

**Examination of the effectiveness and acceptability of a transdiagnostic group for
clients with common mental health problems**

A thesis submitted to the University of Manchester for the degree of Doctor of
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THESIS ABSTRACT

A thesis submitted to the University of Manchester for the degree of Doctor of Philosophy in September 2016.

Candidate: Lydia Morris

Title: Examination of the effectiveness and acceptability of a transdiagnostic group for clients with common mental health problems

Interventions targeting processes that commonly maintain different psychological disorders have demonstrated promising effectiveness data. However, very few studies have examined brief transdiagnostic groups. Qualitative explorations of the acceptability of both transdiagnostic and brief groups are also very limited. A brief transdiagnostic group, the Take Control Course (TCC), has been developed for clients with common mental health problems in primary care services.

This thesis examined the effectiveness and acceptability of the TCC, which is a 6-session transdiagnostic group intervention. The TCC is explicitly theory-driven and targets mechanisms of psychological change specified by Perceptual Control Theory (PCT). Three papers are presented within this thesis that examined: i) the empirical and conceptual background of the TCC; ii) whether the TCC was non-inferior compared to an active control (individual low-intensity Cognitive Behavioural Therapy, CBT); iii) whether the TCC was acceptable to participants using qualitative examination of participants' experience of the TCC and perceptions of what contributed to psychological change (or lack of change).

The thesis comprises: i) a narrative review; ii) a non-inferiority RCT; iii) a qualitative interview study using Thematic Analysis. The thesis utilised mixed methods in order to understand the TCC from multiple perspectives. The overall programme of research that the thesis is part of is strongly informed by the Medical Research Council (MRC) framework for developing and evaluating complex interventions. Although the MRC guidelines stress the utility of randomised experimental designs in evaluating an intervention, they also recognise the contribution that qualitative methodologies make to such evaluations.

The narrative review outlined how the development of a transdiagnostic intervention, which targets specific transdiagnostic processes, could provide an efficient way of promoting psychological change. It explicitly detailed how the theoretical basis informed intervention components. Within the RCT, intention-to-treat analyses at 6-month follow-up found that the TCC was non-inferior to individual low-intensity CBT on anxiety and depression outcomes, functioning and an idiosyncratic problem measure. 156 clients were randomised. Secondary, per-protocol analyses, found inconclusive evidence of non-inferiority. This was the first randomised trial providing evidence for the non-inferiority of a brief transdiagnostic group compared to established individual therapy. The qualitative study of 12 in-depth interviews indicated that the flexible group format of the TCC was appreciated, as participants felt able to engage at their own pace and adapt components. Greater clarity regarding what was within participants' control reduced distress and enabled effective pursuit of valued goals. This was the first qualitative study of participant experience of a brief transdiagnostic group.

Findings indicated that TCC was acceptable and non-inferior to an established CBT intervention. This adds to the evidence base for transdiagnostic interventions.

DECLARATION

No portion of the work referred to in this thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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CHAPTER 1: Thesis overview

1. Introduction

The overall aim of this thesis was to examine the effectiveness and acceptability of a theory-driven group intervention, the Take Control Course (TCC), for clients with common mental health problems. The TCC is transdiagnostic¹ and aimed at clients with a range of problems (including anxiety and depression). Therefore, a related overarching aim was to contribute to the body of knowledge regarding transdiagnostic interventions. A key specific aim was to establish whether TCC was non-inferior compared to an active control (individual low-intensity Cognitive Behavioural Therapy, CBT). A related aim was to examine participants' experiences of the TCC. The third aim was to examine whether the theoretically-grounded components of TCC, as specified by Perceptual Control Theory (PCT; W. T. Powers, 1973, 2008; W. T. Powers, Clark, & McFarland, 1960a, 1960b), were accessible and useful to participants.

Overall this thesis contributes to the literature that indicates that certain cognitive and behavioural processes and mechanisms maintain a range of psychological problems. Specifically it focuses on how such an understanding can be translated into a psychological intervention and whether this treatment is non-inferior to an established psychological intervention.

1.2 Overview of the thesis

There are three main studies reported within this thesis: a narrative review; a non-inferiority RCT; and a qualitative study.

¹ Transdiagnostic interventions target processes that commonly maintain a range of psychological disorders. Therefore, they can be offered to clients diagnosed with different disorders.

Chapter 2 (Paper 1) is a narrative review that provides a detailed account of the empirical and conceptual background to this thesis.

Chapter 3 discusses the methods used in the thesis.

Chapter 4 (Paper 2) reports a non-inferiority Randomised Controlled Trial (RCT) comparing the TCC to individual low-intensity CBT.

Chapter 5 (Paper 3) reports qualitative data from participants in the RCT who accessed the TCC; this focuses on participants' experience of the TCC and examines their perceptions of what contributed to psychological change (or lack of change).

Chapter 6 ends with an overview and general discussion of the previous chapters.

1.3 Specific aims and hypotheses

1. Narrative review (Paper 1, Chapter 2). Aims: To explore whether a Perceptual Control Theory (PCT) explanation of psychopathology across disorders is a valid one. To illustrate the process of developing a novel transdiagnostic intervention (Take Control Course; TCC) from a transdiagnostic theory of functioning (PCT).

2. RCT (Paper 2, Chapter 4). Aim: To assess whether TCC is non-inferior compared to an active control condition (individual low-intensity CBT). Hypothesis: Participants in both groups will show reductions in symptom scores on measures of anxiety and depression, and outcomes in the TCC group and individual low-intensity interventions will be non-inferior.

3. Qualitative study (Paper 3, Chapter 5). Aim: To explore participants' experiences of the TCC, specifically, to examine what experiences contribute to psychological change.

1.4 Medical Research Council framework for developing complex interventions

The overall programme of research that this PhD thesis forms part of has been strongly informed by the Medical Research Council (MRC) framework. The MRC framework follows a staged approach to the development of complex interventions: developing the intervention; piloting and feasibility; evaluating the intervention (e.g. through a RCT); and implementation (Craig et al., 2008). The RCT presented in this thesis builds upon data from a feasibility prospective cohort study comparing TCC to individual low-intensity CBT. This feasibility study was completed as part of the PhD student's doctoral thesis for the award of Clinical Psychology Doctorate (ClinPsyD) (L. Morris, 2013). Therefore, the development and feasibility stages for the TCC are described in this previous thesis, and in L. Morris et al. (2015). A summary of these stages is provided in Chapter 2. Details regarding how the MRC guidelines specifically informed the methodology of studies within the thesis are provided in Chapter 3 (the 'Methodology' chapter).

CHAPTER 2: The Take Control Course: Conceptual rationale for the development of a transdiagnostic group for common mental health problems

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Frontiers in Psychology (section 'Psychology for Clinical Settings')

PREFACE

This paper has been accepted for publication. The version depicted in the thesis differs slightly from the published version. This is in order to integrate the paper into the thesis and preserve the overall narrative. As this review summarises ideas formulated prior to the PhD and the primary input was from Dr Warren Mansell and Dr Phil McEvoy they are listed as the co-authors of the paper. Professor Karina Lovell, Professor Richard Emsley and Dr Dawn Edge provided feedback on the thesis version of this paper.

2.1 Abstract

Background: Increasingly, research supports the utility of a transdiagnostic understanding of psychopathology. However, there is no consensus regarding the theoretical approach that best explains this. Transdiagnostic interventions can offer service delivery advantages; this is explored in the current review, focusing on group modalities and primary care settings.

Objective: This review seeks to explore whether a Perceptual Control Theory (PCT) explanation of psychopathology across disorders is a valid one. Further, this review illustrates the process of developing a novel transdiagnostic intervention (Take Control Course; TCC) from a PCT theory of functioning.

Method: Narrative review.

Results and Conclusions: Considerable evidence supports key tenets of PCT.

Further, PCT offers a novel perspective regarding the mechanisms by which a number of familiar techniques, such as exposure and awareness, are effective.

However, additional research is required to directly test the relative contribution of some PCT mechanisms predicted to underlie psychopathology.

2.2 Introduction and overview

In this chapter, firstly, research supporting a transdiagnostic approach to understanding psychological distress will be detailed. Secondly, PCT (W. T. Powers, 1973) will be introduced as a transdiagnostic theoretical framework to explain psychological distress and how this can be resolved. Thirdly, the TCC will be described as a transdiagnostic group intervention derived from the principles of PCT. These sections summarise the rationale for the development of the TCC and provide the background literature for the current thesis. Given that one of the key novel elements of the TCC is its theoretical basis this is described in some detail.

2.3 The transdiagnostic approach

Increasingly, research has identified processes that are common, or transdiagnostic, across disorders. A comprehensive review of cognitive behavioural processes in psychological disorders identified 12 processes that could be considered transdiagnostic maintenance processes across the numerous disorders investigated (Harvey, Watkins, Mansell, & Shafran, 2004). Since this review, many more transdiagnostic processes have been identified (Mansell, 2011; Nolen-Hoeksema & Watkins, 2011); for example, perfectionism and emotional regulation difficulties (Aldao, Nolen-Hoeksema, & Schweizer, 2010; Egan, Wade, & Shafran, 2011). Deficits in executive control, such as difficulties in disengaging from a current task, are also found across a range of disorders (Fernandez-Serrano, Perez-Garcia, & Verdejo-Garcia, 2011; Gotlib & Joormann, 2010; Schultz & Searleman, 2002). See Nolen-Hoeksema & Watkins (2011) for a more detailed summary of transdiagnostic processes.

One possible advantage of a transdiagnostic approach is the potential to bring us closer to understanding the mechanisms that underpin psychopathology, in light of increasing cross-disciplinary evidence for common processes (Mansell, Harvey, Watkins, & Shafran, 2009; Nolen-Hoeksema & Watkins, 2011; Pierre, 2010). Convergent evidence from neurobiological and cognitive-behavioural research suggests that current diagnostic categories do not precisely specify the factors that cause and maintain psychopathology (S. E. Morris & Cuthbert, 2012). For example, neurobiological research has indicated that “genetic and environmental risk factors for mental illness induce susceptibility to broad domains of psychopathology, rather than discrete categorical disorders, because they disrupt core connectivity circuits in ways that necessarily produce transdiagnostic symptoms” (Buckholtz & Meyer-Lindenberg, 2012, p. 990). At the risk of oversimplifying the detailed and complex neurological findings presented in Buckholtz & Meyer-Lindenberg (2012), one conclusion of the paper is that there is rarely just one distinct and dissociable brain area affected in a specific psychological disorder. There are networks of mechanisms that underlie cognitive, affective and social functioning, and similar patterns of dysconnectivity within these networks are observed across multiple diagnostic categories.

Further, transdiagnostic interventions may offer pragmatic, implementation advantages. It has been proposed that transdiagnostic interventions provide replicable interventions, which are flexible to deliver and disseminate and do not require training in numerous disorder-specific protocols (McHugh, Murray, & Barlow, 2009; Wilamowska et al., 2010). Some interesting and promising transdiagnostic groups have already been developed; for example, Barlow and colleague’s Unified Protocol has recently been delivered in a group-format and

Norton's transdiagnostic anxiety groups are well-established (Bullis, Fortune, Farchione, & Barlow, 2014; Norton, 2008). [See Newby et al. (2015) for a meta-analysis of transdiagnostic interventions, and group interventions are reviewed in more detail in section '2.5 Specific background to the development of the Take Control Course']. However, these differ from the TCC in a number of ways. A key difference is that none of the previous transdiagnostic interventions draws on PCT. It is advantageous to develop interventions from different theoretical perspectives so that mechanisms of change can be compared and understood (Follette & Beitz, 2003; Rosen & Davison, 2003). Other differences are described in L. Morris et al. (2015) in summary:

The features of TCC that differentiate it from pre-existing interventions are: a) basis in PCT; b) no explicit emphasis on challenging the content of cognitions; c) briefer group-based format; d) explicitly flexible delivery mode; e) broadly transdiagnostic focus that targets generic mechanisms (maladaptive/inflexible control and goal conflict). (p. 3).

2.4 An introduction to Perceptual Control Theory (PCT)

PCT provides a functional transdiagnostic model of how psychopathology arises and how recovery can be facilitated (W. T. Powers, 1973). It was founded as a framework for understanding psychological functioning as a whole and so the suggested mechanisms apply across all individuals, and across all disorders (Alsawy, Mansell, Carey, McEvoy, & Tai, 2014). The following sections introduce PCT, and summarise relevant research. Key terms are summarised in Table 1.

