTP improved reasoning biases in participants 4 and 5, both packages also reduced GPTS scores and conviction in a discrete manner (see table 3.47). Similarly, the CBM-I package induced reliable change in GPTS scores of participant 11, followed by a dramatic

reduction following the MRTP, which became clinically significant. The gains were not maintained at follow up, but the results lend some support to the above hypothesis.

(3) Do processes that maintain social anxiety also serve to maintain paranoid thoughts (Freeman, 2007)? Supporting this research question is more difficult due to lack of interpretation bias measures; however, the results do indicate some potential relationship between this maintaining factor and paranoia. The results of this study showed that in two cases where clinical and/or reliable change in social anxiety occurred following CBM-I, there was also a corresponding reduction in paranoia (participants 4 & 5). It must be noted that in these two cases, improved reasoning biases occurred also, indicating lack of a clear, exclusive link between interpretation bias and paranoia. Given the results, it appears that targeting interpretation bias and social anxiety alone might not have been enough to induce reduction in paranoia in many cases. However, it is interesting to note that group effect sizes of CBM-I on social anxiety and paranoia were similar ($T = 5$, $r = -0.51$, $p < .01$ and $T = 7$, $r = -0.51$, $p < .01$, respectively). Although not measured, bias modification may have occurred to an unknown extent across the sample, which may then have reduced social anxiety and so led to a reduction in paranoid thoughts. There were also four out of twelve cases where the CBM-I package significantly improved delusional conviction rates, a dimensional aspect of paranoia directly related to threat from other people. One possible explanation for this is that CBM-I may be acting on paranoia through a mechanism other than social anxiety, due to lack of improvement in social anxiety found. Another more likely possibility is that use of clinical/reliable change was not sensitive enough to detect relationships between changes in social anxiety and paranoia – increased sample size may have allowed for greater powered analyses, e.g., mediation analysis to clarify the differential mediating roles of social anxiety and reasoning biases and their mediating effects on paranoia.

(4) Are threat beliefs most likely to become of delusional intensity when accompanied by data gathering biases such as JTC, or belief inflexibility (measured by EoE, PBM and

RTHC; Freeman, 2007)? This study has also provided experimental evidence that improving reasoning biases led to a corresponding reduction in paranoia in six out of twelve cases (participants 3, 4, 5, 7, 8 & 9). In two cases (participants 4 & 5), improvements with reasoning biases occurred alongside improved social anxiety and a corresponding reduction in paranoia. In three cases (participants 2, 10 & 12) improved reasoning biases did not correspond with a reduction in paranoia. Improved reasoning biases corresponding with improved ideas of reference, ideas of persecution and/or reduced delusional conviction do suggest that presence of reasoning biases exacerbates delusional severity. Further initial support for this relationship may be found when considering those participants whose reasoning biases did not respond (participants 1, 6 & 11). In two out of three cases (participants 1 & 6), neither GPTS scores nor delusional conviction improved. In one case (participant 11), GPTS scores, not conviction improved and the GPTS scores returned to time-points one and/or two clinical rate at follow up.

4.5 Clinical implications

The last research question asked by Freeman (2007; pp 452) is 'can the developments in the understanding of paranoia be used to improve treatments?' This question raises important ideas about how to develop clinical packages for persecutory delusions that the results of this study may be able address to some degree. In the introduction, the limitations of treating heterogeneous clinical phenomena found in psychosis were discussed. Potentially, the advantages of the single-symptom approach could be extended to tailored clinical packages depending on presentation. A clear clinical advantage is how discrete the effects of both computerised packages have been shown to be in this study. It indicates that mechanisms of change can be targeted relatively specifically and with a fair amount of confidence that secondary benefits in paranoia may ensue. This study also suggests that different packages may be indicated, depending on how the individual presents during assessment.

The results of the current study, as well as other studies (Hallion & Ruscio, 2011, Waller et al., 2011) indicate that CBM-I and the MRTP may not exert clinical effects large enough to be used as the only means of input for individuals. However, they might prove to be a useful adjunct to other evidence based packages, such as CBT for social anxiety (Clark & Beck, 2010) and/or CBT for paranoid thoughts (Freeman & Garety, 2006). Use of the CBM-I scenarios may facilitate development of behavioural experiments, which may help to decrease isolation and begin processing of disconfirmatory information. The individual may have also presented with some overt reasoning biases during assessment. The MRTP may help the individual to practice some of the techniques as behavioural experiments, or between session tasks, in keeping with the scientific theme of inquiry of the tasks themselves.

Use of computerised packages also departs from traditional CBT for psychosis in that much of the clinical activity does not involve the client talking about past experiences, or developing a formulation with the clinician. This may be preferable for some people, who, for various reasons, may not wish to explore their past in great detail with another person. Although difficult to research and subject to debate, limited evidence suggests that some individuals with psychosis find the process of developing a formulation to not be helpful and to actually be distressing (e.g., Chadwick, Williams & MacKenzie, 2003). A combination of some initial computerised sessions may also be helpful for individuals who are suspicious and/or anxious and may therefore be unwilling to engage with services in the initial stages of therapy. As people make increased use of technology and computers in many areas of their lives (e.g., purchases, socialising, etc.), the idea of computerised therapy delivered at home gains merit and feasibility. It also may be seen as an attractive option for NHS trusts that are continually striving for cost effectiveness and meeting increased demands with less financial resources.

4.6 Limitations of the study

4.6.1 Study design. This study has several limitations. Although single case series and multiple baseline designs are appropriate for initial clinical studies, there is debate about whether or not findings from these designs can be generalised back to the populations from which the samples came (Kazdin, 2010). As this debate is still ongoing, and due to further limitations described below, it may be sensible to interpret the findings of this study with caution.

Due to the repeated measures nature of single case series designs, study of more than one package becomes difficult, due to the potential for cross-over and interaction effects. This is particularly true for studies that use packages designed to induce lasting change in cognitive processes, such as CBM-I and the MRTP. Although counterbalancing of treatment does control for this effect somewhat, the design itself suffers this disadvantage. There may have been alternative study designs better able to address the hypotheses. For example, a group experimental design may have been more appropriate, where one group were randomised to CBM-I and another group were randomised to the MRTP. Using comparative statistics would probably have yielded clearer results, whereas using two different groups would have controlled better for cross-over effects and may potentially have measured differential effects more clearly. Although ten of twelve participants' changes on measures of social anxiety, reasoning biases and paranoia support a relationship between them, use of the above group design employing multiple regression statistics could perhaps more objectively clarify the relationship and the strength of the relationship between these mechanisms of persecutory delusions. However, this must be balanced with the constraints of the time and resources allocated to the study, as well as the scope of the study itself, i.e., an initial test of theoretically driven hypotheses. The single case series design has been shown to be a good design of initial exploration of hypotheses, which can pave the way for larger scale studies.

