Doctoral Thesis

A Cognitive Bias Modification for Interpretation (CBM-I) Task with Individuals Experiencing Clinical Levels of Generalised Anxiety: A Single Case Series

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Abstract

Objectives

The study investigated the efficacy of an online multi-session cognitive bias modification for interpretation (CBM-I) package for reducing worry and negative interpretive bias in individuals presenting with clinical levels of generalised anxiety.

Design

Single case-series using a non-concurrent multiple-baseline across participant design with follow-up.

Method

Seven patients referred from Psychological Wellbeing Services completed a seven day CBM-I programme at home via the internet. The CBM-I task trained the participants to imagine ambiguous scenarios and to interpret them in a benign or positive manner. To assess change in worry, anxiety and interpretive bias, participants completed a battery of self report measures.

Results

Two participants demonstrated a positive response in their level of worry upon starting the CBM-I training and for both, gains were maintained one week after its completion. For the sample as a whole, negative interpretation bias reduced at post CBM-I and at one week follow-up.

Conclusions

The results indicate the potential value of CBM-I as a clinical tool for modifying interpretation bias in patients experiencing clinical levels of generalised anxiety. The ability of CBM-I to attenuate generalised anxiety disorder (GAD) associated symptomatology appears equivocal. In light of methodological constraints, the findings are tentative warranting further investigation.

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What a journey.

But I've not been alone.

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Contents

List of Tables

List of Figures

Introduction

1.1 Overview

The chapter begins with an overview of the symptoms and epidemiology of Generalised Anxiety Disorder (GAD). General cognitive theory as applied to pathological worry; the defining feature of GAD, is described followed by a consideration of GAD - specific cognitive conceptualisations and the efficacy of cognitive-based treatments. An information processing understanding of GAD is then presented, focusing on the role of interpretation bias. Following this, computer-based tasks that attempt to modify interpretation bias in a bid to ameliorate GAD associated symptoms (called 'cognitive bias modification for interpretation'; CBM-I) are discussed. A structured review of the literature critiques studies that have investigated CBM-I specifically in anxious individuals. Recent developments in understanding the importance of imagery in CBM-I are then described. The chapter concludes by outlining the research hypotheses investigated in the present study.

1.2 Generalised Anxiety Disorder (GAD)

1.2.1 Symptoms.

According to the Diagnostic and Statistical Manual of Mental Disorders-fifth edition (DSM-V), GAD is a disorder characterised by excessive, uncontrollable worry and anxiety about a number of different events or activities that causes symptoms such as restlessness, muscle tension and irritability (American Psychiatric Association; APA, 2013). For a formal diagnosis to be considered using the DSM-V classification, all symptoms must have been present for at least 6 months and cause clinically significant distress or impairment in social, occupational or other important areas of functioning (APA, 2013).

1.2.2 Prevalence and epidemiology.

GAD is one of the most common anxiety disorders seen in primary care with a current prevalence rate of between 3.7% and 8%, and a 12 month prevalence rate of 10% (Holaway,

Rodebaugh, & Heimburg, 2006). Investigations of clinical populations have found the typical age of onset of GAD to be between the late teens and late 20s, with later onset occurring when GAD develops after another anxiety disorder (e.g., Barlow, Blanchard, Vermilyea, Vermilyea, & DiNardo, 1986; Yonkers, Warshaw, Massion, & Keller, 1996).

Epidemiology surveys and long term investigations have found GAD to be a pervasive condition. In the Epidemiologic Catchment Area (ECA) study in the United States, 40% of respondents with GAD reported having had it for more than five years (Blazer, Hughes, George, Swartz, & Boyer, 1991). Participants in clinical samples have often reported suffering from GAD for more than 20 years (Barlow et al., 1986). Regarding remission rates, Yonkers et al. (1996) found that only 40% of individuals with GAD were in full remission of symptoms after two years. The same study later found the full remission rate to be 38% after five years, with 27% experiencing a full relapse at some point during the follow-up (Yonkers, Dyck, Warshaw, & Keller, 2000).

The degree of co-morbidity between GAD and other psychiatric disorders is high. Sanderson and Barlow (1990) found that 59% of their 22 patients meeting GAD criteria also met criteria for social phobia. They also found that 27% met criteria for panic disorder and that depression was reported by 14%. Yonkers et al. (1996) reported that of their GAD sample, 52% also fulfilled panic disorder or panic with agoraphobia criteria, 32% had clinical levels of social phobia and 37% fulfilled the major depression criteria.

Personality disorders and also substance abuse are often associated with GAD. In one study almost half of the GAD patients qualified as having some type of personality disorder (Sanderson & Wetzler, 1991). Grant et al. (2004) conducted a large scale survey that comprised of over 43,000 respondents in the United States and found GAD to have a lifetime co-morbidity prevalence of 25-35% with drug/alcohol abuse and dependence.

Research by Schacter, Gilbert, and Wegner (2011) found that the populations most at

risk of developing GAD are individuals of low and middle socio-economic status and separated, divorced and widowed individuals. There are also gender differences for it is around twice as prevalent amongst women as it is amongst men. The authors suggested this as being related to the fact that women are reportedly more likely than men to live in poverty and to be the victims of discrimination and abuse.

1.3 Cognitive Theory of GAD

1.3.1 Worry.

Pathological worry is the cardinal feature of GAD (DSM-V) and has much in common with rumination, normally associated with depression, as both are characterised by repetitive thinking concerning negative self-relevant topics (Nolen-Hoeksema, 1991). In fact a series of factor analyses conducted on questionnaires designed to measure these two constructs failed to reveal clear independent underlying factors (Segerstrom, Tsao, Alden, & Craske, 2000). Nevertheless the content of what is labelled as worry and rumination is typically different. 'Worry' tends to describe thoughts of perceived threat whereas 'rumination' tends to be applied to thoughts of past negative events or of self-criticism (Watkins, Moulds, & Mackintosh, 2005).

Studies have consistently found that people who experience pathological worry as part of GAD rate their worry as more pervasive and less controllable than people without pathological worry (e.g., Craske, Rapee, Jackel, & Barlow, 1989). Studies comparing the content of worry among GAD individuals and non-anxious controls report mixed results. The majority of studies have found interpersonal relationships to be the most common domain of worry, however this has been found to be the case for both GAD individuals and non-anxious individuals alike (e.g., Sanderson & Barlow, 1990). The most consistent findings regarding differences in worry content between non-anxious controls and GAD samples have been miscellaneous worry topics (e.g., car mechanical issues or arriving late at an appointment).

Across three studies, miscellaneous worry topics reported by non-anxious controls accounted for between 0% and 20% of all reported worries whereas among individuals diagnosed with GAD the proportion of miscellaneous worries was between 25% and 31% (e.g., Borkovec, Shadick, & Hopkins, 1991; Craske et al., 1989; Roemer, Molina, & Borkovec, 1997).

Whilst it is clear that individuals with GAD worry significantly more than individuals without an anxiety disorder (Holaway et al., 2006), it is less clear why it is so difficult for individuals with GAD to disengage from worry. Although anticipation of probable danger can be adaptive (Beck, 1976), there seems little adaptive value in excessive worry persisting for unlikely events causing debilitating distress. As part of an attempt to understand this process better, a number of cognitive models of GAD (e.g., Borkovec, 1994; Dugas, Letarte, Rheaume, Freestone, & Ladouceur, 1995; Wells, 1995) have emerged since GAD was recognised as an independent diagnostic construct. Each of these models focus on important aspects of beliefs, attitudes and thought patterns associated with pathological worrying in GAD to create idiosyncratic conceptualisations.

1.3.2 Cognitive models of GAD.

The Avoidance Model of Worry and GAD (AMW; Borkovec, 1994; Borkovec, Alcaine, & Behar, 2004) proposes that worry is a thought-based activity that operates as a form of avoidance particularly of emotional processing. As part of this process, distressing mental imagery is replaced by less distressing, less somatically intolerable, verbal linguistic activity. The model holds that worry is maintained by negative reinforcement and positive beliefs about worrying. In terms of empirical backing for the model, there is evidence to support worrying being a verbal linguistic process rather than an imagery-based process (Behar & Borkovec, 2005). There is also some evidence that finds worrying to have a somatic reducing effect (Borkovec & Hu, 1990; Borkovec, Lyonfields, Wiser, & Deihl, 1993; Peasley-Miklus & Vrana, 2000; Thayer, Friedman, & Borkovec, 1996).

The Intolerance of Uncertainty Model (IUM; Dugas, Buhr, & Ladouceur, 2004; Dugas et al., 1995) proposes, as its name suggests, that individuals with GAD are unable to tolerate uncertainty very well. Rather, any situation with ambiguity or uncertainty triggers chronic worry. Individuals with GAD believe that worrying will help them either cope with feared events or stop them from happening in the first place. The IUM proposes that worry and the associated emotions results in a negative problem orientation and cognitive avoidance, both of which maintain the worry. The model is supported by evidence linking GAD with negative problem orientation (Robichaud & Dugas, 2005) and IU (Dugas, Marchand, & Ladouceur, 2005; Ladouceur et al., 1999).

Finally, the Metacognitive Model (MCM; Wells, 1995) uniquely includes positive and negative beliefs in its explanation of pathological worry. The model distinguishes between Type 1 worry – which refers to concern about external and non-cognitive threats and Type 2 worry or 'meta worry' – which is essentially worry about worry. The individual with GAD is understood as essentially being locked in a continual conflict between positive and negative beliefs about worry. A growing body of evidence supports several aspects of the MCM, for example positive and negative beliefs about worry have been found to predict proneness to pathological worry (e.g., Cartwright-Hatton & Wells, 1997) and distinguish GAD from other anxiety disorders (Wells, 2001). Also, Type 2 worry has been found to be a key predictor of pathological worry (Wells & Carter, 1999).

The cognitive models share a common emphasis on the central role that avoiding internal experiences plays in the maintenance of worry. For example, the AMW posits that worry is a strategy for avoiding uncomfortable emotions, the IUM identifies worry as a strategy for avoiding uncertainty and the MCM focuses on individuals engaging in strategies aimed at avoiding worrying about worry. However there are also key theoretical differences. For the AMW, the crucial factor maintaining pathological worry is its usage as a means of

avoiding emotional processing whereas for the MCM and the IUM, metacognitive beliefs about worry and an intolerance of uncertainty are the key factors, respectively.

Furthermore the treatments proposed by each are unique. The therapy protocol developed from the AMW involves a variety of different components including the identification of and exposure to threatening cues that are habitually avoided, relaxation training, cognitive restructuring, and more recently, interpersonal and emotional processing (IEP) difficulties (Borkovec, 2006). Interventions derived from the IUM include challenging IU by applying problem-solving techniques to addressable worries, altering positive beliefs about worry, appreciating the role of IU in worry, using imaginal exposure to deal with core beliefs and carrying out behavioural exposure to uncertainty- triggering situations (Robichaud & Dugas, 2006). In Metacognitive therapy, derived from the MCM, emphasis is on modifying the dysfunctional metacognitive beliefs and reducing usage of worry (Wells, 2006).

1.3.3 Efficacy of cognitive therapy for GAD.

Despite important conceptual differences in the treatments that have been developed from each of the cognitive models they all have common components including psycho-education, self-monitoring, and a focus on facilitating patients to tolerate uncomfortable internal experiences (Behar, DiMarco, Ilyse, Hekler, Mohlman, & Staples, 2009). They can all be very broadly described as Cognitive Therapy (CT). In this definition, CT describes a class of psychotherapeutic approaches that include cognitive methods, often accompanied with behavioural techniques (often referred to as Cognitive Behaviour Therapy; CBT) that typically aim to reduce anxiety and worry to a sub-clinical level (Hanrahan, Field, Jones, & Davey, 2013). According to Hanrahan et al. (2013), CT interventions can be classified into three general categories: (1) Those that try to modify the content of GAD maintaining cognitions (e.g., positive and negative beliefs about worry), (2) ‘third wave interventions’

such as mindfulness-based cognitive therapy that aim to promote acceptance of cognitions, (3) CT plus other therapeutic components such as emotion-focused and interpersonal therapy and motivational interviewing.

CT is one of the most widely researched and implemented forms of psychological treatment for GAD (Davey, 2008). Meta-analyses have consistently found that CT out performs placebo pills, no treatment, waitlist controls and non-directive support therapy as a treatment for GAD (Borkovec & Ruscio, 2001; Covin, Ouimet, Seeds, & Dozois, 2008; Fisher, 2006; Gould, Safren, Washington, & Otto, 2004; Hanrahan et al., 2013; Norton & Price, 2007). Some recent meta-analyses which have emphasised the need to measure pathological worry as the key GAD outcome index, have found CT to reduce worry with large effect sizes (d = 1.15, Covin et al., 2008; d = 1.81, Hanrahan et al., 2013). There is also evidence for CT's superiority over alternative psychological treatments such as relaxation therapies (Borkovec & Ruscio, 2001; Fisher, 2006) and that treatment gains maintain 1 year post-therapy (Ruscio & Borkovec, 2004; Fisher, 2006; Gould et al., 2004; Hanrahan et al., 2013). However evidence for the overall effectiveness of CT in treating pathological worry is more limited with the most recent meta-analysis finding that 43% of GAD patients were not classified as recovered at 12 months (Hanrahan et al., 2013). Therefore whilst it can be confidently said that CT is effective at reducing worry, as Hanrahan et al. (2013) pointed out, there is a need to improve CT interventions so that a greater proportion of patients achieve recovery.

1.4 Information Processing Accounts of GAD

Whilst cognitive models such as the AMW, MCM, and IUM offer valuable frameworks for understanding GAD, the treatment derived from these models, whilst effective for many, still have considerable room for improvement (Hanrahan et al., 2013). Also, these models offer limited conceptualisations of the function of cognitive biases

operating at a deeper level, outside of awareness, which are known to be implicated in GAD (Hayes & Hirsch, 2007). Although the AMW acknowledges the role of emotional processing in worry, information processing models exist that provide a more comprehensive explanation of how selective processing biases operate in this disorder.

1.4.1 Information processing models of anxiety.

Information processing accounts of anxiety disorders were pioneered by Beck and his colleagues (Beck, 1976; Beck, Emery, & Greenberg, 1985) who proposed that the locus of the problem was in maladaptive cognitive structures termed 'danger schemata'. Beck's schema model (e.g., Beck et al., 1985) proposed that in pathological anxiety, danger schemata continually process information about oneself, the world and the future in a distorted way as dangerous. Beck considered that this distorted information processing produces automatic thoughts and images relevant to danger and associated anxiety.

Another early theory influential in this field of information processing was Bower's network theory (Bower, 1981; Bower, Sahgal, & Routh, 1983) which advocated pathological anxiety to be the product of over-active anxiety nodes within semantic memory which result in the priming of threat related information. Although theoretically different, both models concord that individuals with GAD display processing biases of selective attention to threatening stimuli, negative interpretation of events and negative memory retrieval. These characteristics have tended to accompany other information processing models of anxiety that have been developed since (e.g., Beck & Clark, 1997; Eysenck, 1997; Mathews & Mackintosh, 1998; Ohman, 1993; Williams, Watts, MacLeod, & Mathews, 1988, 1997).

1.4.2 An information processing model of GAD.

Hirsch and Mathews (2012) have gone beyond a generic information processing theory of emotional disorder and developed a specific cognitive model of pathological worry. Unlike prior models of GAD such as the IUM, MCM and AMW, this model elucidates the

role of emotional processing biases not only in bringing thoughts into awareness but also their continuing impact on the content of worry itself. The central premise of the model is that worry arises from an interaction between involuntary (bottom-up) processes (i.e., processing biases) and voluntary (top-down) processes (e.g., attentional control).

The model suggests that if a worry prone individual experiences an external cue or internal reminder of some potential threat, their internal representation of threat activates more strongly than non-anxious individuals. This is due to the greater influence of involuntary bottom-up processes in worry prone individuals which includes a stronger interpretation processing bias. Consequently the worry prone individual's mental representation of whatever task they are trying to engage in (e.g., reading, cooking etc) is more strongly inhibited leading to insufficient voluntary top-down control (i.e., poor maintained attention for the intended task). Eventually the threat representation gains enough strength to intrude into awareness in the form of intrusive thoughts.

Over time negative intrusions develop into streams of verbal thoughts about perceived threats and this process becomes increasingly habitual. This means intrusions are more likely to occur. Once an intrusion enters awareness, other conscious processes are involved. Intrusions perceived as troubles to be solved tend to arouse efforts to deal with them taking verbal form of 'what if...?'. Intrusions can also trigger prior worry related content, augmenting processing biases leading to increasingly catastrophic thoughts making the task of redirecting attention away from them more difficult. Further attentional impairment may come from maladaptive beliefs about worry (e.g., that it is uncontrollable or that it is useful). The model posits that individuals can become locked in cycles of worry and that this is how GAD develops.

Like other information processing models previously mentioned (e.g., Beck et al., 1985; Bower, 1981) the one developed by Hirsch and Mathews (2012) assumes that

automatic cognitive biases of attention and interpretation are essential to the development and maintenance of clinical anxiety although consistent with more recent findings a specific memory bias is not included (for reviews see Coles & Heimberg, 2002; MacLeod & Mathews, 2004).

In terms of experimental evidence for the model and its assumptions, firstly, the existence of a robust association between information processing and anxiety has been firmly established for some time (Mathews & Macleod, 2005). It has been consistently demonstrated that anxious individuals, including those with GAD (e.g., Martin, Williams, & Clark, 1991), display a stronger attentional bias towards threatening stimuli across a variety of experimental tasks than do non-anxious controls and that this bias causally relates to anxiety (for a review see Bar-Haim, Lamy, Pergamin, Bakermans-Kranenburg, & Ijzendoom, 2007). There is also evidence to support the notion of competition effects between alternative processing options, for example task related representations versus threat related representations (Duncan, 2006) and between processing biases (Macleod & Mathews, 1991; Mogg, Mathews, Eysenck, & May, 1991). A number of findings are consistent with the assumption that trait-like poor attentional control is a risk factor for GAD (Bishop, 2009; Fales et al., 2008) and that worry makes attentional control worse (Hayes, Hirsch, & Mathews, 2008; Leigh & Hirsch, 2011). The effect of maladaptive beliefs on worry is consistent with the MCM and supporting evidence (Wells, 2006), although Hirsch and Mathews (2012) proposed that such beliefs are more likely post-hoc rationalisations of worry rather than causes of worry (see Nisbett & Wilson, 1977). Consistent with the AMW, there is evidence to suggest that worry is predominantly verbal (e.g., Behar & Borkovec, 2005) and that it results in increased subsequent negative intrusions (e.g., Butler, Wells, & Dewick, 1995; Leigh & Hirsch, 2011). In terms of empirical support for the role of interpretation bias in GAD as advocated by the cognitive model of pathological worry (Hirsch & Mathews,

2012) and other models that came before it (e.g., Beck et al., 1985; Bower, 1981), this will be the focus for the next section.

1.4.3 Interpretation bias.

There is evidence to suggest that individuals with GAD have a tendency to interpret ambiguous information in a threatening way. It has been shown that when individuals with diagnosed GAD were presented with ambiguous scenarios they selected threatening interpretations as being more likely to come to mind (Butler & Mathews, 1983) and as being more likely to be true (Eysenck, Mogg, May, Richards, & Mathews, 1991) than non-anxious controls. Similarly, individuals with GAD have been found to write down more threat related words when presented with ambiguously threatening homophones (words with the same sound, but alternative meanings and spellings) (Eysenck, Mogg, May, Richards, & Mathews, 1991) and to have reported more concern for ambiguous situations (Anderson, Dugas, Koerner, Radomsky, Savard, & Turcotte, 2012). Indirect evidence suggestive of the existence of a negative interpretive bias in GAD comes from the wealth of studies that have observed the bias in individuals with high trait anxiety (e.g., MacLeod & Cohen, 1993; Mogg et al., 1994; Richards & French, 1992) and other anxiety disorders such as panic (e.g., Pitts & McClure, 1967), social phobia (e.g., Derakshan & Eysenk, 1997) and PTSD (Elwood, Williams, Olatunji, & Lohr, 2007). In sum there is a strong case for the conclusion that GAD is characterised by an interpretive bias that favours negative resolutions of ambiguity (MacLeod & Rutherford, 2004).

1.5 Cognitive Bias Modification-Interpretation (CBM-I)

1.5.1 Causal relationship.

The compelling evidence of an interpretive bias-anxiety link suggests that a negative interpretation bias may play a causal role in pathological anxiety development and maintenance (MacLeod & Rutherford, 2004). However, these findings cannot rule out the

possibility that it is anxiety that contributes to a negative interpretation bias rather than the other way round. Examination of the causal nature of biases is not only of theoretical importance but is also clinically relevant in terms of designing effective interventions for GAD and other anxiety disorders (Salemink, 2008). Indeed psychotherapy interventions grounded in cognitive theory rely in large part on the assumption that cognitive biases directly impact on symptoms. Researchers have recently started turning their attention to interventions targeted at the information processing level (e.g., Grey & Mathews, 2000; Mathews & Mackintosh, 2000). The aim being to reveal more about the causal contributions of cognitive biases on anxiety and to see whether interventions that modify cognitive bias ameliorate symptoms in disorders such as GAD (MacLeod & Mathews, 2012).

1.5.2 Modifying interpretation bias.

In a series of pioneering experiments, Grey and Mathews (2000) investigated whether an interpretive bias could be induced in low trait anxious volunteers. Participants were first presented with homographs that had one positive and one negative meaning (e.g., batter). On every trial the homograph was followed by a word fragment that required quick completion. The completed word always related to a meaning of the homograph which consequently could be a useful aid to such completion. In the group designed to induce a negative interpretation bias the completed defragmented word always corresponded to a negative meaning of the homograph e.g. ‘a s s - - l t’ (assault) whereas in the other group designed to induce a more positive interpretation bias, the completed word corresponded to a more positive meaning of the homograph e.g. ‘p - n c - k e’ (pancake). After participants had completed up to 240 trials of this, the induced pattern of interpretative selectivity was assessed by inspecting solution times for defragmenting the target words. The results revealed that participants in the positive interpretive condition demonstrated more benign interpretations of ambiguity than did those in the negative interpretive condition.

In an attempt to provide material more relevant to everyday concerns, Mathews and Mackintosh (2000) employed short passages of text describing ambiguous situations relevant to social anxiety. In their classic study, volunteers were required to read and imagine themselves in about 100 social scenarios (training) that had either a positive or a negative outcome. In the first experiment, at the end of each scenario, participants were required to solve a word fragment that always concluded the scenario in a positive or negative way depending on the group assignment. They were then immediately presented with a 'comprehension question' that required a 'yes' or 'no' answer that was congruent with the imposed emotional valence of the scenario. The results revealed that participants who experienced negatively resolved scenarios in the training phase gave higher recognition ratings to threatening interpretations in a subsequent recognition task than did the participants who received positively resolved scenarios. Thus, repeatedly restricting participants to endorse either positive or negative interpretations resulted in a measurable induced bias. In addition, participants in the positive interpretation trained group reported a decrease in state anxiety whereas those in the negative interpretation trained group reported an increase. Training participants to interpret information according to a prescribed emotional valence was termed Cognitive Bias Modification for Interpretation (CBM-I) and has been the subject of much investigation since.

Subsequent research has replicated the effects of CBM-I training on interpretation biases. For example, Hertel, Mathews, Peterson, and Kintner (2003) presented non-anxious college students with a homograph task and found that the number of threat related interpretations in a later transfer task significantly increased if participants had experienced threat related interpretation training as opposed to other training conditions. Other studies adopting Mathews and Mackintosh's (2000) CBM-I paradigm (Yiend, Mackintosh, & Mathews, 2005; Salemink, van de Hout, & Kindt, 2007a) using non-anxious volunteers have

observed training congruent effects for interpretation bias.

Interestingly, Salemink, van de Hout, and Kindt (2007b) found that participants in the positive interpretive condition, but not the negative interpretive condition, reported a significant decrease in state and trait anxiety. In a mediational analysis, the researchers (Salmink, van de Hout, & Kindt, 2010) demonstrated that reductions in state anxiety seemed to be directly caused by the CBM-I procedure, but that the reductions in trait anxiety seemed to be due to changes in interpretation bias. This finding supports the hypothesis that interpretation biases causally relate to anxiety vulnerability.

To exclude the possibility that the reductions in trait anxiety were exclusive to interpretations relating to past experiences rather than anxiety vulnerability generally, Salemink et al. (2007a) investigated whether CBM-I could impact upon emotional reactivity in a subsequent anagram task designed to induce stress and raise anxiety. The researchers failed to observe an effect of earlier CBM-I training on trait anxiety with the inclusion of this stressor. However the researchers pointed out that the anagram stressor may have involved insufficient ambiguity for differences in interpretive bias to influence anxiety responses, thereby making conclusions difficult.

In support, evidence for the causal role of interpretation bias on anxiety vulnerability has come from other stressors that lend themselves to less ambiguous emotional interpretations. Wilson, MacLeod, Mathews, and Rutherford (2006) exposed undergraduate students to brief video clips of real life emergency situations in which a protagonist is injured but eventually rescued. The researchers found that participants who had received negative CBM-I training previously experienced elevated anxiety in response to the video clip whereas those who had received positive CBM-I previously were not significantly affected during the video clip.

CBM-I training effects have also been observed in children and adolescents. For

example, in a sample of healthy adolescents (aged 13-17 years), Lothmann, Holmes, Chan, and Lau (2011) found that adolescents who received negative training went on to make a greater proportion of negative interpretations compared to adolescents who had received positive training. Furthermore positive training was associated with a decrease in negative affect.

1.5.3 Summary of CBM-I in non-anxious samples.

These studies, carried out using non-anxious samples provide clear support for the hypothesis that interpretation biases causally contribute to variations in anxiety vulnerability. However this does not necessarily mean that such interpretation biases are causally implicated in the types of abnormal experiences associated with anxiety disorders such as GAD. Evidence that CBM-I could ameliorate symptoms of pathological anxiety would require testing in clinical populations.

1.6 Literature Review of CBM-I Research with Anxious Samples

Whilst CBM-I is associated with improvements in interpretation bias and anxiety, until relatively recently few studies had investigated its efficacy in anxious populations (Beard, 2011). The aim of the literature search is to explore the effectiveness of CBM-I for individuals presenting with anxiety both at clinical and non-clinical levels.

1.6.1 Search strategy.

The primary phase involved using the Metalib online database to search eight computerised databases (AMED, Cochrane Library, EBSCO, EMBASE, ERIC, psychINFO, Science Direct & MEDLINE). An initial search was performed using the search terms ‘anx*’ OR ‘worry’ (n=217998). A second search then refined the results using the terms ‘cognitive bias modification’ OR ‘CBM*’ OR ‘bias modification’ OR ‘bias training’ (n=234). At this stage eight articles were identified as suitable. The same key terms were also entered into the University of East Anglia’s ‘Primo One Search’ digital repository resulting in four new

suitable articles. Prominent authors in the field (Amir, N., Beard, C., Hirsch, C.R., Holmes, E.A., Mackintosh, B., MacLeod, C., Mathews, A., & Salemink, E) were subject to further searching in the databases as well as in Google, yielding two new suitable articles. Finally the reference sections from the selected papers and three relatively recent CBM review papers (Beard, 2011; Hallion & Ruscio, 2011; MacLeod & Mathews, 2012) were hand searched and no new articles were found.

1.6.2 Inclusion and exclusion criteria.

All studies which investigated the effect of interpretation modification procedures (e.g., CBM-I) on anxiety symptoms or worry in anxious selected adult samples were eligible for inclusion.

A study was immediately excluded if it was not published in a peer reviewed journal in the English language. If a study had a selected sample of participants with diagnoses that were not an anxiety disorder, such as Schizophrenia, it was not included. The rationale was that the cognitive biases that contribute to those disorders may differ in important ways from those that contribute to GAD (e.g., Garcia, Sacks, & Weisman de Mamani, 2012).

1.6.3 Review of selected studies.

A total of 14 suitable studies were identified. A descriptive outline is presented in Table 1.

Using a similar CBM-I paradigm to that of Mathews and Mackintosh (2000), Murphy, Hirsch, Mathews, Smith, and Clark (2007) investigated whether a benign interpretation bias could be experimentally induced in socially anxious individuals. Participants were allocated to either a benign condition in which they had repeated practice at accessing positive or non-negative interpretations, or a neutral control condition in which they were presented with the same scenarios but without outcomes specified. The researchers found that participants trained to make benign interpretations of threat related scenarios made less negative

interpretations of new ambiguous scenarios than control participants. They also found that benign trained participants rated their anxiety for a future social situation as significantly lower compared to controls, although no differences in state anxiety were observed. This study showed for the first time that the positive effects of CBM-I demonstrated by Mathews and Mackintosh could be extended to a socially anxious population. Other studies since, using socially anxious individuals, have reported similar findings, for example Amir, Bomyea, and Beard (2010) found that participants assigned to a single session of an interpretation modification program (IMP) demonstrated reduced interpretation bias compared to participants assigned to an interpretation control condition (ICC).

While interpretation bias modification procedures have mainly targeted social anxiety (Beard, 2011), positive effects using a single session of Mathews and Mackintosh's CBM-I training paradigm have also been demonstrated in individuals high in anxiety sensitivity (AS). Steinman and Teachman (2010) trained participants to imagine themselves in scenarios relating to AS and found that positive training resulted in reduced negative interpretations and self reported symptoms of AS compared to control conditions. However this study failed to find an expected significant effect of positive training on emotional vulnerability. One possible explanation for this put forward by the researchers was that the amount of training participants received was not substantial enough to allow effects to emerge.