Table 1: Summary of key Perceptual Control Theory (PCT) terms used

Term	Definition	Example
Reference values or goal	Internal standard that is based on genetic predisposition and/or past experience. <i>'Goals' and 'reference values' refer to a broad range of reference points that encompass values, beliefs, schemas etc.</i>	Reference values can be considered as a set of personal 'just rights'. There is a huge range of possible examples, from reference values for a good cup of coffee (e.g. milky but strong) to reference values for being a good person (e.g. kind, honest etc.).
Control	Keeping a perception as close as possible to a desired reference value	Being a caring friend; Keeping feelings of anxiety at zero; Living a good life.
Error (or discrepancy)	The difference between the wanted and the experienced reference value	Feeling that have let a friend down by not being caring enough; Anxiety more than can tolerate; Feeling not living life as wanted.
Control hierarchy (system)	Internal reference values that are arranged in a hierarchical network	Each individual will have a multitude of hierarchies. Higher-level goals (for example, the self-concept of being successful) leading to the setting

		of sub-goals for an individual's principles (e.g. achieving at work), which in turn regulate lower-level, shorter-term goals (e.g. working long hours).
(Goal) conflict	The state when two control systems attempt to control an experience with respect to two (or more) opposing reference values	Carey (2008) gives this example of a client who presented with depression, indecisiveness and lack of sense of purpose. The client had a conflict between reference values of a child self that is spontaneous and reckless and a parent self that has duties. Both the 'child self' and 'parent self' values would often apply to the same decision or behaviour.
Reorganisation	When there is awareness of conflict between reference values (or error) within an individual then the reorganisation process begins to make random changes. Trial-and-error changes continue until the error is reduced	A shift in perspective, or 'aha moment', during the therapy process (or outside of therapy) could indicate that reorganisation has successfully occurred (Gianakis & Carey, 2011). For example, to return to the client in the goal conflict example, once this client becomes aware of the conflict between child and parent selves they could realise one self better fits certain contexts (such as the parent self at work).

2.4.1 Living is control

The tenet that perception is controlled by behaviour (rather than behaviour that is controlled) is a particular emphasis of PCT (Marken & Mansell, 2013). See Figure 1 for the closed ‘negative feedback’ loop that is the basic unit of control within PCT. A full pathway round such a closed loop is necessary to implement control of perception by behaviour. Even when a stimulus is subliminally presented it will seem that a stimulus triggers a response, when in fact a control system always acts against disturbances in the environment to minimise a discrepancy. For example, a socially anxious person who wishes to keep a long interpersonal distance away from other people during a conversation will be regularly moving forward or backward to maintain this distance without needing to be aware of every movement of the person they are talking to. Therefore, there is greater acknowledgement of feedback processes within PCT than in traditional stimulus response models, whereby processing a stimulus triggers an observable behaviour and no feedback process to regulate goal states is explicitly implicated.

As a simplified version of the ‘negative feedback’ loop, three essential aspects enable living beings to make events happen the way they want (control), which are *perception*, *comparison* and *action* (Powers, 1973). These processes are specified precisely in terms of mathematical equations that can be used to model these relationships (Marken, 2009). *Perception* refers to perceiving the current experience or situation, *comparison* refers to assessing the current experience against an internal standard and then the ability to *act* refers to acting on the environment to make what is perceived match the internal standard. Current perception is constantly compared to internal standards and actions occur to minimise any discrepancies from these standards. For example, in a noisy café a

person will speak at a particular volume to make themselves heard, if a noisy group leaves they will reduce their voice so that it does not appear too loud. The reduction in volume occurs because the voice they hear (*perceive*) has become different from their standard for ‘acceptable volume’ (*compare*) and they decrease volume to reduce the discrepancy (*act*).

Research using computerized tracking tasks has provided evidence for the proposition that perception is controlled through action. Tasks involve participants keeping a pointer lined up with a target while the computer program randomly moves the pointer around. Such tasks require participants to keep the pointer ‘on target’ and use their actions to dynamically alter their trajectory when the movements of the computer program take them away from their goal. A number of studies have found that what is being controlled is the perception of keeping the marker aligned rather than the behaviour of moving the mouse (e.g. Marken, 2014; Marken, Mansell, & Khatib, 2013). These tasks are an analogue of everyday control, such as keeping a comfortable interpersonal distance or moderating the loudness of speech.

Tenets of PCT have been supported by around 60 experimental studies (Marken & Mansell, 2013; Pellis & Bell, 2011). There is increasing support for some of the components at the neurological and biological level (for reviews, see Grawe, 2007; Marken & Mansell, 2013; Pellis & Bell, 2011). Areas for future development of PCT are detailed in this chapter.

One significant challenge to the fundamental tenet that behaviour is a process of controlling perception is from studies that could indicate that behaviour occurs in the absence of perception, i.e. organisms producing behavioural results without perception of these results. Such studies involve participants who do not have nerve

feedback from touch and proprioception (Mechsner, Stenneken, Cole, Aschersleben, & Prinz, 2007). Therefore, when visual feedback is removed, movement behaviours are conducted in the absence of the majority of the perceptual feedback normally utilised. However, it is suggested within these studies that perception of these behaviours may still be a controlled process, relying on visual imagery (internal perception) or memory of the behaviour (Guillaud, Simoneau, & Blouin, 2011; Mechsner et al., 2007). Further research is required in order to test whether participants are producing controlled results without perception and to establish whether these studies do undermine a fundamental tenet. The interested reader is directed towards M. Taylor (1999) for a summary of a number of objections directed at PCT and how these can be addressed.

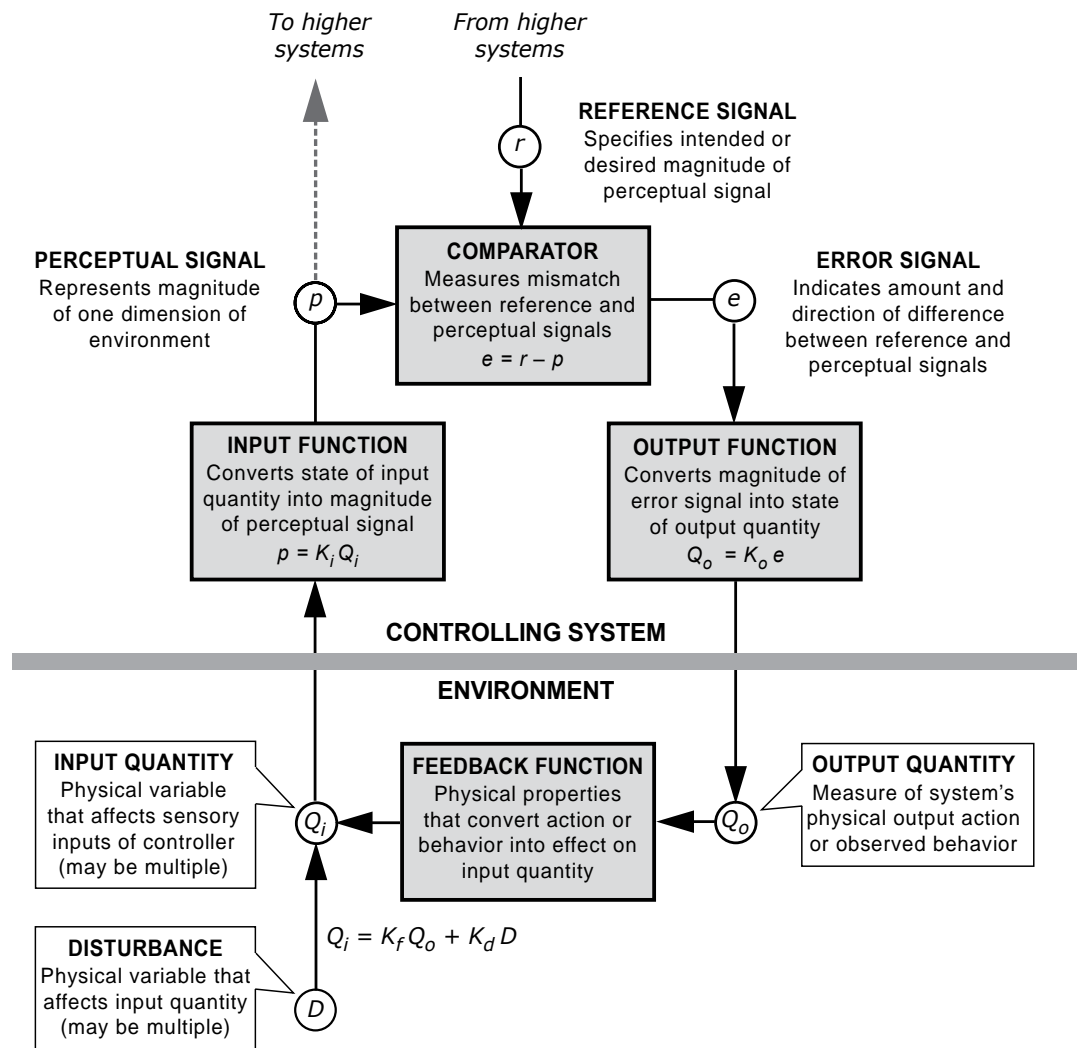


Figure 1: A model of the closed negative feedback loop described in PCT; definitions of key components are included within the diagram [Redrawn by Dag Forssell from a diagram by William T. Powers].

2.4.2 Loss of control is a cause of distress

A central tenet of PCT is that well-being involves maintaining control over one's life, and that psychological distress represents loss of this control. The associations between control and well-being, and between lack of control and psychological distress, have been extensively reviewed elsewhere (Chorpita &

Barlow, 1998; Forgeard et al., 2011; Grawe, 2007). For example, research suggests that early experience of loss of control contributes to anxiety/depression (Chorpita & Barlow, 1998). Perceived loss of control of teenagers and adolescents has been shown to mediate the relationship between family environment (e.g. communication, behavioural control) and anxiety (Ballash, Pemble, Usui, Buckley, & Woodruff-Borden, 2006; McLeod, Weisz, & Wood, 2007; Nanda, Kotchick, & Grover, 2012). Research also indicates that the inability to influence internal events (e.g. thoughts, feelings, impulses) is related to psychological distress, including anxiety and depression (Dell’Osso, Altamura, Allen, Marazziti, & Hollander, 2006; Teachman, Joormann, Steinman, & Gotlib, 2012). Overall, substantial research supports the principle that loss of control is associated with psychological distress.

In line with this research, the ‘loss of control’ described in PCT can be over external or internal events; this refers to a state whereby an individual’s perceptions are not sufficiently close to their reference value (or desired standard). For example, they are worrying much more than they want (more than their standard for an acceptable level of worry). Whether an individual reports they have lost control, i.e. their perceived level of control, may vary. Commonly, when individuals access therapy they are aware that aspects of their experience are not as desired and this can be described in terms of ‘loss of control’. However, there will also be instances whereby an individual would not describe their experiences in terms of ‘loss of control’ but would be experiencing that things are not quite right (i.e. experiencing loss of control). An example of this would be someone who describes difficulties in their relationship with their partner but feels that they are in control of their expression of anger when they commence therapy, then later realises that this expression conflicts with an important goal of maintaining a loving relationship (this

understanding is further detailed in later sections on the role of conflict and awareness). The inability to influence undesired external and internal events is more likely to lead to actual (and perceived) loss of control, as individuals will be less able to bring their experience in line with their desired standard. Multiple conceptualizations of control exist within the extant literature; for example, in the mid-1990s over 100 uses of control were identified within the psychological literature (Skinner, 1996). PCT provides an operational definition of control, which is based on a functional theoretical explanation of the mechanisms of control.

One specific example of the loss of control experienced within psychopathology is loss of control of emotions, i.e. an individual perceiving that their emotional experience is not as desired. A number of accounts, including PCT, suggest that ‘negative’ emotions arise in response to perceiving stimuli (internal or external) in order to prepare the individual for action and to meet a goal (Boudreaux & Ozer, 2013).² Further, it has been suggested and evidenced elsewhere that negatively valenced emotions endure when progress towards a goal is impeded (Carver & Scheier, 1998; W. T. Powers, 2005). In accordance with this, a PCT model specifies that these negative emotions arise when there is *error* within the control system (Carey, 2011). Error refers to the signal within the individual that something is discrepant, i.e. when a conflict between goals is experienced. Negative emotions endure when the goal is not (or cannot be) pursued and the error is not corrected (Carey, Mansell, & Tai, 2014), i.e. at times of loss of control. Therefore, on-going negative affect and anxiety indicate a loss of control, as they occur when error persists and goals are not obtained.

² The term ‘negative’ is used here to distinguish emotions (e.g. anger, fear and depression) from emotions commonly described as pleasant and that do not promote the same tendency towards action (e.g. contentment, equanimity) (Powers, 2007).

2.4.3 Control is managed over many levels

A number of psychological theories have conceptualised the human mind as being organised hierarchically (e.g. Trope & Liberman, 2010). Grafton and Hamilton (2007) review varied strands of evidence, including functional imaging and computer modelling studies, to support the premise that complex motor actions are organised hierarchically with respect to distal goals. Uithol and colleagues (2012) reviewed additional evidence and conclude that the explanation most consistent with the data is one that specifies dynamic interaction between the levels of the hierarchy and that “elements higher on the hierarchy are represented longer or are more stable than lower ones” (Uithol, van Rooij, Bekkering, & Haselager, 2012, p. 1083). Such a conclusion is highly compatible with a PCT account of the hierarchical structure of control.