4.6.2 Discrepancy between idiographic and standardised ratings. In several cases (participants 1, 3, 4, 5, 8, 10 & 11), the idiographic and standardised ratings of social anxiety and/or paranoia did not follow a similar trajectory. This means that the improvement or deterioration of symptoms captured by the high frequency idiographic data did not reflect the scores obtained by the standardised measures. Similarly, in several cases, the idiographic ratings did not reflect the severity of social anxiety and/or paranoia symptoms elicited using the standardised measures (i.e., in participants 3, 5, 6, 8, 9, 10 & 12). In most cases, (with the exception of participant 5) the idiographic social anxiety and/or paranoia data reflected a more positive appraisal of symptoms than the score on their respective measures.

One potential explanation for this is the general nature of the idiographic measures, e.g., the daily measure of paranoia 'Today, I am feeling under threat from others __%,' may not have had direct relevance to the participants' delusional content. Another explanation may involve demand characteristics. This idea refers to the experimental artefact from research participants being aware of what the researcher is investigating and changing their responses accordingly (Orne, 1962). One particular feature of this that may be a relevant criticism of this study is the role of the 'good subject,' which Orne (1962) describes as research participants seeking to satisfy the perceived needs of the researcher. This may explain why many of the idiographic ratings reported improved symptoms, when the standardised measures indicated stasis, or even decline. It may also explain the discrepancy in severity of idiographic and standardised ratings, as in many cases, the idiographic ratings reflected less severity.

One way that the current study differs from other studies using CBM-I is that the researcher visited the participants in person for every session, whereas other research has promoted delivery of sessions without the researcher present (e.g., through providing computers, or delivery via the internet; Salemink, Kindt, Rienties, & van den Hout, 2014). This means that the potential for the researcher to give cues about the intentions of the study

to the participants may have helped to foster a desire for the participants to help the researcher in their aims. This can have negative consequences for the data, as they may become skewed in various ways, depending on what the participant believes the goal of the study is. This has implications for interpretation of the results, and should always be borne in mind when studies are conducted interpersonally, as opposed to remotely, e.g., via the internet.

Conversely, the idea that certain research participants were motivated to make a positive contribution to the study could be interpreted as helpful. This indicates that at least a certain proportion, if not all of the participants were willing to engage with all of the assessments and multiple computer sessions fully. Research does show that individuals who have positive expectations of therapy tend to receive the most benefit from it (the opposite has also been shown; that low expectations may result in poorer benefit; Constantino, Ametrano & Greenberg, 2012).

Orne (1962) identifies some ways experimenters can mitigate demand characteristics. He notes that 'considerable self-discipline' is needed on the part of the investigator in order to obtain a valid inquiry. There were some instances where the researcher tried to at least be uniform in the information given to all research participants. For example, all research participants read the Participant Information Sheet and had the opportunity to question it with the researcher. The researcher also made efforts to conceal the purpose of certain parts of the study, e.g., several research participants queried the purpose of the 85:15 and 60:40 beads tasks. All participants were happy to continue with the tasks until after the follow up assessment (or after dropping out of the study, if they wished), when the purposes and hypotheses behind the tasks were explained and discussed. Although Orne (1962) recommends deception as to the purpose of the study to avoid the participant working out what the hypotheses might be, this would have presented some ethical difficulties in the current study. In striving for just the opposite (clarity as to the purpose of both computerised packages in the Participant Information Sheet without making the differential hypotheses or

their relationship to paranoia explicit), this study may have reduced attempts of participants to guess at differing hypotheses, which may have idiosyncratically skewed the data (Orne, 1962). Finally, another control was to use the idiographic data to inform the analyses, but to only attribute an effect if the standardised measures indicated this.

4.6.3 Interpretation bias. As discussed in section 1.7, social anxiety is hypothesised to develop and be maintained by negative interpretative biases (Stopa & Clarke, 2000; Mathews & Mackintosh, 2000). Many studies have examined the relationship between the effects of CBM-I on reducing interpretative biases and the relationship that bias modification has with anxiety symptoms (e.g., Salemink et al., 2014). Not measuring interpretative biases and their relationship to social anxiety symptoms is a limitation of this study. It was decided to assume that social anxiety symptoms would be, to some extent, explained by negative interpretative biases and that these biases and symptoms would be amenable to modification, in line with previous research in anxiety generally (e.g., Hallion & Ruscio, 2011) as well as research into social anxiety in psychosis (e.g., Turner et al., 2011). Although three participants did not meet clinical levels of social anxiety symptoms, this does not mean that interpretation biases were not present in the sub-sample. Much research indicates presence of interpretation biases in sub-clinical levels of anxiety (e.g., MacLeod & Cohen, 1993; Mogg et al., 1994; Richards & French, 1992). It should also be noted that the research questions and hypotheses did have a different focus in this study; looking at differential effects of CBM-I, rather than replicating previous findings related to bias modification and symptom reduction.

4.6.4 Statistical analyses. Although Harrington (2013) proposes using both visual inspection and inferential statistics to complement analysis, it must be re-iterated that all inferential tests were underpowered, and therefore their results must be interpreted with caution. The primary method of analysis was that of visual inspection and clinical/reliable reductions, which did indicate mixed support for hypothesis one and modest support for all other hypotheses. The fact that two analytical strategies, derived from different

methodological perspectives, seem to agree with one another may increase confidence in the findings, however it is probably sensible to interpret these findings with caution.

4.6.5 Anomalous experiences. Anomalous experiences are the third mechanism of paranoia implicated within the Threat Anticipation Model (Freeman, 2007) and are likely to play an important role in the genesis of persecutory thinking, given some findings (e.g., Freeman, 2008). However, perceptual anomalies are difficult to describe, to measure and to treat, given their phenomenology (Freeman, 2007). Having said this, this study may have been improved by a third dimension of measuring and treating the distress associated with perceptual anomalies, and determining their relationship to reductions in paranoia.

4.6.6 Qualitative observations. Although it could be argued that including qualitative observations and comments by participants was very helpful for understanding the data and interpreting the results on a case-by-case basis, there were limitations with this approach also. No theoretically-driven qualitative analysis strategy was used on the data, therefore it is possible that the included comments are misleading, biased, or skewed in other ways. Having said this, the qualitative observations were primarily for informational purposes only; the primary analysis of the study was that of visual inspection and clinical/reliable change to determine effects of each package.

4.7 Advantages of the study

Despite the weaknesses outlined above, this study also has several strengths. One of the main criticisms of the case studies in the systematic literature review was lack of sufficient baseline length. This study employed randomly allocated baseline lengths of either two or three weeks – without any treatment phase being longer in duration than the baseline, which is methodologically sound for interpretation of temporal changes (Kazdin, 2010). A further strength of this design is that, although there is the potential for carry-over effects (which counterbalancing of treatment did address to some extent), it does still enable differential

effects to be explicitly tested. For example, in some cases, reasoning biases did not improve until the MRTP was introduced, even after introduction of CBM-I, so we can be more certain that improvements in reasoning biases are attributed to the MRTP as opposed to generic therapeutic effects.