Likewise, Macdonald, Koerner, and Antony (2013) examined the impact of a single session of CBM-I on individuals high in AS and they too found that not all of their hypotheses were supported. Although only CBM-I trained participants demonstrated a significant decrease in AS, the difference was not significantly different to that observed in control participants. Furthermore CBM-I did not increase tolerance for uncomfortable sensations. Macdonald and colleagues questioned whether their control condition was more active than intended but they also shared the concerns of Steinman and Teachman (2010) that

a single session of CBM-I may be insufficient.

To investigate whether increasing the amount of CBM-I produces enhanced outcomes, studies have increasingly included multi-session CBM-I interventions. Beard and Amir (2008) provided socially anxious participants with eight sessions of their IMP that took place over a four week period. Compared to participants in a control condition, participants who completed the IMP endorsed more benign interpretations and fewer threat interpretations, and demonstrated a greater reduction in social anxiety symptoms. Furthermore these changes were observed up to one week after training.

To explore the durability of positive effects associated with CBM-I, some studies have included an actual follow-up assessment. Bowler, Mackintosh, Dunn, Mathews, Dalgleish, and Hoppitt (2012) found that socially anxious students who received four sessions of CBM-I demonstrated reduced levels of social anxiety and trait anxiety two weeks after their first session compared to participants who did not receive any intervention. Interestingly this study also included a computerised CBT (cCBT) intervention and found no superiority of either intervention, although CBM-I was more effective at reducing interpretative bias. Whilst the study by Bowler et al. (2012) is not clear on how long the improvements lasted upon completion of the training, Mathews, Ridgeway, Cook, and Yiend (2007) measured trait anxiety in high trait anxious participants one week after they had completed their fourth and final session of CBM-I and found it to be reduced compared to untrained controls. Whilst CBM-I training was also associated with more positive interpretations after the final session, this outcome was not assessed at follow-up.

The large majority of CBM-I studies have involved participants receiving CBM-I type procedures in a laboratory or some form of test centre (Beard, 2011). Given the experimental nature of CBM-I research, this is to be expected however it offers limited insight into how well CBM-I performs in more naturalistic settings. An exception to this is the study by

Salemink, van de Hout, and Kindt (2009) in which high trait anxious participants accessed CBM-I training over the internet from their home. Not only was this study novel in the way CBM-I was provided but also novel in its intensity as training consisted of eight sessions that took place on consecutive days lasting approximately one hour each. Another advantageous aspect to this study was that the control group included training which was designed to be non-contingent (i.e., a sham). This is in contrast with, for instance, the study by Mathews et al. (2007) in which control participants received no training at all thereby undermining confidence that effects observed in the experimental group are due to the CBM-I training and not other confounding features of repeated training. Although their findings on social anxiety were equivocal, Salemink and colleagues found that their online CBM-I was successful in modifying interpretations and reducing state and trait anxiety. This study did not include any follow-up nevertheless in the context of CBM-I potentially having a use one day as a home-based therapeutic adjunct (Beard, 2011) these findings hold increased ecological validity.

All of the reviewed studies so far have consisted of non-clinical samples and many of them students (Beard & Amir, 2008; Bowler et al., 2012; Murphy et al., 2007; Salemink et al., 2009; Steinman & Teachman, 2010). One limitation with this common over reliance on testing students is that it undermines the generalisability of the CBM-I findings to the general population. A further limitation is that their symptoms are unlikely to be as severe as those found in clinical populations. Consequently it is less clear how effective CBM-I is for individuals with more deeply entrenched biases and anxiety disorders such as GAD.

Two randomised double-blind placebo controlled trials have tested multi-session bias modification tasks in individuals meeting DSM-IV diagnostic criteria for social anxiety disorder (SAD) (Amir & Taylor, 2012a; Beard, Weisberg, & Amir, 2011). Beard et al. (2011) delivered a combined CBM-I and CBM-A multi-session package called Attention and Interpretation Modification (AIM). The interpretation module involved completing a word

sentence association task whereby the pairing of benign word sentences resulted in positive feedback for the participants whereas the pairing of negative word sentences resulted in negative feedback. Compared to controls, participants in the AIM condition experienced a significant reduction in social anxiety symptoms and gave higher quality impromptu speeches, to medium and large effect respectively.

In the study by Amir and Taylor (2012a), participants who received the IMP made interpretations that were less threatening and more benign relative to sham trained participants in the control group. Moreover IMP participants displayed larger reductions in clinician rated social anxiety symptoms and functional impairment as well as self reported trait anxiety relative to the control group. Of the participants that completed the IMP, 56% no longer met diagnostic criteria for SAD compared to 13% in the control group.

SAD is the most common anxiety disorder featuring in studies investigating CBM-I (Beard, 2011) and the reviewed studies indicate that it is amenable to interpretation bias modification (e.g., Amir et al., 2010) and symptom reduction (Beard & Amir, 2008; Bowler et al., 2012; Murphy et al., 2007). Nevertheless some studies have set out to examine the potential efficacy of CBM-I for GAD.

Hirsch, Hayes, and Mathews (2009) provided non-clinical high worriers with either CBM-I or a sham analogue. CBM-I trained participants went on to report fewer negative thought intrusions and lower levels of anxiety during a breathing focus task compared to controls. This suggests that CBM-I can enable worriers to have more effective control over their worry and experience less concomitant anxiety as a result. While these findings are encouraging, the study also had some limitations, mainly: that its 'worriers' were voluntary university staff and students, that it did not measure interpretation bias change and that the CBM-I intervention consisted of two types of tasks (homograph and ambiguous scenarios). As the authors note, the dual task approach makes it difficult to establish whether the

outcomes are attributable to either task or both in combination thereby precluding evaluations of each.

Hayes, Hirsch, Krebs, and Mathews (2010) addressed some of these issues by conducting a similar study using 40 patients who were in treatment for GAD. Trained participants made less negative interpretations of ambiguous scenarios on a later sentence completion task than controls and experienced fewer negative intrusions during the breathing focus task. However, the CBM-I intervention still consisted of dual tasks raising the same issues as in Hirsch et al. (2009) and the CBM-I intervention was brief, comprising only of a single session. Nevertheless, with these potential drawbacks considered, the study does suggest that it is possible to modify interpretive bias and worry in patients with GAD.

Only one other CBM-I study to date has selected individuals with GAD. Brosan, Hoppitt, Shelfer, Sillence, and Mackintosh (2011) administered multi-session bias modification training to 13 patients with diagnoses of either SAD or GAD who had been referred to an outpatient psychological treatment service for cognitive therapy. Upon completion of training, participants demonstrated a reduction in threat related interpretive bias and this change was accompanied by reduced trait and state anxiety. It is important to note that the adopted modification procedure was a combined CBM-A and CBM-I package designed to target attention and interpretation biases which like some other studies reviewed (Amir et al., 2010; Beard et al., 2011) means that it is not possible to distinguish the independent contribution of CBM-I on the outcomes. Furthermore no control feature was included and, similar to Hayes et al. (2010), there was no follow-up.

1.6.3.1 *Theoretical implications.*

The resounding success of the various bias modification procedures, adopted by the reviewed studies in producing improvements on bias assessment tasks, supports the notion that CBM-I training can induce a more benign interpretive bias. The fact that in some studies

training also improved symptomatology (Amir & Taylor, 2012a; Brosan et al., 2011; Hayes et al., 2010; Hirsch et al., 2009; Mathews et al., 2007; Salemink et al., 2009) lends support to cognitive models (e.g., Hirsch & Mathews, 2012) that negative interpretive biases contribute to anxiety dysfunction.

However the unexpected improvements observed in some sham trained participants (Beard & Amir, 2008; MacDonald et al., 2013; Murphy et al., 2007) raises the possibility that non-specific aspects of training (i.e., unrelated to bias modification) such as exposure to valenced material may be responsible for improvement (Salemink et al., 2010). This may be more the case for state anxiety than trait anxiety (Salemink et al., 2010).

Mediational analyses conducted in the reviewed studies tended to find that CBM-I affected outcomes via bias modification (Amir & Taylor, 2012a; Beard & Amir, 2008; Bowler et al., 2012). Further evidence that interpretation bias modification is the primary mechanism of change of CBM-I training comes from the fact that some of the studies which incorporated independent measures of bias change did detect change (e.g., Hayes et al., 2010; Mathews et al., 2007). These findings indicate that CBM-I does not simply create a response bias consistent with the training condition but produces genuine, generalisable cognitive change.

1.6.4 Summary critique of overall findings.

All of the studies reviewed found that participants who completed CBM-I type training demonstrated significantly less negative interpretation bias (where measured) post intervention compared to pre-intervention. Some of the studies also found that training positively impacted on anxiety (Amir & Taylor, 2012a; Brosan et al., 2011; Mathews et al., 2007; Salemink et al., 2009) and worry (Hayes et al., 2010; Hirsch et al., 2009). Furthermore mediation analyses support CBM-I as an effective method of change (Amir & Taylor, 2012a; Beard & Amir, 2008; Bowler et al., 2012). However there are some limitations within the

research base that warrant consideration when evaluating the efficacy of CBM-I as a potential treatment for individuals with GAD.

Findings regarding the effect of CBM-I on anxiety and related emotional outcomes were more mixed than was the case for interpretive bias change. Some studies found no difference between CBM-I trained participants and sham trained controls (Amir et al., 2010; Beard & Amir., 2008; MacDonald et al., 2013; Murphy et al., 2007; Steinman & Teachman, 2010) and in some cases controls even improved (Beard & Amir., 2008; MacDonald et al., 2013; Murphy et al., 2007). This makes it more difficult to discount non-bias related explanations of training effects.

With many of the studies relying on single session CBM-I interventions despite acknowledging multi-session as the ideal (e.g., MacDonald et al., 2013; Steinman & Teachman, 2010), it is difficult to draw any firm conclusions regarding the optimum number of sessions or time frame over which they should occur. Given the robustness of information processing biases (Hirsch & Mathews, 2012) it is conceivable that multi-session might stand a better chance than a single session in bringing about enduring cognitive change.

Although CBM-I appears to be generally successful in producing quick improvements in outcomes, a limitation cited by the researchers in over half of the studies was their absence of a follow-up (e.g., Hirsch et al., 2009; MacDonald et al., 2013; Steinman & Teachman, 2010). Of the four studies that did include one, only three measured anxiety symptoms a week or more later (Amir & Taylor, 2012a; Bowler et al., 2012; Mathews et al., 2007). The longest follow-up took place three months after participants had completed training (Amir & Taylor, 2012a) and in this study treatment gains at post intervention had lasted. The lack of follow-ups makes it difficult to appraise the effects of CBM-I on interpretation biases and anxiety symptoms beyond the moments immediately following completion of training.

Regarding the samples used in the studies, few consisted of participants assessed as

experiencing clinical levels of an anxiety disorder (Amir & Taylor, 2012a; Beard et al., 2011; Brosan et al., 2011; Hayes et al., 2010) and many consisted of students (Beard & Amir, 2008; Bowler et al., 2012; Murphy et al., 2007; Salemink et al., 2009; Steinman & Teachman, 2010) undermining the generalisability of the findings.

Despite CBM-I being widely hailed as a potential home-based treatment (Bar-Haim et al., 2007; Beard, 2011), only two of the studies tested it in this setting (Brosan et al., 2011; Salemink et al., 2009). The preponderance of laboratory tested training protocols makes it more difficult to appraise the clinical application of CBM-I.

Finally, only two studies tested CBM-I on individuals with GAD (Brosan et al., 2011; Hayes et al., 2010) although Brosan et al. (2011) administered a combined CBM-I/CBM-A treatment package and neither study included a follow-up.

The reviewed studies generally support the cognitive theoretical position that interpretation bias causally contributes to dysfunctional anxiety as seen in anxiety disorders such as GAD. They also support the hypothesis that CBM-I attenuates symptoms via interpretation bias adjustment.

Table 1

Studies which met Inclusion Criteria for Literature Search

Number	Authors	Aim	Participants	Design	Outcome Measures	Main Findings
1	Amir, Bomyea, and Beard (2010).	To examine whether a computerised IMP can be used to modify attentional bias (and interpretation bias) in individuals high in social anxiety.	57 socially anxious individuals (score > 25 on the LSAS-SR).	Between subjects design.	STAI, Interpretation test.	Participants who had completed the IMP demonstrated less interpretation bias than controls.
2	Amir and Taylor (2012a).	To examine the efficacy of a multi-session computerised IMP in the treatment of GSAD.	49 individuals that met GSAD criteria. Clinical sample.	Between subjects design (double-blind).	LSAS, SPAI, SDS, STAI, BDI-II.	The IMP group demonstrated decreased threat interpretations and increased benign interpretations relative to control group. The IMP group displayed larger reductions in social anxiety symptoms and trait anxiety compared to the control group.

3	Beard and Amir (2008).	To examine the effect of a computerised IMP on interpretation bias and social anxiety symptoms.	27 socially anxious students (score > 91 on the SPAI-SP).	Between subjects design.	SPAI, STAI, BDI-II.	The IMP group endorsed more benign interpretations and fewer threat interpretations at post assessment than the control group. The IMP group were less socially anxious compared to the control group at post assessment.
4	Beard, Weisberg, and Amir (2011).	To examine the efficacy of a CBM programme designed to modify attention and interpretive biases (AIM) in SAD.	32 socially anxious individuals (score > 29 on the LSAS-SR). Clinical sample.	Between subjects design (double-blind).	LSAS-SR, PRF (in relation to an impromptu speech), Credibility, Acceptability, Satisfaction questionnaires.	Participants in the AIM condition experienced a significant reduction in social anxiety symptoms and gave higher quality impromptu speeches compared to controls.

5	Bowler, Mackintosh, Dunn, Mathews, Dalgleish, and Hoppitt (2012).	To compare the efficacy of cCBT and CBM-I in alleviating social anxiety.	63 socially anxious students (score >16 on the FNE).	Between subjects design.	FNE, SPIN, STAI, BDI-II, ASSIQ, SST.	Both the CBM-I and cCBT group reported reduced levels of social anxiety, trait anxiety and depression compared to a control group. CBM-I was more effective than cCBT at reducing interpretation bias.
6	Brosan, Hoppitt, Shelfer, Sillence, and Mackintosh (2011).	A pilot test of the effectiveness and acceptability of a combined package of CBM-A (attention) and CBM-I for individuals with clinical anxiety.	13 patients referred to a psychological treatment service with a diagnosis of either SAD or GAD. Clinical sample.	AB design.	STAI, Word relatedness test.	Training was associated with reductions in interpretation bias, state and trait anxiety.

7	Clerkin and Teachman (2011).	To test the causal relationship between negative interpretations of intrusive thoughts and distress in OCD.	100 students high in OCD symptoms (score >28.01 on OCI-R).	Between subjects design.	III, PANAS, OBQ, Recognition task, OCD stressor-neutralising urge ratings.	Trained participants endorsed more adaptive and fewer unadaptive OCD related interpretations and beliefs compared to controls. Training was associated with reductions in some but not all aspects of subsequent emotional vulnerability to a stressor.
8	Hayes, Hirsch, Krebs, and Mathews (2010).	To investigate whether facilitating a benign interpretive bias decreases negative thought intrusions in GAD.	40 GAD patients currently in treatment. Clinical sample.	Between subjects design.	Worry ratings, Thought intrusion ratings, Sentence completions, Mood ratings.	Trained participants made less negative interpretations of emotionally ambiguous test scenarios in training and during a later sentence completion task than did controls.

9	Hirsch, Hayes, and Mathews (2009).	To investigate whether increasing access to benign outcomes of ambiguous events decreases worry.	40 high worry volunteers (score >55 on the PSWQ).	Between subjects design.	Mood rating scales, Thought intrusion ratings.	Trained participants reported fewer negative thought intrusions during a breathing focus task than did controls. Trained participants reported lower levels of anxiety during breathing focus periods in comparison with controls.
10	MacDonald, Koerner, and Antony (2013).	To examine the impact of interpretation training on AS, interpretive biases and reactions to bodily sensations.	34 participants high in AS (scoring >27 on the ASI).	Between subjects design.	MINI, ASI, BBSIQ, VAS (fear), Time tolerated and desire to terminate a symptom induction exercise (VAS), Word sentence association task.	Only trained participants reported decreases in overall AS however there were no between-group differences with controls. Trained participants and controls demonstrated more adaptive beliefs regarding sensations.

11	Mathews, Ridgeway, Cook, and Yiend (2007).	To investigate whether modifying interpretation biases produces congruent changes in emotional vulnerability.	40 high anxious volunteers (scoring >40 on the trait scale of the STAI).	Between subjects design.	STAI, Reasons for ambiguous events, Imagined ambiguous events.	Trained participants demonstrated greater positive change in interpretation bias and trait anxiety scores compared to untrained controls.
12	Murphy, Hirsch, Mathews, Smith, and Clark (2007).	To facilitate a benign interpretation bias in high socially anxious individuals.	66 socially anxious participants (score > 16 on the FNE).	Between subjects design.	STAI, Anticipated anxiety and predicted performance ratings forms, Recognition test.	Trained participants demonstrated less negative interpretation bias than controls. Trained participants rated their anticipated anxiety in an upcoming social situation as significantly lower compared to controls.

13	Salemink, van de Hout, and Kindt (2009).	To investigate whether it is possible to modify the negative interpretive bias in highly anxious individuals and evaluate what benefit this has on certain clinical outcomes.	36 highly trait-anxious participants (score > 44 on the trait scale of the STAI & a score > 1.56 on the ASSIQ).	Between subjects design.	STAI, FNE, SCL-90, Pleasure and arousal subscale of the SAM, VAS, ASSIQ, Recognition test, Reaction time solving word fragments.	Trained participants showed reduced state and trait anxiety compared to the control group. Trained participants scored lower on general psychopathology.
14	Steinman and Teachman (2010).	To examine the causal relationship between cognitive biases and anxiety.	75 students high on anxiety sensitivity (score > 27.4 on the ASI).	Between subjects design.	PANAS, BBSIQ, ASI, Recognition test, SIQ.	Trained participants showed less negative bias and less AS compared to controls.

Note. STAI = The State Trait Anxiety Inventory (Spielberger, Gorsuch, & Lushene, 1970); SAD = Social Anxiety Disorder; SDS = Sheehan Disability Scale (Leon, Olfson, Portera, Farber, & Sheehan, 1997); AIM = Attention and Interpretation Modification; GAD = Generalized Anxiety Disorder; GSAD = Generalized Social Anxiety Disorder; cCBT = Computerised cognitive behavioural therapy; AS = Anxiety Sensitivity; PRF = Performance Rating Form; IMP = Interpretation Modification Program; SST = Scrambled Sentences Test (Wenzlaff, 1993); MINI = The Mini Neuropsychiatric Interview (Sheehan, Lecrubier, Sheehan, Amorium, Janavs, & Weiller, 1998); OCI-R = Obsessive Compulsive Inventory- Revised (Foa et al., 2002); III = The Interpretations of Intrusions Inventory (Obsessive Compulsive Cognitions Working

Group, 2003); OBQ = The Obsessional Beliefs Questionnaire- Short Form (Obsessive Compulsive Cognitions Working Group, 2005); ASSIQ = Ambiguous Social Situation Interpretation Questionnaire (Stopa & Clark, 2000); FNE = Fear of Negative Evaluation Questionnaire (Watson & Friend, 1969); SCL-90 = Symptom Check List (Arrindell & Ettema, 1986); SAM = Self-Assessment Manikin (Hodes, Cook, & Lang, 1985); ASI = Anxiety Sensitivity Index (Reiss, Peterson, Gursky, & McNally, 1986); PANAS = The Positive and Negative Affect Schedule (Watson & Clark, 1994); BBSIQ = The Brief Body Sensations Interpretation Questionnaire (Clark et al., 1997); SPAI-SP = Social Phobia and Anxiety Inventory- Social Phobia Subscale (Turner, Stanley, Beidel, & Bond, 1989); BDI-II = Beck Depression Inventory- 2nd Edition (Beck, Steer, & Brown, 1996); LSAS-SR = Liebowitz Social Anxiety Scale-Self-Report score (Liebowitz, 1987); PSWQ = Penn State Worry Questionnaire (Meyer, Miller, Metzger, & Borkovec, 1990).

1.7 Modification of Imagery

Whilst CBM-I methods are proving effective at modifying biases and often anxiety, the optimal ingredients are yet to be identified. In a quest to enhance the efficacy of CBM-I as an intervention for emotional dysfunction, some researchers have targeted mental imagery (see Holmes & Mathews, 2010).

There has been a long held assumption that imagery and anxiety share a special relationship (Holmes & Mathews, 2005). Imagery can powerfully provoke emotional states (Holmes & Mathews, 2010) and this has resulted in a range of therapeutic approaches being developed that incorporate the manipulation of mental imagery. For example, in systematic desensitisation of phobias, individuals are repeatedly directed to imagine feared objects until anxiety subsides (Wolpe, 1958). Another technique, 'imagery re-scripting' involves modifying the content of emotionally inducing imagery and has been used in treatment for varying disorders (e.g., Arntz & Weertman, 1999).

Imagery features in many CBM-I procedures. Studies that replicate Mathews and Mackintosh's (2000) ambiguous scenario paradigm instruct participants to imagine themselves in the scenarios presented to them (e.g., Mathews et al., 2007; Murphy et al., 2007). Mathews and Mackintosh (2000) showed that active generation of meaning was essential in bringing about emotional change and Mathews and MacLeod (2002) proposed that imagery might be the key mechanism by which this generation has an effect.

It is interesting, as Holmes, Lang, and Shah. (2009) point out, that there is no mention of imagery in the CBM-I procedure of Salemink et al. (2007) and that only marginal effects on emotional outcomes were found in this study. Similarly there is no reporting of imagery instructions in the CBM-I procedure administered by Hirsch, Mathews, and Clark (2007) and they failed to find any anxiety reduction over training. However, when the participants in this study were required to imagine ambiguous items

and report on anticipated anxiety to imagined social stress, training congruent effects were then observed.

Recently there has been an increased focus on imagery within CBM-I tasks to see if it makes training more potent. Holmes and Mathews (2005) compared outcomes for imagery and verbal processing instructions within a CBM-I task. In the first experiment, participants either imagined negative scenarios or listened to descriptions of them while thinking about their meaning in verbal terms. The results showed that participants in the imaginary condition felt more anxious and rated new ambiguous test descriptions as more emotional than participants in the verbal condition. In a second experiment, participants listened to either benign or unpleasant descriptions and were provided with either imagery or verbal instructions. The researchers found that again, anxiety increased more after unpleasant imagery (but not benign) than after verbal processing but that there were no differences between the groups on emotional ratings for new ambiguous scenarios after a ten minute filler task. Overall, the findings of the two experiments supported the hypothesis that imagery of negative material has a stronger effect on anxiety than verbal processing. However the failure to find differences between imagery and verbal processing in the benign training condition was attributed to these scenarios not being particularly positive.

Consequently Holmes, Mathews, Dalgleish, and Mackintosh (2006) compared interpretation training using imagery versus verbal processing of descriptions that were resolved in a more overtly positive way. Participants in the imagery condition experienced a reduction in state anxiety and rated new descriptions as being more positive than those in the verbal condition. The finding suggests that positive imagery can enhance the ability of CBM-I to effect change.

Holmes et al. (2009) replicated the benefits of imagery-focused training compared

with verbal-focused training using a larger sample. Within the imagery condition alone there were improvements in positive affect and state anxiety compared with baseline. In contrast, positive CBM-I with verbal instructions led not only to a lack of improvement in mood but also an actual increase in anxiety over the training phase. The researchers concluded that imagery can play a critical role in CBM-I procedures and that task instructions are crucial.

The superiority of imagery versus verbal processing in training positive interpretation has also been found in clinically depressed samples. Blackwell and Holmes (2010) conducted a single-case series examining an imagery-focussed CBM-I task. Seven participants experiencing a major depressive episode completed a 'baseline' week in which daily measures of mood and cognitive bias took place, and then an 'intervention' week in which one session of CBM-I was completed each day at home. Large effect sizes were found for depressive symptomatology (of which improvements remained at a two week follow-up), interpretation bias and general mental health.

In a follow-up study (Lang, Blackwell, Harmer, Davison, & Holmes, 2012), twenty six depressed participants were randomised to either a positive imagery-focussed CBM-I condition or a closely matched control condition. Participants in the positive imagery-focussed condition demonstrated greater improvements in depressive symptomatology, intrusive images and cognitive bias than those in the control condition.

Holmes et al. (2009) proposed that mental imagery can have greater effects on positive emotion than verbal processing of the same material. They argued that imagery has perceptual correspondence to direct sensory experience 'as if' it were really happening (Kosslyn, Ganis, & Thompson, 2001). By mimicking real life perceptions, engaging in imagery can enhance access to representations of emotionally congruent autobiographical memories (Conway, 2001) and thereby activate emotional effects. In contrast, the

researchers argued that positive verbal information may be less believable and more easily contrastable with other disconfirmatory information in semantic networks. They pointed out that this may be advantageous in other domains, for example debating, but not so in feeling less anxious when presented with positive information.

Holmes et al. (2009) also suggested that verbal processing of positive material may even maintain worry. Hayes and Gifford (1997) proposed that trying to avoid negative affect through the use of verbal language simply results in delayed and more severe negative affect later. As discussed already, cognitive models propose that thinking about potential threat in a verbal form is a contributory factor in pathological worry and GAD (e.g., Borkovec, 1994; Hirch & Mathews, 2012). Indeed there is evidence that individuals with GAD display a more pronounced deficit of imagery during worry than non-anxious individuals (e.g., Hirsch, Hayes, Mathews, Perman, & Borkovec, 2012).

In sum, the prevailing opinion of the literature base concerning imagery and bias modification is that CBM-I procedures that target mental imagery should achieve better anxiety related outcomes.

1.8 Aims of the Current Study

Only two studies to date have tested CBM-I in GAD samples (Brosan et al., 2011; Hayes et al., 2010) and promisingly it was found that CBM-I trained participants demonstrated reduced interpretation bias, anxiety (Brosan et al., 2011) and worry (Hayes et al., 2010). The present study aims to build on this previous research by investigating the efficacy of an adapted version of Mathews and Mackintosh's (2000) CBM-I paradigm for individuals who are experiencing clinical levels of generalised anxiety.

The study will utilise a single-case research design and employ a methodology similar to Blackwell and Holmes (2010). Given the paucity of research that has been carried out on CBM-I and GAD this paradigm can probably be considered as in the early

stages of investigation. According to Salkovskis (1995), single-case designs are vital in the early stages of new psychological treatments. Similarly, Kazdin (2011) asserts that single-case designs are especially suitable during preliminary development and are a natural precursor to larger trials. Adopting a single-case design will permit greater depth of examination and reveal more about the dynamic effects of the CBM-I program on the participants than would be obtained using a traditional group design (Dallery, Cassidy, & Raiff, 2013).

The current study will seek to address some of the limitations of the previous GAD focused CBM-I studies (Brosan et al., 2011; Hayes et al., 2010) in a bid to advance our understanding of the clinical potential of CBM-I. By virtue of the single-case design it will contain an inbuilt control aspect, something which is missing from Brosan et al. (2011)'s pre/post study design. Whereas Brosan et al. (2011) and Hayes et al. (2010) delivered bias modification procedures to their participants across four sessions and a single session respectively, this study will test a more intensive, multi-session CBM-I program consisting of seven, consecutive daily sessions. In addition the CBM-I program will be pure in so much as it will not be combined with CBM-A, as was the case with Brosan et al. (2011). In Hayes et al. (2010) the effect of CBM-I on worry, as measured using a breathing focus task, was assessed. In the current study, the primary outcome will be pathological worry; the defining GAD symptom and this will be assessed using a standardised measure. Unlike Brosan et al. (2011) and Hayes et al. (2010), a follow-up will be included to see if gains last beyond simply the moments immediately following training.

The CBM-I will not be delivered in some form of test centre as is common with CBM-I research (Beard, 2011). Instead it will be accessed online, from patients' homes, in keeping with Beard (2011)'s predicted application of this potential treatment. In line with a relatively new avenue of research that has found imagery processing of training materials

to enhance CBM-I outcomes (predominately using depressed samples) (e.g., Holmes et al., 2009), the CBM-I protocol in the current study will contain an imagery component and will extend findings in an anxious sample experiencing clinical levels of generalised anxiety.

1.9 Research Hypotheses

- Primary hypothesis: An online multi-session CBM-I package will reduce levels of worry in individuals presenting with clinical levels of generalised anxiety and this will be maintained at one week follow-up.
- Secondary hypothesis: Individuals presenting with clinical levels of generalised anxiety receiving an online multi-session CBM-I package will demonstrate a reduction in level of negative interpretation bias and this will be maintained at one week follow-up.

Methodology

2.1 Overview

This chapter details the methodology employed in the study. Information is provided on the design, participants, outcome measures, CBM-I task, ethical considerations and full procedure used to carry out the research.

2.2 Design

The study adopted a single-case series using a non-concurrent multiple-baseline across participants design with follow-up. In multiple-baseline designs, the effect of the intervention is evaluated by way of introducing it to different baselines at different points in time. If each baseline changes when the intervention is introduced, then such change can be more confidently attributed to the intervention rather than extraneous variables (Kazdin, 1982).

In the present study, the participants were each allocated to a baseline phase of 7, 9 or 11 days (see figure 1). Because of the small targeted sample size, block randomisation was used to ensure equal numbers in each baseline. This was achieved using a predetermined algorithm generated by the free online random number generator, RANDOM.ORG. During the baseline phase, participants completed the daily measures of worry, anxiety and an anxiety related bias (anxiety-bias). The intervention phase involved the daily completion of the CBM-I training task in addition to the daily measures, for seven days. Finally there was the follow-up phase where participants completed the daily measures for one more week.

In addition to daily measures, a measure of interpretation bias and other anxiety measures were completed at pre-baseline, pre-CBM-I, post CBM-I and follow-up.