Although this evidence for hierarchy supports a PCT account, PCT offers a distinct account of the hierarchical organisation of control. For example, only PCT states that the output of each level in a hierarchy is the reference value for what the level below in the hierarchy should perceive (W. T. Powers, 1973). A higher-level goal of ‘being successful’ could lead to the setting of sub-goals, such as ‘meeting work deadlines’; this in turn could lead to the setting of lower-level goals, such as ‘stay late to work on an important project’ and to corresponding perceptual goals for motor actions. A range of simulations have used hierarchical PCT-based models, from a multi-legged robot to human arm movement, and indicate the functionality of this understanding (Kennaway, 1999; W. T. Powers, 1999, 2008).

2.4.4 Conflict undermines control

An important cause of loss of control within PCT is conflict (W. T. Powers,

1973). Although conflicts between goals will arise frequently, circumstances in which this conflict is enduring can result in distress and psychopathology. For example, Carey (2008) gives the example of a client with anxiety, and possible Post Traumatic Stress Disorder, who has a conflict between ‘wanting to let her daughter do normal things’ and ‘wanting to keep her safe’. One of the ways in which wanting to keep her daughter safe manifests is a reluctance to let her go out of the house (Carey, 2008); however, it would seem plausible that many parents would experience conflicts like this but would have some degree of flexibility regarding meeting these goals. Flexibility of goal awareness is discussed in more detail in the next section (2.4.5).

Large numbers of studies support correlational and predictive relationships between elevated goal conflict and psychopathology, including relationships with depression, anxiety and negative affect; similarly self-concordance (low goal conflict) is associated with and predictive of well-being (e.g. Brockmeyer et al., 2013; Kelly, Mansell, & Wood, 2015). Although overall the relationship between conflict and psychopathology is supported, a minority of studies have failed to replicate this (explained below).

2.4.5 Conflict between higher-level goals is more detrimental than conflict between lower-level goals

A specific prediction of PCT is that chronic conflicts at higher-levels will result in greater psychopathology than conflict at lower levels (Alsawy et al., 2014). The studies that did not replicate the findings described in the previous section (of a relationship between elevated goal conflict and psychopathology) primarily measured conflict using methods that involve participants explicitly quantifying the extent of conflict between their self-generated goals (Kelly et al., 2015). It has been

suggested that the null findings are due to these measures assessing lower-level conflicts that participants have easy access to (Kelly et al., 2015). Direct evidence for the greater pathological effects of conflicts at higher-levels comes from studies that indicate that higher-level conflict is particularly problematic (e.g. Kelly, Mansell, & Wood, 2011).

It is also acknowledged that healthy individuals are able to flexibly move their awareness up and down the hierarchy to address both long-term and short-term goals, i.e. it is important to implement higher-level goals via lower-level ones (Watkins, 2011). Flexible movement of awareness entails responding to the contextual demands of different circumstances, i.e. the employment of most appropriate level within the goal hierarchy to meet the current task demands. For example, in circumstances where a relatively concrete goal is being pursued (such as, meeting a particular friend), but the goal is currently unobtainable then a higher-level focus (e.g. having social contact) will be more adaptive than a lower-level focus because this enables greater flexibility. Watkins (2011) provides a useful account of circumstances in which different levels of goal identification are predicted to be adaptive/maladaptive. However, he focuses on the dimension of abstraction, whereas PCT would suggest that different levels of goals can be functionally different on other dimensions. A greater level of abstraction often characterises higher-levels, but there are other differences, such as the highest levels taking longer to process than the lowest levels (Marken et al., 2013).

2.4.6 Control without awareness can exacerbate conflict

As mentioned above, measures of implicit goal conflict are more consistently related to psychopathology than measures of explicit goal conflict (Kelly et al., 2015). A PCT account proposes that this is because without awareness of conflicted

goals, i.e. when goals are implicit and less consciously accessible, conflicts will not be resolved. When a reference value (or goal) is controlled for without taking into account another reference value that is also controlling this experience, this is described as *arbitrary control* (W. T. Powers, 1973). For example, after a traumatic accident an individual might experience sleep problems and flashbacks and want to discuss this with others. However, they might struggle to talk about these experiences due to a reference, which they are not aware of, 'other people will think I'm crazy'. Without awareness of this reference their experience is likely to be of loss of control and by not discussing their problems an important goal is blocked.

Due to the importance of awareness in resolving goal conflict, and meeting important goals, processes that limit such awareness will maintain psychopathology. Therefore, repeated and prolonged employment of processes (e.g. worry and rumination), which limit attention and disrupt awareness of goal conflict, promote on-going difficulties (Watkins, 2008). It should be noted that it is the extent to which these processes prevent the achievement of other goals that determines whether these are maladaptive. There is some evidence that processes/strategies that maintain psychopathology (such as, rumination or suppressing emotions) are applied more rigidly than 'adaptive' strategies (Aldao & Nolen-Hoeksema, 2012). Further, to focus on the example of rumination, research has found that a form of 'rumination'³ can have adaptive consequences (Ottaviani, Shapiro, & Couyoumdjian, 2013; Watkins, 2008). Evidence suggests that it is when rumination involves abstract evaluative thoughts regarding the self and emotions, particularly when it is

³ Sometimes rumination is defined in terms of repetitive negative, abstract, self-focused thinking and this construct is associated with depression and negative affect (Nolen-Hoeksema, Wisco, & Lyubomirsky, 2008). However, it is noted that in clinical settings clients do not always describe this experience with such specificity. It is more common to talk about experiences, such as 'dwelling on things', which can refer to a broader processes of self-reflection that may have adaptive as well as maladaptive functions.

negatively valenced, that it is maladaptive (Nolen-Hoeksema, Wisco, & Lyubomirsky, 2008; Watkins, 2008). Arguably it is this type of ‘rumination’, rather than a non-evaluative conceptual focus on present experience, that is more likely to limit awareness and constitute arbitrary control. This can be compounded when an individual feels unable to control their thinking (Ottaviani et al., 2013; Teachman et al., 2012). This understanding corresponds with the wider literature on control and self-regulatory theories (e.g. Carver & Scheier, 1998; Pyszczynski, Holt, & Greenberg, 1987), but a PCT account differs in some important respects (the emphasis on the role of conflict, specification of a reorganisation mechanism). Cognitive and behavioural inflexibility has been associated with psychopathology in a number of studies across disorders (Kashdan & Rottenberg, 2010).

2.4.7 Change is spontaneous but its focus is guided by awareness

Psychological change in therapy is often conceptualised as a linear process that occurs over a certain number of therapy sessions; for example, clients are often offered a set contract (e.g. six or twelve sessions) and are assessed for symptom reductions at the end of these. However, there is accumulating evidence that change does not always occur in such a predictable way with evidence that clients can experience sudden gains (sometimes described as insights, eureka moments etc.), early in therapy, that can account for a significant amount of their improvement (Aderka, Nickerson, Bøe, & Hofmann, 2012).

Therefore, a change mechanism is required that would enable diverse experiences of change. The proposed change mechanism is known as *reorganisation*. When there is a loss of control (or error) within the control system then the reorganisation process begins to make random changes, until the error is reduced (W. T. Powers, 1973). The reorganisation system responds to error, it does

not require volitional control. It functions in the same way as other homeostatic processes within the human body; for example, an optimal internal temperature is maintained within our bodies without us having to think about it. Changes in response to error occur at the point that awareness is directed within the control system. The clinical implications of this include explaining the findings that sudden gains can result in lasting symptom change because these would be examples of successful reorganisation. The functional effects of this model, i.e. whether such a process leads to effective change, have been tested and confirmed using computer simulations (Marken & Mansell, 2013). Support for the proposal that reorganisation is activated by error in the system is provided by research showing that unconsciously activated goals are more likely to reach awareness when goal progress is obstructed (i.e. when conflict occurs) (Dijksterhuis & Aarts, 2010).

2.4.8 Shifting awareness to the systems driving enduring higher-level conflicts is the key to recovery

Within PCT, it is proposed that it is vital for long-term recovery that reorganisation occurs at the source of the goal conflict(s) (Alsawy et al., 2014). Reorganisation occurs at the point that awareness is directed and, therefore, bringing awareness to enduring conflicts is vital to recovery (Marken & Carey, 2014).

Initial support for the proposal that reorganisation promotes psychological change, and ‘follows’ awareness, comes from research demonstrating that greater awareness of conflict and higher-level processes during a psychological intervention predicted greater distress reduction and problem resolution (Gaffney, Mansell, Edwards, & Wright, 2013). In a clinical sample accessing PCT-based individual therapy, research has found that participants’ scores on a self-report measure of reorganisation processes was negatively associated with depressive symptoms and

increased following therapy, effect size $d = 1.11$ (Bird, 2013).

According to PCT, the primary reason for using awareness/mindfulness techniques, i.e. techniques that develop sustained non-reactive attention, is to develop a ‘window’ of awareness that can be brought to bear on conflicted goals. Effective therapies use various methods to shift and sustain awareness on sources of goal conflict (Carey, 2011; Higginson, Mansell, & Wood, 2011). Given that this is a shared aspect of psychological therapies, targeting this aspect will resemble facets of other therapies; for example, motivational interviewing promotes awareness of competing goals (Miller & Rose, 2009). But the explicit emphasis on processes, such as control, hierarchy and reorganisation, in the TCC result in differences (see ‘Components of the TCC’). There is convergent evidence that techniques that involve shifting and sustaining awareness lead to significant psychological change (Carey, 2011; Fjorback, Arendt, Ørnbøl, Fink, & Walach, 2011). It is beyond the scope of this paper to give a comprehensive account of theories of exposure and mindfulness.

An individual CBT therapy has been developed based on PCT; called Method of Levels (MOL) (Carey, 2006). This aims to help clients to become aware of higher-level goals and facilitate the process of reorganisation, in order to resolve goal conflicts (Carey, Carey, Mullan, Spratt, & Spratt, 2009). There have been a number of evaluations of MOL in routine clinical practice trials. These have shown significant post-treatment reductions in symptoms on standardised measures of psychological distress, with moderate to large effect sizes, for clients experiencing a range of problems including depression, anxiety disorders and anger issues (Carey et al., 2009; Carey & Mullan, 2007, 2008; Carey, Tai, & Stiles, 2013). A pilot RCT was conducted in primary care (Bird, Tai, Hamilton, & Mansell, 2013) where MOL

was compared to control (waiting list or regular CBT treatment). Significant improvements were demonstrated on ratings of anxiety and depression in both conditions at follow-up, with larger improvements in the MOL condition for ratings of anxiety. Although a promising individual treatment, a MOL approach cannot be used with large groups. TCC is informed by MOL and includes some similar treatment components, such as a curious questioning style and an explicitly flexible delivery style.

2.4.9 Interim summary

In summary, PCT gives a functional explanation of how psychopathology develops across disorders and also indicates how this can be resolved. As would follow from this, causal accounts of psychopathology based on conflict between higher-level goals are found across a variety of presentations, such as obsessive-compulsive disorder (Pitman, 1987), PTSD (Carey, Mansell, Tai, & Turkington, 2014), depression (Hyland, 1987), bipolar disorder (Mansell, 2010), addiction (Webb, Sniehotta, & Michie, 2010) and dissociative disorders (Johnson, 2009; Mansell & Carey, 2012). In the next section, the potential service delivery advantages of a transdiagnostic approach in primary care are explored and the ways in which PCT informs the TCC are described.

2.5 Specific background to the development of the Take Control Course

Studies have indicated that as much as half of those seeking treatment for mental health problems access primary care services alone (Kessler et al., 2005), highlighting the importance of cost-effective and accessible interventions in these contexts (Alexander, Arnkoff, & Glass, 2010). Although a substantial proportion of clients accessing primary care have problems with depression and/or anxiety, clients

with a range of presenting problems are treated (Barkham, Stiles, Connell, & Mellor-Clark, 2012; Glover, Webb, & Evison, 2010) and PCT offers an understanding of psychopathology relevant to this range.

Furthermore, significant numbers of people do not receive evidence-based psychological interventions for mental health problems (Hofmann, 2013; Shafran et al., 2009), providing an on-going imperative for the development of broadly accessible interventions that develop generalisable clinician skills (Alexander et al., 2010; McHugh & Barlow, 2010; Shafran et al., 2009). Transdiagnostic interventions could be more flexible to use than interventions based on disorder specific models (Clark & Taylor, 2009; McManus, Shafran, & Cooper, 2010). For example, despite compelling efficacy research for disorder specific CBT (Butler, Chapman, Forman, & Beck, 2006; Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012), the diversity of protocols creates challenges in training clinicians to feel confident to offer evidence-based treatments to treat novel presenting problems (McHugh et al., 2009).

Therefore, a transdiagnostic group aimed at clients with common mental health problems could increase accessibility of interventions by offering a flexible intervention that can be accessed by clients with a range of presenting problems.

The current study follows on from a feasibility prospective cohort study comparing TCC to individual low-intensity CBT; this project was completed as part of the PhD student's doctoral thesis for the award of Clinical Psychology Doctorate (ClinPsyD) (L. Morris, 2013). Therefore, the relevant evidence for the brief transdiagnostic group-format of the TCC are reviewed in more detail elsewhere (L. Morris et al., 2015), but will be briefly summarised.