Another weakness of many of the studies reviewed was lack of standardisation of treatment protocol. The CBM-I package was delivered in identically the same way across all 60 sessions, as described in the methods section. Although the MRTP encourages discussion and participant feedback, the tasks are highly structured, with the result that many of the discussions took similar themes. A further advantage was no participant drop out and no loss of data. All individuals who consented to take part completed the study fully, including the one-month follow up assessment, which means that this study does not suffer from loss to follow up, like many research studies in psychosis. Recent studies have shown that clinician involvement helps with engagement and outcome in self-help packages, (e.g., Cuijpers, Donker, van Straten, Li, & Andersson, 2010). Therefore, although there are potential reasons as to why researcher involvement may be a disadvantage, there are also clear advantages for this approach.

4.8 Further research

Although the findings are mixed, further research into the effects of both packages in individuals with psychosis is warranted. This study identifies some potential further research questions. Although some support has been found for a relationship between JTC and belief conviction for delusions of varying types (e.g., Garety et al., 2005), these findings (to the author's knowledge) have not yet been replicated. An experimental prospective design manipulating change in the JTC bias would help to clarify the relationship with belief conviction, and potentially other measures of paranoia. The results may stimulate theoretical and clinical advances. Larger group designs as described previously could test out more

complicated associations, such as how does social anxiety interact with reasoning biases on paranoia, and which mechanisms of change (if any) exert greater effect sizes on reduction of paranoia. Alternative designs could include well powered RCTs using mediation analysis, e.g., manipulation of social anxiety symptoms using CBM-I may clarify the relationship between social anxiety and paranoia via a mediating variable, perhaps anomalous experiences, as the Threat Anticipation Model (Freeman, 2007) postulates. Conversely, testing out moderating factors would also be beneficial, e.g., would other clinical problems common to psychosis (for instance, negative symptoms), mitigate the efficacy of the MRTP package on reasoning biases and therefore paranoia? Studies such as this may help to refine the active components of these packages, as mentioned in the introduction, and improve their effects.

This study has replicated other literature on the clinical efficacy of CBM-I in reducing anxiety symptoms with small – moderate effect sizes (e.g., Hallion & Ruscio, 2011). If further research is warranted in the application of CBM-I to samples with psychosis, then the next step may be to test out ways of increasing its efficacy. This could be tested by trying different modalities, such as audio (e.g., Steel et al., 2010), or visual, as well as augmentation using behavioural components of treatment, such as *in vitro* computerised self-immersion or behavioural experiments, which have been found to be effective for psychosis (Hagen & Nordal, 2008). Clinical research may also focus on the feasibility, tolerability and clinical gains made from incorporating the CBM-I and MRTP tasks into CBT for persecutory delusions, with a focus on such issues as using the tasks themselves as homework, or to generate behavioural experiments. Larger group studies would also provide more data on the relationship between baseline clinical characteristics of participants, and response to the computer packages. Addressing this important research question could result in tailoring the computer packages according to presentation, which would improve efficacy. The applicability of these tasks in group therapeutic settings may be a further innovation. Target samples could include other clinical groups, such as individuals who comply with command

hallucinations, or individuals experiencing a first episode psychosis. Small-scale single case series designs may be adequate to test out hypotheses related to these potential clinical applications.

4.9 Conclusion

In summary, despite some methodological limitations, this study indicated that multiple sessions of CBM-I selectively improved social anxiety, not reasoning biases, with a moderate effect size. However, it must be noted that improvements were only significant using underpowered statistics across the sample, with only three participants experiencing reliable/clinical reduction. This study also showed that the MRTP improved reasoning biases, but not social anxiety in eight out of twelve participants. These findings suggest that social anxiety and reasoning biases may have aetiology unique from one another, although this study could not establish this for certain. The results did indicate specificity of response to either treatment, which holds interesting theoretical and clinical implications. Furthermore, the relationship between improved anxiety, improved reasoning biases and a corresponding improvement in paranoia suggests further support for the Threat Anticipation Model (Freeman, 2007). Future research focusing on various clinical applications of these packages may help to improve their effectiveness and potentially increase the effectiveness of CBT for distressing psychotic symptoms.

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Appendix 1 – Participant Information Sheet

A study exploring the usefulness of computer packages designed to help with social anxiety and thinking style

Participant Information Sheet

Invitation Paragraph
You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others or the researcher if you wish. Please ask the researcher if there is anything that is not clear or if you would like more information.

Thank you for reading this.

What is the purpose of the study?
This study has two aims, which are explained here.

1. Many people have worries about being harmed or upset by others. These worries may make some people look at social situations in a way that increases their anxiety. One aim is to see if computer package A, known as cognitive bias modification for interpretation, helps to reduce social anxiety.

2. People who experience worries about being harmed or upset by others may also find that they make hasty decisions in uncertain situations. The second aim is to find out if computer package B, known as the Maudsley review training programme, helps to slow down any hasty decision making.

The researchers are trying to find out if these two computer packages are useful for other people who experience similar worries about being harmed or upset by others. To find this out, you will also be invited to take part in a short interview to talk about your experiences of using computer package A.

Why have I been chosen?
The researcher is approaching people who have worries about being harmed or threatened in any way.   We would like to include you in this study if you are aged between 18-65 years and have experienced or are experiencing psychosis, and have current worries about being harmed or threatened by others.   As all of the materials used in this study are written in English, in order to take part participants will need to have sufficient English to be able to read and understand this information sheet.

Unfortunately we cannot include everyone in this study. People with a learning disability or who have significant problems with drugs and alcohol will not be asked to take part. We are also not approaching people who are currently receiving psychological therapy. People for this study were selected by talking to people working in care teams. It is these people that will have first contacted you, to ensure your confidentiality. There will be 12 participants selected in this way for the study.

If you are interested in taking part, you will have an initial meeting with the researcher to talk about your current worries and see whether the study is suitable for you. More detail about this is provided below.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time or a decision not to take part will not affect the care you receive in any way. If you do withdraw, the data collected up until this point may still be used.

What will happen to me if I take part?
If you express an interest in taking part, you will have an initial meeting with the researcher for about 30 minutes. During this meeting, the researcher will ask you about your current worries, how upsetting they are to you and how they are affecting you at the moment. This is so that you and the researcher can find out if the study is suitable for you. If it turns out that the study is not suitable, you will be thanked for your time and you will not take further part in the study. If the study is suitable and you would like to take part, you will be asked to sign a consent form. You will then be asked to fill in some questionnaires for up to 3 weeks. After this you will meet again with the researcher to start the computer-based packages.