3 x participants	Pre baseline	Daily measures (7 days)	Pre-CBM-I	Daily measures (7 days)	Post CBM-I	Daily measures (7 days)	Follow up
2 x participants	Pre baseline	Daily measures (9 days)	Pre-CBM-I	Daily measures (7 days)	Post CBM-I	Daily measures (7 days)	Follow up
2 x participants	Pre baseline	Daily measures (11 days)	Pre-CBM-I	Daily measures (7 days)	Post CBM-I	Daily measures (7 days)	Follow up

Figure 1. Multiple-baseline design.

The multiple-baseline across participants design is a common research strategy for assessing clinical interventions in applied settings and has been found to uphold critical empirical validity criteria in a variety of research contexts (Kazdin, 1992). The staggered delivery of the intervention across differing baseline phase lengths helps to eliminate alternative explanations of outcome change and enhances external validity by way of the multiple inter-participant replications (Morgan & Morgan, 2009). Furthermore it acts as a control against maturation and test-retest sensitivity (Harvey, May, & Kennedy, 2004).

The non-concurrent feature meant that participants initiated the baseline and CBM-I phases at different times to one another. This method has been proposed as an effective strategy in settings where more rigorous designs are not feasible (Harvey et al., 2004). Given that CBM-I is an innovative approach that is relatively untested in GAD populations (Beard, 2011), the adopted design offers a feasible, suitable framework with the resources available to the present study.

2.3 Participants

All participants were patients referred to Wellbeing Services within Norfolk and

Suffolk NHS Foundation Trust (NSFT) seeking help for anxiety.

2.3.1 Sample size.

A total of seven participants completed the present study (see table 2). Such a sample size is considered to be appropriate for single-case research (Kazdin, 2011) and is similar to other single-case studies investigating CBM-I (Blackwell & Holmes, 2010; Clarke, 2012; Turner et al., 2011). Recruitment was impacted by challenging times across recruitment sites in which potential referrers spoke of having to deal with increased stressors such as service flux and job insecurity. Consequently their capacity to hold in mind the present study and refer patients was diminished (see appendix A for recruitment activity log).

Table 2

Demographic Data and Screening Measure Scores of All Participants who Completed the Study

	Participant						
	1	2	3	4	5	6	7
Age	26	38	68	45	64	33	22
Gender	Female	Female	Male	Female	Female	Female	Male
Ethnicity	White British	White British	White British	White British	White British	White British	White British
Baseline length (days)	11	9	7	7	9	7	11
PHQ-9	17	14	13	10	4	16	12
GAD-Q-IV	11.67	9.67	10.16	11.5	10.58	11	9.91
BSI- GSI	2.87	1.19	1.34	2.6	0.81	1.34	1.28
BSI- PST	46	35	30	40	22	36	34
BSI-PSDI	3.3	1.8	2.37	3.45	1.95	1.97	1.56
BSI- Somatization	2.43	0.71	0.71	3	0	1.23	1
BSI- Obsessive Compulsive	3.17	2.33	1.33	3.83	0.83	3	2
BSI- Interpersonal-Sensitivity	4	1.75	1	4	2	1.25	2.25
BSI-Depression	2.83	0.67	2.33	0.83	0.33	1.5	1.83
BSI- Anxiety	3	1.33	0.5	3.33	2.5	1.83	1.83
BSI-Hostility	3	0.8	1.4	2.4	0.2	1.2	1.8
BSI- Phobic-Anxiety	3.6	2	0.2	2	0	0.6	0.8
BSI- Paranoid-Ideation	2.2	0.6	0.2	3.6	0.2	0.4	0.6
BSI- Psychoticism	1.6	0.2	0.8	1.4	0.6	0.4	0.4

Note. PHQ-9 = The Patient Health Questionnaire (Kroenke, Spitzer, & Williams, 2001); GAD-Q-IV = The Generalized Anxiety Disorder Questionnaire (Newman et al., 2002); BSI = The Brief Symptom Questionnaire (Derogatis, 1975); GSI = Global Severity Index; PST = Positive Symptom Total; PSDI = Positive Symptom Distress Index.

2.3.2 Inclusion criteria.

The inclusion criteria were as follows:

1. All participants were required to be at least 18 years old as the present study is specifically interested in the efficacy of CBM-I for adults.
2. All participants were required to obtain a score of 5.7 or greater on the Generalized Anxiety Disorder Questionnaire (GAD-Q-IV; Newman et al., 2002) to increase the likelihood that they meet clinical criteria for GAD.
3. All participants were required to have a working home computer with access to the internet and basic computer skills. This was necessary so that they could access and navigate the CBM-I task.
4. All participants had to be proficient in reading and spoken English so that they could complete the self-report measures and understand the CBM-I training material.

2.3.3 Exclusion criteria.

The exclusion criteria were as follows (see figure 2 for a participant flow chart):

1. A score of 20 or higher on the Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001) indicating severe depression would have excluded participants. The rational was that severe low mood may significantly impact engagement with the CBM-I task and possibly affect biases associated with anxiety in a way that may not be detected by the present study. Furthermore depression is associated with different information processing biases (e.g., Rude, Wenzlaff, Gibbs, Vane, & Whitney, 2002) that require different training materials (e.g., Blackwell & Holmes, 2010).
2. A known psychotic illness, brain injury, learning disability or alcohol problem

would exclude participants on the grounds that their response to the CBM-I would be more difficult to anticipate and therefore presented greater risk.

3. Engaging in psychotherapy at any stage of the study would have resulted in exclusion as this could potentially confound the findings.

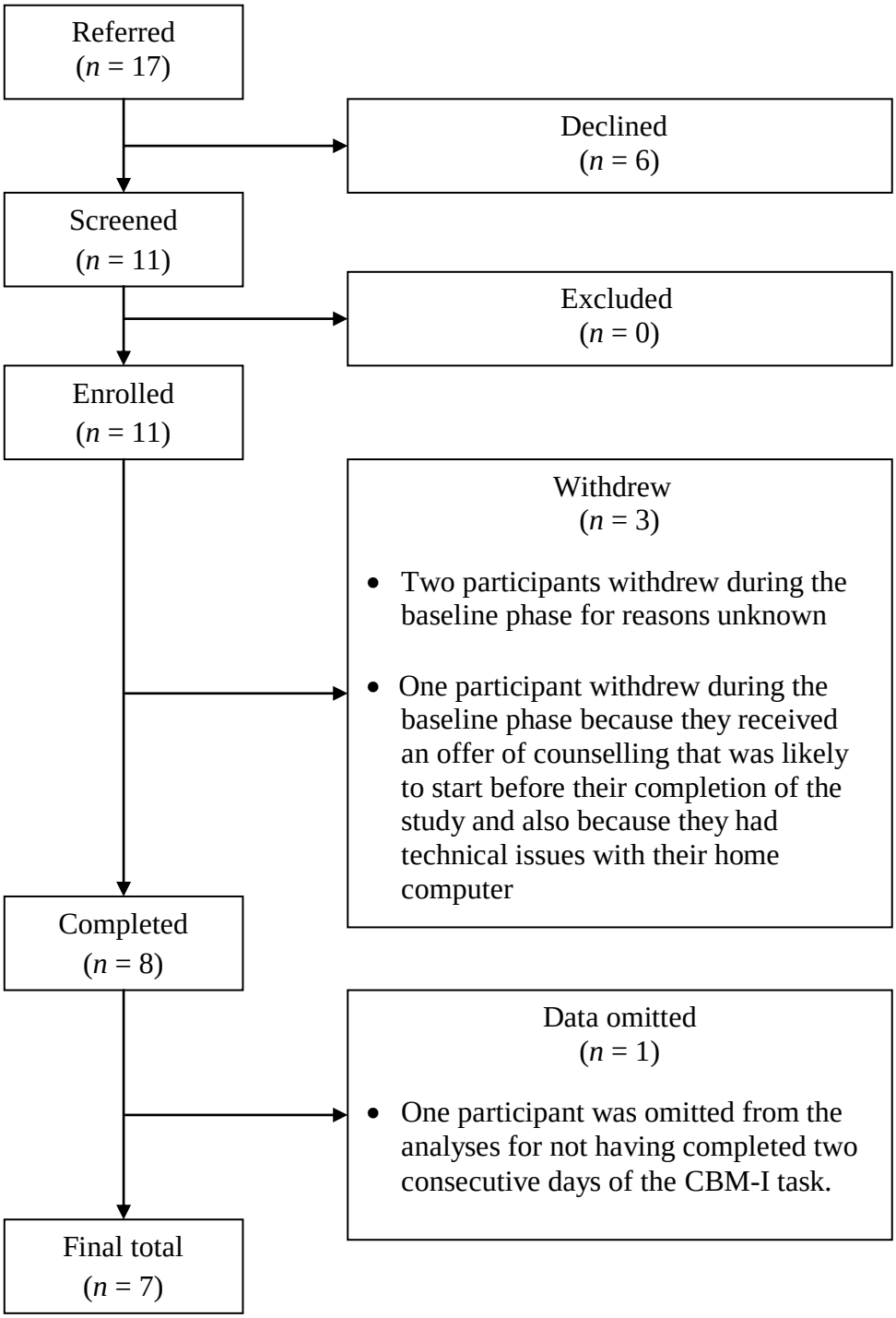

Figure 2. Participant flow chart.

2.3.4 Individual participants.

The following summaries for each participant include the reasons for their referral to the Wellbeing Service, whether they have received any previous psychological help, and the nature of their anxiety.

2.3.4.1 *Participant one.*

Participant one was a 26 year old female referred to the Wellbeing Service due to an increase in anxiety triggered by health related complaints from her children. She reported to have struggled with anxiety since she was sexually assaulted at the age of 14 years and that she has had three different courses of counselling over the past 10 years. She described her most frequent topics of worry as her family, financial, work, and the future generally.

2.3.4.2 *Participant two.*

Participant two was a 38 year old female referred to the Wellbeing Service due to an increase in anxiety triggered by a combination of work and family related stressors occurring in a short space of time. She reported her anxiety to be lifelong and that she has never received any psychotherapy. She described her most frequent topics of worry as her family, work and domestic responsibilities.

2.3.4.3 *Participant three.*

Participant three was a 68 year old male referred to the Wellbeing Service due to an increase in anxiety and depression symptoms in response to difficulties adjusting with retirement. He reported to have struggled with anxiety all his life, that he worries about everything and that he has never received any psychotherapy.

2.3.4.4 *Participant four.*

Participant four was a 45 year old female referred to the Wellbeing Service in response to repeated visits to her General Practitioner (GP) complaining of worsening

anxiety and medically unexplained symptoms. She reported that her anxiety was triggered 3 years ago due to work related stress and that since then she has received a few counselling sessions for anxiety and depression and completed a stress control workshop. She described her biggest worries as crowds and of being attacked by a stranger.

2.3.4.5 *Participant five.*

Participant five was a 64 year old female who self referred to the Wellbeing Service after accompanying her husband to a stress control workshop for support and deciding that she would like to manage her own anxiety better. She reported to have struggled with anxiety since she was a child and that she received some form of counselling about 10 years ago for depression. She described worrying most about her family, driving, death and other people's perceptions of her.

2.3.4.6 *Participant six.*

Participant six was a 33 year old female referred to the Wellbeing Service due to anxiety, panic and exhaustion. She reported longstanding anxiety but that since 2008 it had become increasingly unmanageable due to the death of her father, her own chronic pain resulting in her having to give up her career, and her mother's deteriorating health. She reported having previously received grief counselling as well as psychology input at a pain clinic. She described her biggest worries as her mother's health, her future job prospects and how others perceive her.

2.3.4.7 *Participant seven.*

Participant seven was a 22 year old male who had been referred to the Wellbeing Service prompted by his father learning of the existence of GAD and persuading him that he might have it. He reported to have always worried but that it had got worse since starting university a couple of years ago. Since then he has received some low intensity CBT-based treatment with a Primary Wellbeing Practitioner. He reported to worry most

about his family, his girlfriend and university.

2.4 Measures

This subsection is divided into three parts: i) the screening measures; ii) the primary outcome measure; and iii) the secondary outcome measures. To view all uncopyrighted measures please refer to the Appendices.

2.4.1 The screening measures.

2.4.1.1 *Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001).*

This brief questionnaire was used to screen out participants with severe levels of depression (see appendix B). It consists of nine questions that match the criteria in the Diagnostic and Statistical Manual of Mental Disorders-fourth edition (DSM-IV) for a major depressive episode.

For the purposes of the present study, the PHQ-9 was used as a depression severity measure. Total scores range from 0 to 27 and scores for each question range from '0' (not at all) to '3' (nearly every day). A total score of 1-4 represents minimal depression; 5-9, mild depression; 10-14, moderate depression; 15-19, moderately severe depression; and 20-27, severe depression.

The PHQ-9 is routinely used in primary care including the Wellbeing Services that the present study recruited from and typically takes two-three minutes to complete. It was therefore a suitable depression measure to use.

The authors of the PHQ-9 report various psychometric findings (Kroenke et al., 2001). Internal reliability was found to be excellent when it was completed by 6,000 patients in multiple primary care and obstetrics-gynaecology clinics, demonstrating Cronbach α of 0.89 and 0.86 respectively. At the severe level threshold, the specificity of the PHQ-9 for diagnosing major depression was 95% with a likelihood ratio of 13.6. It was also found to have good construct validity with severe levels associated with worst

functioning on all six domains of the Study Short Form General Health Survey (SF-20; Stewart, Hays, & Ware, 1988). Cameron, Crawford, Lawton, and Reid (2008) also validated the PHQ-9 using primary care patients and found this measure to demonstrate discriminant validity when compared to an established anxiety measure, internal consistency (e.g., a Cronbach α of 0.89) and robustness of factor structure.

2.4.1.2 ***Brief Symptom Inventory (BSI; Derogatis, 1975)***.

This 53-item questionnaire assesses the psychological symptom status of patients. In the present study it was used to gain an overall clinical picture of the participant's presentation. The BSI consists of nine dimensions relating to general symptoms of mental health, namely somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation and psychotism. The questionnaire typically takes approximately ten minutes to complete. All items are ranked on a 5-point rating scale of '0' (not at all) to '5' (extremely) to reflect perceived distress during the past seven days. Of primary interest to the researcher were items relating to psychotism to check whether further assessment was required to ensure that participants were not floridly psychotic, and therefore ineligible.

Derogatis and Melisaratos (1983) reported good internal consistency reliability for the nine dimensions of the BSI with Cronbach α ranging from 0.71 to 0.85. The BSI manual (Derogatis, 1993) sites factor analyses results confirming the a-priori construction of the different dimensions and correlations with the Symptom Checklist-90-Revised (SCL-90-R; Derogatis, 1977) ranging between 0.92 and 0.99.

2.4.1.3 ***Generalized Anxiety Disorder Questionnaire (GAD-Q-IV; Newman et al., 2002).***

This self-report diagnostic measure of GAD is closely based on criteria for GAD set out in the DSM-IV (see appendix C). It is described by Newman et al. (2002) as an

effective way to screen for the presence or absence of diagnosable GAD and so this was its primary purpose in the present study. It is a much more convenient and quicker method of screening for GAD compared to structured diagnostic interviews and typically takes approximately five minutes to complete. The GAD-Q-IV has been used as a screening tool for GAD in other CBM-I studies (Hayes et al., 2010; Hirsch et al., 2009). In the current study it will also be used as an outcome measure to assess severity of generalised anxiety.

The GAD-Q-IV consists of nine questions that include: five yes/no checklists assessing the occurrence of worry, a DSM-IV symptom check list, a listing of the most frequent topics of worry and two 8-point Likert scales ranging from '0' (none) to '8' (very severely) assessing distress and interference of worry and physical symptoms. The authors recommend a weighted scoring system that provides an overall index of the severity of GAD.

The maximum score is 13 however the authors reported that a score cut-off of 5.7 yields the optimal balance between sensitivity (83%) and specificity (89%). The authors also noted this cut-off to have generated a false positive rate of 11% and a false negative rate of 17% with the Anxiety Disorders Interview Schedule for DSM-IV (ADIS-IV; Brown, Di Nardo, & Barlow, 1994); that is, it incorrectly classified 11% of cases as having GAD and incorrectly classified 17% of cases as not having GAD.

Newman et al. (2002) found that in a sample of undergraduate students, the GAD-Q-IV successfully discriminated individuals diagnosed with GAD using either the ADIS-IV or the Anxiety Disorders Interview Schedule for DSM-IV, Lifetime Version (ADIS-IV-L; Di Nardo, Brown, & Barlow, 1994) from individuals diagnosed with panic disorder and social phobia - common co-morbid diagnoses of GAD. Newman and colleagues also found the GAD-Q-IV to have good convergent and discriminant validity compared to a battery of other anxiety-related measures. When test-retest reliability was

examined using the 5.7 cut-off score, a Kappa agreement between Time 1 and Time 2 of 0.64 was generated. In addition, the authors performed a logistic regression which showed that the GAD-Q-IV score at time 2 was reliably predicted by time 1 score ($X^2(1, N = 148) = 42.1, p < .001$).

In another study where the ADIS-IV-L and the GAD-Q-IV were administered using a cut-off score of 5.7 (Luterek, Turk, Heimberg, Fresco, & Mennin, 2002), the GAD-Q-IV correctly classified 50 of 53 non-anxious community participants as not having GAD (96.2% specificity) and all of the 31 participants with GAD as having GAD (100% specificity).

Newman et al. (2002) also compared their study's undergraduate sample to a community sample of individuals with GAD and found that they did not differ on the PSWQ and the STAI suggesting that these results are generalisable to community samples.

Beyond these studies, relatively little psychometric data is available on the GAD-Q-IV although it has been tested favorably in some research using older adult samples (Diefenbach, Tolin, Meunier, & Gilliam, 2009; Staples & Mohlman, 2012; Webb et al., 2008). Also some confusion remains over the optimal cut-off to use and optimal scoring system (Rodebaugh, Holaway, & Heimberg, 2008).

Because of these considerations and in the absence of a rigorous diagnostic assessment in the present study, caution was exercised when describing the diagnostic status of eligible participants who met Newman and colleagues' advised cut-off of 5.7. Participants in the current study are viewed as experiencing clinical levels of generalised anxiety, rather than as having diagnosed GAD.

2.4.2 The primary outcome measure.

2.4.2.1 *The Penn State Worry Questionnaire (PSWQ; Meyer et al., 1990).*

The PSWQ is the most popular measure of pathological worry in clinical

populations (Fresco, Mennin, Heimberg, & Turk, 2003) and is widely considered as the best assessor of symptom change in GAD (e.g., Fisher, 2006; Gould et al., 2004). This questionnaire typically takes approximately five minutes to complete. In the present study it was used to monitor, daily, the participant's level of worry.

The PSWQ is a 16-item inventory consisting of statements designed to capture the generality, excessiveness and uncontrollability of pathological worry (Fresco et al., 2003). It has a 5-point answer scale ranging from '1' (not at all typical of me) to '5' (very typical of me) with a total score ranging from 16 to 80 (see appendix D).

The PSWQ has been found to have good internal consistency in GAD patients: Brown, Antony, and Barlow (1992) reported a Cronbach α of 0.86 in their GAD patient group, as does Dear et al. (2011). The PSWQ has also been shown to discriminate patients with GAD from community controls and patients with other anxiety disorders (Brown et al., 1992) and been found to be sensitive to the detection of GAD (Fresco et al., 2003). Furthermore the PSWQ is positively correlated with other self-report measures of worry (e.g., Beck, Stanley, & Zebb, 1995) and has demonstrated good test-retest reliability (e.g., Meyer et al., 1990) and responsiveness to change, with large effect sizes at post treatment (Cohen's d = 0.71) and at follow-up (Cohen's d = 1.48) (Dear et al., 2011).

2.4.3 The secondary outcome measures.

2.4.3.1 *Anxiety Visual Analogue Scales (VAS)*.

Based on Blackwell and Holmes (2010), two VAS were designed: one measures subjective anxiety by asking the participant to rate the statement 'How anxious have you felt over the past 24 hours?' and the other measures a typical anxiety bias pertaining to catastrophisation with the statement 'when I imagine outcomes for events, I expect the worst' (see appendix E). The VAS are quick and easy to complete, take less than one minute to complete, and are ideal for monitoring daily change. The scales were 10cm long

anchored with ‘0’ (not at all) at one end and ‘100’ (extremely) at the opposite end.

2.4.3.2 ***The Generalized Anxiety Disorder Assessment (GAD-7; Spitzer, Kroenke, Williams, & Lowe, 2006).***

The GAD-7 is both a brief screening tool for GAD and a general measure for anxiety that is routinely used in primary care services (see appendix F). The questionnaire typically takes 2-3 minutes to complete. In the present study it was used to assess any changes in the participant’s level of general anxiety.

The measure consists of seven statements that pertain to anxiety symptoms. The participant must rate how often he/she has been bothered by each of them for the past two weeks. Scores for each question range from ‘0’ (not at all) to ‘3’ (nearly every day). Total scores range from 0 to 27 with the following severity ranges: minimal, 0-4; mild, 5-9, moderate, 10-14, and severe, 15-21.

Although there is relatively limited data available on its psychometric properties, the GAD-7 has been found to have impressive internal consistency (Cronbach α of 0.89 - 0.92) (Lowe et al., 2008; Spitzer et al., 2006), good test-retest reliability (intraclass correlation = 0.83) and a cut-off point of 10 or greater yields sensitivity and specificity exceeding 0.80 (Spitzer et al., 2006). The study by Dear et al. (2011) found the GAD-7 to have good internal consistency (Cronbach α of 0.79) and responsiveness to change with large effect sizes between pre-treatment and post treatment (Cohen’s d = 1.10) and pre-treatment and follow-up (Cohen’s d = 1.85).

2.4.3.3 ***The Spielberger State-Trait Anxiety Inventory (STAI; Spielberger et al., 1983).***

The STAI is a self-report measure of the severity of current symptoms of anxiety and a generalised propensity to be anxious. It contains two subscales: the state anxiety scale which evaluates current anxiety and the trait anxiety scale which evaluates relatively

stable aspects of 'anxiety proneness' (Julian, 2011).

Many other CBM studies using clinically anxious populations have used at least one of the STAI subscales to measure anxiety (e.g., Amir et al., 2010; Brosan et al., 2011).

The STAI has 40 items in total, 20 within each the two subscales. It typically takes around ten minutes to complete. Responses for the state anxiety subscale assess the intensity of current feelings and there are four options ranging from '1' (not at all) to '4' (very much so). Responses for the trait anxiety scale assess frequency of feelings generally, with options ranging from '1' (almost never) to '4' (almost always). Scores range from 20 to 80 on each subscale with higher scores indicating greater anxiety. A cut-off point of 39-40 has been suggested by the authors to detect clinically significant symptoms for the state subscale.

The trait scale has been widely used in treatment studies of GAD and has been related to change following interventions (Fisher & Durham, 1999). Spielberger et al. (1983) report excellent internal consistency coefficients ranging from 0.86 to 0.95 and good test-retest reliability (e.g., median test-retest correlations of 0.77 for college students and 0.70 for high school students). Because the state subscale is designed to detect transitory states, test- retest coefficients are lower for this subscale compared to the trait subscale. With regard content validity, the STAI has been found to have strong correlations with other anxiety measures (0.73 & 0.85) (Spielberger et al., 1983) although its construct and discriminant validity appear to be less robust (Julian, 2011).The STAI's ability to detect change is stronger for the state subscale however the mediation analysis conducted by Salemink et al. (2010) suggests that changes on the trait subscale are more reflective of changes in interpretive bias.

2.4.3.4 *The Scrambled Sentences Test (SST; Wenzlaff, 1993).*

The SST was used to measure level of negative interpretation bias (an example SST

can be viewed in appendix G).

There were a total of 80 scrambled sentences, each comprising six words with two possible coherent resolutions made up of five words (see appendix H). One combination would form a positive resolution and another combination would form a negative resolution. The participant was required to place numbers above each word indicating the intended order. For example:

The participant was presented with the following scrambled sentence:

will me most help hurt people

There are two possible resolutions:

a) most people will hurt me (negative resolution)

which they would number as :

3	5	1		4	2
will	*me*	*most*	*help*	*hurt*	*people*

b) most people will help me (positive resolution)

which they would number as:

3	5	1	4		2
will	*me*	*most*	*help*	*hurt*	*people*

Prior to completing the sentences, participants were presented with the same instructional set as that used by Standage, Ashwin, and Fox (2010). This explained the format of the task and included a completed, unscrambled sentence as an example.

They were then presented with a six digit number for ten seconds and asked to remember it. This acted as a cognitive load so as to reduce the influence of effortful processing that can lead to a positive response bias (Bowler et al., 2012).

They were then required to unscramble as many sentences to ‘form the first statement that comes to mind’ as quickly as possible. The time limit was four minutes,

after which they were required to write down the six digit number.

Interpretation bias scores are obtained by calculating the proportion of negative resolutions generated.

The 80 scrambled sentences were 'scrambled' using RANDOM.ORG and their order was block randomised for each participant with 20 sentences presented at pre-baseline, 20 sentences at pre-CBM-I, 20 at post CBM-I and 20 at follow-up. The six digit number, instructions and scrambled sentences were all contained on three A4 sheets.

All of the sentences are based on the main worry themes identified in the Worry Domains Questionnaire (WDQ: Tallis, Davey, & Bond, 1994) and some are replications of those used by Standage et al. (2010). The sentences were checked for content and relevance to GAD by two independent Clinical Psychologists and a Trainee Clinical Psychologist.

The SST is a suitable measure for the purposes of the current study because it has been successfully used to detect interpretation bias change in other CBM-I studies (e.g., Blackwell & Holmes, 2010; Bowler et al., 2012; Standage et al., 2010) and is easily tailored to general worry related biases.

2.5 Training Materials

2.5.1 Text-based ambiguous scenarios task.

The text-based ambiguous scenarios paradigm developed by Mathews and Mackintosh (2000) was used as the CBM-I task to modify interpretation bias. This is the most commonly used CBM-I task within CBM-I studies (Beard, 2011).

In accordance with other studies testing CBM-I in GAD populations (Hayes et al., 2010; Hirsch et al., 2009), scenarios covering common worry topics identified in the WDQ were used including relationships, lack of confidence, aimless future, work incompetence, financial and physical threat. Some scenarios were replications or adaptations of those used

by Mathews and Mackintosh (2000) and Clarke (2012); the rest were created for the current study.

Scenarios were checked for content and relevance to GAD by two independent Clinical Psychologists and a Trainee Clinical Psychologist. The aim was to try to ensure that the scenarios and word fragments would make sense and be applicable to as many ability levels and life experiences of participants as possible.

The format of the CBM-I task is that participants are presented with scenarios (four lines in length) that remain ambiguous until the final word which is presented as a word fragment. The final word always resolves the scenario in either a benign or positive manner. Participants are required to solve the word fragment by entering the first letter that is missing. At the conclusion of each completed scenario participants are presented with a comprehension question, consistent with the scenario, to ensure that they have understood the disambiguated scenario and, importantly, its benign/positive conclusion. Participants must answer either *yes* or *no* to this question and are then presented with immediate feedback as to whether or not their answer is correct or incorrect. Correct answers always resolve the scenario in a benign/positive manner and incorrect answers always provide a negative resolution.

In total there are 350 scenarios which are split into seven daily blocks of 50 trials. Within each daily block the scenarios are further divided into blocks of 10, between which participants can take a rest break if they desire. Each daily session takes approximately 30-45 minutes to complete depending on rest breaks and task speed.

To ensure an equal spread of the scenarios by worry topic across the sessions, scenarios were block randomised (using RANDOM.ORG) to each block of 10, within each day, according to their associated worry topic.

The following is an example of a training scenario with a comprehension question:

'You see a job vacancy advertised in your local paper.

You are interested in what would be involved and ask for details.

On hearing the details,

you think that you would be'

i d _ _ l (ideal)

'Do you think the chances of you getting the job are poor?' (No)

Instructions are presented at the beginning of each daily session to remind participants of the structure of training and to emphasise the importance of visual imagery (see appendix I).

2.5.1.1 ***Imagery instructions.***

The following was included in the instructions and pertains to imagery: '*In order for you to get the most out of completing the sessions, it is really important that you create an image in your head of each situation as if you are the main person in it and it is actually happening. The more vividly you can imagine that you are in the situations, the more you will get out of the sessions. Also, when imagining that you are in the situations, try to imagine that you are looking out through your own eyes rather than looking at yourself in the situation'.*

This is followed by an actual imagery exercise, which requires the participant to imagine a scene and then rate how vividly they can imagine it.

Based on Blackwell and Holmes (2010), as a further reminder for participants to actively imagine themselves when completing the training materials, at a random point within each block of 10 scenarios, the following question appears: '*how vividly were you able to imagine yourself in the previous situation?*' Immediately below the question is a horizontal scale with '0' (*I could not imagine it at all*) at one end and '10' (*I could see it perfectly, as if I were there*) at the other end. Participants are required to enter a number

between 1 and 10.

The final exercise participants complete before starting each daily CBM-I session is a practice scenario which, like the imagery exercise, is different each day.

The CBM-I task was programmed and accessed via a web-based platform called 'CBS Trials' provided by Cambridge Brain Sciences Incorporate.

2.6 Ethical Considerations

Prior to commencing recruitment, the study was reviewed by the Proportionate Review Sub-Committee of the North West Greater Manchester South National Research Ethics Service (NRES) on the 22.05.2013 and also by the Norfolk and Suffolk National Health Service Foundation Trust (NSFT) Local Research Governance Committee on the 30.05.2013.

Following some minor amendments the study was given a favourable opinion from each committee and a copy of the relevant paperwork can be found in appendixes J and K. Sponsorship and indemnity insurance was provided by the Research Enterprise and Engagement department of the University of East Anglia (UEA) (see appendix L).