Although initial efficacy and effectiveness data for transdiagnostic groups is promising (e.g. Newby et al., 2015), the groups available involve a significant time

commitment (e.g. 10 weekly 2-hour sessions) (Maia, Braga, Nunes, Nardi, & Silva, 2013; Newby et al., 2015). However, there is considerable evidence that briefer interventions are effective for clients with mild to moderate anxiety or depressive disorders (e.g. Newman, Szkodny, Llera, & Przeworski, 2010; D. A. Richards & Borglin, 2011). The TCC offers a briefer format (6 weekly sessions lasting an average of 1-hour) and has the potential to be offered to large groups. Evidence that psychological change can be achieved in primary care through large group courses (Kitchiner et al., 2009; White, 1998; White & Keenan, 1990), suggests that such groups should not rely on participant disclosure and discussion. The TCC format relies on experiential exercises, worksheets, videos, and facilitator presentations. But using the current TCC delivery model (groups of 5 to 15) some discussion is possible if participants wish. However, the TCC requires further evaluation.

In addition, further research is required into group therapy. Where studies have compared individual and group CBT, group CBT has been found to be more cost-effective and generally to offer similar clinical effectiveness (Tucker & Oei, 2007). Clinical effectiveness data has not always demonstrated equivalence between group and individual format, with individual format superior in some instances; however, evidence is mixed and limited by the number and quality of studies available (L. Morris, 2013). Although a number of studies have compared the cost-effectiveness of groups and individual psychological interventions, only a minority of studies have included broader societal costs and there is variation as to which costs have been factored into comparisons (Tucker & Oei, 2007). Further, offering interventions in different modalities allows clients to choose the modality that they believe would be most effective for them. A number of studies indicate that participants can derive benefits from engaging in group interventions in terms of

normalisation of experience and interpersonal support (Finucane & Mercer, 2006; Mason & Hargreaves, 2001). Therefore, additional evaluation of the clinical and cost-effectiveness of group interventions is warranted.

The TCC is based on PCT and is aimed at clients in primary care settings who do not require higher-intensity interventions (e.g. it is not aimed at clients who are currently psychotic, or with persistent self-injury requiring on-going clinical management). The distinction between high and low-intensity interventions is based on a stepped care model. Stepped care models aim to offer the ‘least restrictive’ treatment options that is still likely to lead to significant improvement to individuals with psychological needs (Bower & Gilbody, 2005; Sobell & Sobell, 2000). This entails offering briefer low-intensity interventions to those with mild-moderate problems and more intensive (longer, more therapist contact) to those with problems that do not respond to low-intensity interventions (Bower & Gilbody, 2005). In the UK, implementation of stepped care models has resulted in services that reflect these distinctions. For example, low-intensity services offer a range of interventions that often involve guided self-help, such as asking clients to read information leaflets relevant to their symptoms. Brief cognitive-behavioural interventions are also offered, such as problem-solving by working through a problem in a structured way (D. A. Richards & Borglin, 2011; D. A. Richards & Suckling, 2009).

The TCC was shown to be feasible and acceptable within an earlier prospective cohort study in a low-intensity service. TCC was compared to individual low-intensity CBT. Full details of the study are reported in L. Morris et al. (2015). Due to the lack of randomisation in this pilot study, a number of sources of bias are likely to have influenced the results. The Randomised Controlled Trial (RCT)

conducted as part of the current PhD follows on from this study; methodological advantages of RCTs are detailed in the 'Methodology' chapter.

Table 2: Key principles of PCT and examples of similarities/differences to familiar psychotherapies

	Therapy			
Principle/process	Take Control Course (based on PCT)	‘Second wave’ CBT ^a	Acceptance and Commitment Therapy (based on RFT)	Mindfulness-based Cognitive Therapy (using ICS theoretical perspective) ^b
Control	Control as fundamental to life; functional process to be restored and refined <i>[See Table 1 for precise definition]</i>	Not emphasised, except in some specific models [e.g. Hofmann’s (2007) social anxiety model; Fairburn, Shafran and Cooper’s (1999) Anorexia model]	Control as problematic (especially regarding internal processes); to be reduced in therapy	Attentional control seen as functional and to be increased
Goal conflict	Higher-level goal conflict key source of distress and	Not explicitly emphasised, although	Not explicitly targeted, but potentially addressed	Not emphasised

	psychopathology [<i>See Table 1 for definition</i>]	approach-avoidance conflicts are identified in some models (e.g. Kimbrel, 2008)		through acceptance focus
Hierarchy	Goals are organised in a complex and many layered hierarchy; eleven layers have been specified [<i>See Table 1 for definition</i>]	Core beliefs, dysfunctional attitudes, strategies are organised hierarchically. These represent distorted and dysfunctional cognitions rather than goals	Values and specific goals are specified, but hierarchical organisation not specified	Nine interacting cognitive subsystems are proposed, some of which are hierarchically arranged; these are specialized for handling a particular type of information
‘High-level goals’ or ‘values’ identified	Pertinent higher-level goals identified through sustained awareness on	Not explicitly emphasised. Concrete goals for therapy are seen	Values identified through value clarification exercises	Not explicitly emphasised, but can be discussed in regards to relapse prevention

	problems [<i>See Table 1 for definition</i>]	as important, but often not specified in the models used		
Reorganisation (and observable indicators of this process)	Provides a mechanistic account of how change happens, indicated by shifts in perspective/ 'insight' moments [<i>See Table 1 for definition</i>]	Cognitive reappraisal and schematic change could be observable indicators (but not mechanistically specified)	Not specified	Modification of affect-related schema, e.g. reducing the likelihood that mild depression will regenerate depressogenic schematic models, could be observable indicator
Awareness	An index of the current focus; reorganisation occurs at the focus of current awareness	Not emphasised	Targets cognitive defusion and acceptance	Targets attention regulation, acceptance, decentering/reperceiving (similar to defusion) etc.

Note: PCT = Perceptual Control Theory; RFT = Relational Frame Theory; ICS = Interacting Cognitive Subsystems

The purpose of this table is not to provide a comprehensive comparison of therapies. It is focused on PCT-relevant processes; for example, cognitive biases are not included because, while these are fundamental to CBT, they are only significant in a PCT conceptualisation to the extent they cause chronic higher-level goal conflict.

^a Second wave CBT refers to the models that emerged during and after the fusion of cognitive and behavioural therapies in the 1970s (Rachman, 1997).

^b There is not a universally agreed theoretical basis for Mindfulness-based interventions. Interacting Cognitive Subsystems (ICS) has been proposed as a theoretical account of Mindfulness-based Cognitive Therapy (Teasdale, Segal, & Williams, 1995) and is included as it provides a detailed explanation of the ways in which interactions between cognitive and affective processes contribute to psychological distress.

2.5.1 Components of the TCC (including the rationale based on PCT)

Distinctive features of TCC were summarised previously (section 2.3 ‘The transdiagnostic approach’). The PCT basis of the TCC is one of its distinctive features and Table 2 illustrates how this basis results in differences in the ways that principles are conceptualised and employed therapeutically.

In accordance with the evidence that change happens at a different pace for different people there is a strong emphasis on client self-direction and control within the TCC. Furthermore, increasing evidence indicates that offering clients flexibility in attending psychological treatments increases effectiveness for services and is valued by clients (Carey & Spratt, 2009; Carey et al., 2013). It has been suggested that in clinical practice clients regulate their on-going treatment attendance and continue treatment until they have achieved a ‘good enough’ level of change (Barkham et al., 2006; Carey et al., 2013). Providing flexibility of attendance and engagement could promote attendance by promoting control and mitigating the impact of internal conflicts that would block attendance (e.g. fears about emotional exposure) (Murphy, Mansell, Craven, & McEvoy, 2014; Schauman & Mansell, 2012).

Flexibility is offered in other ways within the TCC. Specific homework tasks are not given, but at the end of each session participants reflect on what they are taking from the session and can set themselves a task. Sessional evaluation forms are filled in and session content can be adapted in response to feedback. For example, although the core content of each session is prescribed, certain techniques re-occur and so later implementation of techniques can be adapted in accordance with feedback. Furthermore, the emphasis on experiential rather than didactic

learning is employed to promote individual clients to consider the specific ways they can apply techniques to themselves.

Each session has a theme and includes videos of clients who have accessed either previous interventions within the service or earlier TCC. These provide opportunities for the group to hear accounts of other people's experiences of distress and recovery, as relevant to the session theme. Some opportunities are provided for participants to share their experience, but it is strongly emphasised that this is not a requirement.

In accordance with the PCT theoretical account, targeted throughout the TCC are: 1) understanding the process of control, including the degree to which one can, and desires, control over various aspects of one's life; 2) awareness of valued higher-level goals (and reasons for change); 3) awareness of higher-level goal conflict; 4) encouragement of flexible ways to control and reduction of processes (including rules, habits, routines and mental processes) that block valued goals. A description of key components of the six sessions and the empirical justification for these is provided below (a tabular summary of these is provided in L. Morris, 2013, p. 94-98).

Session One: Thinking About Control. Control is the basis of this course. The overall theme is to encourage participants to clarify what responses get in the way of them achieving the things that are important to them and to consider the things that they can, and want to, have more control over. For example, one exercise uses a "continuum of control" to facilitate participants to identify how much control they have over different aspects of their life. This group exercise often promotes discussion regarding the difference between how much control people think they have and how much control they actually have. Other session components begin to

offer techniques that promote sustained attention on problematic experiences that are indicative of goal conflict. These include an awareness exercise, which encourages clients to stay with an experience and notice how this is different from judging (or thinking about) that experience; and a goal-focused exposure exercise that involves imaginal exposure to an uncomfortable experience (e.g. social situation, a recurrent worry, feeling of failure), but not one that will be extremely uncomfortable (Carrier & Greenberg, 2010). Different forms of both goal-focused exposure and awareness techniques can be offered in nearly all of the sessions. Awareness techniques precede exposure components to facilitate enhanced attention prior to exposure.

Session Two: What Blocks Our Control? Addressing Negative Thinking: Self-Critical Voice, Worry and Dwelling on Things. A key message is that individual thoughts, even negative ones, are not a problem. Even worry, rumination and self-criticism are processes that many people engage in without any adverse effects (Watkins, 2008). They are a problem only to the extent that they get in the way of important life goals, or they limit a person's awareness of important goals and goal conflicts. Therefore, more repetitious and prolonged negative thinking can be problematic. Videos and metaphors are used to delineate potentially more problematic thinking processes, e.g. recurrent negative worry and rumination. Strategies are taught to help address thinking processes that block control. For example, a form of problem-solving that emphasises potential goal conflict is offered as an alternative to thinking over the same thing repeatedly.

Session Three: Feeling in Control Short-Term vs. Getting Control of Your Life. The principle that goals are organised hierarchically provides a key basis of this session. A fundamental message of the session is that sometimes (not always) our attempts to control our emotions, avoid distress or keep safe can actually get in

the way of us doing things that are really important to us. This encourages clients to focus on their longer-term (higher-level) goals and to consider prioritizing these over short-term goals that are getting in the way. For example, a common short-term goal that can prevent achievement of long-term goals is “I must avoid all distress/anxiety”. One of the early components is a group exercise that emphasises the normality and functionality of emotions. Later in the session, participants complete a worksheet to weigh up whether examples of things that they do have short-term (e.g. make them feel better) or long-term benefits (e.g. move them toward their goals); then consider if there is anything they would like to change.

Session Four: Taking Control of the Things Around You. A unique focus of PCT is that we are designed to control our environment for our own purposes. There are many things in our environment that we can change in order to make our world more like we want it to be. However, there are also some things that, objectively, we will have limited control over, such as other people. The control continuum is re-employed to consider how much control participants have over aspects of their environment that are causing them problems. An important focus of the session is consideration of control in interpersonal scenarios, e.g. a discussion or argument. The importance of clarification of *higher-level* goals during interpersonal scenarios, especially goals that might be shared, is explored using examples; it is suggested that these processes can help navigate arguments and discussions etc. For example, if someone had a higher-level goal of “having peace of mind”, as well as a lower-level goal of “getting my partner to clean up more” awareness of the higher-level goal could allow greater flexibility in how the lower-level goal can be achieved and could reduce the tendency to get caught in the detail of an argument. Expressing a potentially shared higher-level goal, e.g. valuing the relationship, could further

reduce the escalation of conflict by increasing shared ground. There is evidence from sociological work that interpersonal conflict escalates quicker than it is resolved (McClelland, 2004), hence the importance of a flexible perspective to reduce initial disagreement. Furthermore, studies have found that shared reference values are important to reduce interpersonal conflict (McClelland, 2004).

Session Five: Building on Strengths, Qualities, and Resources. The focus of the session is to encourage participants to recall the strengths, qualities and resources they have, especially at times when things are difficult for them. The rationale behind this session is that self-concept goals are higher-level ones (Mansell & Carey, 2009). Psychopathology can arise when another reference value remains in conflict with a self-concept reference value; for example, “I must be strong” vs. “I am weak and inadequate” (Tai, 2009). An example of a metaphor, used in this session, is that of a tree, which needs water and sunlight and similarly people need resources to grow. Another imagery-based technique used in this session is participants creating an image that represents qualities that they value and believe will support them.