Each step of the study will now be explained in more detail:

Step 1: If you agree, you can meet or speak with the researcher who will ask about your current worries and see if the research is suitable for you.

Step 2: If the study is not suitable, or you do not wish to take part, you will be thanked for your time and the study will finish.

Step 3: If you decide to take part, the researcher will give you a consent form to sign and keep and a calendar with a timetable of the sessions and meetings marked on it, so you can see the overall plan. Next, you will be asked to complete some short questionnaires, talk about your experiences and complete some computerised tasks. You will then be given a length of time which will be either two or three weeks. During this time you will be asked to complete three ratings, once a day. These ratings will be given to you in a booklet that you can keep during the study time, like a diary. If you would like, the researcher can contact you to remind you to fill these in.

Step 4: Once the time period is over, the researcher will arrange to meet with you again. Together, you will complete the same measures that you did at the start, including the computerised tasks. The researcher will then arrange to visit you once every 3 days, to complete each computer package with you. You will start with five sessions of computer package A, followed by five sessions of computer package B, or vice versa. This means you will complete ten sessions in total, about one every three days. The dates and times of these sessions can be arranged to best suit you.

Step 5: After 5 sessions, the researcher will go through the same measures you did at the beginning of the study (the same as Step 3).

Step 6: After 10 sessions, the same interview and measures will be completed again (like in Step 5). Once this is finished, the researcher will arrange a time to meet with you one month later.

Step 7: During the one-month follow up period, you do not need to do anything, but can record any questions or comments for your follow up meeting if you wish.

Step 8: After one month, the researcher will complete the questionnaires, interview and computerised tasks with you for the final time (same as Step 3). The researcher will also ask for your opinion on using computer programme A to see what your experiences of it were like. This interview will be tape recorded. It will be used to explore your experiences of using computer programme A and what you thought about it. You do not have to take part in this interview if you don't want to. The interview will last about 30 minutes. All of the information will be kept secure.

Step 9: You will be thanked for your time and a monetary token of £10 will be given to you.

Participation in this research will last between eleven to twelve weeks, but there will be some long periods during this time when you will not need to do anything. The researcher can explain anything you want to ask about, anytime.

What is the therapy being tested?
This study is testing two types of computer-based therapeutic interventions.

Computer package A presents you with different stories about social activities and gives you the opportunity to practice different ways of thinking about the situations. You need to read the story and fill in the missing letter from the last word of the story. You will then be asked a question about the story, before moving on to the next story. Here is one example:

You arrange to have coffee with your friend. She arrives late and rushes into the café. She explains that she had found it difficult to find somewhere to [word presented with missing letter: p-rk]. [Correct word: park]. [Missing letter: a].Did you meet your friend in a café? [Correct response: Yes].

Computer package B shows you pictures and short videos of everyday events, such as sitting in a cafe, and asks you what you think about them. It breaks down the processes of how we make decisions about things. It explains how everybody jumps to conclusions about their decisions from time to time, because jumping to conclusions can be helpful, but sometimes it's hard to come to the right decision, without all the information. There are a few different exercises and videos to practice these ideas.

Expenses and payments
As a thank you for taking part in this study, you will be offered £10 at the completion of the study. Unfortunately, the researcher will not be able to reimburse your travel costs; however, all visits can be conducted at a location suitable for you, including your own home if you wish.

What will I have to do?
If you like, you could think about whether you would be interested in taking part. If you would like to talk about this informally, please feel free to contact the researcher using the information below. If you prefer, you could wait a few days and the researcher will try to get in touch with you, by telephone if possible.

At different points in time you will be asked to fill in some questionnaires, so that your progress can be monitored. During the therapy sessions, the researcher will talk to you about various way of thinking about your anxiety and guide you through a series of exercises on a computer.

We may wish to tape record some of your sessions with the researcher. This will be so that we can have a record of your experience of being involved in this study so that we can use this information to improve services for other people who have had similar experiences to you. However, if you do not feel comfortable with this, this will not happen. If you do agree to this, the tapes will be transcribed by a member of the research team and you will have the opportunity to read this transcription to make sure it is a true reflection of what was discussed. The tapes will be stored in a locked filing cabinet and destroyed at the end of the study.

What are the alternatives for treatment?
Alternative treatments than the ones being looked at in this study can be other talking therapies, such cognitive behavioural therapy. This therapy looks at how our thoughts, feelings and behaviours can influence how we feel about certain worries, and is available on the NHS. If you would like more information on this, please contact the researcher, using the information below.

What are the possible benefits of taking part?
The aim of computer package A is to help people to feel less worried and stressed about social situations. The aim of computer package B is also to help people gather more evidence about uncertain situations, which can help increase their confidence in the decision they have made about those situations.

We hope that these packages will help you. The information we get from this study may help us develop packages for others who experience social anxiety and worries.

What happens when the research study stops?
When the research study finishes, you will receive normal care from the service you have already been in contact with, or that referred you to this research. If you chose to delay any other treatment until the study ended, the service offering this will be in contact with you.

What if there is a problem?
Your care co-ordinator will know how you are getting on with the study. In the unlikely event that you are upset by taking part in any research project, there are no special compensation arrangements. If you are harmed by someone's negligence you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of the study, the normal National Health Service complaints procedure is available to you.

In the event that you become distressed while participating in this research, please contact the researcher, your GP services or primary care contact. If this is outside of normal working hours please contact your out of hours GP service, NHS direct (0845 4647) or the Samaritans (08457 90 90 90).

Will my taking part in this study be kept confidential?
Yes - all information that is collected about you during the course of the research will be kept strictly confidential. If the researcher is worried about risk to yourself or others during the course of the research then some information may need to be disclosed to relevant persons. This would be discussed with you first.

If you consent, the researcher will inform your GP and the team responsible for your care about your involvement in the study. The researcher will send them a very brief summary of the assessment, unless you do not wish them to do so. Research supervisors at the University of East Anglia may look at data connected to this study.

Involvement of the General Practitioner/Family Doctor (GP)
If you agree, a letter informing your GP about your involvement in this study will be sent. This is not necessary however, and if you would prefer that a letter is not sent, it will not be. Your consent to send a letter will be on the consent form.

Where and how long will records be stored?
Data will be stored in locked cabinets in local health care or university premises. It will be kept for ten years after the completion of the study and then destroyed.

What will happen to the results of the research study?
The results of the study will be reported as anonymous data. The study will be seen by colleagues and supervisors at the University of East Anglia, and other members of the research team. Results may also become available more publicly if the research is published, however no identifiable material will be published.

Who is organising and funding the research?
The study has been designed by James Hurley (Trainee Clinical Psychologist at the University of East Anglia), and his research supervisors. The research is being carried out as part of training for a Doctorate in Clinical Psychology.

Who has reviewed the study?
The research has been considered and approved by the NHS Research Ethics Committee. The research has also been reviewed and approved by the University of East Anglia.