All participants were first approached by clinicians who provided them with a brief description of the study. They were then asked if they were potentially interested in participating in the study and if the researcher was allowed to contact them. Only those that said they were interested and who gave permission to be contacted by the researcher, were contacted. Prior to completing the consent form (see appendix M), all participants were given a detailed verbal explanation by the researcher of what the study involved, had the consent form fully explained to them, had the opportunity to ask any questions and were provided with a participant information sheet (see appendix N) which included the researcher's contact details. All participants were provided with at least 72 hours to read over the patient information sheet before being invited to make a decision of whether they

wished to participate or not. No screening measures were administered until full consent had been obtained.

Confidentiality was upheld in accordance with the criteria set out in the Data Protection Act (1998). All participants were initially identified by clinicians and were only contacted by the researcher after providing verbal consent. The researcher did not have access to client records at any stage. All data containing personally identifiable information was stored securely in a locked cabinet or digitally on password protected files. All data was coded anonymously using participant numbers and was stored separately from any identifying information such as participant name or contact telephone numbers. Access to the material was restricted to the researcher and research supervisors working at UEA. All data are anonymised and will remain stored in secure university premises before eventually being destroyed after approximately ten years.

The study was not anticipated to have any harmful effects as none have been reported in other CBM studies to the best of the researcher's knowledge. Participants were fully informed of their right to withdraw at any stage of the study, without having to provide a reason and they were advised that this would have no impact on their clinical care.

Due to the nature of the study design, participants were required to complete multiple daily measures during the baseline phase (up to 11 days), during the seven day CBM-I phase and the seven day follow-up phase. In addition to this, the CBM-I phase required them to set aside an hour every day in order to complete the training task.

It was made clear to participants from the start that completing the research would require them to delay any psychological treatment that became available to them during their participation and that should they wish not to delay it then they would have to withdraw.

Participants were advised to take a break or to stop the task in the event that they became distressed during a session of CBM-I. If their distress were to persist they were advised that they could contact their GP.

In terms of managing risks to the researcher, risk protocols were agreed with the primary supervisor regarding home visits and a buddy system was implemented in accordance with NSFT lone worker policies.

The financial burden of participating was low as all that was required was a computer with access to the internet. Each participant was provided with up to £5.00 travel expenses if they chose to meet the researcher on NHS premises for the initial contact session rather than their home.

All participants were fully debriefed following the study's completion and encouraged to ask any questions they had. They also indicated whether they wished to receive a simple results summary.

2.7 Procedure

After ethical approval was obtained, Wellbeing Services across Norfolk and Suffolk were contacted and provided with a short presentation followed by a question and answer session. This took place at monthly business meetings and clinician supervision sessions. Within these meetings a plan was collaboratively developed with the clinical team for how best to identify potentially suitable participants and to manage their participation at each recruitment site.

A flow chart detailing the study procedure is presented in figure 3. Once clinical teams had expressed an interest in the study and a willingness to refer, a member of that team approached patients they felt might be eligible to participate and provided them with a brief, simple description of the study and what participating involved. If the patient was interested in learning more they were asked if they would provide verbal consent for the

researcher to contact them and this was evidenced in the patient's clinical notes (e.g., ‘verbal consent for researcher to contact granted by patient’).

The researcher, upon being notified by the referring clinician, then contacted the patient by telephone. The patient was provided with a full explanation of the study and an opportunity to ask questions. The patient was then asked if they were potentially interested in participating. If the patient was interested, the participant details sheet (see appendix O) was completed, an initial appointment was arranged, and the participant information sheet and consent form were sent out to them.

After consent was obtained, the patient and researcher met face to face and the patient completed the screening measures (GAD-Q-IV, PHQ-9 & BSI). If the patient's scores were not suitable on these measures they would have been told that they were not eligible, thanked for their time and their clinical team would have been notified. As it was, all patients that were screened had suitable scores. Consequently they were invited to participate and asked if they wished their GP to be sent a letter notifying them of their participation (see appendix P).

The participant was then block randomised to one of the three baseline lengths (7, 9 or 11 days) and completed all outcome measures (GAD-7, GAD-Q-IV, STAI, SST, PSWQ & VAS).

For the duration of their baseline phase, the participant was asked to complete the daily VAS and PSWQ at approximately the same time each day. They were offered daily reminders to assist them with this however they all declined.

At the end of the baseline phase, the researcher met up again with the participant and non-daily outcome measures were completed for a second time. Following this the participant accessed the CBM-I program on their personal computer and completed their first session with the researcher present for instructional guidance. Similar to Blackwell

and Holmes (2010), the participant was asked to take a 'field perspective' when completing the training scenarios (i.e., to imagine that they are in the scenarios looking through their own eyes as opposed to looking at themselves from an 'observer perspective') (see Holmes, Coughtrey, & Connor, 2008).

For the remaining six sessions of the CBM-I phase, the participant was asked to continue completing daily sessions of the CBM-I task and to do so at approximately the same time every day in addition to the daily measures. Again, daily reminders were offered but all were declined.

After the CBM-I phase, the researcher met with the participant and outcome measures were completed for a third time. After this meeting, the participant continued to complete the daily measures for a further seven days during the follow-up phase.

At the one week follow-up, the researcher met with the participant and all outcome measures were completed for a final time. Finally the participant was fully debriefed, given the opportunity to ask any questions and reimbursed any accrued travel costs up to £5.00. Referring clinical teams were then notified of the participant's study completion.

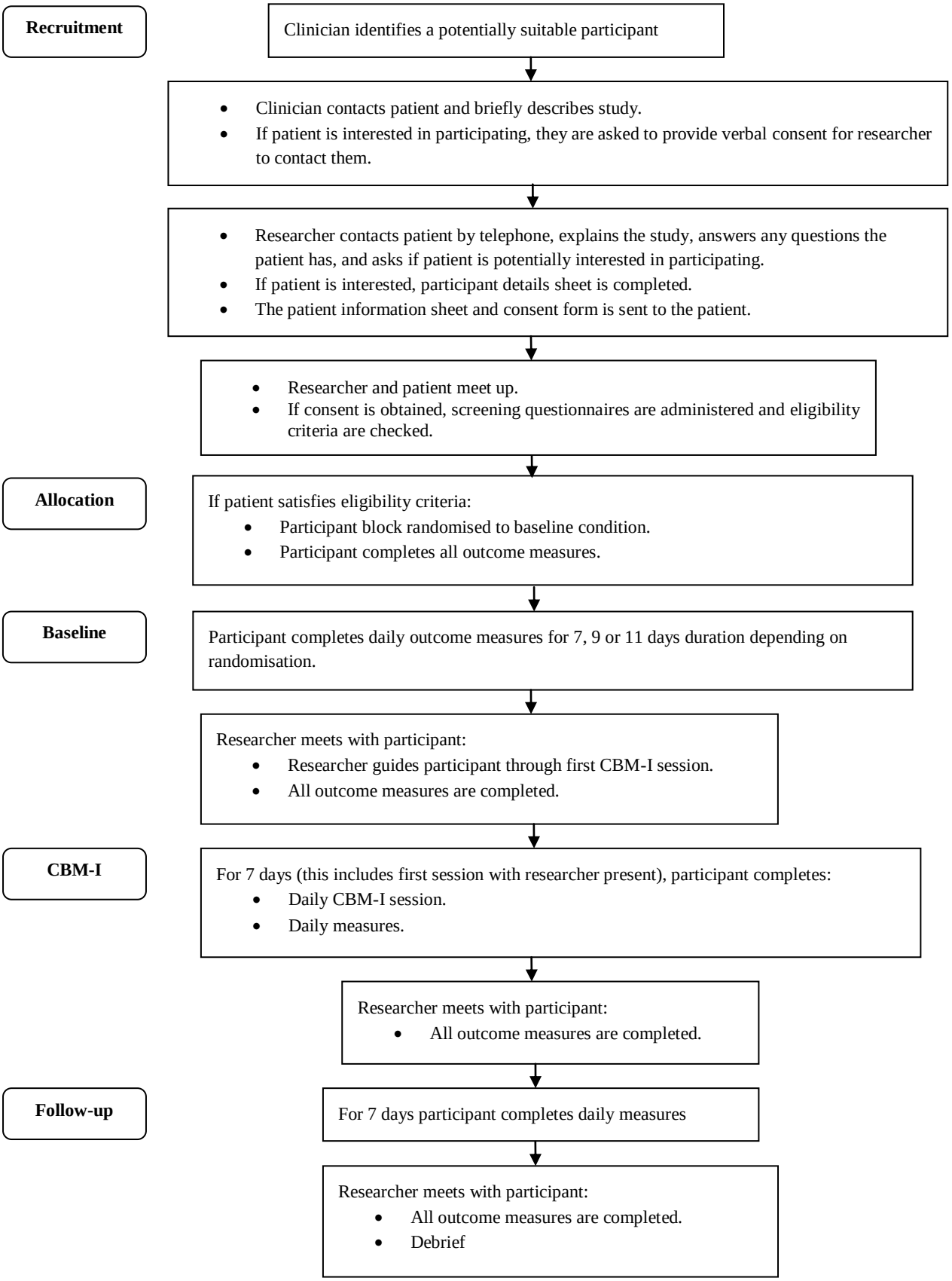

Figure 3. Flow chart of the study procedure.

Results

3.1 Overview

This chapter presents the results of the present study. Data collected on the primary outcome measure, the PSWQ, as well as the VAS, are subjected to visual inspection to evaluate whether the CBM-I package produces a response. This is supplemented by the calculation of reliable change, clinically significant change and statistically significant change on outcomes at pre-assessment, pre-CBM-I, post CBM-I and one week follow-up.

3.2 Visual Inspection of Data

To evaluate the impact of CBM-I training on worry (in accordance with the primary research hypothesis), anxiety and a typical anxiety bias (anxiety-bias), visual inspection is performed on graphic data using the criteria set out by Kazdin (2011).

The first category of criteria is *magnitude of change* which includes changes in mean across the three phases of baseline, CBM-I and follow-up, and changes in level. *Changes in mean* refers to whether mean scores of worry, anxiety and anxiety-bias change across the phases. *Changes in level* refers to whether there is a shift in score at the very beginning of the phase from the very end of the previous phase.

The second category of criteria is *rate of change* which includes changes in trend or slope, and latency of the change. *Changes in the trend or slope* refers to the trend line which characterises the data within each phase and whether it reflects a change from the trend line in the previous phase. *Latency of change* refers to the speed at which change occurs after the onset of the CBM-I phase.

The greater the change in both magnitude and rate between the baseline phase and the CBM-I phase on an outcome, the more confidently it can be ascribed that the CBM-I had an effect and that it was responsible for the change (Kazdin, 2011). In the current study, the CBM-I package is judged to have had an effect on an outcome for any one

participant if there appears to be change in the CBM-I phase and it is judged to be reliable in accordance with Kazdin's (2011) criteria. Similar to the classification system used by Blackwell and Holmes (2010), if reliable change is judged to have occurred on the primary outcome, the PSWQ, then the participant is classed as a responder. Alternatively if it is judged that no reliable change has occurred for worry then the participant is classed as a non-responder.

To assess whether effects last beyond CBM-I training, Kazdin's (2011) criteria is applied to the follow-up phase. If visual inspection reveals no reliable change between the follow-up phase and the CBM-I phase in the direction of deterioration, then it is judged that gains have maintained at follow-up and the participant is classed as a maintainer. Where gains are judged to have not maintained in the follow-up phase, the participant is classed as a non-maintainer.

To aid visual inspection, Kendall's *tau* correlation is calculated for each outcome's baseline phase (between scores & days) enabling a statistical assessment of baseline stability.

3.2.1 Participant one.

3.2.1.1 *Worry.*

Visual inspection of figure 4 and Kendall's *tau* analysis reveals a stable baseline (*tau* = .41, p = .25). At the start of the CBI-I training, there is a small reduction in mean worry and no change in level of worry. However there is a delayed latency of improvement as there is a short downward slope of worry scores (indicating reduced worry) after the second day of the CBM-I phase which then stabilises. In the follow-up phase there is a small increase in mean worry, a small downward shift in level of worry at the start with worry scores reversing to an increasing trend (indicating increased worry) after a couple of days.

Overall the reduced worry observed in the CBM-I phase is of a very small magnitude and it starts after a two day latency period in which worry scores remained totally unchanged from the baseline phase. Consequently the improvement is not considered sufficiently reliable and so this participant is classed as a non-responder and also therefore a non-maintainer.

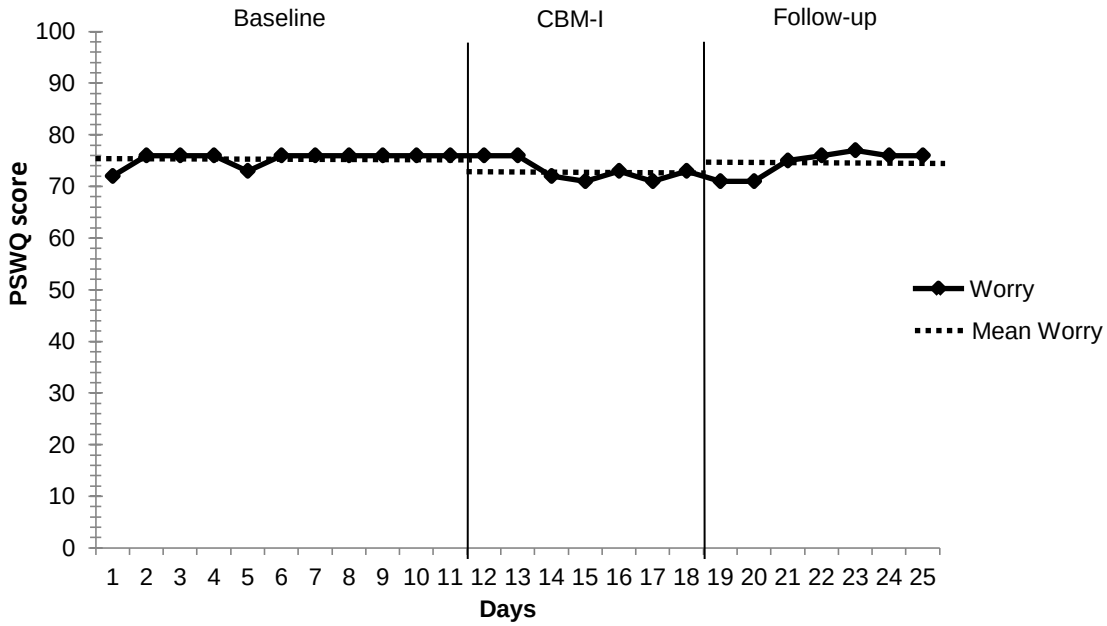

Figure 4. Participant one's (non-responder/non-maintainer) daily and mean worry scores across all phases. PSWQ = Penn State Worry Questionnaire.

3.2.1.2 *Anxiety and anxiety-bias.*

Visual inspection of figure 5 reveals a baseline phase with high variability and increasing trends of anxiety and anxiety-bias scores (indicating deterioration), although not significantly so as indicated by Kendall's *tau* analysis (for both: *tau* = .26, p = .3). In the CBM-I phase there is an equivalent reduction in mean anxiety and anxiety-bias, a large downward shift in level for both at the start (indicating an immediate drop in scores), and a decreasing trend of scores (indicating decreasing anxiety and anxiety-bias). In the follow-up phase there is a further reduction in mean anxiety (indicating improvement).

However there is an increase in mean anxiety-bias, and another downward shift in level of both at the start followed by a fluctuating, mostly increasing, trend (indicating deterioration).

Overall there appears to be an improvement in anxiety and anxiety-bias in the CBM-I and follow-up phases however this is accompanied by large variability making it difficult to interpret whether the CBM-I was responsible for such change. Consequently the CBM-I is judged as not having a reliable effect on anxiety and anxiety-bias for this participant.

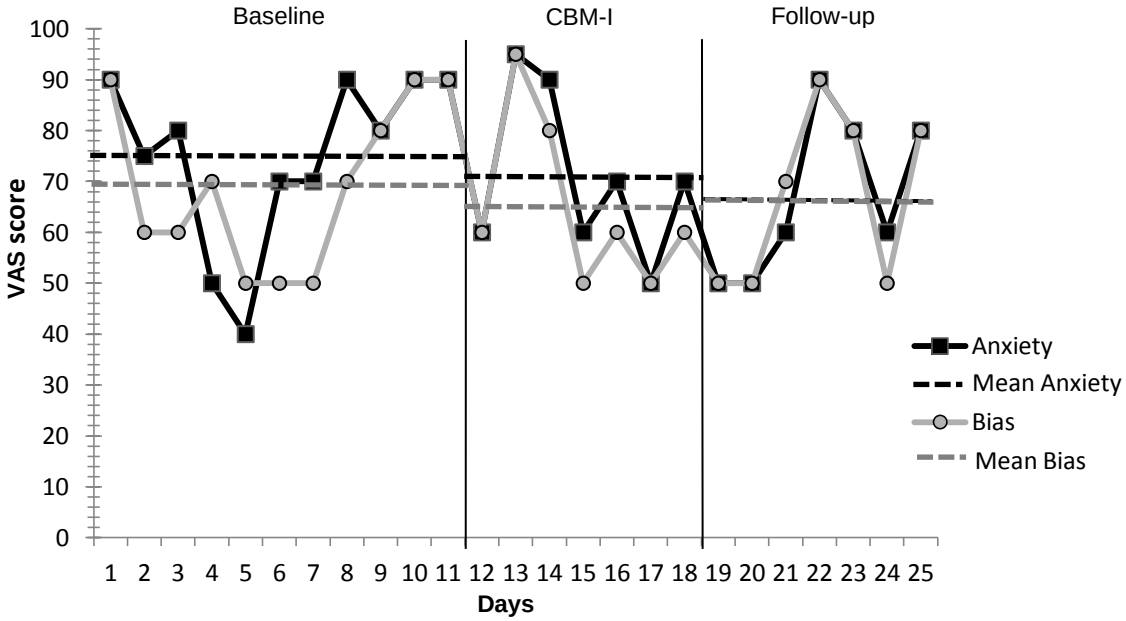

Figure 5. Participant one's daily and mean anxiety and anxiety-bias scores across all phases. VAS = Visual Analogue Scale.

3.2.2 Participant two.

3.2.2.1 *Worry.*

Visual inspection of figure 6 and Kendall's *tau* analysis reveals a significant, increasing trend in the baseline phase (*tau* = .92, p = .001). In the CBM-I phase mean worry increases. At the start of this phase there is no change in level (indicating no immediate CBM-I effect) and this is followed initially by a decreasing worry trend which then reverts to an increasing trend (indicating worry increased again). In the follow-up

phase there is little change in mean or level of worry at the start, and scores stabilise.

Overall there appears to be a slowing in the rate of deterioration of worry in the CBM-I and follow-up phases, however it is minimal, and there is no improvement in worry. Therefore this participant is classed as a non-responder and also therefore a non-maintainer.

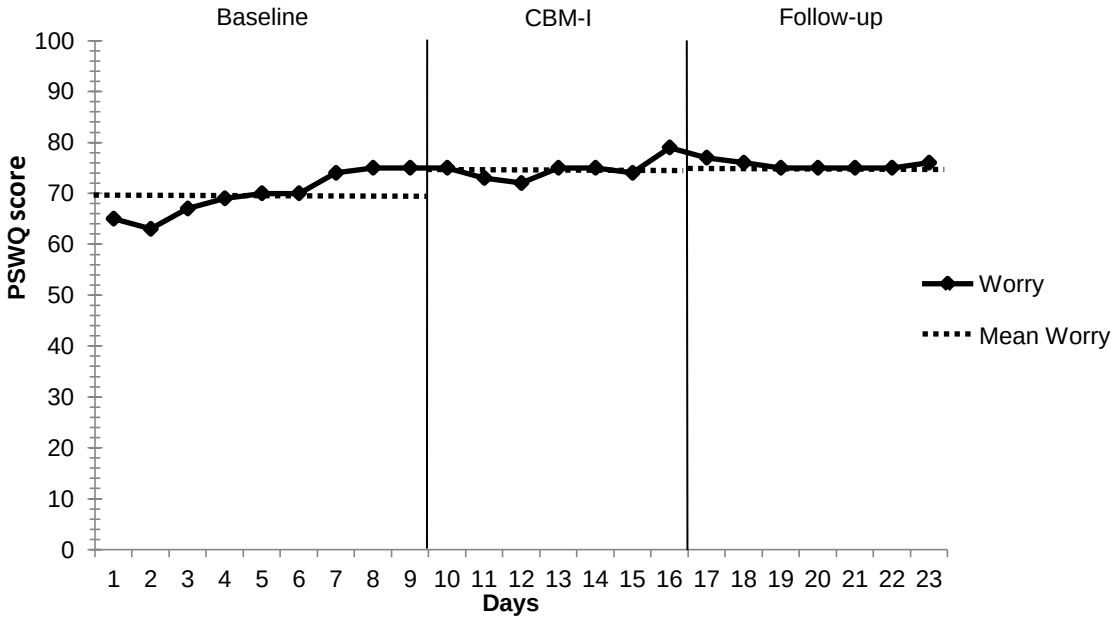

Figure 6. Participant two's (non-responder/non-maintainer) daily and mean worry scores across all phases. PSWQ = Penn State Worry Questionnaire.

3.2.2.2 *Anxiety and anxiety-bias.*

Visual inspection of figure 7 and Kendall's *tau* analysis reveals a non-significant decreasing trend of anxiety (*tau* = -.3, p = .3) and anxiety-bias scores (*tau* = -.52, p = .09) in the baseline phase with anxiety demonstrating a greater degree of fluctuation. In the CBM-I phase there is a clear reduction in mean anxiety and anxiety-bias with no shift in level for both at the start although there is a sharp drop in anxiety-bias scores (a dramatic improvement) after the third CBM-I session and therefore a delayed latency of change. Unlike anxiety-bias scores there is no significant change in trend of anxiety scores in the

CBM-I phase. In the follow-up phase there is a further clear reduction in mean anxiety and anxiety-bias scores, a downward shift in level for both at the start (immediate improvement) and stabilisation of both.

Overall there appears to be an improvement in anxiety and anxiety-bias in the CBM-I and follow-up phases. However the magnitude of this change and rate of change are relatively pronounced for anxiety-bias, but not so for anxiety, mostly due to larger variability, making an interpretation more difficult. Consequently for this participant, the CBM-I is judged as having a reliable effect on anxiety-bias with gains maintaining at follow-up whereas for anxiety it is judged as not having a reliable effect.

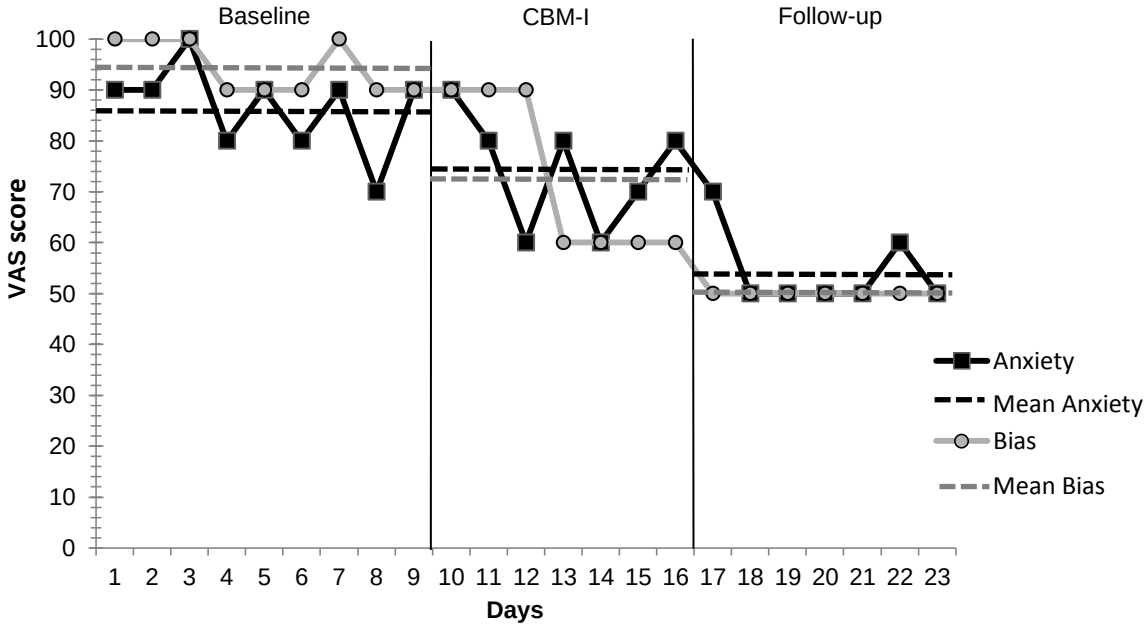

Figure 7. Participant two's daily and mean anxiety and anxiety-bias scores across all phases. VAS = Visual Analogue Scale.

3.2.3 Participant three.

3.2.3.1 *Worry.*

Visual inspection of figure 8 and Kendall's *tau* analysis reveals a non-significant decreasing worry trend in the baseline phase (*tau* = -.45, p = .17). In the CBM-I phase

there is little change in mean worry or level at the start, although the direction of trend reverses upwards (worry increased). In the follow-up phase there is a small change in mean worry and level of worry at the start which then stabilises.

Overall there appears to be little change to worry scores in the CBM-I and follow-up phases therefore this participant is classed as a non-responder and also therefore a non-maintainer.

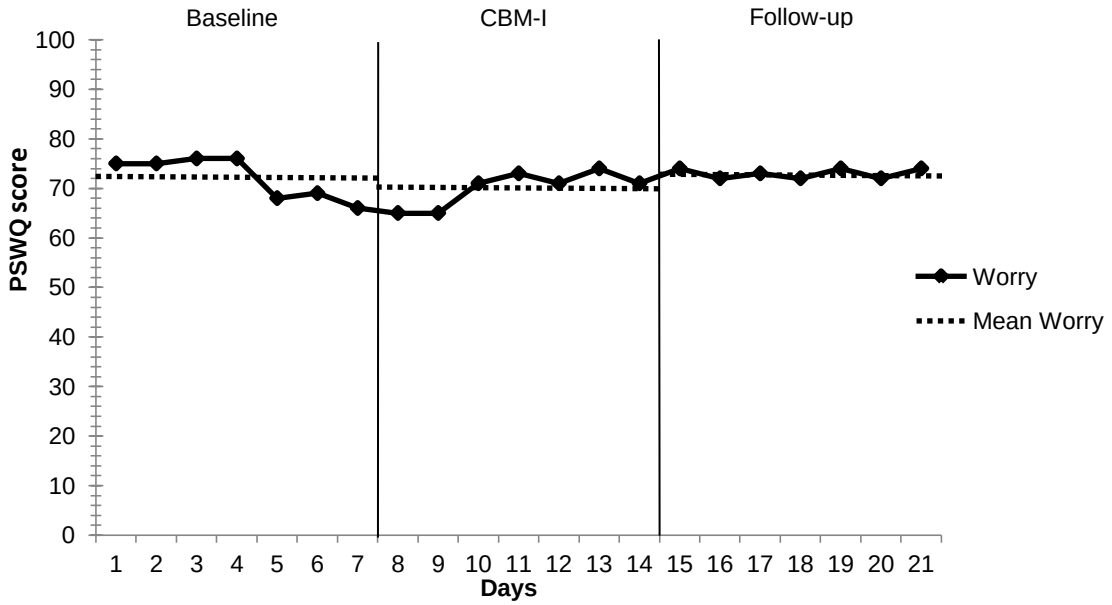

Figure 8. Participant three's (non-responder/non-maintainer) daily and mean worry scores across all phases. PSWQ = Penn State Worry Questionnaire.

3.2.3.2 *Anxiety and anxiety-bias.*

Visual inspection of figure 9 reveals a decreasing trend of scores on both outcomes in the baseline phase, which is most pronounced for anxiety. Kendall's *tau* analysis indicates that the trend is non-significant for anxiety-bias scores (*tau* = -.59, p = .09) whereas it is significant for anxiety scores (*tau* = -.78, p = .02). In the CBM-I phase there is no shift in level for each at the start however there is a reverse shift to an upward trend (deterioration) which is dramatic for anxiety scores. In terms of means, anxiety-bias

decreased whereas anxiety increased in the CBM-I phase. In the follow-up phase there is an increase in mean anxiety and anxiety-bias, an increase in level of anxiety and anxiety-bias, and greater stabilisation.

Overall there appears to be little change in anxiety-bias scores in the CBM-I and follow-up phases whereas for anxiety scores there appears to be a notable change in rate and of magnitude in the direction of deterioration. However because anxiety scores significantly improved in the baseline phase (undermining their validity as a baseline) and because deterioration did not occur immediately after the introduction of CBM-I but rather after a two day delay, it is judged that CBM-I was not responsible for such deterioration.