Session Six: Moving Forward: What Gets Me Stuck? What Helps? A general overview of TCC is provided. Clients are encouraged to choose elements that they want to revisit. They complete a worksheet regarding the things that are helping them feel in control and signs that they are struggling. This worksheet has similarities to a “relapse prevention” session in a traditional CBT approach. Allowing choice in the material covered, and encouraging clients to reflect on what works for them, is intended to encourage them to target their behaviour in order to meet important goals. The emphasis is on the perceptual goal (or reference value) that they are trying to meet and different behaviours may support this at different

times.

2.5.2 Recurrent intervention components

As mentioned in the description of the TCC session content, certain components are repeated. These components include exposure, awareness/mindfulness and metaphor/imagery. The PCT basis of exposure, awareness/mindfulness is detailed below. Although these components are found within other CBT approaches, the PCT basis results in a specific way of utilising and framing these that is distinct from other approaches. However, work is on-going to examine the mediating effects of mechanisms according to PCT.

Imaginal goal-focused exposure. According to PCT, exposure is perceptual and not behavioural. This means that people attempt to keep the properties of their experience (e.g. closeness, intensity) within a desired range using dynamic changes in behaviour (e.g. movement, using substances) (Brady & Raines, 2009; Carey, 2011). The proposed problem is that people have conflicting perceptual goals; for example, the conflict between avoiding a past memory of a distressing assault, with the need to experience this memory to manage similar situations in the future. This leads to loss of control as the person oscillates from one goal to the other. According to PCT, exposure is designed to help people hold this perceptual conflict in mind and establish a new organisation of goals (reorganisation) that allows them to regain overall control. The conflict between personally relevant goals will be most emphasised if clients are able to direct the exposure process (Brady & Raines, 2009), with some guidance. Guided self-direction best promotes change, because if pressure from the therapist is too great the client's awareness will be less directed to their underlying conflicted goals (and more to the conflict created by the therapist's pressure).

Therefore, in the TCC exposure is framed in such a way to ensure it is self-directed, guided by clients' life goals and promotes sustained attention on conflicts (Carey, 2011). Consequently, it is described as 'imaginal goal-focused exposure'. The way in which the exercise is framed is always in the context of important higher-level goals in order to promote awareness of goal-conflict, instead of promoting habituation to anxiety, emotional-processing, or reappraisal of a situation (e.g. Foa, Huppert, & Cahill, 2006). These outcomes may arise, but they are not seen as the reason for exposure.

The majority of empirical studies have found that greater perceived control during exposure reduces anxiety and distress levels; however, findings are not totally consistent (Mcglynn, Rose, & Lazarte, 1994; Rose, McGlynn, & Lazarte, 1995). In one of the studies in which greater perceived control did not reduce anxiety the average exposure durations chosen by participants were very brief, which supports the notion that some therapist direction is useful (Craske, Bunt, Rapee, & Barlow, 1991). A number of theorists, such as Gray and McNaughton, have highlighted the key role of goal conflict in activating an anxiety response (e.g. Hirsh, Mar, & Peterson, 2012). A recent study, which compared the performance of students with high and low levels of spider phobia, found that high spider phobic individuals responded in a way suggestive of goal conflict (Oliver, 2013).

Awareness/ mindfulness. From a PCT perspective, awareness is important in a number of ways. It is important that awareness of higher-level conflicted goals that are causing psychopathology is encouraged, in order to resolve these conflicts (Carey, 2011). According to PCT, the primary reason for using awareness techniques is to develop a 'window' of awareness that can be brought to bear on conflicted goals and therefore awareness techniques used in the TCC are shorter than those

delivered in other approaches; for example, MBCT (Fjorback et al., 2011). Use of awareness techniques support clients to sustain attention on problematic experiences indicative of goal conflict (e.g. during the imaginal goal-focused exposure). It has been suggested that a range of effective therapies enable clients to sustain attention on problem-relevant experiences for longer than would otherwise occur (Carey, 2011). Through this sustained attention on such experiences the individual's perception is likely to become more elaborate, and inherent conflicts more likely to be resolved.

It is also important that individuals are able to flexibly move awareness through the control hierarchy in order to reduce the likelihood of psychopathology and achieve long-term goals (Watkins, 2011). Individual differences in the general level of goal focus maintain symptoms of a number of psychopathologies; for example, a general focus on lower-level goals can lead to greater impulsivity (Fujita & Carnevale, 2012). Emerging research indicates that greater mindfulness is associated with increased clarity regarding important goals and greater flexibility of goal pursuit (Crane, Barnhofer, Hargus, Amarasinghe, & Winder, 2010; Crane, Winder, Hargus, Amarasinghe, & Barnhofer, 2012). Enhanced selective and executive attention can be developed through short-term meditation practice and may increase flexibility of awareness; however, it is not clear whether the amount of practice during the TCC would be sufficient (Chiesa, Calati, & Serretti, 2011). However, TCC participants are provided with support to practice awareness techniques at home if they choose to. Further, even very brief mindfulness conditions have been shown to reduce reactivity to repetitive thoughts (Levin, Hildebrandt, Lillis, & Hayes, 2012).

2.6 Summary and future research

Research at psychological process and neurobiological levels indicates the promise of transdiagnostic accounts in understanding and treating psychopathology (S. E. Morris & Cuthbert, 2012; Nolen-Hoeksema & Watkins, 2011). PCT provides a functional transdiagnostic model of how psychopathology arises and how recovery can be facilitated.

Further research is required to directly test the relative contribution of some of the PCT mechanisms predicted to underlie psychopathology; for example, additional research is required into whether higher-level conflict is a more significant contributor to psychopathology than lower-level conflict. Another important area will be examining the extent to which the PCT basis of TCC facilitates its effectiveness; for example, the extent that the resolution of higher-level goal conflict predicts successful exposure. This would facilitate detailed comparison with other explanatory theories and interventions.

Furthermore, additional data is required as to whether the TCC is an effective intervention. Thus far the effectiveness of TCC has only been examined in a prospective cohort study, which had a number of methodological limitations including high attrition at follow-up and unequal group sizes (L. Morris et al., 2015). If TCC is not effective it is less likely that research examining its mechanisms of change will be helpful. Additional effectiveness data is also required to establish whether TCC promotes reduction of distress and symptom change, at least to the same extent as established interventions. Further, qualitative data on client experience is required to provide detailed information regarding how acceptable the TCC is (L. Morris et al., 2015).

This chapter has presented the theoretical basis and design of a

transdiagnostic intervention based on PCT. While some components of this intervention could be familiar, it is focused around the concept of control and based on the premise that control is exercised at various levels for a human being to continue living. Psychological distress is regarded as the manifestation of loss of control, typically caused by prolonged conflict between high-level goals. Therefore, change is promoted by shifting awareness to this conflict and sufficiently sustaining awareness in order to allow spontaneous changes that resolve the goal conflict and restore control. The TCC provides the tools for individuals to apply these principles in an accessible, succinct manner.

CHAPTER 3

Methodology

3.1 Introduction

The methodologies employed in this thesis are described briefly in each of the relevant chapters. This chapter takes a broader view and considers the justification for the research methods that were used.

3.2 Specific aims

As previously described in Chapter 1, this thesis focuses on examining whether a theory-driven group intervention (the Take Control Course; TCC), is non-inferior compared to an active control (individual low-intensity CBT). The thesis also examines mechanisms of change specified by Perceptual Control Theory (PCT; W. T. Powers, 1973, 2008; W. T. Powers et al., 1960a, 1960b). Therefore, key aims and related studies are re-stated below:

1. Narrative review (Paper 1, Chapter 2). Aims: i) To explore whether a Perceptual Control Theory (PCT) explanation of psychopathology across disorders is a valid one; ii) To illustrate the process of developing a novel transdiagnostic intervention (Take Control Course; TCC) from a transdiagnostic theory of functioning (PCT).

2. RCT (Paper 2, Chapter 4). Aim: To assess whether TCC is non-inferior compared to an active control condition (individual low-intensity CBT). Hypothesis: Participants in both groups will show reductions in symptom scores on measures of anxiety and depression, and outcomes in the TCC group and individual low-intensity interventions will be non-inferior.

3. Qualitative study (Paper 3, Chapter 5). Aim: To explore participants' experiences of the TCC, specifically, to examine what experiences contribute to psychological change.

The recruitment site for both the RCT and the qualitative study was Six Degrees Social Enterprise. Formally the Primary Care Mental Team, Six Degrees is the main provider of low-intensity Improving Access to Psychological Therapies services in Salford (their website is: <http://six-degrees.org.uk/six-degrees-help-at-hand/>). See Appendix A for RCT protocol.

3.3 Medical Research Council framework for developing complex interventions

As introduced in Chapter 1, the overall programme of research that this PhD thesis is part of has been strongly informed by the Medical Research Council (MRC) framework for developing and evaluating complex interventions (Craig et al., 2008). Figure 2 provides a diagrammatic representation of key elements of the framework's staged approach, namely: developing the intervention; piloting and feasibility; evaluating the intervention (e.g. through a RCT); and implementation (Craig et al., 2008). The current thesis focuses on evaluating the TCC intervention using the three elements detailed in the MRC framework: assessing effectiveness, understanding change process, and assessing cost-effectiveness. How PhD studies cohere with these aspects of the framework is detailed below.

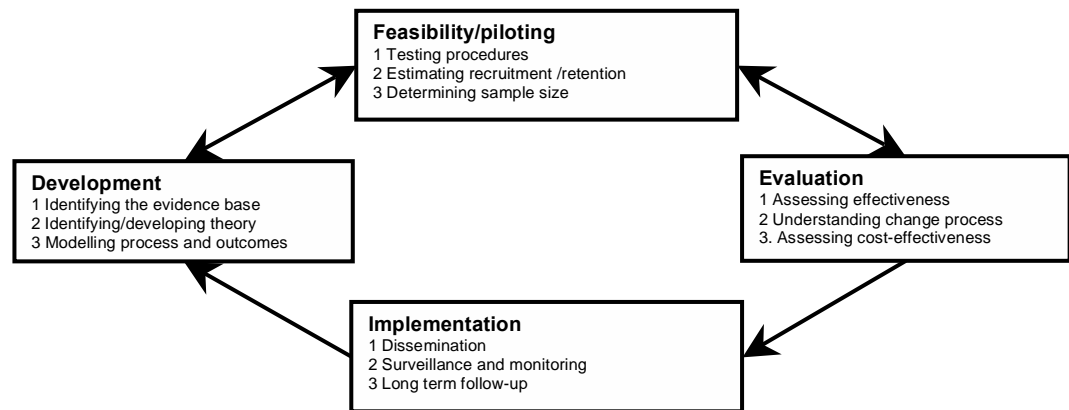


Figure 2: The MRC's key elements in development and evaluation of a complex intervention (Craig et al., 2008).

3.3.1 Narrative review

In order to establish that a psychological intervention offers something unique, it is necessary to regularly review the extant evidence for the intervention being developed and investigated. As the MRC framework specifies, this is particularly important during the initial development stage of the intervention but during later development it is still important to establish whether an intervention makes a unique contribution. Further, given that a key difference between the TCC and pre-existing group interventions is its basis in PCT, it was considered important to review this theoretical background in some detail.

The previous chapter summarised a detailed narrative review that presented the theory that informed the TCC. The purpose of the review was to outline the development and conceptual background of the TCC. A narrative review was conducted instead of a systematic review because pertinent studies had to be identified that were relevant to a range of different concepts, and so even very broad search terms would not capture the breadth of studies required. Further, there are a number of systematic and meta-analytic reviews of transdiagnostic interventions

available so it was not appropriate to just review transdiagnostic intervention studies (Newby et al., 2015; Norton & Philipp, 2008; Reinholt & Krogh, 2014).

3.3.2 Rationale for a mixed-methods approach

The thesis used mixed-methods in order to understand the TCC from multiple perspectives. Although the MRC guidelines stress the utility of randomised experimental designs in evaluating an intervention, they also recognise the contribution that qualitative methodologies make to such evaluations (Craig et al., 2008). In this context, qualitative methods are particularly well-suited to gaining a detailed understanding of what clients find useful or unhelpful about interventions and understanding the complexities inherent in accessing multifaceted interventions within a specific service context (Lewin, Glenton, & Oxman, 2009; Peters, 2010). Consequently, it is becoming common to ‘nest’ qualitative studies within RCTs where additional information regarding participant experience of the intervention will be valuable (e.g. Bee, Lovell, Lidbetter, Easton, & Gask, 2010; Dures et al., 2012).

A nested qualitative study was therefore used to gain an understanding of what clients perceived to be helpful (and less helpful) about the TCC, and what clients perceived to contribute to psychological change. Further, this indicated how ‘acceptable’ the TCC was, as it provided data on clients’ understanding and satisfaction levels. The qualitative data therefore provided information that was not available from the RCT by providing detail regarding participant response to and interactions with the TCC (Moore et al., 2015).