Contact for further information:
If you would like any more information about the study or need to contact the researcher, please feel free to contact James Hurley (Trainee Clinical Psychologist):

Doctoral Programme in Clinical Psychology
University of East Anglia
Elizabeth Fry Building
Norwich
Norfolk
NR4 7TJ

Tel: 07585203167
Email: james.hurley@uea.ac.uk

Alternatively, you could contact
Dr Jo Hodgekins
Clinical Lecturer
Doctoral Programme in Clinical Psychology
Department of Clinical Psychology
Norwich Medical School
University of East Anglia
Norwich
NR4 7TJ

Tel: +44 (0)1603 59 1890
Email: j.hodgekins@uea.ac.uk

For independent advice on participating in research, you can also contact your local Patient Advice and Liaison Service (PALS) at NSFT, Drayton High Road, Hellesdon, NR6 5BE or telephone 01603 421421.

Appendix 2 – Participant Information Sheet Cover Letter

Mr James Hurley, Trainee Clinical Psychologist
Doctoral Programme in Clinical Psychology
University of East Anglia
Elizabeth Fry Building
Norwich
Norfolk
NR4 7TJ

Tel: XXXXXXXXXX
Email: james.hurley@uea.ac.uk

[Participant Name]
[Participant Address]

[Date]

Dear [Participant Name],

Re: A study exploring the usefulness of computer packages designed to help with social anxiety and thinking style

I am writing to invite you to take part in a research study being conducted as part of my clinical psychology training at the University of East Anglia. I received your name, address and telephone number from [Contact Name and Position] who has already spoken to you briefly about taking part in this study.

Please find enclosed a participant information sheet, which explains the study and what would be involved for you if you decide to take part.

Your participation in this study would be greatly appreciated.

If you have any questions or would like to discuss any aspects of the research study, please do not hesitate to contact me. I will be contacting you by telephone in a few days to see if you might be interested.

Best wishes,

_____

James Hurley
Trainee Clinical Psychologist

Appendix 3 – Informed Consent Form

Centre Number:

Study Number:

Participant Identification Number for this study:

CONSENT FORM

Title of Project: A study exploring the usefulness of computer packages designed to help with social anxiety and thinking style

Name of Researcher: James Hurley

Please initial box

1. I confirm that I have read and understand the information sheet dated 16/07/13 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

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

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by the researcher, from regulatory authorities or from the NHS trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. If I withdraw/am withdrawn from the study, I am willing for information that I have provided during the course of the study to be used for research purposes, as stated in the information sheet dated 16/07/13 (version 3).

5. I agree to my GP and care team/clinician involved in my care to be informed of my participation and completion of this project, and for assessment information to be shared with my GP and care team.

6. I give my consent for a qualitative semi-structured interview and for a recording of this to be made. I understand that this is for the purposes of transcribing information, and that any person hearing the tape(s) will sign a declaration of confidentiality and that recordings will be stored under locked conditions.

7. I agree to take part in the above study.

_____   _____   _____

Name of Participant   Date   Signature

_____   _____   _____

Name of Person taking consent   Date   Signature

Appendix 4 – Copies of all measures to be used

CHORD	SUPERFLUOUS
ACHE	SIMILE
DEPOT	BANAL
AISLE	QUADRUPED
BOUQUET	CELLIST
PSALM	FAÇADE
CAPON	ZEALOT
DENY	DRACHM
NAUSEA	AEON
DEBT	PLACEBO
COURTEOUS	ABSTEMIOUS
RAREFY	DÉTENTE
EQUIVOCAL	IDYLL
NAÏVE	PUERPERAL
CATACOMB	AVER
GAOLED	GAUCHE
THYME	TOPIARY
HEIR	LEVIATHAN
RADIX	BEATIFY
ASSIGNATE	PRELATE
HIATUS	SIDEREAL
SUBTLE	DEMESNE
PROCREATE	SYNCOPE
GIST	LABILE
GOUGE	CAMPANILE

Appendix 4 - Measures

PSYRATS PART B Delusions
1 Amount of preoccupation with delusions
0 No delusions, or delusions which the subject thinks about less than once a week
1 Subject thinks about beliefs at least once a week
2 Subject thinks about beliefs at least once a day
3 Subject thinks about beliefs at least once an hour
4 Subject thinks about delusions continuously or almost continuously
2 Duration of preoccupation with delusions
0 No delusions
1 Thoughts about beliefs last for a few seconds, e.g. fleeting thoughts
2 Thoughts about delusions last for several minutes
3 Thoughts about delusions last for at least 1 hour
4 Thoughts about delusions usually last for hours at a time
3 Conviction
0 No conviction at all
1 Very little conviction in reality of beliefs, <10%
2 Some doubts relating to conviction in beliefs, between 10-49%
3 Conviction in belief is very strong, between 50-99%
4 Conviction is 100%
4 Amount of distress
0 Beliefs never cause distress
1 Beliefs cause distress on the minority of occasions
2 Beliefs cause distress on <50% of occasions
3 Beliefs cause distress on the majority of occasions when they occur between 50-99% of time
4 Beliefs always cause distress when they occur
5 Intensity of distress
0 No distress
1 Beliefs cause slight distress
2 Beliefs cause moderate distress
3 Beliefs cause marked distress
4 Beliefs cause extreme distress, could not be worse
6 Disruption to life caused by beliefs
0 No disruption to life, able to maintain independent living with no problems in daily living skills. Able to maintain social and family relationships (if present).
1 Beliefs cause minimal amount of disruption to life, e.g. interferes with concentration although able to maintain daytime activity and social and family relationships and be able to maintain independent living without support
2 Beliefs cause moderate amount of disruption to life causing some disturbance to daytime activity and/or family or social activities. The patient is not in hospital although may live in supported accommodation or receive additional help with daily living skills
3 Beliefs cause severe disruption to life so that hospitalisation is usually necessary. The patient is able to maintain some daily activities, self-care and relationships while in hospital. The patient may be also be in supported accommodation but experiencing severe disruption of life in terms of activities, daily living skills and/or relationships 4 Beliefs cause complete disruption of daily life requiring hospitalization. The patient is unable to maintain any daily activities and social relationships. Self-care is also severely disrupted

Appendix 4 - Measures

Explanations of Experiences

We've talked a bit about the things that led you to conclude…………You talked about…………that happened at the start and…………that has happened since. Asking you to think about it now can you think of any other explanations for the experiences that you have described? Are there any other reasons—other than…………that could possibly account for these experiences even if you think they are very unlikely?

Appendix 4 - Measures

Explanations of Experiences

Are there any other reasons that could possibly account for your experiences even if you think they are very unlikely?

Explanation 1:

How much do you *believe this is true*?

0 – 100%

How much does this explanation **upset** you?

0 – 100%

Explanation 2:

How much do you *believe this is true*?

0 – 100%

How much does this explanation **upset** you?