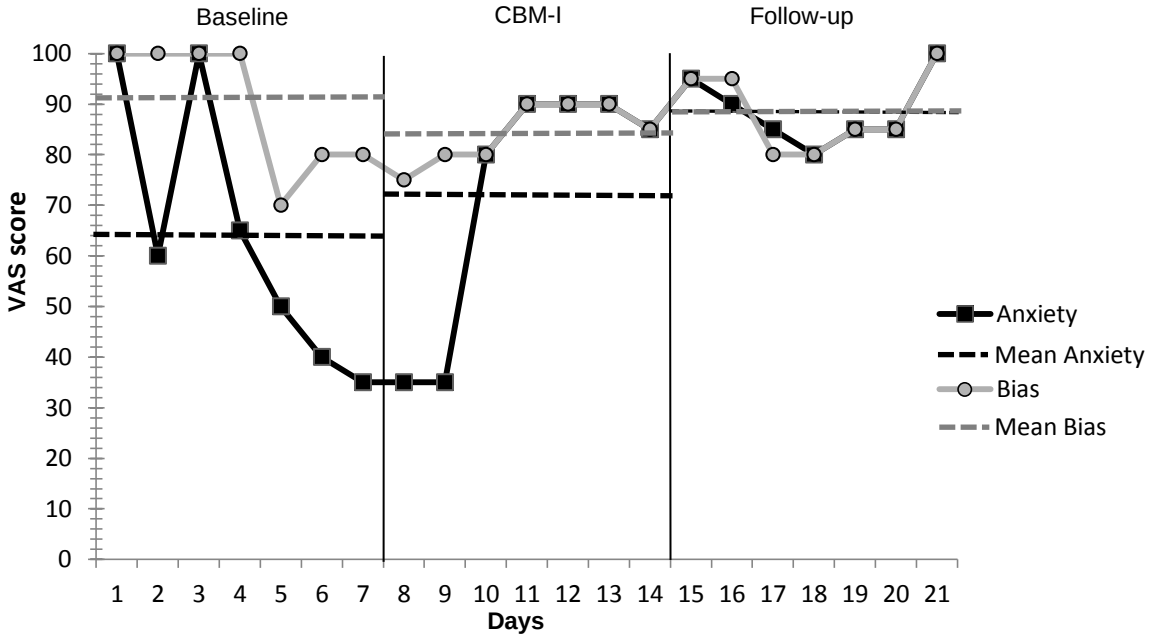

Figure 9. Participant three's daily and mean anxiety and anxiety-bias scores across all phases. VAS = Visual Analogue Scale.

3.2.4 Participant four.

3.2.4.1 *Worry.*

Visual inspection of figure 10 reveals a perfectly stable baseline. In the CBM-I phase there is a small but clear downward shift in level of worry at the start indicating an

immediate latency of change. There is also a decreasing trend of worry (decreasing worry) and a reduction in mean worry. In the follow-up phase there is a further reduction in mean worry and another downward shift in level of worry at the start, which then reverses and stabilises somewhat.

Overall there appears to be a notable improvement in worry scores both in terms of magnitude of change and rate of change in the CBM-I phase with gains appearing to maintain in the follow-up phase. Therefore this participant is classed as a responder and a maintainer.

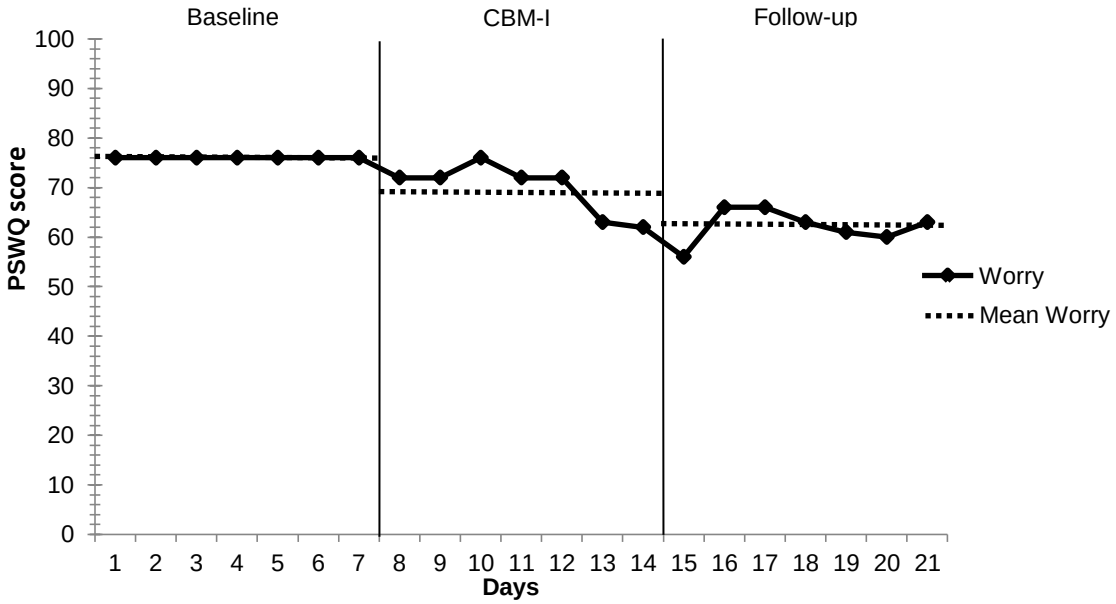

Figure 10. Participant four's (responder/maintainer) daily and mean worry scores across all phases. PSWQ = Penn State Worry Questionnaire.

3.2.4.2 *Anxiety and anxiety-bias.*

Visual inspection of figure 11 and Kendall's *tau* analysis reveals anxiety (*tau* = -.06, p = .87) and anxiety-bias (*tau* = .41, p = .25) to be relatively stable in the baseline phase with anxiety demonstrating a greater degree of fluctuation. In the CBM-I phase, mean anxiety and anxiety-bias reduce (improve), there is an upward shift in level of both at

the start followed by stabilisation and eventually a downward trend of scores indicating a delayed latency of change. In the follow-up phase there is an upward shift in level of anxiety at the start, no shift in level of anxiety-bias, and a further reduction in means of both. Greater stabilisation occurs with the beginnings of a possible upward trend at the end.

Overall there appears to be a reliable improvement in anxiety and anxiety-bias scores both in terms of magnitude of change and rate of change in the CBM-I phase. Although the penultimate anxiety score and the final anxiety-bias score indicate a sharp rise in the direction of deterioration, gains have maintained for the other six time points. Consequently it is judged that CBM-I has had a reliable effect on anxiety and anxiety-bias and that gains have maintained at follow-up for this participant.

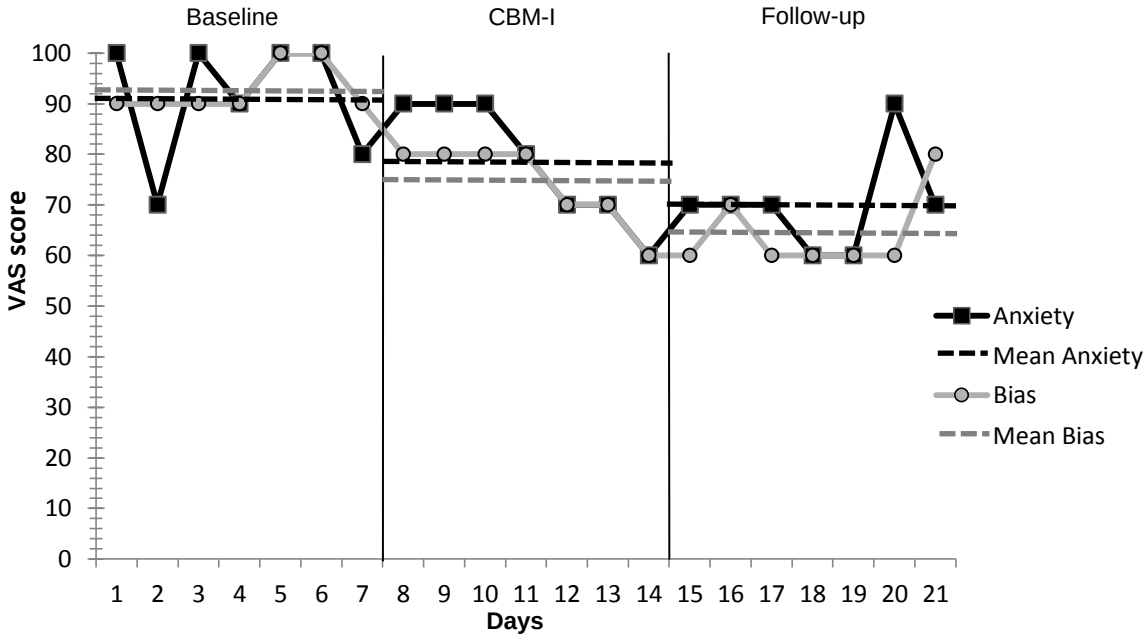

Figure 11. Participant four's daily and mean anxiety and anxiety-bias scores across all phases. VAS = Visual Analogue Scale.

3.2.5 Participant five.

3.2.5.1 *Worry.*

Visual inspection of figure 12 and Kendall's *tau* analysis reveals a significant

decreasing trend in the baseline phase (*tau* = -.76, p = .005). In the CBM-I phase there is a reduction in mean worry with no shift in level of worry at the start and a latency of change of one day. Across the CBM-I phase the downward worry trend continues but at a faster rate (improvement accelerates). In the follow-up phase there is a further reduction in mean worry which then stabilises. Examination of level of change is not possible due to the missing final CBM-I phase data point.

Overall, although there appears to be an improvement in worry scores in the CBM-I phase and beyond, both in terms of magnitude of change and rate of change, it is judged as not being distinct enough from the significantly decreasing trend of the baseline phase to be deemed reliable. Therefore this participant is classed as a non-responder and therefore a non-maintainer.

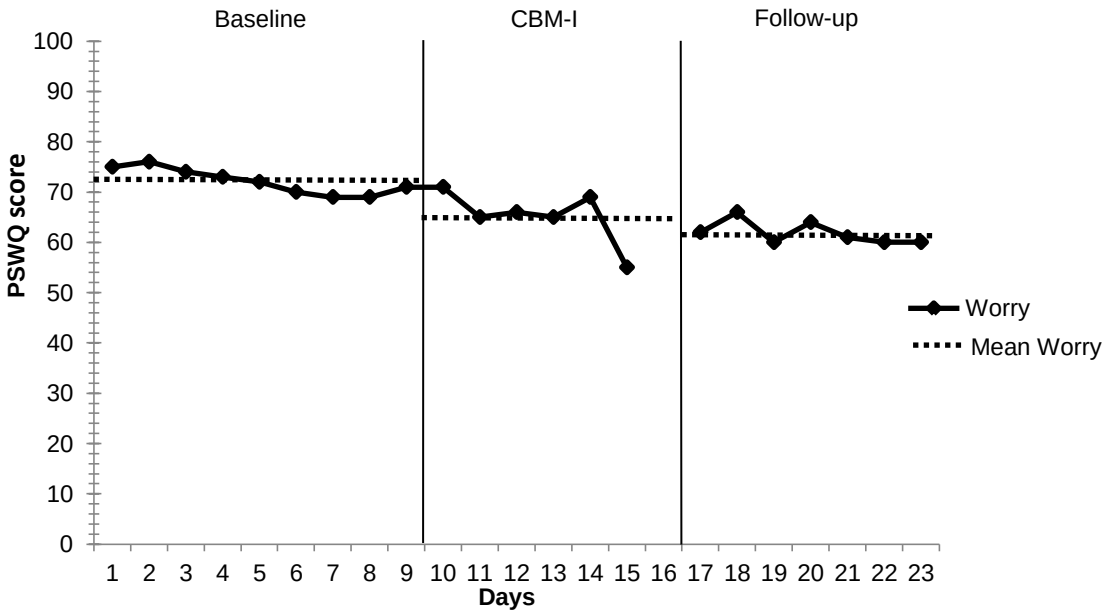

Figure 12. Participant five's (non-responder/non-maintainer) daily and mean worry scores across all phases. PSWQ = Penn State Worry Questionnaire.

3.2.5.2 *Anxiety and anxiety-bias.*

Visual inspection of figure 13 and Kendall's *tau* analysis reveals a significant

increasing trend of anxiety scores (*tau* = .8, p = .005) and a non-significant increasing trend of anxiety-bias scores (*tau* = .39, p = .19) in the baseline phase, although markedly less so for anxiety-bias. Across the CBM-I and follow-up phase there is little change in rate and of magnitude with regard anxiety-bias. In contrast, there is a dramatic downward shift in level of anxiety at the start of the CBM-I phase. This is followed by equally dramatic alternating upward and downward swings and eventual stabilisation in the follow-up phase with delayed latency of change.

Overall there appears to be no reliable change in anxiety-bias in the CBM-I and follow-up phases. With regard anxiety, despite the dramatic downward shift in level at the start of the CBM-I phase and the stabilising of reduced anxiety scores in the follow-up phase (which indicates a possible CBM-I effect) there is too much variability in the scores to allow a meaningful interpretation. Consequently the CBM-I is judged as not having a reliable effect on anxiety and anxiety-bias for this participant.

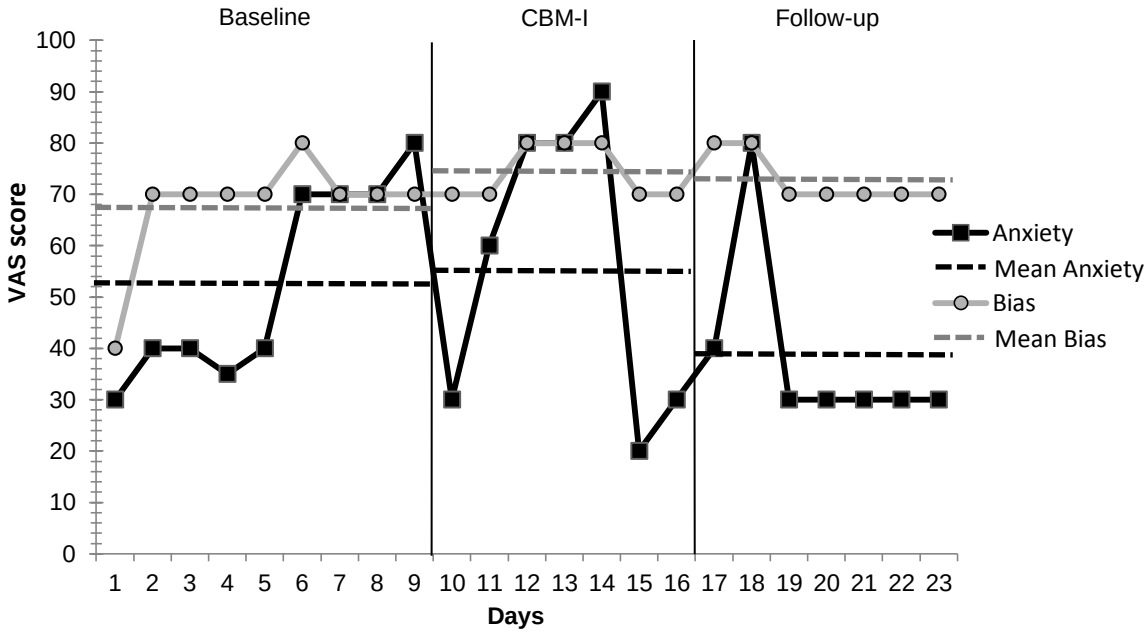

Figure 13. Participant five's daily and mean anxiety and anxiety-bias scores across all phases. VAS = Visual Analogue Scale.

3.2.6 Participant six.

3.2.6.1 *Worry*.

Visual inspection of figure 14 and Kendall's *tau* analysis reveals a fluctuating but statistically stable baseline (*tau* = -.1, p = .76). In the CBM-I phase there is a reduction in mean worry with no shift in level of worry at the start. Latency of change cannot be examined due to a missing data point on the second day. Across the CBM-I phase there is a decreasing worry trend. In the follow-up phase there is a further reduction in mean worry and a downward shift of worry level at the start which then stabilises.

Overall there appears to be a reliable improvement in worry both in terms of magnitude of change and rate of change in the CBM-I phase and such gains appear to maintain generally in the follow-up phase. Therefore this participant is classed as a responder and a maintainer.

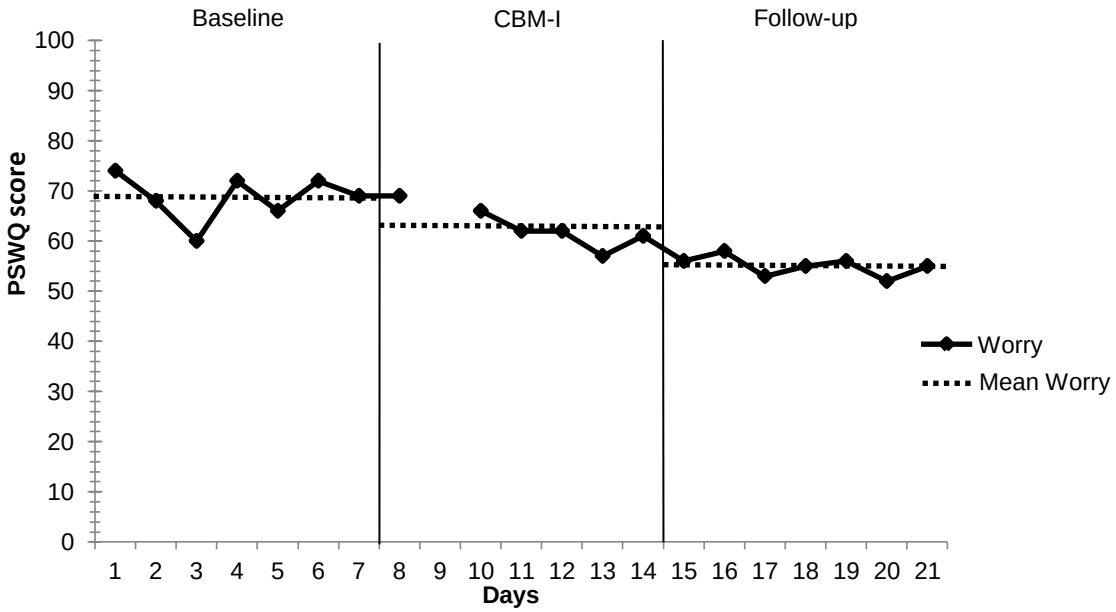

Figure 14. Participant six's (responder/maintainer) daily and mean worry scores across all phases. PSWQ = Penn State Worry Questionnaire.

3.2.6.2 *Anxiety and anxiety-bias.*

Visual inspection of figure 15 and Kendall's *tau* analysis reveals fluctuating but statistically stable baselines for anxiety (*tau* = .11, p = .75) and anxiety-bias (*tau* = .0, p = 1.0). In the CBM-I phase there is a marked reduction in mean anxiety and anxiety-bias, an immediate latency of change evidenced by a downward shift in level of both at the start (dramatically so for anxiety) and a decreasing trend of scores (indicating decreasing anxiety and anxiety-bias). In the follow-up phase there is a further reduction in mean worry and another downward shift in level of anxiety and anxiety-bias at the start which then stabilises.

Overall there appears to be a reliable improvement in anxiety and anxiety-bias scores both in terms of magnitude of change and rate of change in the CBM-I phase and such gains appear to maintain generally in the follow-up phase. Consequently it is judged that CBM-I has had a reliable effect on anxiety and anxiety-bias and that gains have maintained at follow-up for this participant.

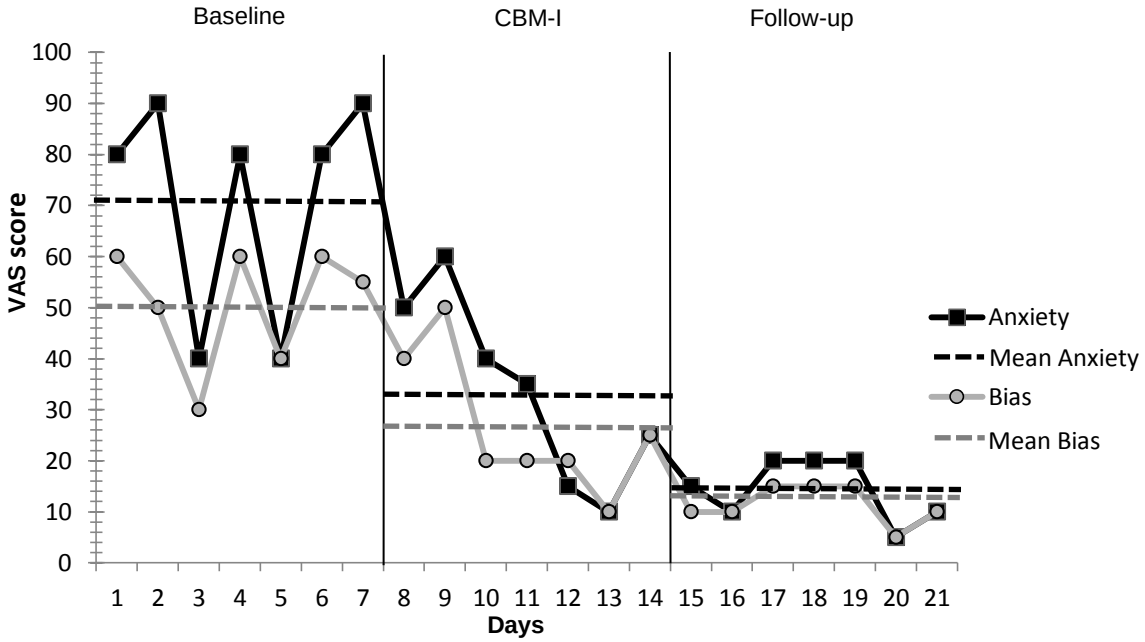

Figure 15. Participant six's daily and mean anxiety and anxiety-bias scores across all phases. VAS = Visual Analogue Scale.

3.2.7 Participant seven.

3.2.7.1 *Worry.*

Visual inspection of figure 16 and Kendall's *tau* analysis reveals a non-significant, increasing trend in the baseline phase (*tau* = .38, p = .10). In the CBM-I phase there is little change in mean worry, level or trend. In the follow-up phase there is very little change in mean, a small downward shift in level of worry at the start followed by an increasing trend of scores.

Overall there appears to be little change to worry scores in the CBM-I and follow-up phases therefore this participant is classed as a non-responder and also therefore a non-maintainer.

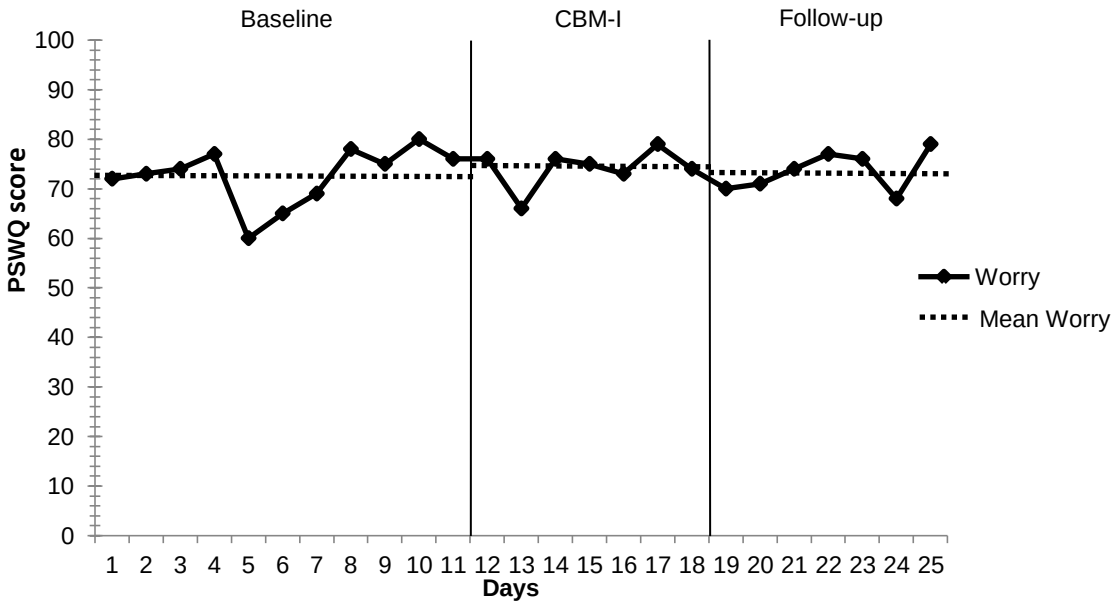

Figure 16. Participant seven's (non-responder/non-maintainer) daily and mean worry scores across all phases. PSWQ = Penn State Worry Questionnaire.

3.2.7.2 *Anxiety and anxiety-bias.*

Visual inspection of figure 17 and Kendall's *tau* analysis reveals a stable anxiety-bias baseline (*tau* = .28, p = .29) and a statistically increasing trend in the anxiety

baseline (*tau* = .56, p = .02). In the CBM-I phase there is no shift in level at the start for each and little change in mean with both scores relatively stable. In the follow-up phase there is a greater reduction in mean for anxiety and anxiety-bias, a downward shift in both at the start with scores then fluctuating between upward and downward swings for the rest of the phase.

Overall there appears to be improvement in anxiety and anxiety-bias both in terms of rate of change and magnitude of change however it is somewhat delayed which makes interpretation difficult. Consequently the CBM-I is judged as not having a reliable effect on anxiety or anxiety-bias for this participant.

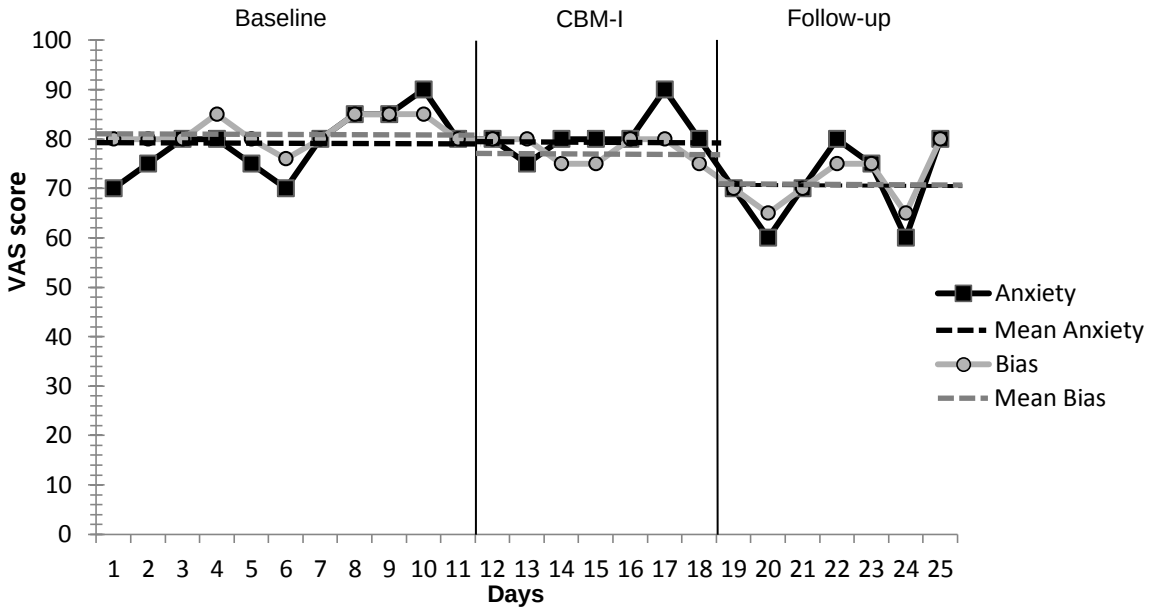

Figure 17. Participant seven's daily and mean anxiety and anxiety-bias scores across all phases. VAS = Visual Analogue Scale.

3.3 Reliable and Clinically Significant Change

Clinically significant change and reliable change is assessed using the criteria set out by Jacobson and colleagues (Jacobson, Follette, & Revenstorf, 1984; Jacobson & Truax, 1991) where normative data is available. Accordingly, clinically significant change

can be said to occur when a participant moves from a score typical of an individual with GAD to a score typical of the non-disordered or normal population. Applying Jacobson and colleagues' methodology, clinical significant change is determined on each measure by generating a cut-off point according to two different criterions:

1) The least arbitrary, termed criterion (c) is calculated where normative data is available on both GAD and 'normal' samples. Criterion (c) assesses whether the likelihood is greater that the participant's score falls within the normal population. Calculation requires the means of a GAD sample (M_1) and normal sample (M_2), and the standard deviation (SD) of the GAD sample (S_1) and normal sample (S_2). The formula is:

$$\text{criterion (c)} = \frac{S_1M_2 + S_2M_1}{S_1 + S_2}$$

2) Where normative data for normal samples is available, but normative data for GAD samples is not, criterion (b) is calculated. Criterion (b) assesses whether the participant has moved to within 2 SDs of the mean of the normal population. The formula is:

$$\text{criterion (b)} = M_2 + 2(S_2)$$

Where neither GAD samples nor normal population data is available on a measure, clinically significant change is said to occur if the participant moves from a score that lies above a recommended or widely used clinical cut-off at pre-CBM-I to one that lies below the cut-off at post CBM-I or follow-up.

Reliable change requires that improvement is statistically reliable and unlikely to be due to simple measurement unreliability. It is calculated using Jacobson & Truax's (1991) reliable change index (RCI) and requires a reliability coefficient (r).

The formula is:

$$RCI = 1.96 \times (S_1) \times \sqrt{2} \times \sqrt{(1 - r)}$$

3.3.1 Worry.

3.3.1.1 *Reliable and clinical change on the PSWQ.*

Clinically significant and reliable change is determined using Fisher's (2006) standardised criteria for recovery on the PSWQ (criterion (c), RCI = 7, cut-off point <47). Reliable change was achieved by three participants, all at post CBM-I and at follow-up (see table 3): participant four (responder/maintainer), participant five (non-responder/non-maintainer) and participant six (responder/maintainer). No participants achieved clinical change.

Table 3

PSWQ Scores over the Four Time Points for each Participant

Participant	Pre-assessment	Pre-CBM-I	Post CBM-I	Follow-up
1	72	76	71	76
2	65	75	79	76
3	75	65	74	74
4	76	72	56+	63+
5	75	71	62+	60+
6	74	69	56+	55+
7	72	76	74	79

Note. PSWQ = The Penn State Worry Questionnaire.

*Indicates clinical change compared to pre-CBM-I.