3.3.3 Rationale for a RCT design

The ‘evaluation’ stage of the MRC framework involves assessing the effectiveness of an intervention. The RCT reported within the PhD assessed the

effectiveness of the TCC as compared to individual low-intensity CBT. The design and implementation of this RCT was informed by a previous prospective cohort study comparing TCC to individual low-intensity CBT. A non-inferiority design was utilised as the prospective cohort study found no significant difference between treatments. In addition, to justify its use in clinical practice it is important that TCC is at least as effective as low-intensity interventions. However, the primary arguments for offering the TCC are that the transdiagnostic group delivery mode offers particular advantages (e.g. cost-effectiveness). Furthermore, offering an intervention that uses a different theoretical model to traditional CBT enables clients to choose an intervention that suits the problems they want to work on. A non-inferiority design was therefore chosen because these arguments for offering TCC are not purely based on effectiveness.

Clients were offered a choice between accessing individual low-intensity CBT and accessing the trial. Within the trial clients were not routinely offered treatment as usual (individual CBT); the comparison within the trial was TCC condition compared with treatment as usual. Clients were able to choose to access individual CBT, even if they were randomised to TCC, but this was not offered to all clients (it was offered if clients expressed difficulties with the TCC or a desire for different/ further treatment). Although such a design offers methodological advantages because TCC can more directly be compared to treatment as usual across time points, sometimes treatment as usual is offered to all clients after the experimental treatment to account for the fact that these clients are offered a less well-established intervention. The potential implications of this design are discussed in the discussion section of this thesis (6.3 Strengths and limitations).

Randomised designs are recommended by the MRC because random

allocation produces groups that have, on average, the same distribution of measured and unmeasured characteristics and so control for bias between groups (Campbell et al., 2000; Matthews, 2006). Therefore, a RCT design allowed conclusions regarding the non-inferiority of the TCC compared to individual low-intensity that were methodologically robust (Campbell et al., 2000; Matthews, 2006).

3.3.4 Examining cost-effectiveness

Comparative cost-effectiveness was also examined within the RCT. The MRC guidelines state: “An economic evaluation should be included if at all possible, as this will make the results far more useful for decision-makers” (Craig et al., 2008, p.12). The plan was to compare outcome data at 12-month follow-up; this is the most appropriate time-point to use as it covers service use over the longest possible duration. However, due to recruitment difficulties (discussed in section ‘3.5 Challenges and issues’) the full 12-month data was not available prior to PhD submission. Therefore, the cost-effectiveness analysis is not included within the PhD, but will be included in a journal submission.

The cost-effectiveness analysis will examine whether the two treatment arms differ regarding the use of all hospital, community health and social services, productivity losses and costs to patients (which is a societal perspective as it does not just focus on the costs to the service). The MRC guidelines suggest that a societal perspective is preferable to a narrower, e.g. health service specific, perspective (Craig et al., 2008). A societal perspective gives a broader indication of the costs of an intervention and has been argued to be the most effective way of ensuring optimal decisions about allocation of resource (Jönsson, 2009). Furthermore, few studies have compared group and individual interventions using a societal perspective (Tucker & Oei, 2007).

3.4 Qualitative methods

The qualitative study examined change processes, which constitutes part of the 'evaluation' stage of the MRC framework. It also provided valuable information regarding the implementation of the TCC; for example, the importance of offering a flexible format.

Originally the intention was to interview those allocated to the TCC group only. However, the Research Ethics Committee considered this a potential source of bias and the design was amended. The amended study received ethical approval (Appendix B). Therefore, participants' broad experiences of both interventions were explored, such as their experience of the modality and their perceptions of what contributed to psychological change (or lack of change) (Mason & Hargreaves, 2001). However, only the analysis of the TCC data is included in this thesis. A Masters student analysed the data regarding individual low-intensity interventions and this was reported in their thesis (Amos, 2015).

Thematic Analysis was the method chosen for this study because the purpose of the analysis was not theory generation and the analysis sought to understand themes across the data, as well as obtaining a detailed understanding of individuals' experiences. Therefore, Thematic Analysis was preferred to qualitative methods that support theory generation, such as Grounded Theory (Glaser & Strauss, 1967) or methods that provide a very detailed account of individuals' internal world, such as Interpretative Phenomenological Analysis (Smith, 2004; Smith, Jarman, & Osborn, 1999).

The theoretical approach was critical realist (Creswell, 2009) and therefore it was assumed the language utilised by participants reflected their subjective meaning

and experience (Braun & Clarke, 2006). Further, the combination of mixed methods and reliability checks were used to try to establish how reliably participants' experiences were conceptualised. However, it is also acknowledged that pure objectivity is unlikely because both participants' accounts and researchers' interpretation will be influenced by their perspective (e.g. beliefs about the world, social context) (Creswell, 2009). Interpretation of accounts is inherent within the qualitative methodology (Attride-Stirling, 2001), but qualitative methods offer the potential to comprehend in some depth the nuanced meanings and understandings of individuals and groups (Creswell, 2009).

The study utilised a purposive sampling approach to obtain a maximum variation sample of participants who attended a range of numbers of sessions, i.e. those who attended one session through to six sessions. Due to the flexibility of the TCC, it was not appropriate to categorise clients as 'completers' and non-completers' on the basis of the number of sessions attended. A client could attend one session and perceive that they got what they needed. However, in practice, participants who attended low numbers of sessions (e.g. one or two) were reluctant to participate in the study and therefore the full range of session attendance was not fully represented.

3.4.1 Rigour in qualitative research

Qualitative research does not claim to be a measure of objective reality and researchers accept that it is not possible to set aside their individual perspective (Creswell, 2009; Elliott, Fischer, & Rennie, 1999). Therefore, 'reflexivity' is commonly used, which entails the recognition and appraisal of the researcher's assumptions and role. It is also considered important by many qualitative researchers to take measures to empirically ground the subject matter, such as

methods to establish reliability and validity (Creswell, 2009; Elliott et al., 1999). However, there are differing views regarding whether it is appropriate to use such methods (Schwandt, 1996; Seale, 1999). For example, it is argued that the constructs of reliability and validity are premised on the possibility of achieving objective knowledge, but scientific methods are not purely objective (Schwandt, 1996). Such a perspective recognises the influence of the researcher, their experiences, aims and intentions. Although the PhD student recognises that fully representing objective reality is difficult (and perhaps impossible), they would argue that it is possible to represent an objective reality more or less accurately. Therefore, within the qualitative study reported within this PhD measures have been used to establish the credibility, dependability/reliability, transferability, and confirmability of the data collected (Shenton, 2004). These measures will be discussed in turn.

One means of establishing credibility was that throughout the period of the qualitative study the PhD student regularly met with research supervisors; these meetings were particularly with Dr Warren Mansell and Dr Dawn Edge. Each aspect of the study was discussed in detail from the sampling frame to appropriate ways of promoting validity. Further, a detailed description of themes was provided within the qualitative study, using quotes, in order to demonstrate the data from which themes were developed.

Information regarding the qualitative data obtained was collected from a number of different sources (Shenton, 2004). Such triangulation is regarded as a particularly important way of establishing credibility (Loh, 2013). Emergent themes were reviewed by a qualitative methods expert independent of the study (peer verification). Member checking was used to verify the validity of themes, i.e. participants were asked whether the themes that the researcher derived reflected their

experiences and perspectives (Creswell, 2009). This process involved presenting themes to a subset of key informants to establish the extent to which themes reflected participants' experiences; an important test of the validity of the researcher's interpretation. Key informants are those who are particularly representative of the sample as a whole (Onwuegbuzie & Leech, 2007).

Further, the PhD student reflected on her role and perspective within the research. This contributes to the process of reflexivity. Some reflections are included within this chapter and a brief account of the student's theoretical and profession background provided in Chapter 5 (which reports the qualitative study). Such reflection is useful because it helps the researcher consider when their perspective could influence the way they approach the research, and because this helps the reader interpret the researchers' data (Elliott et al., 1999). In addition, the processes used within the study are reported in detail in Chapter 5 as detailed reporting has been suggested to promote dependability (Braun & Clarke, 2006; Shenton, 2004).

Issues of transferability were considered and a description of the service context is provided in Chapter 5 (which reports the qualitative study). However, given that the RCT sampled from only one service context, it could be argued that the results were not very transferable. The extent to which qualitative studies should strive for transferability has been questioned, as qualitative findings will be inevitably influenced both by the service context and the context of the researcher's view of the world (Shenton, 2004).

3.4.2 Reflection on conducting interviews

Although a Masters student supported data collection, I (the PhD student)⁴ conducted the majority of interviews with TCC participants (8 out of 12). I was involved in the team that developed the TCC so it could be argued that I would be biased in my interview style (e.g. not engaging fully with negative feedback). However, I was interested in the broad range of comments that participants expressed, even apparently negative or critical feedback could be very useful in understanding how the TCC could best be offered and delivered. Similarly if participants realised that I was part of the development team for TCC they might be reluctant to give critical feedback. There was no obvious way that participants could have established this, and it was emphasised that both positive and negative feedback was welcome. Semi-structured interview guidelines were also used to ensure that similar areas were covered in all interviews (Appendix C).

The fact that two different researchers conducted the interviews offered advantages in this respect, as the Masters student had no prior involvement in TCC. However, it is likely that there were some differences in style between the two interviewers. I have trained as a Clinical Psychologist, worked in primary care low-intensity services prior to completing this training, and I also know the content of the TCC very well. Therefore, it may have been easier for me to identify when additional clarity was required regarding something that a participant said. For example, if participants referenced a particular technique but it was not clear exactly what they were referring to or how they implemented this, then I would know to ask follow-up questions until this was clearer. Although the Masters student had read about the TCC and related areas, and had access to the session breakdown, this does not provide such a comprehensive understanding. Overall, however, it was deemed

⁴ 'I' is used in this section, as is the convention within qualitative research (Creswell, 2009).

beneficial to limit researcher-dependent factors by having two different researchers conducting interviews.

3.5 Challenges and issues

3.5.1 RCT recruitment

The number of participants who provided primary outcome data at 6-month follow-up was not substantially below target; 118 participants provided this data and the target was 126. Recruitment was stopped prior to the target being achieved due to the time frame of the PhD, in order to enable full 6-month follow-up data to be reported in the PhD thesis. However, recruitment did take longer than anticipated and it was not possible to collect full 12-month follow-up data within the time frame of the PhD.

The time frame of the RCT was carefully planned based on the time line of the previous feasibility prospective cohort study and the considerable experience of running trials within the supervisory team. But there were a number of greater than anticipated issues with recruitment to the RCT. Recruitment was expected to be significantly slower than the prospective cohort study, as randomisation introduces an uncertainty that was not present previously (using a prospective cohort design participants could choose their treatment).

However, the most significant issue that affected recruitment was the substantially greater changes to the staff team of the main recruitment site, than during the previous study. This had a number of implications, such as numerous times when the service was short staffed. Also this had an impact on when TCC could be run. As clinicians leaving the service varied in how much notice they gave, and initially only a limited number of staff members were trained, TCCs had to sometimes be postponed or rearranged. Even if this was not necessary, staff

turnover made running courses at a range of times difficult as timings relied on the availability of facilitators. For example, evening courses were particularly appealing to clients, and the service recognised a need for these, but it was only possible to run one evening course towards the end of the RCT. The resultant limited time options and gaps between courses made participating in the project less appealing for clients. Regular training in TCC was offered and increased numbers of staff members trained, but overall the on-going staff changes had a significant impact on the project.

Although taking on an additional recruitment site was considered, recruitment levels were initially good and by the time these had decreased it was not feasible to take on another site. Further, high staff turnover can be common within low-intensity services and so a similar problem could have arisen within another recruitment site. Many methods were used to keep clinicians engaged and promote recruitment within Six Degrees, such as attending their meetings, telephoning the office, and update emails. Small expressions of gratitude, e.g. biscuits, were given and time was spent responding to any queries about the study and other areas. In the later stages of the project, the TCC facilitator team took more responsibility for the in-team communication (supported by the PhD student) this was to give the team more ‘ownership’ of the project and so that encouragement to recruit came from a range of people. Further, a very brief recruitment monitoring system was embedded into the routine electronic reporting system, which had to be completed after every initial assessment. This was in order to remind clinicians to ask clients about the project and to obtain detailed data of clients assessed; for example, whether clients were eligible for the project or not.

3.5.2 Consequence of recruitment difficulties

The primary consequence of the recruitment difficulties was that the 12-month data had not been fully collected by the submission deadline for the PhD. Therefore, Chapter 4 only reports the 6-month follow-up RCT outcome data. This was considered appropriate as 6-month was the primary outcome point. Data from both 6 and 12-month follow-up points will be included in journal submissions.

3.6 Roles and responsibilities

The supervisory team is detailed in the RCT protocol (Appendix A); this section will focus on the primary responsibilities of the PhD student and others involved in the project in a non-supervisory role. The PhD student analysed the relevant data for all the PhD studies.

3.6.1 RCT

The PhD student created a 129 A4-page TCC manual for use in the RCT. This manual was one of the desired outputs of the PhD and the intention is to submit this for publication once the RCT data had been finalised. See Appendix D for the contents page and a sample of manual chapters (including the introductory chapters and the chapter outlining Session 1).