0 – 100%

Explanation 3:

How much do you *believe this is true*?

0 – 100%

How much does this explanation **upset** you?

0 – 100%

Appendix 4 - Measures

<u>JTC</u>

<mark>*Ok, we're now going to do a task using my laptop.*</mark> Do JTC.

<u>Trial 1</u>

- Correct/Incorrect
- Number of beads taken…………

<u>Trial 2</u>

- Correct/Incorrect
- Number of beads taken…………

REFER TO REFERENCE BOOKLET OF SLIDES TO KEEP TRACK.

Appendix 4 - Measures

Belief Ratings Scale

So, still thinking about your worries that……….. (state belief and write below, if reminder needed):

Please rate how you have been feeling over the last week about …………. *by rating from 0-100%*

_____%

Ask the first item, *How much do you believe this is true*? (How much do you believe it right now, not how much is it happening right now) and rate.

Then ask:

*When you think about it now, is it at all **possible that you are mistaken** about this?*

Hesitant: Yes/No

Write down the person's response, and whether they hesitate, then ask to fill in visual analogue scale as well.

Let me suggest something to you – something that does not fit with your view and you could tell me how you think you would react right now.

Suggestion:

Response:

RTHC -		
	Ignores or rejects	3
	Accommodates	2
	Changes conviction	1
	Dismisses belief	0

Appendix 4 - Measures

Green et al. Paranoid Thought Scales

Participant Code:_____   Date:_____

Please read each of the statements carefully.
They refer to thoughts and feelings you may have had about others over the last month.
Think about the last month and indicate the extent of these feelings from 1 (Not at all) to 5 (Totally).
Please complete both Part A and Part B.

(N.B. Please do not rate items according to any experiences you may have had under the influence of drugs.)

Part A

Item No	Item	Not at all		Somewhat		Totally
1	I spent time thinking about friends gossiping about me	1	2	3	4	5
2	I often heard people referring to me	1	2	3	4	5
3	I have been upset by friends and colleagues judging me critically	1	2	3	4	5
4	People definitely laughed at me behind my back	1	2	3	4	5
5	I have been thinking a lot about people avoiding me	1	2	3	4	5
6	People have been dropping hints for me	1	2	3	4	5
7	I believed that certain people were not what they seemed	1	2	3	4	5
8	People talking about me behind my back upset me	1	2	3	4	5
9	I was convinced that people were singling me out	1	2	3	4	5
10	I was certain that people have followed me	1	2	3	4	5
11	Certain people were hostile towards me personally	1	2	3	4	5
12	People have been checking up on me	1	2	3	4	5
13	I was stressed out by people watching me	1	2	3	4	5

Item No	Item					
14	I was frustrated by people laughing at me	1	2	3	4	5
15	I was worried by people's undue interest in me	1	2	3	4	5
16	It was hard to stop thinking about people talking about me behind my back	1	2	3	4	5

Part B

Item No	Item	Not at all		Somew hat		Totally
1	Certain individuals have had it in for me	1	2	3	4	5
2	I have definitely been persecuted	1	2	3	4	5
3	People have intended me harm	1	2	3	4	5
4	People wanted me to feel threatened, so they stared at me	1	2	3	4	5
5	I was sure certain people did things in order to annoy me	1	2	3	4	5
6	I was convinced there was a conspiracy against me	1	2	3	4	5
7	I was sure someone wanted to hurt me	1	2	3	4	5
8	I was distressed by people wanting to harm me in some way	1	2	3	4	5
9	I was preoccupied with thoughts of people trying to upset me deliberately	1	2	3	4	5
10	I couldn't stop thinking about people wanting to confuse me	1	2	3	4	5

11	I was distressed by being persecuted	1	2	3	4	5
12	I was annoyed because others wanted to deliberately upset me	1	2	3	4	5
13	The thought that people were persecuting me played on my mind	1	2	3	4	5
14	It was difficult to stop thinking about people wanting to make me feel bad	1	2	3	4	5
15	People have been hostile towards me on purpose	1	2	3	4	5
16	I was angry that someone wanted to hurt me	1	2	3	4	5

Appendix 4 - measures

Social Interaction Anxiety Scale

Instructions

In this section, for each item, please circle the number to indicate the degree to which you feel the statement is characteristic or true for you. *The rating scale is as follows:*

0	=	**Not at all** characteristic or true of me.
1	=	**Slightly** characteristic or true of me.
2	=	**Moderately** characteristic or true of me.
3	=	**Very** characteristic or true of me.
4	=	**Extremely** characteristic or true of me

	Characteristic	Not at all	Slightly	Moderately	Very	Extremely
01.	I get nervous if I have to speak with someone in authority (teacher, boss).	0	1	2	3	4
02.	I have difficulty making eye contact with others.	0	1	2	3	4
03.	I become tense if I have to talk about myself or my feelings.	0	1	2	3	4
04.	I find it difficult to mix comfortably with the people I work with.	0	1	2	3	4
05.	I find it easy to make friends my own age.	0	1	2	3	4
06.	I tense up if I meet an acquaintance in the street.	0	1	2	3	4
07.	When mixing socially, I am uncomfortable.	0	1	2	3	4
08.	I feel tense when I am alone with just one person.	0	1	2	3	4
09.	I am at ease meeting people at parties, etc.	0	1	2	3	4
10.	I have difficulty talking with other people.	0	1	2	3	4
11.	I find it easy to think of things to talk about.	0	1	2	3	4
12.	I worry about expressing myself in case I appear awkward.	0	1	2	3	4
13.	I find it difficult to disagree with another's point of view.	0	1	2	3	4

(continued)

	Characteristic	Not at all	Slightly	Moderately	Very	Extremely
14.	I have difficulty talking to attractive persons of the opposite sex.	0	1	2	3	4
15.	I find myself worrying that I won't know what to say in social situations.	0	1	2	3	4
16.	I am nervous mixing with people I don't know well.	0	1	2	3	4
17.	I feel I'll say something embarrassing when talking.	0	1	2	3	4
18.	When mixing in a group, I find myself worrying I will be ignored.	0	1	2	3	4
19.	I am tense mixing in a group.	0	1	2	3	4
20.	I am unsure whether to greet someone I know only slightly.	0	1	2	3	4

Appendix 5 – Idiographic Measures of anxiety, paranoia and conviction

Daily measures of anxiety, worry and belief certainty

For a, b and c, please pick any percentage (0-100%) which best describes how you are feeling. Use the examples below as a guide and write down a percentage in each space, e.g. 53%.