+ Indicates reliable change compared to pre-CBM-I.

3.3.2 General anxiety.

3.3.2.1 *Reliable and clinical change on the GAD-7.*

Clinically significant and reliable change is determined using reliability data (Cronbach $\alpha = 0.92$), GAD sample data (Mean = 14.4, SD = 4.7) and normal sample data

(Mean = 4.9, SD = 4.8) from the original GAD-7 validation study (Spitzer et al., 2006). This generates a criterion (c) cut-off point of <9.8 and an RCI of 3.68. Reliable change was achieved by two participants: participant four at post CBM-I and at follow-up and participant one at follow-up only (see table 4). Clinical change was achieved by two participants: participant five at post CBM-I and participant one again at follow-up.

Table 4

GAD-7 Scores over the Four Time Points for each Participant

Participant	Pre-assessment	Pre-CBM-I	Post CBM-I	Follow-up
1	17	15	14	8*+
2	10	13	14	11
3	16	14	16	16
4	15	18	13+	10+
5	15	10	9*	11
6	14	13	13	10
7	12	17	16	18

Note. GAD-7 = The Generalized Anxiety Disorder Assessment.

* Indicates clinical change compared to pre-CBM-I.

+ Indicates reliable change compared to pre-CBM-I.

3.3.3 GAD.

3.3.3.1 *Clinical change on the GAD-Q-IV.*

The GAD-Q-IV is a GAD diagnostic measure and so reliable change is not calculated. Clinically significant change is determined using Newman et al's (2002) recommended clinical cut-off of 5.7 (which the authors generated using receiver operating characteristics analyses). No participants achieved clinical change on this measure (see table 5).

Table 5

GAD-Q-IV Scores over the Four Time Points for each Participant

Participant	Pre-assessment	Pre-CBM-I	Post CBM-I	Follow-up
1	11.67	11.42	11.67	11.33
2	9.67	9.66	9.5	9.59
3	10.16	10.66	10.33	11.25
4	11.5	11.5	11.17	11
5	10.58	10.92	10.5	8.83
6	11	10.17	9.92	9.59
7	9.91	12.17	9.92	10.16

Note. GAD-Q-IV = The Generalized Anxiety Disorder Questionnaire.

* Indicates clinical change compared to pre-CBM-I.

3.3.4 Trait and state anxiety.

3.3.4.1 *Reliable and clinical change on the STAI.*

For trait anxiety, clinically significant and reliable change is determined using Fisher and Durham's (1999) standardised criteria for recovery on the STAI-T (criterion (c), RCI = 8, cut-off point <46).

For state anxiety, due to a lack of available GAD sample data, clinically significant change is determined using criterion (b). Following the methodology of Fisher and Durham (1999), normal sample data from Spielberger et al. (1983) is collapsed across gender to generate a mean of 35.45 and an SD of 10.40. This produces a cut-off point of 56.20. Reliable change is determined using the alpha coefficient of 0.93 from the same normative sample (Spielberger et al., 1983) which generates an RCI of 7.63.

On the STAI-T, three participants achieved reliable change: participant four at post CBM-I and follow-up, participant five at post CBM-I only and participant six at follow-up only (see table 6). Two participants achieved clinical change: participant two at post CBM-I and follow-up and participant six again at follow-up only.

Table 6

STAI-T Scores over the Four Time Points for each Participant

Participant	Pre-assessment	Pre-CBM-I	Post CBM-I	Follow-up
1	74	62	59	56
2	53	49	44*	43*
3	61	52	56	59
4	70	74	52+	61+
5	58	56	48+	53
6	58	56	53	44*+
7	53	58	61	63

Note. STAI-T = The Spielberger State-Trait Anxiety Inventory-Trait subscale

* Indicates clinical change compared to pre-CBM-I.

+ Indicates reliable change compared to pre-CBM-I.

On the STAI-S, five participants achieved reliable change (see table 7): four at post CBM-I and follow-up (participants two, four, five & six) and one at post CBM-I only (participant seven). Two participants achieved clinical change, both at post CBM-I and follow-up (participants four & seven again).

Table 7

STAI-S Scores over the Four Time Points for each Participant

Participant	Pre-assessment	Pre-CBM-I	Post CBM-I	Follow-up
1	61	52	46	56
2	45	39	28+	22+
3	41	26	33	26
4	78	65	47*+	54*+
5	33	50	38+	39+
6	43	48	32+	37+
7	38	61	42*+	55*

Note. STAI-S = The Spielberger State-Trait Anxiety Inventory-State subscale

* Indicates clinical change compared to pre-CBM-I.

+ Indicates reliable change compared to pre-CBM-I.

3.3.5 Interpretation bias.

3.3.5.1 *Change on the SST.*

Reliable and clinical change cannot be calculated for the SST as it has not been validated as a measure. Nevertheless all but one participant (participant five) improved at post CBM-I and every participant improved at follow-up (see table 8).

Table 8

SST Scores over the Four Time Points for each Participant

Participant	Pre-assessment	Pre-CBM-I	Post CBM-I	Follow-up
1	43.75	44.44	25	25
2	58.33	70	33.33	21.43
3	8.33	10	0	6.25
4	71.43	20	0	0
5	42.86	43.75	55.56	35.71
6	16.67	17.65	5	0
7	52.94	80	40	45

Note. SST = The Scrambled Sentences Test.

Scores represent percentage of completed sentences with a negative valence.

3.4 Imagery

At randomly pre-selected points within each block of ten scenarios, participants were required to rate how vividly they were able to imagine the previous scenario. A total mean was calculated for each participant (see table 9) and a Spearman's Rho test assessed whether there was a relationship between imagery ratings and changes in PSWQ scores. The analysis revealed positive but non-significant correlations between mean imagery rating and: a) pre-CBM-I/post CBM-I PSWQ difference scores (r_s= .34, p = .23) and b) pre-CBM-I/follow-up PSWQ difference scores (r_s= .1, p = .42).

Table 9

Mean Imagery Ratings for each Participant and if they Responded to the CBM-I

Participant	Mean Imagery Rating†	Respond?
1	6.97	No
2	8.54	No
3	7.26	No
4	9.71	Yes
5	8.29	No
6	8.46	Yes
7	8.54	No

Note. † Higher scores indicate greater vividness of imagined scenarios (maximum score is 10).

In addition, the mean imagery ratings of responders (Mean = 9.09, SD = 0.88) and non-responders (Mean = 7.92, SD = 0.75) were compared (see figure 18). A Mann-Whitney test indicated that responders did not differ significantly in their imagery ratings to non-responders ($U = 2.0$, $p = 0.38$, $r = 0.44$).

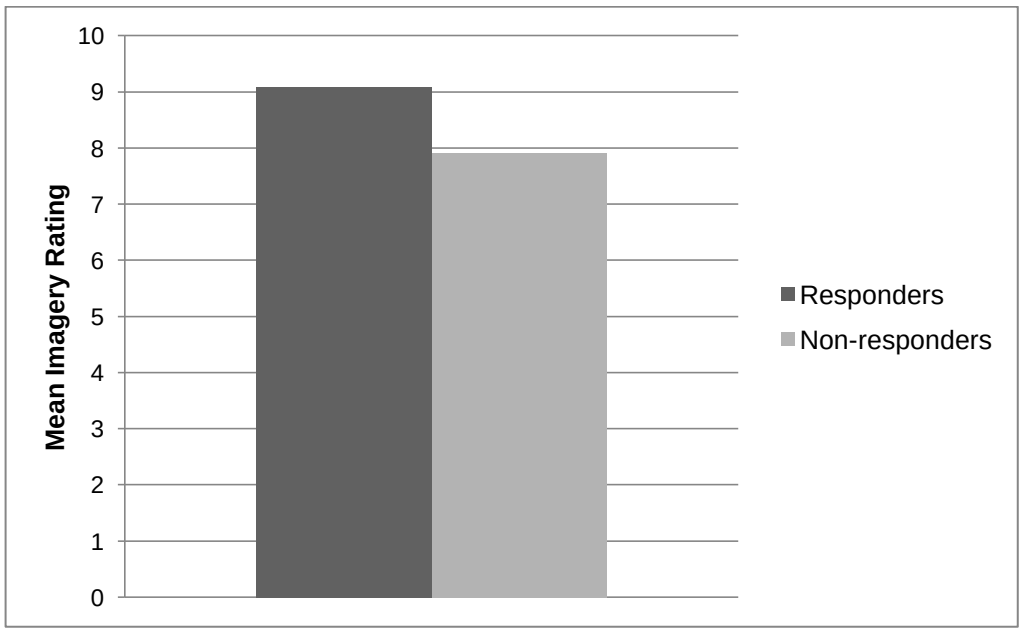

Figure 18. Mean imagery ratings for responders and non-responders

3.5 Statistical Analyses of Outcomes

Sample means for outcome measures at pre-assessment, pre-CBM-I, post CBM-I and follow-up are displayed in Table 10. All mean scores reduced from pre-CBM-I to post CBM-I and follow-up. To investigate whether the improvement was statistically significant, Wilcoxon signed-rank tests were performed.

No significant differences were reported for any of the measures between pre-assessment and pre-CBM-I: PSWQ (z = -.43, p = .67, r = -.12); GAD-7 (z = -.26, p = .4, r = -.07); SST (z = -1.18, p = .24, r = -.32); STAI-T (z = -.93, p = .35, r = -.25); STAI-S (z = .0, p = .5, r = 0) and GAD-Q-IV (z = -.52, p = .3, r = -.14).

Significant reductions were found between pre-CBM-I and post CBM-I with large effect sizes on the SST (z = -2.03, p = .02, r = -.54), the GAD-Q-IV (z = -1.95, p = .03, r = -.52) and the STAI-S (z = -2.03, p = .02, r = -.54). Significant reductions with large effect sizes were also found between pre-CBM-I and follow-up on the SST (z = -2.37, p = .009, r = -.63) and STAI-S (z = -2.01, p = .02, r = -.54).

Therefore the study found that the group demonstrated reduced SST scores at the end of the CBM-I and that this maintained at one week follow-up, which supports the secondary research hypothesis.

No other significant differences were found at post CBM-I (PSWQ, z = -1.27, p = .1, r = -.34; GAD-7, z = -.65, p = .26, r = -.17; STAI-T, z = -1.34, p = .09, r = -.36) or follow-up (PSWQ, z = -.84, p = .2, r = -.22; GAD-7, z = -1.27, p = .1, r = -.34; GAD-Q-IV, z = -1.52, p = .06, r = -.41; STAI-T, z = -1.19, p = .12, r = -.32).

Table 10

Mean Outcome Scores for Participants over the Four Time Points

Measure	Pre-assessment	Pre-CBM-I	Post CBM-I	Follow-up
PSWQ				
M	72.71	72	67.43	69
SD	3.73	4.08	9.34	9.45
GAD-7				
M	14.14	14.29	13.57	12
SD	2.41	2.69	2.37	3.61
STAI-T				
M	61	58.14	53.29	54.14
SD	8.12	8.13	5.99	7.97
STAI-S				
M	48.43	48.71	38	41.29
SD	15.68	13.16	7.33	14.12
GAD-Q-IV				
M	10.64	10.93	10.43	10.25
SD	0.78	0.85	0.76	0.97
SST				
M	42.04	40.83	22.7	19.06
SD	22.48	26.86	21.76	17.71

Note. PSWQ = The Penn State Worry Questionnaire; GAD-7 = The Generalized Anxiety Disorder Assessment; STAI-T = The Spielberger State-Trait Anxiety Inventory-Trait subscale; STAI-S = The Spielberger State-Trait Anxiety Inventory-State subscale; GAD-Q-IV = The Generalized Anxiety Disorder Questionnaire; SST = The Scrambled Sentences Test.

Discussion

4.1 Overview

The chapter begins with a restatement of the aims of the study. This is followed by a discussion of the findings in relation to the research hypotheses, the literature, and theory. Where results do not support the research hypotheses, possible explanations are considered. Next, methodological limitations are identified and future research recommendations are suggested. The chapter completes with a discussion of the potential clinical implications of the findings and a conclusion.

4.2 Aims of the Study

The primary aim of the present study was to investigate whether an online multi-session CBM-I package would positively impact on the level of worry in individuals experiencing clinical levels of generalised anxiety and whether any benefits would last one week after CBM-I completion. The secondary aim was to investigate whether such individuals would experience positive change in their level of negative interpretation bias and whether this too would maintain one week later.

4.3 Primary Research Hypothesis

The first research hypothesis predicted that the CBM-I training task would reduce levels of worry and that this would be maintained at one week follow-up. The present study found mixed support for this hypothesis.

In support of the primary research hypothesis, visual inspection of daily PSWQ scores indicated that two of the seven participants demonstrated a reliable positive response to the CBM-I and that their gains had maintained one week later (participants four & six – 'responders' & 'maintainers'). Furthermore, participants four and six, and one other participant (participant five), satisfied Jacobson and colleagues' (1984, 1991) criteria for reliable improvement on the PSWQ upon completion of the CBM-I and one week later.

No participants achieved clinically significant change on this measure.

As is routine in CBM-I research, anxiety was also assessed (MacLeod & Mathews, 2012). Visual inspection of daily anxiety VAS scores indicated that two participants reliably responded to the CBM-I and that their gains maintained for one week (participants four & six).

Additional anxiety measures were given at the four assessment time points of pre-assessment, pre-CBM-I, post CBM-I and follow-up. On the GAD-7, which is a measure of general anxiety, one participant demonstrated a reliable change which maintained at follow-up (participant four), and one other participant demonstrated reliable and clinical change on the GAD-7 at follow-up only (participant one). Only one participant demonstrated clinically significant change on the GAD-7, which was at post-CBM-I (participant five). On the GAD-Q-IV, only clinically significant change was assessed and no participants achieved this. On the STAI-T, a measure of trait anxiety, three participants demonstrated reliable change: participant four at post CBM-I and follow-up, participant five at post CBM-I only, and participant six at follow-up only. Two participants demonstrated clinically significant change on the STAI-T: participant two at post CBM-I and follow-up and participant six at follow-up only. Most improvements occurred on the STAI-S, a measure of state anxiety. Five participants demonstrated reliable change on the STAI-S at post CBM-I (participants two, four, five, six & seven) and for four of them this maintained at follow-up (participants two, four, five & six). Clinically significant change on the STAI-S was demonstrated by two of the participants, at both time points (participants four & seven).

Supplementing these findings, statistical analyses showed that none of the change observed on the PSWQ was significant (post CBM-I, $p = .1$; follow-up, $p = .2$). With regard anxiety, statistically significant improvement was found on two of the outcomes:

the GAD-Q-IV at post CBM-I ($p = .03$) and the STAI-S at both post CBM-I ($p = .02$) and follow-up ($p = .02$).

These findings are relatively weak compared to several previous studies that have investigated CBM-I on emotionality. Positive effects of CBM-I on worry have been observed in non-clinical high worriers (Hirsch et al., 2009) and GAD patients (Hayes et al., 2010). Other studies have found bias modification training to positively impact on trait and state anxiety (e.g., Brosan et al., 2011; Salemink et al., 2009). Furthermore reductions in trait anxiety have been observed one week following training (e.g., Mathews et al., 2007), and later (e.g., Amir & Taylor, 2012a). Possible explanations for the mixed findings in the present study are considered below in *Theoretical considerations*.

In sum, the findings show that the CBM-I package had variable success in reducing participants' worry over the training week and the week that followed. Consequently the efficacy of the CBM-I package for individuals with clinical levels of generalised anxiety is equivocal: it would appear that some individuals may benefit from it but that many, perhaps most, will not.

4.4 Secondary Research Hypothesis

The second research hypothesis predicted that participants would demonstrate a reduction in level of negative interpretation bias and that this would be maintained at one week follow-up. The present study mainly found support for this hypothesis.

All but one of the participants (participant five) demonstrated reduced SST scores at post CBM-I, and at follow-up all SST scores were reduced. Statistical analysis revealed these reductions to be significant (post CBM-I, $p = .02$; follow-up, $p = .009$). These results suggest that training was associated with improved interpretive bias upon completion of the CBM-I programme and one week later. This finding is consistent with Brosan et al. (2011) and Hayes et al. (2010) who used GAD samples. The finding that interpretation bias

remained reduced one week later is consistent with other studies using anxious samples (e.g., Amir & Taylor, 2012a; Bowler et al., 2012).

In addition to measuring interpretation bias, a typical anxiety bias was also assessed; specifically the tendency to expect the worse. Visual inspection of daily anxiety-bias VAS scores indicated that three participants (participants two, four & six) experienced reliable reductions in this particular bias and that this maintained for all three of them one week later.

Whereas CBM-I training only appeared to reduce worry levels for two participants at its conclusion and one week later (participants four & six), significant effects were found across participants on interpretation bias at both time points. Although the present study is unable to infer whether the CBM-I programme was the cause of the interpretive bias improvements, the findings are consistent with the possibility that CBM-I can induce a more benign interpretive bias in individuals experiencing clinical levels of generalised anxiety.

4.5 The Role of Imagery

The CBM-I protocol in the present study included a notable imagery component. Prior to their first CBM-I session participants received guidance by the researcher on how to adopt a field perspective when visualising the scenarios. In addition, participants were provided with instructions at the beginning of each CBM-I session and during it they were required to frequently rate how vividly they were able to imagine the scenarios. In line with research by Holmes and colleagues (e.g., Holmes et al., 2009), it was predicted that placing emphasis on the need for participants to imagine themselves in the scenarios would enhance the effectiveness of the CBM-I task.

The results show that there was a non-significant positive correlation between imagery self report ratings and changes in PSWQ scores from pre-CBM-I to post CBM-I

and follow-up. It was also found that the mean imagery rating of responders was higher than of the non-responders however the difference was not significant. Whilst these results indicate that the success of the CBM-I task in reducing worry was not related to how vividly participants imagined the training scenarios, the lack of a non-imagery matched control group and the small number of participants, particularly responders, means that such findings should be considered with caution (Field, 2005).

4.6 Theoretical Considerations

CBM-I training is predicated on a fundamental cognitive theory assumption that pathological worry, like anxiety, is maintained in part by cognitive biases in emotional processing, such as the tendency to interpret ambiguous information in a negative manner (Hirsch & Mathews, 2012). Moreover it is assumed that modification of interpretation bias should impact on levels of worry by reducing it. Therefore in light of the improvements observed in interpretation bias, a pure CBM-I explanation would be that the CBM-I task's modus operandi of repeatedly requiring participants to generate benign interpretations of ambiguous imagined scenarios reduced their negative interpretation bias (Mathews & Mackintosh, 2000). According to Mathews and Mackintosh (2000), through CBM-I training participants may implicitly acquire an interpretation rule that without explicit awareness or intent they apply to novel situations, which includes bias manipulation checks such as the SST.

The finding that some of these participants also reported less worry (participants four & six - responders) is consistent with information processing models which would predict that a reduction in worry would occur as a result of interpretation bias modification (e.g., Beck et al., 1985; Bower et al., 1983). For instance, in line with Beck's schema model (e.g., Beck et al., 1985), the improvement demonstrated by responders could be attributed to the CBM-I task successfully modifying their maladaptive schemata. That is,

the responders' schemas became less distorted in their processing of information as dangerous which then resulted in less negative automatic thoughts associated with threat. Or, drawing on Bower's network theory (Bower et al., 1983), the CBM-I might have lead to the deactivating of anxiety nodes within semantic memory resulting in less priming for threat information.

Alternatively the CBM-I task may have lead to a reduction in worry in the responders by adjusting the balance between bottom-up and top-down processes, as conceptualised by the information processing model of pathological worry (Hirsch & Mathews, 2012). More specifically, when the responders encountered an external or internal cue of some potential threat in their daily lives outside of the training sessions, their representation of threat may have activated less than occurred pre-CBM-I. The model would indicate that this was due to less activation of involuntary bottom-up influences, namely interpretation bias. Consequently the responders would have been less likely to experience intrusions of negative thoughts into awareness, the overall effect being less protracted worry.

Qualitative feedback was obtained from all participants with the exception of participant six (responder) of which example quotes, organised into different themes, can be found in Appendix Q. Consistent with her reliable 'response' to the CBM-I as indicated by the PSWQ, participant four (responder) reported experiencing positive cognitive as well as behavioural change e.g. 'these thoughts go in your head but now I, I am thinking of positive rather than negative'.

The qualitative feedback concerning change perceived by the non-responders was mostly concordant with their visually inspected PSWQ scores. Participants three and seven for instance described gaining no benefits. The notable exception was participant one (non-responder) who's qualitative feedback indicated improvements not captured by her PSWQ

scores. For example participant one described significant adaptive shifts in cognition (e.g., 'I've just decided to try and start sort of living my life rather than being scared of it') and behaviour, including less avoidance (e.g., 'I've booked a holiday for next year to go abroad with the two children in the last week which is something which terrifies me').

Qualitative feedback notwithstanding the case remains that the CBM-I training did not appear to impact on worry for most of the participants despite significant reductions indicated in negative interpretation bias for the sample as a whole. Before considering why this may have occurred, it is important to note that such findings are not unusual within CBM-I research. Other studies have also found results concerning the effect of CBM-I on anxiety and other emotional outcomes to be more mixed than interpretation bias (Amir et al., 2010; Beard & Amir., 2008; MacDonald et al., 2013; Murphy et al., 2007; Steinman & Teachman, 2010).

In hypothesising why CBM-I failed to have an impact on five participants' worry and daily anxiety in the present study (participants one, two, three, five & seven), the nature of the training procedure adopted warrants consideration. One possibility is that the amount of CBM-I training was not sufficient to positively impact upon emotion and that with more training there might have been more responders. In line with such reasoning, three participants provided feedback that they thought extending the CBM-I training would be helpful (participants one, three & six). Interestingly studies by Beard et al. (2011) and Amir and Taylor (2012a) included bias modification training that spanned notably longer periods than the present study and both were associated with reductions in anxiety. In the study by Beard and colleagues, training consisted of eight 30 minutes sessions that took place twice weekly, over a month, and in Amir and Taylor's study participants underwent 12 x 20 minute sessions over a six week period.

However Hayes et al. (2010) and Brosan et al. (2011) found effects on emotional

outcomes in their GAD samples after less training sessions than in the present study. Brosan et al. (2011) reported reduced state and trait anxiety in their participants after they had received two and half hours of training over four sessions and Hayes et al. (2010) found that just a single session was enough to reduce worry in their participants. Similarly Hirsch et al. (2009) found that their non-clinical high worriers benefitted from a single session of training, as have other non-clinically anxious participants in other studies (e.g., Mathews & Mackintosh, 2000).

Whilst such findings indicate that the extent of CBM-I training in the present study should have been enough to produce a response it is worth considering that there are important differences in the training tasks used. In the other studies looking at CBM-I and worry (Hirsch et al., 2009) and GAD (Brosan et al., 2011; Hayes et al., 2010), training consisted of dual modification tasks i.e. two different bias modification procedures, whereas in the present study training consisted solely of the ambiguous scenarios paradigm. Additionally, previous studies have assessed training effects on worry by way of participants reporting the number of thought intrusions experienced during a breathing focus task (Hayes et al., 2010; Hirsch et al., 2009). This is very different to participants completing the PSWQ, a psychometrically verified measure of pathological worry for between 21 and 25 days as occurred in the present study. Consequently, it is difficult to conclude whether the five non-responders (participants one, two, three, five, & seven) were influenced by the schedule of training not being sufficient to modify worry. Taken together, and considering the pervasiveness of GAD (Hanrahan et al., 2013), it seems fair to propose that longer training may be necessary.

Another possibility is that the CBM-I task itself, or at least some aspect of it, may benefit from being redesigned. The ambiguous scenarios paradigm is the most commonly used interpretation bias modification procedure and is associated with positive outcomes

(Beard, 2011). It is important to consider that although the basic format of the task adopted in the present study was consistent with previous research (e.g., Bowler et al., 2012; Salemink et al., 2009; Steinman & Teachman, 2010) the training scenarios were more unique. Following the studies of Hayes et al. (2010) and Hirsch et al. (2009), the scenarios were designed by the researcher to represent common worry topics as identified in the WDQ. It therefore remains possible that some or many of the scenarios were not perceived as believable, personally relevant or potentially anxiety provoking to some of the participants. This would in all likelihood reduce their level of engagement with the task and inhibit the deployment of their interpretive bias.

Active engagement within CBM-I training has been shown to be a crucial factor in determining its success on anxiety vulnerability. In support, Mathews and Mackintosh (2000) developed a passive CBM-I procedure whereby participants received disambiguated scenarios rather than having to actively generate them. They found that in this passive procedure anxiety was not affected. This contrasted with the reduced anxiety observed in their active condition in which participants had to resolve the ambiguity themselves. The researchers proposed that in order for participants to achieve emotional modification from CBM-I, they must take ownership of generating emotional meanings. Mathews and MacLeod (2002) argued that only through active generation will participants learn the crucial implicit production rule to generate and select benign or positive meanings when they encounter and process ambiguous events in their daily lives. Confirmation of this hypothesis comes from studies that have found active but not passive selection of meaning to increase emotionality (Hoppitt, Mathews, Yiend, & Mackintosh, 2010a; Hoppitt, Mathews, Yiend, & Mackintosh, 2010b).

The success of the CBM-I program for each participant may therefore have been influenced by issues relating to level of engagement. Qualitative feedback tended to be

consistent with this notion. Of those interviewed, the two participants who reported the most positive change (participants one & four) appeared to find the scenarios personally relevant to their worries and emotionally engaging. For example participant one reported 'a lot of the erm, situations in it were very similar to the situations I find myself in or I'm scared of'. In contrast, the two participants who described the least change (participants three & seven) did not appear to engage well with the scenarios, for example participant seven reported 'I was looking at the questions it was asking me and I'd think about myself in that situation and it's that ninety percent of those situations would never worry me anyway'.

A similar divide existed between participants over their attitude towards the CBM-I program. The two participants who reported the most change and who appeared to find the scenarios most emotionally engaging (participants one & four) appeared to have the most positive attitude towards the CBM-I whereas the two participants who found the scenarios least engaging and whom reported the least change (participants three & seven) appeared to have the least positive attitude towards it. For example, participant one reported 'the idea behind it is, is good and I think it will make a difference to people' whereas participant three reported 'I think it's better to have a person, personally, rather than a computer program'. Therefore within the qualitative feedback there appears to be a relationship between perceived improvement, emotional engagement with the scenarios and attitude towards the CBM-I task.

Interestingly, Bendelin, Hesser, Dahl, Carlbring, Nelson and Andersson (2011) report similar patterns within their qualitative data. They explored participants' views of an internet administrated cCBT and found that it was appraised differently depending on outcome and that those who had issues with the treatment material were less positive in their appraisals and reported less favourable outcomes. Also Curtis (2013) found that if

adolescent participants stated that they enjoyed their CBM-I task, then this was linked to positive outcomes in relation to symptomatology and interpretation bias.

It is also possible that other factors such as motivation could have influenced the extent of meaningful engagement with, and impact of, the CBM-I task for participants. Regardless of what these factors may be, limited task engagement could be why some participants, namely non-responders minus participant one, appeared to gain little if any benefit from the CBM-I task. As a consequence of this they would not have obtained sufficient practice in the active generation of emotional resolutions even though they were able to provide correct word fragment solutions. This would have meant that their ability to generate benign emotional resolutions in their daily lives remain relatively unchanged and so therefore their proclivity to worry.

This obviously does not account for why participant one, who appeared to engage well with the task, did not demonstrate an improvement in worry level, despite reporting various positive changes in thinking and behaviour. However it is worth noting that this participant reported a significant family related stressor occurring during the CBM-I phase which she said was increasing her worrying. Therefore one possibility, although purely speculative, is that her worry level, whilst not notably reduced, was less than it would have been had this stressful event occurred prior to her CBM-I training.

With regard the participants' improved SST scores, interestingly, passive engagement with CBM-I can still give the impression of interpretation bias modification (Hertel & Mathews, 2012). Hoppitt et al. (2010b) proposed that in passive training participants experience some kind of training-congruent generic emotional priming. The effects of this generic priming can resemble interpretive bias modification, for example, CBM-I trained participants may show a tendency to endorse positive interpretations which are offered to them (e.g., Grey & Mathews, 2000). It is important to note that the present

study is not aware of active and passive procedures being compared in clinical samples, who may behave differently. Nonetheless in the present study, it is possible that the reduced scores at post CBM-I and follow-up may have reflected training induced priming as much as, perhaps even more than, genuine interpretive bias modification. This might explain why in the present study, there appeared to be greater improvement in interpretation bias than for worry. The implication is that participants could have selected benign interpretations on the SST not necessarily because they experienced generalisable erosion to their level of negative interpretation bias but because the CBM-I primed them to do so.

Priming alone, however, is unlikely to fully account for the improvement in SST scores as despite similarities in the demands required by the CBM-I and the SST, they are ultimately different tasks. The CBM-I required solutions to benignly valenced word fragments and the selecting of benign meanings (comprehension question). The SST on the other hand required generation, albeit restricted to two possible options, of benignly valenced sentences. As such, the SST can be considered an independent measure (Standage et al., 2010) and its inclusion therefore a strength of this study. The SST also contained a cognitive load which means that a response bias is less likely (Bowler et al., 2012). So in considering why it was that most participants appeared to demonstrate greater improvement in interpretation bias than in worry and anxiety from post CBM-I to follow-up, it may be that, for whatever reason, most did not actively engage with the CBM-I enough for training to generalise. Because of this it did not impact on emotionality, although completing the scenarios was nonetheless sufficient to achieve a reduction in assessed interpretation bias.