The PhD student was responsible for the overall management of the RCT. This included coordinating the Research Assistants, liaising with the main recruitment site Six Degrees Social Enterprise, implementing recruitment systems, promoting recruitment, and supporting arrangements for the TCC (e.g. booking rooms). A number of these tasks were carried out with members of Six Degrees management team; for example, when developing recruitment, and other, systems that were embedded within the service there was considerable consultation with the management team. An overall process map of the recruitment procedure was

developed to ensure that clients would have the most straightforward pathway through the research project; the RCT was embedded within the normal service pathways.

A member of the Six Degrees administration team conducted the randomisation procedure; they were not involved in recruitment, or follow-up of randomised clients, in any way. This was to ensure that there could be no claims of bias during the randomisation procedure. The actual randomisation procedure was conducted using 'Sealed Envelope', a computerised randomisation programme. This ensured that the PhD student and research assistants remained blind to treatment allocation.

As the PhD student sometimes conducted follow-up appointments, particularly in the earlier stages of the project, she needed to stay blind to treatment allocation. Therefore, she did not deliver any of the interventions. She provided training in the TCC and on-going clinical and practical supervision to the TCC facilitators. Six Degrees employed all the facilitators. The same clinicians also delivered the low-intensity interventions, although there was a larger team of clinicians delivering the low-intensity interventions.

Primarily, the follow-up appointments (and many of the baseline appointments) were conducted by four voluntary research assistants. The PhD student could not conduct 12-month follow-up assessments because (due to her involvement in the qualitative study) she was unblinded to treatment group of many participants by 12-month. The voluntary research assistants were undergraduates at the University of Manchester. They applied for this voluntary role to gain relevant experience, and were interviewed, DBS checked and trained. The PhD student was part of the interview panel and 10 applicants were interviewed. One research

assistant successfully applied for a paid role (funding for this role was requested from the Economic Social Research Council by the PhD student). All research assistants also entered trial data and were involved in contacting participants. The paid research assistant also conducted data checking to ensure that the data entered in the trial databases was accurate.

The PhD student offered regular supervision to the research assistants, and also dealt with any more complicated risk issues. A detailed ‘standard operating procedure’ document was developed, and this included a comprehensive risk management procedure (Appendix E). All research assistants were trained (by the PhD student) in using this procedure and managing suicide risk or suspected abuse within the context of this role.

3.6.2 Qualitative study

As aforementioned, the qualitative study was conducted by both the PhD student and a Masters student. Although the PhD student analysed the TCC data and the Masters student analysed the individual low-intensity CBT data, both interviewed participants who had accessed either treatment. The PhD student offered practical and clinical supervision (e.g. risk management), and was part of the overall supervisory team for the Masters student. Dr Warren Mansell and Dr Dawn Edge were the primary supervisors for the Masters student.

3.7 Summary

This chapter has provided an overall account of why certain methods were used and expanded on notable methodological decisions made during the PhD. The rationale for the mixed methods approach has been presented. An account of roles and responsibilities within the team working on the PhD has also been provided.

**CHAPTER 4: A brief transdiagnostic group (the Take Control Course)
compared to individual low-intensity CBT for depression and anxiety: a
randomized non-inferiority trial**

PREFACE

The paper will be submitted to ‘British Journal of Psychiatry’ and it has been prepared in accordance with their requirements. The authors will be: Dr Lydia Morris, Professor Richard Emsley, Professor Karina Lovell, Dr Phil McEvoy, Dr Dawn Edge, Rachel Bates, Tanya Wallwork and Dr Warren Mansell.

Dr Warren Mansell, Professor Richard Emsley, Professor Karina Lovell and Dr Dawn Edge were the academic supervisory team for the PhD. Dr Warren Mansell, Professor Richard Emsley and Professor Karina Lovell provided feedback on the thesis version of this paper, but the other authors will be asked for feedback prior to submission to the journal.

4.1 Abstract

Background: Interventions targeting processes that commonly maintain different psychological disorders appear promising. Very few studies have examined brief transdiagnostic groups. One such intervention, the Take Control Course (TCC), has been developed for patients with common mental health problems in low-intensity IAPT services.

Aims: To evaluate whether TCC is non-inferior to individual low-intensity cognitive behaviour therapy (CBT).

Methods: Single-blind individually randomized parallel non-inferiority trial comparing the TCC to individual low-intensity CBT. Primary outcomes (depression and anxiety scores) were measured at 6-month follow-up.

Results: 156 patients were randomised. Intention-to-treat analyses indicated that TCC was non-inferior to individual low-intensity CBT on anxiety and depression outcomes, functioning and an idiosyncratic problem measure. Secondary, per-protocol analyses found inconclusive evidence of non-inferiority.

Conclusions: This is the first randomised trial providing evidence for the non-inferiority of a brief transdiagnostic group compared to established individual therapy.

Declaration of interest: None

4.2 Introduction

Common mental health problems, such as depression and anxiety, are often treated in primary care settings (Aillon et al., 2014). Due to the prevalence of these problems, psychological therapies are required that can meet such demand. One response to this has been offering varied intervention modalities, and different lengths of treatment (Bennett-Levy, Richards, & Farrand, 2010). Such approaches have been used within Improving Access Psychological Therapy (IAPT) services as part of a stepped care model where by the ‘least restrictive’ treatment option is offered while still providing a treatment that is likely to lead to significant improvement (Bower & Gilbody, 2005). Individual brief (low-intensity) CBT, which often includes guided self-help, is a common treatment within IAPT services (Glover et al., 2010). Two meta-analyses found that brief CBT was more effective than control conditions for patients with anxiety and depression (Cape, Whittington, Buszewicz, Wallace, & Underwood, 2010; Nieuwsma et al., 2012). Given the effectiveness of brief individual CBT for patients with common mental health problems, it seems plausible that brief group-based interventions could be effective and provide a cost-effective alternative (Tucker & Oei, 2007).

Brief transdiagnostic groups potentially combine the service delivery advantages of brief interventions and of a transdiagnostic approach. Transdiagnostic interventions target cognitive and behavioural maintenance processes that are common across disorders, such as repetitive thinking, behavioural avoidance (Mansell et al., 2009). Therefore, transdiagnostic interventions can address multiple and co-morbid problems within one intervention (Andersson & Titov, 2014). However, despite the evidence suggesting that brief interventions in primary care are effective, transdiagnostic groups tend to be delivered using a time-intensive format

(e.g. 10-12 2-hour sessions); at a minimum eight 2-hour sessions (Newby et al., 2015). In contrast the Take Control Course (TCC) is six sessions, with an average session length of an hour (L. Morris et al., 2015). TCC is tightly based on a transdiagnostic theory, Perceptual Control Theory (PCT; W. T. Powers, 1973). Therefore, the primary aim of this study was to examine whether a brief transdiagnostic group, TCC, was non-inferior to established individual low-intensity CBT.

4.3 Method

4.3.1 Participants

Participants were recruited from Salford Six Degrees Social Enterprise, a low-intensity IAPT Service.

Inclusion criteria were: A) Aged 16 and above. B) Individuals with mild-moderate depression and anxiety that has emerged within the 12 months prior to referral (i.e. the problem is not a chronic and enduring one). C) Sufficient English language skills to understand material (i.e. verbal and written language abilities required to read and complete simple worksheets and understand verbal presentations).

Exclusion criteria were: A) Aged under 16. B) Suitability for higher intensity services that is primarily determined after first assessment with the service; for example, patients with Post Traumatic Stress Disorder or severe Obsessive Compulsive Disorder; patients with persistent self-injury requiring clinical management or who were potentially intent on and/or planning suicide; patients who are currently experiencing psychotic symptoms; have current substance dependence; or have an organic brain impairment, such as dementia. C) Literacy or language

difficulties that will preclude them from reading simple worksheets or from conversing with a healthcare professional.

4.3.2 Measures

4.3.2.1 Primary outcome measures

Patient Health Questionnaire Depression Scale (PHQ9; Kroenke, Spitzer, & Williams, 2001). A nine-item measure of depression with scores from 0 to 27. The PHQ9 has been validated in a UK depressed population (Cameron, Crawford, Lawton, & Reid, 2008) and has good psychometric properties; Cronbach's alpha .89 (Kroenke et al., 2001).

Generalized Anxiety Disorder Questionnaire (GAD7; Spitzer, Kroenke, Williams, & Lowe, 2006). A seven-item measure with scores from 0 to 21. The GAD7 has not been validated in a UK population, but has good psychometric properties from studies in the USA; Cronbach's alpha .92 (Spitzer et al., 2006).

The primary endpoint for both PHQ9 and GAD7 was at 6-months after baseline.

4.3.2.2 Secondary measures

Work and Social Adjustment Scale (WSAS; Mundt, Marks, Shear, & Greist, 2002). A five-item measure of work, social, and other functioning. Cronbach's alphas were .70–.94 in clinical populations (Mundt et al., 2002).

The WSAS has been validated in a UK sample (Mataix-Cols et al., 2005).

Psychological Outcome Profiles (PSYCHLOPS; Ashworth et al., 2005). A patient-generated outcome measure. Patients are asked to describe their main problem(s) and how this affects them. Cronbach's alphas were .79–.94 in a UK clinical population

Credibility/Expectancy Questionnaire (CEQ; Devilly & Borkovec, 2000). A scale for measuring treatment credibility and expectancy of improvement prior to treatment. Treatment credibility was also measured at 6-month follow-up using two items from the CEQ (e.g. Watts et al., 2013).

4.3.3 Procedure

Patients were predominantly referred to Six Degrees by their GP, but could be also referred by other healthcare professionals. At a generic initial assessment, with a Six Degrees clinician, patients who met the inclusion criteria were informed of the study alongside the service's other treatment options, and were able to discuss participation. Interested patients were offered an appointment to further discuss the study, give informed written consent and fill in baseline measures.

After written consent to participate in the RCT and completion of baseline measures, the randomisation process was conducted. An administrator within Six Degrees randomised patients using a computerised randomisation programme (Sealed Envelope); therefore assignment was concealed from the research team and assessors.

Research assistants primarily conducted follow-up assessments, although the first author conducted some assessments. Assessors were blind to treatment allocation and were not involved in providing the interventions.

4.3.4 Treatments

4.3.4.1 Take Control Course (TCC): group intervention

The TCC consists of six weekly sessions (the first session is 1 hour 15 minutes and all other sessions are 1 hour). See L. Morris, Mansell, and McEvoy (2016) for further details of the sessional content and the development of the TCC. The TCC is not focused on patient self-disclosure and discussion, but rather

emphasises experiential learning, videos, facilitator presentations and worksheets. Specific homework tasks are not given, but at the end of each session time is allocated for participants to reflect on what they are taking from the session and to set themselves a specific task. Sessional evaluation forms are filled in and session content can be somewhat adapted in response to feedback. Control is the basis of this course. In accordance with a PCT theoretical account, targeted throughout the TCC are:

- (1) Understanding the process of control, including the degree to which one can, and desires, control over various aspects of one's life;
- (2) awareness of valued higher-level goals (and reasons for change);
- (3) awareness of higher-level goal conflict;
- (4) encouragement of flexible ways to control and reduction of processes (including rules, habits, routines, and mental processes), that block valued goals (Morris, Mansell & McEvoy, 2016, p. 8).

Clinicians and treatment integrity. Facilitators were 10 trained clinicians with 0.5–6 years' clinical experience (degree educated with further training in low-intensity treatments). Many of the clinicians were Psychological Wellbeing Practitioners (PWPs), meaning that had done a specific training to become a PWP (usually a year long and focusing on low-intensity CBT). However, some clinicians came from other professional backgrounds, such as Social Work or Nursing, and had received other training in CBT interventions. TCC training was a day long. Training focused on familiarisation with the content of the TCC and on addressing group process issues, e.g. what to do if a patient becomes distressed during a TCC session. Whenever possible new facilitators were paired with a more experienced facilitator for their first course. During each TCC all facilitators accessed two weekly half hour peer supervision sessions. In addition, one hour of external supervision was

provided after session 2 (by the first author).

4.3.4.2 Control condition: Individual low-intensity CBT (LI CBT)

The guided self-help interventions offered included cognitive and behavioural strategies; for example, behavioural activation, cognitive restructuring, sleep management, and problem-solving. Emphasis was on participant self-help, and participants were often given homework tasks to do between sessions (D. A. Richards & Borglin, 2011). There is debate as to whether such low-intensity interventions should be described as ‘CBT’ due to differences, such as the duration and adherence ratings used; however, given that the techniques used are CBT based, have a CBT rationale and a number of common components (e.g. setting homework) we have chosen to call these interventions ‘low-intensity’ CBT. These interventions differ from the TCC in a number of ways; for example, they comprise of traditional CBT techniques (such as cognitive restructuring) and treatment rationale is explained in terms of traditional CBT (such as thoughts, feeling, behaviour cycles) rather than control and goal conflict. Sessions were individual, lasted 30-minutes, and participants were generally offered six sessions.

Clinicians and treatment integrity. All clinicians were degree educated and had received further training to deliver low-intensity treatments. The same clinicians who delivered TCC also delivered individual low-intensity CBT (LI CBT), alongside additional members of the clinical team; clinicians delivering the LI CBT had a range of 0.5–31 years’ clinical experiences. All clinicians received at least 1.5-hours of weekly supervision. Supervision sessions included skill monitoring and development using audio recordings of sessions, and often last 2-hours. Additional supervision was provided regarding specific therapeutic skills; for example, fortnightly supervision is was available to specifically develop skills in CBT.