A. **Today, I am feeling _____% socially anxious**

0%	**=**	**Not at all socially anxious**
25%	**=**	**Somewhat socially anxious**
50%	**=**	**Moderately socially anxious**
75%	**=**	**Very socially anxious**
100%	**=**	**Extremely socially anxious**

B. **Today, I am feeling under threat from others: _____%**

0%	**=**	**Not at all**
25%	**=**	**Somewhat**
50%	**=**	**Moderately**
75%	**=**	**Very**
100%	**=**	**Absolutely**

C. **Thinking about your main worry, how much do you believe it is true? _____%**

0%	**=**	**Not at all**
25%	**=**	**Somewhat**
50%	**=**	**Moderately**
75%	**=**	**Very**
100%	**=**	**Absolutely**

Appendix 6 – examples of CBM-I scenarios developed by Turner et al. (2011)

You arrange to have coffee with your friend. She arrives late and rushes into the café. She explains that she had found it difficult to find somewhere to [word presented with missing letter: p-rk]. [Correct word: park]. [Missing letter: a].Did you meet your friend in a café? [Correct response: Yes].

You plant some tomato seeds. After a couple of weeks the seedlings start to grow. In the summer you will be able to have home grown tomatoes in your [word presented with missing letters: s—ad}. [Correct word: salad]. [Missing letters: al]. Did your tomato plants grow? [Correct response: Yes].

You watch a comedian on the television. Some of their jokes are not very funny. You decide to find something else to watch, and so you change [word presented with missing letters: c-an-el]. [Correct word: channel]. [Missing letters: h, n]. Was the comedian funny? [Correct response: No].

You arrange to have coffee with your friend. She arrives late and rushes into the café. She explains that she had found it difficult to find somewhere to [word presented with missing letter: p-rk]. [Correct word: park]. [Missing letter: a].Did you meet your friend in a café? [Correct response: Yes].

Appendix 7 – synopses of the Maudsley Review Training Programme, Waller et al., 2011

Task 1: 'What's the Picture?'

This task introduces the idea that it can be difficult to come to an informed decision without all of the evidence. This teaches participants to look for more evidence before making a decision.

Task 2: 'illusions.'

This introduces the idea that things are not always as they first seem and that sometimes we only see part of the story, which can lead us to jump to conclusions and make mistakes. A series of optical illusions are presented, which helps to illustrate this.

Task 3: 'first impressions'

This task gives 3 real life examples in video vignettes of scenarios. Participants are asked to rate what they believe is going on at early stages of the scenarios, which illustrates how we can all make incorrect assumptions, if we do not slow down and gather all the necessary evidence.

Task 4: 'looking for other possible explanations.'

This introduces the idea of thinking flexibly about alternative explanations before reaching a conclusion. 3 video vignettes are shown, each with the option of positive, neutral or paranoid interpretation. Participants are encouraged at various points to use the interactive software to interpret the scenario as they see fit, with a debrief after the end of each vignette, depending on their interpretation.

Task 5: 'JTC summary'

This final task is aimed at being somewhat light-hearted, allowing review of the key learning points throughout the tasks. Participants are shown 4 video scenarios, involving characters who jump to conclusions. They are encouraged to identify who the characters that jump to conclusions will be. Finally, they are asked about how the characters might have avoided the situations they got themselves into, by not jumping to conclusions.

Appendix 8 – Pilot Interview Schedule (adapted from Bendelin & Dahl, 2011)

General opinion

Description
How would you describe the treatment you've been through?
Please tell me what you did in the treatment?

Attitude
How did you experience this treatment?
How has your life changed as a result of the treatment?
If you were in the position to modify this treatment program based on your experiences of it, what would you choose to change, withdraw or add?
Please tell me your view of computerised therapy.

The accomplishment of the treatment

Surroundings, time plan, structure of work, privacy-openness,
How did you complete the treatment?
How did others in your life find the treatment?
Did the treatment lead to any practical changes in your everyday life?
Is there any part of the material that you particularly remember?

Efficient mechanisms, reinforcement
What parts of the treatment were most important to you?
Did you find any parts troublesome? Describe these please.
Did you find your anxiety improving? What do you think improved your anxiety?

Motivation, resistance, ambivalence, doubts
What motivated you during the treatment?
Did you have any doubts throughout the treatment time?

Processes of change, key moments, problem situations, time
Was there a certain point in the treatment when you felt things were changing for you? Can you describe this?
Were there any moments of difficulty during treatment where you felt that nothing was happening in the treatment? Can you please describe this?
To what extent could you yourself decide about the pace of the treatment?

After the treatment

Experiences at the end of treatment, hopes
How did you feel when the treatment was over?
How did you find the treatment before you entered it and now afterwards?

Power, attribution of results
What was your view on your problem before entering treatment?
What is the reason for how you feel today?
Has your view on your difficulties changed in any way?

General opinion, recommendation
Do you feel that this treatment has helped you? In what way has this treatment helped you?

Life ahead
How has life been since the treatment?
Do you have any other thoughts about going through this that you would like to share?
How has it been like to do this interview?
Is there anything you'd like to ask me?

Appendix 9 –Letter to care coordinator/GP

Mr James Hurley, Trainee Clinical Psychologist
Doctoral Programme in Clinical Psychology
University of East Anglia
Elizabeth Fry Building
Norwich
Norfolk
NR4 7TJ

Tel: XXXXXXXXXXX
Email: james.hurley@uea.ac.uk

[Clinician Name]
[Clinician Address]

[Date]

Dear [Clinician Name],

Re: A study exploring the usefulness of computer packages designed to help with social anxiety and thinking style

I am writing to confirm that your client/patient Mr/Ms XXXXXX has given informed consent (see copy of the consent form) to participate in the above research programme.

Please find enclosed a participant information sheet, which explains the study and what would be involved for Mr/Ms XXXXXXXX.

Upon completion of the project, I will send another letter to you summarising what Mr/Ms XXXXXXX participated in.

If you have any questions or would like to discuss any aspects of the research study, please do not hesitate to contact me.

Best wishes,

_____

James Hurley
Trainee Clinical Psychologist

Cc   GP

Appendix 10: Screenshot of the MRTP (Waller et al., 2011).

TASK 4: DIFFERENT EXPLANATIONS

You're in a pub or cafe and notice someone seems to be pointing and staring in your direction

TASK 4: DIFFERENT EXPLANATIONS

Can you think of some possible explanations for what might be going on?

1.
2.
3.
4.
5.
6.

Idea: They have met you before and recognise you.

Give me an Idea   Continue

TASK 4: DIFFERENT EXPLANATIONS

At this stage it is difficult to work out what is going on!

Let's...

Slow down to avoid hasty decisions!

And...

Look for more evidence before reaching a conclusion!

TASK 4: DIFFERENT EXPLANATIONS

Gather more information before coming to a conclusion!

Click on each box to gather more information

Look at the clip again   Look around you   Look more closely at the person

Come to a conclusion

TASK 4: DIFFERENT EXPLANATIONS

Look more closely at the person

TASK 4: DIFFERENT EXPLANATIONS

Look around you

TASK 4: DIFFERENT EXPLANATIONS

Some people watching that scene might jump to the conclusion that the person was pointing angrily at them!