Interestingly in other studies that have also included independent measures of interpretation bias change, results have been mixed regarding generalisation, with some

finding evidence in support (e.g., Hayes et al., 2010; Mathews et al., 2007; Standage et al., 2010) and others not finding support (e.g., Salemink et al., 2007; Salemink et al., 2009; Salemink et al., 2010; Steinman & Teachman, 2009). Beard (2011) noted that these inconclusive findings suggest that CBM-I may not change cognition in real-life situations. However, Beard also suggested that this is likely related to the inherent difficulties involved in measuring interpretative processes in real world situations. Indication that CBM-I training effects can transfer to people's lives comes from studies that have found evidence of generalisation when a stressor task has been included (e.g., Beard et al., 2011; Clerkin & Teachman, 2011; Hirsch et al., 2009; Wilson et al., 2006). Further support for this comes from studies in which interpretation bias change has been found to mediate the effect of CBM-I on symptom severity (e.g., Hayes et al., 2010; Mathews et al., 2007).

In sum, the observation that five of the participants in the current study did not appear to derive notable benefit in their level of worry after starting CBM-I training (participants one, two, three, five & seven) is not totally disparate from the CBM literature base. One possible suggestion is that the degree of active meaningful engagement within the CBM-I task may be a critical factor, which could be related to how personally relevant the scenarios are perceived to be amongst other factors.

4.7 A Methodological Critique and Consideration for Future Research

The results of the present study should be considered in the context of a methodological critique. On balance, the study design employed offered an effective means of investigating the main research hypotheses. The single-case design has been considered an appropriate method to evaluate potential interventions that are at an early stage of clinical testing (Kazdin, 2011), which is the case for CBM-I, particularly with regard GAD (MacLeod & Mathews, 2012). Flyvbjerg (1994) advocates that the single-case design is an underutilized, important research method and one which the social sciences

would benefit from having more of. According to Flyvbjerg, single-case research has advantages over large sample quantitative methodologies such as being able to offer greater closeness to real life, greater depth of phenomenon studied and more concrete, practical (context dependent) knowledge.

The non-concurrent, multiple-baseline aspect of the design meant that participants could start the study as soon as they wanted to, without delay, whilst awaiting treatment. Ethically this was positive as it meant that there was no disruption to participants' clinical care to referring clinical teams.

The study design adopted also has some intrinsic drawbacks. Probably the most obvious limitation concerns the generalisability of the results (Barlow, Nock, & Hersen, 2009). The small sample size of seven participants is relatively typical for a single-case series (Kazdin, 2011), however this invariably limits how much can be inferred from the findings to other individuals experiencing clinical levels of generalised anxiety. In addition, by virtue of the single-case design, the study cannot explain why the CBM-I task appeared to be effective for some participants but not others (Kazdin, 2011).

With regard the method of data evaluation used in the present study, in accordance with single-case methodology, the effect of the CBM-I task on worry, and also anxiety, was assessed through visual inspection of the data. Therefore the decision as to whether or not participants responded to the CBM-I or not was a subjective one (Kazdin, 2011). However in an attempt to make this evaluation as systematic and objective as possible, Kazdin's (2011) criteria for visual inspection was implemented.

As for judging whether or not an effect had occurred, this task was not straight forward for a number of reasons. Firstly, most of the participants demonstrated instability in at least one of their baselines (participants two, three, five & seven). Moreover, for almost half of the participants (participants two, three & five), at least one of their

baselines showed improvement. Such baseline issues are not uncommon to single-case research (Kazdin, 2011) and made for difficult interpretation as to whether or not the CBM-I phase surpassed the projected baseline trajectory. Secondly, the high variability in VAS scores for some participants made assessing responses for anxiety and anxiety-bias challenging. Thirdly, the absence of dramatic changes or what has been referred to as 'slam bang' effects (Gilbert, Light, & Mosteller, 1975) observed between the baseline and CBM-I phases across the sample needs to be considered when interpreting the findings.

Consequently, there was opportunity for error when evaluating whether or not the CBM-I produced an effect for the participants, which is always a risk when visual inspection is adopted (Kazdin, 2011). The risk of error was probably greater in the judging of whether or not a participant was a maintainer as the parameters were less defined and there wasn't systematic criteria to guide decisions. According to Kazdin (2011), visual inspection is typically associated with greater risk of assuming effects where there are none (type 2 error) as even if an effect is real, if it is not eye catching or clear then it is likely to be overlooked. This insensitivity to weak effects means that reliable but weak effects can be easily missed (Kazdin, 2011). It is therefore possible that there were actually more instances of CBM-I effects in the present study than was detected. To reduce subjectivity and error, the present study's inspection was reviewed by the primary research supervisor. In future studies, to improve data evaluation, it could be helpful to recruit independent trained researchers to perform visual inspection on the daily outcomes (Kazdin, 2011).

A strength of the multiple-baseline single case design is that it provides some control for threats to internal validity such as maturation and testing (Kazdin, 2011). However it is possible that confounding, non-specific aspects of the CBM-I phase could have increased the chances of a response occurring. For instance, the introduction of something active, structured and potentially rewarding into their lives (i.e., the CBM-I

task), could increase self-mastery, self-esteem and mood which might positively impact on worry. With that said, the opposite could also be true; that the CBM-I task was an added stressor which could have elevated worry. This difference in appraising the CBM-I task may explain some of the variability in findings.

In consideration of the reduction in state anxiety, there was a degree of contact between the researcher and participants, most of which was face to face. It is possible that participants could have become increasingly comfortable and relaxed with the researcher's presence with subsequent appointments. With regard the other non-daily outcome measures, the contact also meant that there was potential for the participants to experience empathy, warmth, unconditional regard and understanding despite the concerted efforts of the researcher to remain as neutral as possible. All of these relationship related factors facilitate the construction of a therapeutic alliance; a core psychotherapy process which has been shown to contribute to treatment gains (e.g., Stiles, Shapiro, & Elliot, 1986). Nevertheless the lack of significance found between scores at pre-assessment and pre-CBM-I on any of the non-daily outcome measures suggests that the instances of improvement cannot be fully accounted for by a testing bias. Furthermore, in spite of the potential for bias in the present study, findings on worry and anxiety outcomes were generally weak which if anything indicates that if bias had an effect, it wasn't notable. To help eliminate potential researcher effects it would be important to reduce the amount of contact between them in future research. It may be helpful if all communication is via email and text messages and the researcher's telephone contact provided only as an emergency number.

A key strength of this study is the inclusion of an interpretation bias measure. A general problem within the CBM-I research base is the lack of a psychometrically verified interpretation bias measure (Beard, 2011). The choice was even more limited for the

present study as most were originally developed for measuring social anxiety related interpretation bias and have been used primarily to detect between group differences where there is also a control group. Examples include the word sentence association paradigm (Beard & Amir, 2008), the recognition task (Mathews & Mackintosh, 2000) and the ASSIQ (Stopa & Clark, 2000). Consequently the SST was deemed as the most appropriate interpretive bias assessment that is currently available. Efforts were taken to enhance its validity and reliability in the present study which included using the WDQ as a guide for the sentences, obtaining approval from two independent Clinical Psychologists, and randomising the order of sentences for each participant at each time point. Future research aimed at the development of a psychometrically robust interpretation bias measure which is relevant to GAD would be useful.

There were also some potential limitations with some of the other measures used in this study. Following Blackwell and Holmes (2010), a daily measure of a typical cognitive bias was included, which in the present study was an anxiety bias pertaining to catastrophisation. However this outcome was less defined than the others and did not closely relate to the research hypotheses. Replacing this measure with perhaps a daily mood measure could be advantageous in future research given that depression is often co-morbid with GAD (Yonkers et al., 1996). Although adopting the present study design would not be able to offer any further clarification of the relationship between the CBM-I task, mood and worry, given that all but one of the participants scored in the clinical range of depression at assessment (participant five), any improvements in mood would be valuable and of clinical interest.

The use of the GAD-Q-IV as an assessor of the presence of clinical levels of generalised anxiety was appropriate however its additional use as an outcome measure to detect changes in generalised anxiety severity was less so as it was not designed for this

purpose. Similar issues pertain to the suitability of the PSWQ as an assessor of daily worry change. Whilst the PSWQ has demonstrated good responsiveness to changes in worry level over periods of several weeks and longer (e.g., Borkovec & Costello, 1993; Borkovec, Newman, Pincus, & Lytle, 2002), it contains several characteristic worry statements undermining its suitability to monitor daily fluctuations (Stober & Bittencourt, 1998). Substituting the PSWQ for a measure of worry that is designed to assess daily change such as the Penn State Worry Questionnaire-Past Day (Joos et al., 2011) may allow more effects of worry to emerge. Nevertheless the present study is not aware of any other CBM-I studies that have included a standardised measure of worry and so the inclusion of the PSWQ is a strength.

With regard the CBM-I task, as mentioned already, most of the scenarios were developed by the researcher in accordance to common worry topics as identified in the WDQ. They were also trialled on a Trainee Clinical Psychologist and, just like with the SST, the final set were submitted to and approved for applicability to GAD by two Clinical Psychologists. Nonetheless it was not possible to ensure that the scenarios fit with the participants' main sources of worry. To enhance their effectiveness, a similar iterative approach to that used by Blackwell and Holmes (2010) could be adopted in which the CBM-I task evolved according to the feedback of each successive participant. The fact that the present study's CBM-I task consisted of seven sessions, had a notable imagery aspect, was administered online, and accessed by participants in their homes means that it could be considered progressive.

The present study was unable to fully assess for the participants' compliance to the CBM-I task although data was gathered on whether or not participants fully completed sessions or not and encouragingly every participant did. Capturing data on word fragment and comprehension accuracy would be helpful in future research as it would allow more

insight into their level of engagement with the CBM-I task.

Finally the sample used in the current study consisted of patients referred from psychological services who scored above the clinical threshold on a GAD screening questionnaire (GAD-Q-IV). The fact that people with clinical presentations were studied is useful as this is generally lacking in the CBM research (MacLeod & Mathews, 2012). At assessment all participants reported to have experienced excessive, uncontrollable worry about multiple worry topics on more days than not for at least six months. They also all scored above the clinical thresholds on the STAI-T, the GAD-7 and the PSWQ. These results increase the chances that they had diagnosable GAD however this was not assessed using a structured diagnostic interview. Consequently the participants are representative of treatment seeking individuals experiencing clinical levels of generalised anxiety not individuals with GAD. To enhance the generalisability of findings to GAD, future research should use an approved diagnostic tool such as the Anxiety and Related Disorders Interview Schedule for DSM-5-Lifetime Version (ADIS-5L; Brown & Barlow, 2014) to screen participants. To further explore how long treatment gains last for with this CBM-I task, with this population, the inclusion of additional follows-up beyond one week post CBM-I would be interesting.

The limitations and weaknesses associated with the present study could be addressed by a larger, group controlled study like an RCT. For instance, with a control condition, it would be possible to investigate the direct effect of CBM-I on negative interpretation bias and help to eliminate non-bias modification explanations of training effects. It would also be possible to compare the CBM-I package with other established low intervention CT-based approaches and to directly test the benefit of the task's enhanced imagery component for this population. However despite the potential advantages of carrying out an RCT, the results of the present study do not indicate that one

is warranted with the CBM-I program in its current form. Rather, more development is needed with this paradigm to enhance its effect with this population. Small scale studies, like the current one, are therefore appropriate at this moment in time.

Qualitative feedback indicates some ideas to be tested out in future research that might improve the potency of the CBM-I task for reducing pathological worry. Firstly, extending the time frame over which the CBM-I sessions take place, as suggested by participants one, three and five could be efficacious. Psychological interventions such as therapy often occur weekly therefore a more longitudinal CBM-I program might allow better consolidation of the implicit production rule necessary for training effects to transfer to real life (MacLeod & Mathews, 2012) and facilitate more enduring bias modification. Secondly, ensuring the scenarios are perceived as personally meaningful and congruent with the participant's own main worries could be beneficial. It was clear that the two participants who described the least benefit from their CBM-I experience did not think that the scenarios were relevant to their worries (participants three & seven). For example participant seven reported 'I think it's, for me it wasn't very beneficial but I think for some people it would be if they worry about those situations a lot'. The impression gained from this participant's feedback is that the scenarios are appraised as important in determining outcomes for others and that with greater concordance to personal worries, gains might be possible.

Quite how the matching of scenarios to individuals can best be achieved is unclear. One idea could be to tailor scenarios according to the participant's main topics of worry. The first necessary step in achieving this would be for individuals to undergo an assessment prior to CBM-I to help identify what they worry most about. The next step would involve creating an individualised training set consisting of scenarios that are most relevant to their worries. For example, if a participant reports that they worry most about

their finances and work but less so relationships, then their allocated scenarios could reflect this. Creating a larger database of scenarios that could be categorised into specific domains of worry, that goes beyond the WDQ, would be useful as it would allow CBM-I users to receive hopefully a more tightly matched training set.

Whilst a one size fits all approach has clearly demonstrated efficacy in CBM-I studies (MacLeod & Mathews, 2012), most of these have targeted social anxiety (Beard, 2011). Social anxiety, by definition, involves a specific type of anxiety. Because of this, one might expect less variability between sufferers of this disorder in terms of the types of scenarios that trigger their anxiety (i.e. primarily social situations) than would be the case for GAD sufferers whose anxiety triggers are, by definition, more wide ranging. Consequently the chances of scenario mismatch occurring may be greater for GAD and so a one size fits all approach may be less effective with this particular disorder.

In sum, increasing emotional engagement with the training materials would appear to be critical. Based on participant feedback, future research should consider creating and testing a more individualised CBM-I program.

4.8 Clinical Implications

The current study found that an online multi-session CBM-I task was able to reduce level of worry in two individuals presenting with clinical levels of generalised anxiety (participants four & six). In addition, the group as a whole demonstrated reduced negative interpretation bias one week after completion of CBM-I. Therefore the CBM-I task may hold potential as a clinical tool for pathological worry. This notion is consistent with other studies that have included GAD participants and observed CBM-I benefits (Brosan et al., 2011; Hayes et al., 2010).

There are many reasons to be optimistic about the clinical application of CBM-I. As Beard (2011) noted, CBM-I has many advantageous unique features: Firstly, it lends

itself to standardised computer delivery, is relatively brief, and non-invasive for patients. Secondly, it is cost efficient as it requires no therapy contact. Thirdly, rooms in mental health services are not required as patients can access it from home. Fourthly, it offers flexibility regarding the times and dates of sessions as it can be used 24 hours a day, seven days a week. Fifthly, it does not suffer some of the fallibilities of human therapists such as memory problems and fatigue. Finally, it allows privacy, consistency of care and easy data collection.

CBM-I is also well placed with the recent Mental Health Outcomes Strategy of the National Operating Framework for the NHS 2012/2013 (Department of Health, 2011) which calls for more innovative and choice of treatments for patients in the least restrictive environment. CBM-I could provide patients who have anxiety disorders such as GAD with a new, standalone treatment as a potential option in stepped care, which could be helpful as a waitlist initiative or for those who do not respond to or cannot access current treatments. This is important as many people who might benefit from treatment for anxiety disorders are unable or unwilling to seek it (Kessler et al., 2005). CBM-I is also in keeping with the recent movement towards convergent treatments of anxiety disorders as it focuses on transdiagnostic mechanisms.

There is some overlap between CBM-I and conventional CT approaches such as CBT. Both attempt to modify cognitive processes believed to maintain anxiety and both involve systematic exposure to the events that trigger it (MacLeod & Mathews, 2012). However in traditional CT the method of change is to directly challenge accessible thoughts believed to be generating anxiety. CBM-I on the other hand involves changing a specific cognitive process that lies outside of conscious awareness, which gives rise to such thoughts. The present study is aware of only one study that has investigated the efficacy of CBM-I against a CT-based treatment (Bowler et al., 2012), although with a non-clinical

sample.

As mentioned previously, Bowler et al. (2012) compared CBM-I with cCBT and found that both groups reported significantly reduced levels of social anxiety and trait anxiety relative to the control group but that CBM-I was significantly more effective at reducing negative interpretation bias. As a standalone treatment, CBM-I has some potential advantages over CT-based interventions. For example, as Bowler et al. (2012) noted, CBM-I does not rely on insight or disclosure. This may be helpful for patients who find it difficult or who are unwilling to reflect on their own thinking patterns or to disclose personal thoughts and emotions, even to a computer. Also, CBM-I operates in a manner more congruent with the biases it seeks to modify (MacLeod & Mathews, 2012). As Beard (2011) explained, biases are relatively automatic in nature and so can be thought of as habits. With this reasoning, repeated experiential practice on tasks, as occurs with CBM-I, would appear to be a superior strategy for achieving bias modification than verbal dialogue and explicit instruction, as occurs with CT-based approaches (MacLeod & Mathews, 2012).

Alternatively CBM-I may be an effective adjunctive therapeutic tool. Combining CBM-I with CT-based treatments may lead to optimal results if the former serves to alter cognitive bias of threatening thinking at a more habitual level and the latter challenges the believability of these negative thoughts (MacLeod & Mathews, 2012). CBM-I may be helpful for patients experiencing difficulties in cognitive restructuring by bypassing some of their automatic mental habits. Likewise CBM-I may augment exposure treatments as it does not require feared situations to be physically confronted for change to occur. Individuals who are initially unwilling to engage in exposure could receive CBM-I prior to CT. Evidence is now emerging that combining CBM and CT-based paradigms can indeed improve outcomes (Wiers, Eberl, Rinck, Becker, & Lindenmeyer, 2011) and that this is an

effective therapeutic partnership for individuals with GAD (Amir & Taylor, 2012b).

4.9 Conclusion

In conclusion, the results of the present study indicate the potential value of CBM-I in ameliorating negative interpretation bias in individuals presenting with some of the symptomatology that is associated with GAD. However the findings concerning the ability of CBM-I to reduce worry are equivocal as only two of the seven participants demonstrated a positive response in their level of worry (participants four & six); in both cases gains maintained one week after CBM-I completion. The findings need to be considered carefully within the methodological constrains of the current study. At this point in time, further exploration and development of CBM-I for reducing pathological worry using patients meetings meeting GAD diagnostic criteria is warranted. Qualitative feedback indicates that extending the duration of CBM-I and ensuring that scenarios are perceived as meaningful; achieved possibly by matching scenarios to users' main disclosed worries, may be ways of enhancing the training effect. As a clinical tool, CBM-I has many advantageous features and is well placed within current NHS strategies. The present study advances CBM-I research by extending findings on the efficacy of online, home-accessed, multi-session, imagery-focused CBM-I for patients experiencing clinical levels of generalised anxiety.

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Appendices

Appendix A: Recruitment Activity Log

Date	Recruitment Activity	Location
10/06/13	Met with City locality Clinical Lead and discussed study and recruiting.	Hellesdon Hospital, Norwich
14/08/13	Presented study to clinicians at East Locality business meeting and emailed study information to an Enhanced Therapist.	Northgate Hospital, Great Yarmouth
09/09/13	Met with Suffolk Clinical Lead and discussed study and recruiting.	G-block, Ipswich
11/09/13	Met with Enhanced CBT Therapist and discussed study and recruiting.	Northgate Hospital, Great Yarmouth
20/09/13	Arranged to meet with West Locality Clinical Lead but she could not make it. She advised that her service did not have capacity to refer currently.	Northgate Hospital, Great Yarmouth
27/09/13	Emailed East Locality Clinical Lead and asked to re-present at next team meeting. Also emailed Suffolk Clinical Lead for an update.	NA
15/10/13	Presented study to clinicians at centrality locality business meeting.	Gateway House, Wymondham
15/10/13	Emailed Enhanced CBT therapist about study and recruiting.	NA
15/10/13	Met with PWP Lead and discussed study and recruiting.	Northgate Hospital, Great Yarmouth
06/11/13	Emailed Enhanced Therapist from City Locality who said would go through waitlist. Also emailed an Enhanced Therapist from East Locality requesting referrals.	NA
13/11/13	Emailed another City Locality Lead and requested study information to be distributed to clinicians across the locality.	NA
27/11/13	Met with three PWPs and discussed recruiting.	Northgate Hospital, Great Yarmouth
17/12/13	Met with three Enhanced Therapists and discussed study, left message with a PWP and emailed an Enhanced Therapist with study information.	Northgate Hospital, Great Yarmouth
08/01/14	Emailed PWP requesting referrals.	NA
08/01/14	Emailed East Locality, West Locality, City Locality, South Locality Clinical Leads, and two PWP Leads asking for referrals.	NA
15/01/14	Presented to PWPs at West Locality team meeting.	Queen Elizabeth Hospital, Kings

		Lynn
28/01/14	Presented study to a PWP supervision session.	Mariner house, Ipwsich
11/02/14	Emailed West Locality PWP lead requesting more referrals.	NA
18/02/14	Emailed PWP Lead from East Locality requesting referrals.	NA
04/03/14	Emailed all past referrers requesting referrals.	NA
06/03/14	Emailed Suffolk Clinical Lead and requested referrals.	NA
13/03/14	Presented study to two PWP supervision sessions.	Mariner house, Ipwsich
26/03/14	Emailed Suffolk Clinical Lead requesting referrals.	NA
31/03/14	Emailed different Suffolk Clinical Lead requesting referrals.	NA
31/03/14	Spoke to a city locality PWP Lead about study and recruiting.	Hellesdon Hospital, Norwich
01/04/14	Presented study to clinicians at City Locality team meeting.	Hellesdon Hospital, Norwich
01/04/14	Emailed West Locality PWP Lead requesting more referrals.	NA

Note. This is not an exhaustive list of all recruitment related activity but rather that for which correspondence is contained in the researcher's email inbox.

Appendix B: The Patient Health Questionnaire (PHQ-9)

PHQ-9 Patient Questionnaire

Participant Identification Number: _____ Date: _____

Over the *last 2 weeks*, how often have you been bothered by any of the following problems?

	Not at all	**Several Days**	**More than half the days**	**Nearly every day**
	0	**1**	**2**	**3**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless.	0	1	2	3
3. Trouble falling/staying asleep, sleeping too much.	0	1	2	3
4. Feeling tired or having little energy.	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down.	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television.	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual.	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way.	0	1	2	3

Appendix C: The Generalized Anxiety Disorder Questionnaire (GAD-Q-IV)

GAD-Q-IV

1. Do you experience excessive worry? Yes___ No___

2. Is your worry excessive in intensity, frequency, or amount of distress it causes? Yes___ No___

3. Do you find it difficult to control your worry (or stop worrying) once it starts? Yes___ No___

4. Do you worry excessively and uncontrollably about minor things such as being late for an appointment, minor repairs, homework, etc.? Yes___ No___

5. Please list the most frequent topics about which you worry excessively and uncontrollably:

a._____ d._____

b._____ c._____

c._____ f._____

6. During the last six months, have you been bothered by excessive and uncontrollable worries more days than not? Yes___ No___

IF YES, CONTINUE. IF NO, SKIP REMAINING QUESTIONS.

7. During the past six months, have you often been bothered by any of the following symptoms? Place a check next to each symptom that you have had more days than not:

___ Restlessness or feeling keyed up or on edge

___ Difficulty falling/staying asleep or restless/unsatisfying sleep

___ Difficulty concentrating or mind going blank

___ Irritability

___ Being easily fatigued

___ Muscle tension

8. How much do worry and physical symptoms interfere with your life, work, social activities, family, etc.? Circle one number:

0	1	2	3	4	5	6	7	8
None		Mildly		Moderately		Severely		Very Severely

9. How much are you bothered by worry and physical symptoms (how much distress does it cause you)? Circle one number:

0	1	2	3	4	5	6	7	8
No distress		Mild distress		Moderate distress		Severe distress		Very Severe Distress

Appendix D: The Penn State Worry Questionnaire (PSWQ)

The Penn State Worry Questionnaire (PSWQ)

Participant Identification Number: _____ Date: _____

Instructions: Rate each of the following statements on a scale of 1 ("not at all typical of me") to 5 ("very typical of me"). Please do not leave any items blank.

	Not at all typical of me				Very typical of me
1. If I do not have enough time to do everything, I do not worry about it.	1	2	3	4	5
2. My worries overwhelm me.	1	2	3	4	5
3. I do not tend to worry about things.	1	2	3	4	5
4. Many situations make me worry.	1	2	3	4	5
5. I know I should not worry about things, but I just cannot help it.	1	2	3	4	5
6. When I am under pressure I worry a lot.	1	2	3	4	5
7. I am always worrying about something.	1	2	3	4	5
8. I find it easy to dismiss worrisome thoughts.	1	2	3	4	5
9. As soon as I finish one task, I start to worry about everything else I have to do.	1	2	3	4	5
10. I never worry about anything.	1	2	3	4	5
11. When there is nothing more I can do about a concern, I do not worry about it any more.	1	2	3	4	5
12. I have been a worrier all my life.	1	2	3	4	5
13. I notice that I have been worrying about things.	1	2	3	4	5
14. Once I start worrying, I cannot stop it.	1	2	3	4	5
15. I worry all the time.	1	2	3	4	5
16. I worry about projects until they are all done	1	2	3	4	5

Appendix E: The Visual Analogue Scales (VAS)

Visual Analogue Scales: Version 1 (03/01/2013)

Study Participant Number:

The following scales are to be **completed daily**, at the same time every day. Please indicate below the date, time and whether it was before or after CBM-I training session for that day of completion. Please indicate by marking on the lines below, your response to the questions or statements; please consider your answers based on today.

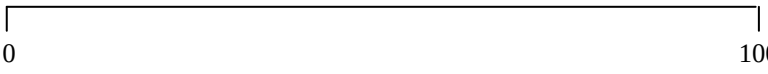
Date: Time: Before CBM-I / After CBM-I (circle)

How anxious have you felt over the past 24 hours?

0 100

Not at all Extremely

Please answer the following statement:
When I imagine outcomes for events, I expect the worst.



0 100

Not at all Extremely

Appendix F: The Generalized Anxiety Disorder Assessment (GAD-7)
GAD-7 Patient Questionnaire

Participant Identification Number: _____ Date: _____

Over the *last 2 weeks,* how often have you been bothered by any of the following problems?

	Not at all	**Several Days**	**More than half the days**	**Nearly every day**
	0	**1**	**2**	**3**
1. Feeling nervous, anxious or on edge.	0	1	2	3
2. Not being able to stop or control worrying.	0	1	2	3
3. Worrying too much about different things.	0	1	2	3
4. Trouble relaxing.	0	1	2	3
5. Being so restless that it's hard to sit still.	0	1	2	3
6. Becoming easily annoyed or irritable.	0	1	2	3
7. Feeling afraid as if something awful might happen.	0	1	2	3

Appendix G: An Example Scrambled Sentences Test (SST)

SCRAMBLED SENTENCE TEST

Unscramble the sentences to form statements. Each of the scrambled sentences contains six words. Unscramble five words in each sentence by placing a number over each of the five words indicating the proper order. For example:

3 4 2 1 5
has green child the eyes blue

Each sentence can be unscrambled into more than one statement, but you should choose only one statement to unscramble. You have 4 minutes to unscramble as many sentences as possible. Work as quickly and as accurately as possible.

me support people love I leave

my past I’m of ashamed proud

enough money I’ll have always never

badly others think of me well

as people me irresponsible view responsible

appear to sensible I foolish others

are poor my good credentials work

rarely me always sensations strange bother

my are bad good job prospects

falling I never behind always am

stupid come as capable I across

a rarely headaches tumour signal often

okay will end up I poor

goals my eventually happen will never

usually are palpitations harmless harmful heart

regularly mistakes make I bad rarely

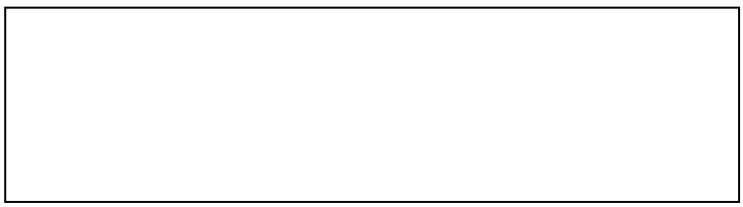
find mostly ugly attractive me people

make I bad impression a good

are attacks threatening aren’t life panic

health likely my will worsen improve

Write the 6 digit number in the box below



Appendix H: All 80 Scrambled Sentences (in no particular order)

my past I'm of ashamed proud

I enough cannot can fast work

me tend people to accept judge

ignore will bother stranger the me

the I say wrong things right

usually are palpitations harmless harmful heart

succeed fail I at work will

light common can alarming be headedness

find mostly ugly attractive me people

assertive can be I cannot very

up normally can't I keep can

very looks angry excited the dog

appear to sensible I foolish others

stupid come as capable I across

cannot bills I pay my can

okay will end up I poor

my reach will goals I won't

successes my many failures life contains

new approaching risky is fine people

with unhappy appearance I'm happy my

unmanageable usually manageable is workload the

good bad look think I I

health likely my will worsen improve

interesting my others opinion boring find

look I fool a won't will

will things better worse get probably

about pessimistic the I'm future optimistic

think loveable I am I unloveable
regularly mistakes make I bad rarely
accident I'll avoid have an probably
up will I crashing won't end
can't can I good jobs get
enough money I'll have always never
are attacks threatening aren't life panic
indifferent opinion I'm others' worried about
I'm people confident nervous new with
I errors make typically many few
social circles anxious in I'm comfortable
things cannot many I afford can
I'll rate this at quit manage
produce I work can't can accurate
many things right go can wrong
my are bad good job prospects
a rarely headaches tumour signal often
I social dread usually love gatherings
won't will of disapprove others me
with relaxed I people stressed am
care about people do me don't
will me most help hurt people
possible deadlines keeping impossible is to
annoying little is getting sleep harmful
to me good bad happen things
employers many few me will hire
merits my other notice people faults
easy people uneasy other with I'm

problems my end financial will continue
much haven’t I very have achieved
never my achieve definitely ambitions I’ll
face will always won’t hardship I
I’m with reflection comfortable my uncomfortable
usually from people I withdraw don’t
have lot accomplished a I haven’t
rarely me always sensations strange bother
as people me irresponsible view responsible
to friendships easy maintain difficult it’s
stay uncomfortable feelings pass tend to
buy can many I things can’t
me support people love I leave
with something nothing me wrong there’s
goals my eventually happen will never
are poor my good credentials work
falling I never behind always am
mostly the is safe world scary
on scared own I’m my okay
blunders can cannot making I avoid
make I bad impression a good
badly others think of me well
will out my run won’t money
able I’m finish to unable things
listen others to don’t do me

Appendix I: CBM-I Task Instructions

First screen of instructions.