BUT slowing down our decision making and looking closely around us showed us that the person was actually watching sport on the television behind!

TASK 4: DIFFERENT EXPLANATIONS

Jumping to that conclusion can affect how we feel and act!

In this case, jumping to the conclusion that the person was pointing angrily could have made us feel upset or angry

It could affect our behaviour, e.g. By making us leave the pub, or even becoming angry with the person

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Appendix 11 – REC Letter of Approval

NRES Committee East of England - Norfolk

Nottingham REC Centre
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 8839368

14 June 2013

Mr James Hurley
ClinPsyD Office
Elizabeth Fry Building
University of East Anglia
NR4 7TJ

Dear Mr Hurley

Study title:	Investigating the differential efficacy of Cognitive Bias Modification for Interpretation and the Maudsley Review Training Programme on social anxiety and reasoning biases in individuals with persecutory delusions: a single case series.
REC reference:	13/EE/0134
Protocol number:	N/A
IRAS project ID:	120141

Thank you for your letter of 24 May 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

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

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Ms Tracy Leavesley, NRESCommittee.EastofEngland-norfolk@nhs.net

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.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Evidence of insurance or indemnity	UEA - Zurich Municipal	15 May 2012
GP/Consultant Information Sheets	1	15 October 2012
Interview Schedules/Topic Guides	Pilot Interview Schedule - Version 1	15 October 2012
Investigator CV	James Hurley	18 April 2013
Investigator CV	Professor David Fowler	12 November 2012
Letter of invitation to participant	1	15 October 2012

Other: Participant Recruitment Flow Diagram	1	15 October 2012
Other: Scenario Examples	1	15 October 2012
Other: MRTP Task Summaries	1	15 October 2012
Other: Flow Chart	1	15 December 2012
Participant Consent Form	1	15 October 2012
Participant Information Sheet	4	07 June 2013
Protocol	1	16 October 2012
Questionnaire: Validated Questionnaires	1	15 October 2012
Questionnaire: Non-Validated Questionnaire	1	15 October 2012
REC application	120141/439808/1/666	31 January 2013
Referees or other scientific critique report	Thesis Proposal Assessment and summary	06 November 2012
Response to Request for Further Information	Letter from James Hurley	24 May 2013

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/EE/0134   Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Michael Sheldon
Chair

Email:NRESCommittee.EastMidlands-Derby@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Ms Deborah Graver, UEA

                     Ms Bonnie Teague, Norfolk and Suffolk Foundation Trust

Appendix 12 – NSFT R&D Letter of Access

Norfolk and Suffolk **NHS**

NHS Foundation Trust

Research and Development
The Knowledge Centre
Hellesdon Hospital
Drayton High Road,
Norwich, NR65BE
Telephone 01603 421255
E mail: RDofficemailbox@nsft.nhs.uk

Mr James Hurley,
ClinPsyD Office
Elizabeth Fry Building
University of East Anglia
Norwich Research Park
Norwich
NR4 7TJ

31st July 2013

Dear Mr Hurley,

Re: 2013MH15 Exploring two computerised packages for worries about being harmed v1

Thank you for submitting the above project for local research governance approval. I am pleased to inform you that your project has been given full approval and you may begin your research at the following site:
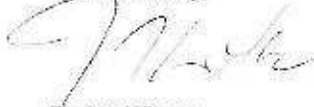
- Norfolk & Suffolk NHS Foundation Trust

I have enclosed two copies of the Standard Terms and Conditions of Approval. Please sign both copies returning one copy to the Research and Development office, at the above address, and keeping the other in your study file. Failure to return the standard terms and conditions may affect the conditions of approval. **Under the agreed Standard Terms and Conditions of Approval you must inform the R&D department of any proposed changes to this study and submit annual progress reports to the R&D department.**

Any researcher(s) whose substantive employer is not the Norfolk & Suffolk NHS Foundation Trust must have a Letter of Access or Honorary Research contract and evidence of Good Clinical Practice (GCP) training before coming on site to conduct their research in this project. Please note that you cannot take part in this study until you have this documentation. If a Letter of Access / Honorary Research Contract has not been issued – please contact us immediately.

If you have any queries regarding this or any other project. please contact, Tom Rhodes, Research Governance Administrator, at the above address.

The reference number for this study is: **2013MH15**, and this should be quoted on all correspondence.

Yours sincerely,

Dr Jon Wilson
Deputy Medical Director (Research)

MINDFUL EMPLOYER

Chair: Gary Page
Acting Chief Executive: Andrew Hopkins
Trust Headquarters: Hellesdon Hospital,
Drayton High Road, Norwich, NR6 5BE
Tel: 01603 421421 Fax: 01603 421440 www.nsft.nhs.uk

Stonewall
DIVERSITY CHAMPION

Your research governance approval is valid providing you comply with the conditions set out below:

1. You commence your research within one year of the date of this letter. If you do not begin your work within this time, you will be required to resubmit your application.
2. You notify the Research and Development Office should you deviate or make changes to the approved documents.
3. You alert the Research and Development Office by contacting the address above, if significant developments occur as the study progresses, whether in relations to the safety of individuals or to scientific direction.
4. You complete and return the standard annual self-report study monitoring form when requested to do so at the end of each financial year. Failure to do this will result in the suspension of research governance approval.
5. You comply fully with the Department of Health Research Governance Framework and Trust Research Policies, and in particular that you ensure that you are aware of and fully discharge your responsibilities in respect to Data Protection, Health and Safety, financial probity, ethics and scientific quality. You should refer in particular to Sections 3.5 and 3.6 of the Research Governance Framework.
6. You ensure that all information regarding patients or staff remains secure and strictly confidential at all times. You ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice, Data Protection Act and Human Rights Act. Unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.
7. **UKCRN Portfolio Studies** only: You will make local Trust research team members aware that it is expected that the "first participant, first visit" date should be within 70 days of the full submission for Trust Research Governance Approval, and this date must be reported to the Research and Development office using the email address above. Delay to recruitment due to study-wide developments must be reported to the Trust as soon as possible.
8. **UKCRN Portfolio Studies** only: You will report and upload Trust recruitment to the UKCRN portfolio accurately and in a timely manner, and will provide recruitment figures to the Trust upon request.

List of Approved Documents:

Documents		
Protocol	1	16.10.12
Participant Information Sheet	5	16.07.13
Participant Consent Form	3	16.07.13
CBMI Scenario Examples	1	15.12.12
Flow Chart	1	15.10.12
Participant Cover Letter	1	15.12.12
Validated Questionnaire	1	15.10.12
Non Validated Quesionnaire	1	15.10.12
Participant Recruitment Flow Diagram	1	15.10.12
MRTP Task Summaries	1	15.10.12
Pilot Interview Schedule	1	15.10.12
GP Cover Letter	1	15.12.12

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