In this task you will be presented with descriptions of many different situations. Each description consists of four lines of text. Each line of text will appear when you press the downward arrow on the keyboard. The last line of text always has the final word missing from it. When you press the downward arrow key again, the missing word will appear but it will have some letters missing. (For example, 'a_azi_g: the 'm' and 'n' is missing from 'amazing').

Please try to picture in your head each situation to help you fill in the word using the right letter(s). When you know what the unfinished word is, press the downward arrow key. Then enter the FIRST missing letter (in the 'amazing' example above, this would be 'm'), by finding this letter on the keyboard and pressing that letter key. When you have pressed the key the missing word will show on your computer screen.

Then, after each situation, a question will be shown on your screen. This is to check you have understood, so remember to answer it based on the situation you have just read. For this you will be using the left (for NO) and right (for YES) arrow keys. When you begin the task each day, you will first have a practice situation.

Click the underlined link below to continue.

Second screen of instructions.

Now, let's talk about why you are doing this! It has been suggested that imagining yourself in a range of unreal situations may help you to have less anxious feelings in real life. The goal of each computer session is to help you get used to being in lots of different situations and imagining positive outcomes.

Importance of imagining yourself in the situations

There will be many situations that do not apply to you personally or fit with your experiences. Some may even just seem downright silly to you. However, in order for you to get the most out of completing the sessions, ***it is really important that you create an image in your head of each situation as if you are the main person in it and it is actually happening****. The more vividly you can imagine that you are in the situations, the more you will get out of the sessions.*

Also, when imagining that you are in the situations, ***try to imagine that you are looking out through your own eyes*** *rather than looking at yourself in the situation.*

Imagery exercise:

To help you with imagining yourself in each situation, an imagery exercise will follow. Please read the situation. For this exercise, the lines of text will appear automatically; you do not need to press the downward arrow key. Try to picture yourself in the situation. You

will then be asked to click on a number between 0 (you could not imagine it at all) and 10 (you could imagine it perfectly, as if you were there).
Click the underlined link below to continue.

Third screen of instructions.

Well done, that is the end of the imagery exercise.

Next you will complete a practice situation. Don't forget to imagine yourself in it.

Click the underlined link below to continue.

Appendix J: Study Approval from the Proportionate Review Sub-Committee of the North West- Greater Manchester South National Research Ethics Service (NRES)

NHS
Health Research Authority
NRES Committee North West - Greater Manchester South
HRA NRES Centre Manchester
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7830

12 August 2013

Mr Liam McNally
Clinical Psychology Course
University of East Anglia (UEA)
Norwich
NR4 7TJ

Dear Mr McNally

Study title:	**A Cognitive Bias Modification for Interpretation Task with Individuals experiencing Clinical Levels of Generalised Anxiety Disorder: A Single Case Series**
REC reference:	**13/NW/0430**
IRAS project ID:	**124723**

Thank you for your email, responding to the Proportionate Reviews Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

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 Assistant Co-ordinator Miss Nicola Burgess, nrescommittee.northwest-gmsouth@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.

Ethical review of research 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).

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).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Evidence of insurance or indemnity		15 May 2013
GP/Consultant Information Sheets	2	03 May 2013
Interview Schedules/Topic Guides	1	10 January 2013
Investigator CV	Liam McNally	03 March 2013
Investigator CV	Dr Margarita Ononaiye	
Investigator CV	Dr Hodgkins	
Other: Participant Details Sheet	2	03 May 2013

Other: SST (Scrambled Sentence Test)	1	18 July 2013
Other: Flow Diagram	5	15 July 2013
Other: RGC Responses		06 June 2013
Participant Consent Form	4	26 June 2013
Participant Information Sheet	5	26 June 2013
Protocol	3	04 June 2013
Questionnaire: GAD-7		
Questionnaire: PHQ-9		
Questionnaire: PSWQ		
Questionnaire: VAS	1	03 January 2013
Questionnaire: Recognition Test	1	03 January 2013
REC application	3.5	17 May 2013
Response to Request for Further Information		

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/NW/0430	**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

Professor Sobhan Vinjamuri
Chair

Email: nrescommittee.northwest-gmsouth@nhs.net

Copy to: *Ms Sue Steel*

Ms Bonnie Teague, Norfolk and Suffolk NHS Foundation Trust

Appendix K: Study Approval from the Norfolk and Suffolk National Health Service Foundation Trust (NSFT) Local Research Governance Committee

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 Liam McNally
Clinical Psychology Course
University of East Anglia
Norwich
NR4 7TJ

23rd August 2013

Dear Mr McNally,

Re: 2013MH10 A multi-session CBM-I task for individuals with generalised anxiety

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: **2013MH10**, and this should be quoted on all correspondence.

Yours sincerely,

Dr Jon Wilson
Deputy Medical Director (Research)

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	2	19/02/2013
Patient Information Sheet	5	25/06/2013
Consent Form	4	26/06/2013
Participant Details Sheet	2	03/05/2013
GP Information Sheet	2	03/05/2013
Interview Schedule	1	10/01/2013
Flow Diagram for study procedure	5	15/07/2013
Questionnaire: GAD-7		
Questionnaire: PHQ-9		
Questionnaire: PSWQ		
Questionnaire: VAS		
Questionnaire: Recognition Test		
Questionnaire: SST	1	18/07/2013

Appendix L: Study Insurance Cover from the Research Enterprise and Engagement Department of the University of East Anglia (UEA)

Research & Enterprise Services
West Office (Science Building)
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Telephone: +44 (0)1603 591490
Email: Deborah.Graver@uea.ac.uk

Web: www.uea.ac.uk/researchandenterprise

TO WHOM IT MAY CONCERN

31st July 2013

Study: A Cognitive Bias Modification for Interpretation Task with Individuals experiencing Clinical Levels of Generalised Anxiety Disorder: A Single Case Series
Chief Investigator: Liam McNally

This is to confirm that the University of East Anglia and Subsidiary Companies have arranged insurance cover as detailed on the attached Company Public Liability and Professional Negligence Insurance certificates

The cover is subject to the terms and conditions of the policy. If you require further details, please contact the undersigned.

Yours faithfully

pp Deborah Graver
Project officer

Appendix M: Consent Form

Participant Consent Form: Version 4 (26/06/2013)

Norfolk and Suffolk NHS
NHS Foundation Trust

Centre Number

Patient Identification Number for this study .....

Study Number .....

CONSENT FORM

Title of Project: Modifying Interpretation Biases in Generalised Anxiety

Name of Researcher: Mr Liam McNally

Please initial box

1. I confirm that I have read and understand the information sheet dated 26.06.13 (version 5) for the above study. I have had the opportunity to consider the information, ask questions and had these answered satisfactorily. ☐

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

3. 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. ☐

4. I will inform the researcher of any changes in medication during my involvement in the study, including dates of the change, dose and name of the medication. ☐

5. I am willing for my GP and care team/clinician involved 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 understand that I can choose to withdraw from the study or delay any other therapy or intervention, if offered during my participation. I understand that if this occurs it will be negotiated with the relevant care team/clinician and therapy will commence at the earliest opportunity after my participation in the above study. ☐

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

Name of Patient	Date	Signature
Name of Person taking consent	Date	Signature

Appendix N: Participant Information Sheet

Norfolk and Suffolk NHS
NHS Foundation Trust

Modifying Interpretation Biases in Generalised Anxiety

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. Ask the researcher if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

There is a large body of evidence indicating that people who are anxious often have a tendency to interpret ambiguous situations, information and things in general, in a threatening way. Furthermore, this tendency or bias to interpret things negatively is thought to maintain anxiety.

New evidence is emerging that by modifying these interpretations so that one looks at situations etc in a more positive or neutral light will help reduce feelings of anxiety. Even though this is only one aspect involved in the maintenance of anxiety, the researcher is interested in how helpful modifying these interpretation biases may be.

The aim of the study is to try and find out whether Cognitive Bias Modification for Interpretation (CBM-I), a computer based program accessed over the internet helps reduce negative interpretation biases and levels of anxiety. This involves accessing and engaging with the program, which is located on internet, from your home, once a day, at the same time each day, for one week in total. The researchers are trying to find out whether CBM-I might be a useful therapeutic tool to use in the future for other people with anxiety.

Why have I been chosen?

The researcher is approaching people who may be experiencing clinical levels of generalised anxiety and whom are seeking help for this through primary NHS teams such as Gateway workers and Improving Access to Psychological Therapy (IAPT) workers. 'Clinical levels of generalised anxiety' refers to experiencing excessive anxiety i.e. feeling fearful, worried and tense (as measured on a specific anxiety questionnaire) on most days. Potentially suitable people for this study were selected by talking to primary NHS teams. It is these people that will have first contacted you, to ensure confidentiality.

There will be approximately 9 participants selected in this way for the study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide that you would like to take part then please read the attached consent form. If you have any questions regarding the consent form, you must contact the researcher before signing it so that you understand exactly what taking part involves. When you are happy that you completely understand the consent form, you can complete it and provide either consent or no consent depending on your decision. You can then post it to the researcher in the pre-paid envelope that is provided.

It is important to understand that 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 standard of care you receive. If you do withdraw or in the unlikely event that you lose capacity to consent, the data collected up until this point may still be used.

What will happen to me if I take part?

If you do agree to take part and provide consent on the consent form, once the researcher has received this he will contact you by telephone to complete some questionnaires with you over the phone. This should hopefully take no longer than 25 minutes.

If your answers suggest that you might not be suitable for taking part in this research study, then the reasons why will be explained. This will be the end of the process for you in terms of taking part in the study and you will be returned to your NHS primary care team.

However if your answers suggest that you might be suitable for taking part, then you will be invited to meet up with the researcher to complete the final stage of suitability checking. You can choose whether to meet the researcher for this session in your own home or on NHS premises. This session will involve the researcher asking some questions about your current problems. If the researcher then feels you are suitable for taking part in the study, you will be asked to fill in some questionnaires which shouldn't take more than half an hour and the whole session will last about 45 minutes.

You will be allocated to a length of assessment period which will be between seven and eleven days. During this time, you will be asked to fill out two short questionnaires about anxiety every day which should take no longer than about five minutes. If you would like, the researcher can email or text you to remind you to fill them out.

Once this assessment phase (seven, nine or eleven days later) is complete the researcher will arrange to meet with you again to complete the same questionnaires that you did at the start, and show you how to access and use the computer program for the intervention phase.

The intervention phase (CBM-I) will last for seven consecutive days, whereby you must try to complete the CBM-I computer program at home, at roughly the same time of your choosing (or as close to as possible) every day. This should take around 30 minutes or a little

longer if you take breaks in between the training material. The same short daily questionnaires that you filled in the assessment phase should also be completed. If you get stuck or have any questions about the CBM-I, then you can always contact the researcher on the details given at the end of this Information sheet.

After completing the seven day treatment phase, the researcher will meet with you again to ask you to complete the same questionnaires you completed at the start of the assessment phase and at the end of it. You will continue to complete the very short daily questionnaires of anxiety. You will then be contacted by the researcher one week later to see how you are getting on and to complete the same questionnaires again. The researcher will also ask for your feedback on the computer programme and whether you feel it has helped or not. The information taken from this feedback will be used to write a separate piece of research exploring participants' experience of an internet delivered CBM-I package.

How long will I be involved for?

Participation in this research will last between 21 and 25 days. If you are on a waitlist for other therapy you may be asked to wait to begin this until the study completion. This will not affect your place on the waitlist and will be discussed with the appropriate clinician or service. The researcher also asks you to inform them of any anxiety medication you are taking and notify the researcher of any changes in medication during the study.

Expenses and payments

The researcher is able to provide you with up to £5.00 towards any travel costs or expenses incurred through meeting up with him should you choose to do it on NHS premises rather than in your home. This is subject to you keeping any travel receipts.

What do I have to do?

As mentioned above, the therapeutic tool we are trialling is called Cognitive Bias Modification for Interpretation (CBM-I). It is an internet- based computer program containing training materials that has proven to help people with high levels of anxiety appraise or interpret situations in a more positive way. The researcher will show you how to use this program guiding you through the first session and you will be provided with clear instructions and a troubleshooting guide. The program is easy to use with on-screen instructions.

You will be presented on the screen with scenarios and all you have to do is complete the sentence. You are asked to imagine yourself in these situations. There is only one possible solution to complete the sentence. You will be required to repeat this using different scenarios 50 times during each daily session. The scenarios will be split in to groups of 10 and you are welcome to have a break in between. You are also required to complete the daily questionnaires, which should take no more than about five minutes to complete once you have become familiar with them. It is really important for you to complete the daily CBM-I sessions and the daily questionnaires. If you would like reminding, the researcher can send you a daily text or email.

It is important that you do not consume alcohol or recreational drugs when completing the measures or when using the computer programme as not to influence the results of the study. It is also important to complete the tasks at a suitable time, and at the same time every day, in suitable surroundings and preferably free from distraction.

During your final assessment session you will be asked to take part in a short interview, exploring your experiences of the CBM-I programme and any changes this may have brought. This part of the final session will be recordedso that the researcher can accurately transcribe the feedback you give. You will have the opportunity to read this transcription to make sure it is a true reflection of what was discussed. The recordings will be anonymous, stored in a locked filing cabinet and destroyed at the end of the study. The information obtained during the interview will be used in a separate service based research project that aims to explore participant's experiences of using an internet delivered CBM-I programme.

What is the programme being tested?

The aim of CBM-I for generalised anxiety is to help people interpret ambiguous situations in a less negative way. By repeated practice of interpreting scenarios more positively it is hoped that this will carry over to real life situations. We know that negative interpretation biases are common within those who have high anxiety and are a maintaining factor in anxiety. If the CBM-I training materials can help make these more positive, it is hoped that anxiety may be reduced. As this reflects early stages of clinical research, it is anticipated that CBM-I will be most beneficial alongside other treatments for generalised anxiety and enhance them.

What are the alternatives for treatment?

Cognitive Behavioural Therapy (CBT) is the main therapy available to help people who are experiencing clinical levels of generalised anxiety. CBM-I and other cognitive bias modification programmes are being developed to see if they might be an effective supplement for CBT or beneficial for people on waitlist awaiting treatment.

What are the possible disadvantages and risks of taking part?

There are few disadvantages to taking part. It is possible that participation may result in a delay in starting therapy if therapy becomes available to you within 25 days of you starting this study.

If you consent to participate in this study you are agreeing to delay any therapy that might become available to you until your participation has ended. However this will be closely monitored and negotiated with your clinical care providers in order to minimize any delay, should there be any. Your participation will not affect your routine clinical care.

Again, even 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 standard of care you receive.

There is no suggestion or evidence that completion of CBM-I worsens anxiety symptoms.

The various assessments and completion of questionnaires required may briefly disrupt your day-to-day routine as it may take up to an hour of your day. This is required for only one week. Some people may perceive the repetition of the training materials to be tedious, however it is this aspect of repeated practice that is hoped to change the interpretation bias. Much like the way repeated exercise improves fitness.

What are the possible benefits of taking part?

The aim of CBM-I is to help people interpret things less negatively and feel less anxious.

We hope that the CBM-I will help you. However, this cannot be guaranteed. The information we get from this study may help us treat future patients with anxiety more effectively.

What happens when the research study stops?

When the research study finishes, all participants will receive normal care from the services that they have already been in contact with or that referred them to this research.

What happens if something goes wrong?

In the unlikely event that you are harmed by taking part in a research project, there are no special compensation arrangements. If you are harmed by someone else'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 procedures should be available to you. Any complaint about the way you have been dealt with during the study will be addressed.

In the event that you become distressed while participating in the study, please contact the researcher in the first instance. If the researcher is not available please contact your GP services or primary care contact. In the event that this falls outside of normal working hours please contact your out of hours GP service or NHS direct (0845 4647).

Will my taking part in this study be kept confidential?

If you consent to take part in the study the researcher will speak with the clinician or team that referred you. All information that is collected about you during the course of the research will be kept strictly confidential. If the researcher is worried about any risk to yourself or others during the course of the research then some information may need to be disclosed to relevant persons. In the unlikely event of this occurring every attempt would be made to discuss this with you first.

Any information about you that leaves NHS premises will have your name and address removed so that you cannot be recognised from it. You will be allocated a participant number to help with this. 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. This summary will be checked with you first and you can choose for this not to be sent.

Results and research data, with personal information removed will be looked at by my research supervisors. Dr Margo Ononaiye (Research Supervisor) will also have access to some personal details such as names, addresses and phone numbers in case a second point of contact is needed by yourself. These details will be kept securely and your name and contact details stored separately using your participant number to help ensure confidentiality.

Where and for 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 up to 10 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, Doctoral programme in Clinical Psychology 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 Liam McNally, Trainee Clinical Psychologist who is a student from the University of East Anglia, and research supervisors. The research is being carried out as part of training for a Doctorate in Clinical Psychology and it is hoped to further the CBM literature and develop the use of CBM as a therapeutic tool.

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.

Thank you for reading this. If you need further information, please contact the researcher directly. If you wish to participate in the study please read the attached consent form. If you understand it fully please complete it and post it in the prepaid envelope provided.

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 Liam McNally (Trainee Clinical Psychologist) or Margo Ononaiye (Research Supervisor):

Doctoral Programme in Clinical Psychology
University of East Anglia

Norfolk and Suffolk NHS
NHS Foundation Trust

Queens Building
Norwich
Norfolk
NR4 7TJ

Tel: 01603 593600 (Mon-Fri, 9am – 5am)

Best contact for researcher:

Email: L.mcnally@uea.ac.uk

Work mobile: 07990900439

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 O: Participant Details Sheet

Participant Details Sheet: Version 2 (03/05/2013)

Norfolk and Suffolk NHS
NHS Foundation Trust

Patient Identification Number for this study: .....

Participant Details Sheet

Title of Project: Modifying Interpretation Biases in Generalised Anxiety

Name of Researcher: Liam McNally

Please circle the appropriate answer or fill in the required details.

Gender: **Male / Female**

Age: _____

GP Name: _____

Registered GP Surgery: _____

Contact Details

Mobile Telephone Number: _____

Home Telephone Number: _____

Email Address: _____

Home Address: _____

_____

_____

Best time to contact/visit: **Weekday Morning (08.00 am – 12 pm)**
Weekday Afternoon (12.00 pm – 7 pm)

Please Specify: _____

Reminders needed: **Text / Email / Both**

Current Medication Details: **Medication**_____

Type_____

Dose_____**Frequency**_____

Since_____

Concordance: **Fully concordant / Mostly / Infrequent/ Rarely/ Not at all**

Any known traumatic brain injury or learning disability	**Yes / No**
Previous Psychological Therapy:	**Yes / No**
Previous or current participation in research:	**Yes / No**
Would you like to know about the results of the study?	**Yes / No**

Appendix P: Letter to Participant's General Practitioner Notifying them of Participation

Norfolk and Suffolk NHS
NHS Foundation Trust

Faculty of Medicine and Health Sciences

Clinical Psychology Doctorate
Postgraduate Research Office

University of East Anglia
Norwich NR4 7TJ
United Kingdom

Email: **********

Study Mobile: 07*** *** ***

Name:
Address:

Date:

Dear Sir/Madam

Patient participation in a research study

Patient Name:
Date of Birth:
Address:

I am writing to inform you that the above patient has consented to taking part in a research study for individuals experiencing clinical levels of generalised anxiety. They have given consent for me to make you aware of their participation.

Please find enclosed a 'Participant Information Sheet' for your information. Please take the time to read it for details about the study and what is expected of the patient.

If you have any questions or would like further information, please do not hesitate to contact me on the above details.

With Best Wishes,

Yours sincerely,

****
Trainee Clinical Psychologist
Supervised by **********
UEA, Doctoral Programme in Clinical Psychology

Appendix Q: Collection of Participant Feedback Quotes

Positive cognitive change.

Participant one:

‘I found that it was actually making me think of the positive outcome rather than just always assuming that it was going to be negative.’

‘It got me thinking more positively and I was instantly looking for the positive outcomes.’

‘I just thought, you know, it doesn’t have to be negative and that got me to thinking about the things that do cause my anxiety and how they don't have to be negative and they could end differently and some things are in my control and that I can do something to change things.’

‘I’ve almost taught myself to, to look at each situation that cause my anxiety and try and sort of work out a different coping mechanism I suppose with it and I don't know if that is to do with the computer program but it definitely did sort of kick start a, a more positive attitude in my brain.’

‘I’ve just decided to try and start sort of living my life rather than being scared of it.’

Participant four:

‘It’s like when I was out walking earlier you know, I’m sort of thinking ‘oh she’s gonna, she’s on the lead’ but I sometimes wonder if she’s going to run over the road and she never has so I sort of say to myself ‘she’s never done it so she’s not

gonna do it', you know what I mean, so it's, cos it's these thoughts go in your head but now I, I am thinking of positive rather than negative.'

'I keep doing these sort of positive things in my head you know because I still sort of think negative a lot you know like all you know 'I can't do this I can't', now I say 'I can, you know, I can do it.'

Positive behavioural change.

Participant one:

'I've joined the gym which is a big thing for me because it means going out and being with different people in an environment I'm not comfortable with, erm, so that is something I wouldn't of done a few weeks ago, erm which I saw as a positive change for me and, I don't know really, I've got, I've booked a holiday for next year to go abroad with the two children in the last week which is something which terrifies me.'

'I've got on top of things again, I was letting things sort of defeat me like the housework and things, I've er, I've gone on a cleaning rampage and er I've done all sorts of things really.'

'I've sort of been out and got my haircut and bought some new clothes and sort of feeling better about my self image.'

'I've been putting like little plans of action together about things and it, it is paying off it is making me feel better like I'm taking control over these situations that were scaring me.'

Participant four:

‘As I said about my erm going to slimming world and I have to talk in front of everybody you know to sort of say what was happening and I sort of, I was scared but I did it. I’ve done it two weeks now running and erm so I was really like nervous. I could feel myself really red, you know when normally I never used to be you know but, but I have said it you know I have talked I could have talked to her at the beginning of the class, asked her not to speak to me, you know but I didn’t so.’

‘At work last week erm I erm we sort of like, we’ve been in the top ten of erm you know like for these like to like which are sort of like never been it before which is like because you know the takings are going up and I got sort of like everybody around and sort of like told them and explained it to them what it was and I went ‘thank you everyone’ like this and I wouldn’t have done that before do you know what I mean, I might have told them individually but I went and told them all you know as a group.’

‘Doing more stuff so erm, even riding me bike you know erm I even rode it a little bit in the wind yesterday and got blown off it twice, you know but I got back on it so, you know what I mean it’s, it’s little things and like that you know.’

Suggesting extending the CBM-I.

Participant one:

‘I felt like I could have done it for more than the seven days, I would have quite happily carried it on for a little while but I know it’s only a trial so I don't know if,

if it's made a sort of proper official treatment, will people be able to access it more frequently or for more than the seven days at a time'.

Participant three:

'A smaller amount perhaps over a longer period of time might be a, a better way of approaching it, that's my personal opinion.'

Participant five:

'I tell you what I did think would be a brilliant idea, if there was a package, a computerised package, so you could actually put yourself online and go through those scenarios on a regular basis, you're not gonna be in those situations in reality but if you can mentally assume yourself in those situations with those positive outcomes, erm I think that might be quite beneficial to a lot of people, we're only doing it for that very short space of time.'

Scenarios personally relevant and emotionally engaging.

Participant one:

'A lot of the erm, situations in it were very similar to the situations I find myself in or I'm scared of, so going through those and seeing the outcome that I would always imagine would always be the worst possible case you know erm especially the scenarios where you're put like at the centre of attention, you're on the spot, like, at work like and things you have to do, presentations and stuff that absolutely terrifies me.'

'The first few times I did it I would get sort of like a panicky feeling because you sort of really hit the nail on the head with the situation for someone like me,

what causes my anxiety, and erm it would make me panic but then towards the end of the week it was more sort of like I knew it wasn't gonna be a stressful situation and I didn't get that panicky feeling when I started reading it.'

Participant four:

'Well some of the scenarios erm you know they were sort of like funny as well you know and I think that was sort of like you know and some others were real you know what I called sort of I think 'oh yeah I've been there' you know what I mean and erm and that and it sometimes I was thinking in me head, you know, like er, I wanted to put all 'god no' you, you know I wanted to press no when it is yes and I think 'no it's yes', you know what it's sort of, it was like that I did press no sometimes because it's there in your head you, you know.'

Scenarios not personally relevant or emotionally engaging.

Participant three:

'I found they were a little predictable and they are going to be because you got three hundred questions in your head and so you are going to have similar situations running through, there's going to be a common thread.'

'It's not the real world, erm the real world is where I worry, erm too much, yes, but erm they're simply questions on how you'd react or should react in situations, erm that was a little bit mechanical and er didn't really bare relevance to, I felt, to how I would feel on a day to day basis.'

Participant seven:

‘I don't think it targeted the things that I was worried about so much, I feel like it was, like a lot of the situations that were coming up, like people could worry about going into those situations, they tended to always be things that I didn’t worry about, I tend to worry about things happening like my family, things like that and failing myself at university and not actually being going to the shop and someone like, I’m not worried about that sort of thing.’

‘I was looking at the questions it was asking me and I’d think about myself in that situation and it’s that ninety percent of those situations would never worry me anyway.’

Positive opinion of CBM-I.

Participant one:

‘Well, I think it works and I hope that it can be sort of used in the future for other people because I do think the you know, the idea behind it is, is good and I think it will make a difference to people.’

Participant four:

‘I’ve enjoyed doing it. Yeah I did, so, found it all helpful.’

Ambivalent opinion of CBM-I.

Participant two:

‘It’s just, that would have been nice if I didn’t worry hardly at all but I still worry but not as much as what I did so, but I don't know how the computer

could have done that anyway if you know what I mean.'

Participant three:

'I think it's better to have a person, personally, rather than a computer program although, although it's got its positive aspects, I mean you're still contributing, you're still doing something.'

'How far it can go I, I don't know.'

Participant four:

'I think it's a big ask you know it's a big kind of ask isn't it you know in so many sessions to think that you are actually gonna, you're not gonna cure anybody are you.'

'So you're talking about almost a long, a very, very long term anxiety, and you're not gonna cure that in just such a short time.'

Participant seven:

'I wasn't expecting anything to work because I've sort of had it; I've always been worrying about things a lot in my eyes. It's going to be very hard to not worry about it so I'm not like disappointed it hasn't worked or anything or, because I was never that expectant of it at the beginning.'

'I think it's, for me it wasn't very beneficial but I think for some people it would be if they worry about those situations a lot.'

Appendix R: End of Study Report Submitted to Norfolk and Suffolk National Health Service Foundation Trust (NSFT) Local Research Governance Committee and North West - Greater Manchester South National Research Ethics Service (NRES)

Objectives

The primary aim of the study was to investigate the efficacy of an online multi-session cognitive bias modification for interpretation (CBM-I) package for reducing worry and negative interpretive bias in individuals presenting with clinical levels of generalised anxiety. The secondary aim of the study was to explore how the patients experienced the CBM-I package. Both objectives were met.

Design

Regarding the primary objective, the study adopted a single case-series using a non-concurrent multiple-baseline across participant design with follow-up. Regarding the secondary objective, the patients' experiences were qualitatively analysed.

Method

Seven patients referred from Psychological Wellbeing Services completed a seven day CBM-I programme at home via the internet. The CBM-I task trained the participants to imagine ambiguous scenarios and to interpret them in a benign or positive manner. To assess change in worry, anxiety and interpretive bias, participants completed a battery of self report measures. Audio-taped semi-structured interviews were carried out with six of the participants. The transcribed interviews were analysed using template analysis. No ethical issues were encountered at any stage of the study.

Results

Two participants demonstrated a positive response in their level of worry upon starting the

CBM-I training and for both, gains were maintained one week after its completion. For the sample as a whole, negative interpretation bias reduced at post CBM-I and at one week follow-up. The most salient themes identified in the transcribed interviews included the convenience of the CBM-I program, ambivalence, low expectations, interaction with the program changing over time, the emotional meaningfulness of the scenarios, the program being easy to interact with, understanding of the program, cognitive changes, difficulties remaining, improving usability and making the program last longer. All participants elected to receive a summary of the main findings and so this will be sent to them. No firm plans are yet in place to publish the results.

Conclusions

Regarding the primary objective, the results indicate the potential value of CBM-I as a clinical tool for modifying interpretation bias in patients experiencing clinical levels of generalised anxiety. The ability of CBM-I to attenuate generalised anxiety disorder (GAD) associated symptomatology appears equivocal. In light of methodological constraints, the findings are tentative warranting further investigation. Regarding the secondary objective, the findings indicate relationships existing between attitude towards the program, the emotional meaningfulness of the scenarios and perceived consequences. Taken together, the data indicates that extending the duration of CBM-I and ensuring that scenarios are perceived as meaningful to CBM-I users e.g. possibly by tailoring scenario training sets to user's main disclosed worries, may be ways of enhancing the potency of CBM-I in treating pathological worry. In its current form, the CBM-I package would appear to offer benefit to some but not all patients experiencing clinical levels of generalised anxiety.