4.3.5 Design and power calculation

The design was a randomised single-blind two parallel group non-inferiority trial comparing TCC and LI CBT with outcomes of depression and anxiety measured at baseline, and 6 months⁵. Block randomisation was performed with a 1:1 allocation. The trial procedure and analyses were specified prior to recruitment commencement.

Power calculations for the primary hypothesis were based on a non-inferiority trial design comparing two groups, with equal numbers in each group. Sixty-three participants per group would have 80% power for a non-inferiority margin of 0.5 *SD* (Tamayo-Sarver, Albert, Tamayo-Sarver, & Cydulka, 2005) with a significance level of 0.025 (as non-inferiority analyses are one-tailed). To allow for attrition at 27%, we aimed to recruit 173 participants at baseline. This figure is an average of the attrition levels within a meta-analysis of individual CBT treatments by Hofmann and Smits (2008), two RCTs of group interventions by Allart-van Dam, Hosman, Hoogduin, and Schaap (2003) and Andersson et al. (2013) and a feasibility study of the TCC (L. Morris et al., 2015). However, the trial team took proactive measures to reduce attrition; for example, checking the best contact means for individual patients.

4.3.6 Statistical analysis

All primary analysis followed the intention-to-treat (ITT) principle. All analysis was performed using Stata version 13.1 (StataCorp, 2011).

The two primary outcome measures were the PHQ9 (depression) and GAD7 (anxiety). To test the primary hypothesis (that participants who were randomly

⁵ As mentioned in the methodology section, the full study also includes 12-month follow-up data. Six-month follow-up is the primary outcome point, and due to time constraints the (currently incomplete) 12-month follow-up data is not included in the thesis.

allocated to TCC would experience non-inferior reductions in separate anxiety and depression symptom scores) we used a mixed effects linear regression model accounting for potential clustering effects of the TCC group, treating the LI CBT as clusters of size 1. Bootstrapping was used where outcomes were non-normal (van der Leeden, Meijer, & Busing, 2008). These results were examined to establish whether treatment effect (and 95% confidence interval around the parameter) for the TCC differs by more than 0.5 *SD* (the non-inferiority value) from LI CBT. Non-inferiority is established if the upper limit of the confidence interval is within the non-inferiority margin, i.e. the upper confidence interval should be less than the non-inferiority margin value. It was pre-specified in the protocol that if non-inferiority was established then we would test whether TCC was superior to LI CBT (Piaggio et al., 2012); to account for this re-testing only p-values less than, or equal to, 0.01 were considered significant for these analyses. ITT analysis was also conducted on the WSAS and PSYCHLOPS.

Per-protocol (PP) analyses were conducted since ITT analysis may increase the risk of falsely claiming non-inferiority, and therefore it is recommended that both ITT and PP analyses be conducted (Piaggio et al., 2012). ITT analyses were conducted as primary because non-compliance and attendance are very likely in routine clinical practice, and such analysis reduces the risk of group and selection bias (Gupta, 2011). Further, the study was powered for ITT analyses and smaller sample sizes lead to wider confidence intervals. Participant data was included in the PP analysis if participants attended one or more sessions of the randomised treatment. It was anticipated that patients might only access one session of the TCC (and still benefit); see literature on early rapid gains and non-linear change in psychological therapies summarised in Morris et al. (2015). Further, in routine

clinical practice where LI CBT interventions are offered it is common that patients access a varied number of sessions (Glover et al., 2010; D. A. Richards & Borglin, 2011). PP analyses were conducted on each outcome using a mixed effects regression model accounting for potential clustering effects of the TCC group.

The number of participants who met criteria for clinically significant change (CSC) and reliable change (RC) were calculated (Jacobson & Truax, 1991). CSC requires that a person be above the cut-off pre-treatment (i.e. is in the clinical range), but below it at post-treatment (Jacobson, Roberts, Berns, & McGlinchey, 1999; Jacobson & Truax, 1991; D. A. Richards & Borglin, 2011). RC indicates whether the change in scores is greater than that which could be due to the inherent unreliability of the measure.

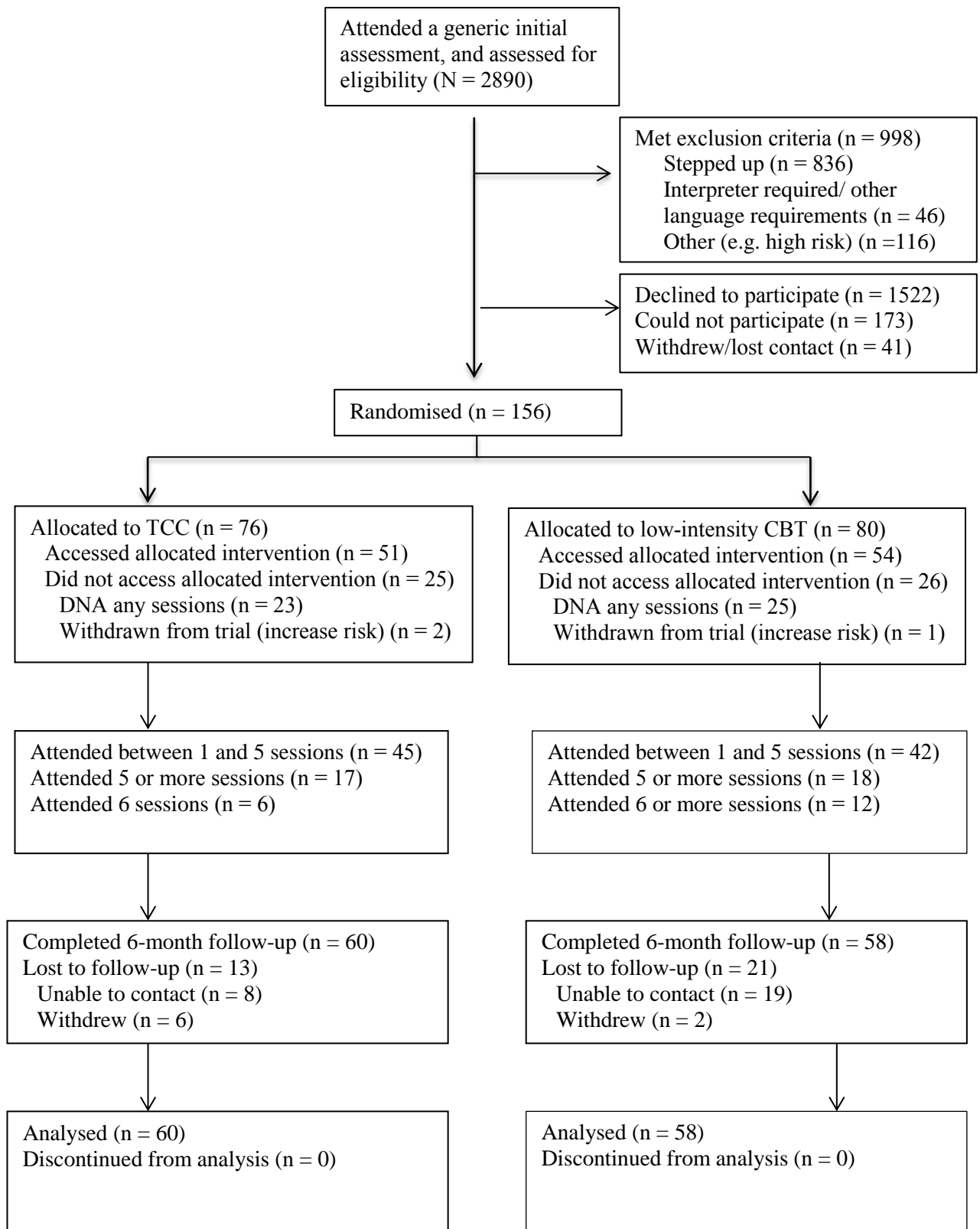


Figure 3: Flow of participants through the study.

4.4 Results

4.4.1 Patient flow and attrition

One thousand, eight hundred and ninety-two patients were consecutively asked if they wanted to participate in the project between July 2014 and October 2015. One hundred and ninety-seven agreed to participate; of these forty-one did not proceed to randomisation (deciding not to access the service 27%, being uncontactable 15%, changing their mind about participation 15%, and other reasons, such as moving out of the country). Some individuals could not take part (6%), e.g. the time of the groups was not convenient, and some did not want to take part (53%). Clinicians were encouraged to include a reason for why patients did not want to take part and the main reasons given were that patients did not want: to access a group, or the uncertainty of randomisation when they could directly access brief individual interventions. Figure 3 shows the CONSORT diagram.

Attrition from baseline to 6-month follow-up was 24%, but due to recruitment difficulties the study is slightly underpowered (119 PHQ9 and 118 GAD7 were available at 6-month follow-up, but the target was 126). The trial stopped recruitment as it had exceeded the specified end date and funding was only available for a specified time-period.

Table 3 reports attendance of intervention sessions for both treatment groups.

Table 3: Frequency of intervention sessions attended

Sessions attended	TCC (%)	LI CBT (%)
0	25 (32.9)	26 (32.5)
1	12 (15.8)	10 (12.5)
2	7 (9.2)	6 (7.5)
3	7 (9.2)	9 (11.3)
4	8 (10.5)	11 (13.8)
5	11 (14.5)	6 (7.5)
6	6 (7.9)	8 (10)
7	N/A	3 (3.8)
8	N/A	1 (1.3)

4.4.2 Participant characteristics and treatment credibility

Table 4 shows participant characteristics. See Appendix F for baseline and 6-month means for all outcome measures.

At baseline, participants rated LI CBT ($M = 13.38$, $SD = 3.07$) as significantly more credible than TCC ($M = 12.83$, $SD = 3.33$); $t(150) = 2.27$, $p = .03$, $d = 0.17$; although the effect size was very low. At 6-month follow-up, using the PP sample participants who were randomised to LI CBT ($n = 31$, $M = 12.90$, $SD = 4.63$) rated it as more credible than those who were randomised to TCC rated the TCC ($n = 37$, $M = 11.41$, $SD = 5.27$); $t(66) = -1.50$, $p = .22$, $d = 0.30$; although the comparison was not significant and effect size was again low.

Table 4: Sample characteristics

Variable	Total sample (<i>N</i> = 156)	TCC (<i>n</i> = 76)	LI CBT (<i>n</i> = 80)
Gender, no. female (%)	88 (43.6)	44 (57.9)	44 (55)
Age, <i>M</i> (<i>SD</i>)	41.2 (13.4)	41.5 (12.8)	41 (14.1)
Ethnicity, no. White British (%)	140 (89.7)	67 (88.2)	73 (91.3)
Employment status (%)			
Employed full or part time	74 (47.4)	42 (55.3)	32 (40)
Unemployed (or on sick leave)	54 (34.6)	22 (28.9)	32 (40)
Other	28 (17.9)	12 (15.8)	16 (20)
Taking psychiatric medication, Yes (%)	103 (66)	55 (72.4)	48 (60)
Number of randomised sessions accessed, <i>Mdn</i> (<i>IQR</i>)	2 (4)	2 (4)	2 (4)
Attended other therapy sessions ^a (%)	21 (13)	11 (15)	10 (13)
Baseline PHQ9 scores, <i>M</i> (<i>SD</i>)	14.2 (6)	13.8 (6.3)	14.7 (5.7)
Baseline GAD7 scores, <i>M</i> (<i>SD</i>)	12.9 (5.5)	12.4 (6)	13.3 (5)

Note. GAD7 = Generalised Anxiety Disorder Questionnaire; PHQ9 = Patient Health Questionnaire Depression Scale.

^a Other therapies accessed included Mindfulness Therapy and high-intensity CBT.

4.4.3 Primary outcome measures: ITT and PP analyses

Table 5 reports ITT and PP analysis of 6-month follow-up data. TCC was non-inferior to LI CBT on both the PHQ9 and the GAD7 using ITT analyses. It was

not possible to establish non-inferiority for both the PHQ9 and the GAD7 on the PP analysis, because the upper confidence intervals crossed the non-inferiority margin.

All the coefficients in Table 5 were in the negative direction, which indicates lower symptom scores at 6-months in the LI CBT controlling for baseline scores.

There was no evidence for superiority of either intervention from any of the analyses (all p values were non-significant) and the ITT analyses on the primary outcomes were powered to detect superiority.

Table 5: Results of ITT and PP regression analyses of 6-month follow-up data for primary outcome measures (PHQ9 and GAD7) and secondary outcome measures (WSAS and PSYCHLOPS).

Measure	Coefficient	Non-inferiority	95% CI		Z	P-value	Cohen's <i>d</i>
			Lower	Upper			
ITT analysis							
PHQ9 (<i>n</i> = 119) ^a	-0.94	2.99	-4.43	2.56	-0.53	0.40	-0.16
GAD7 (<i>n</i> = 118)	-0.40	2.75	-3.45	2.64	-0.26	0.80	-0.07
WSAS (<i>n</i> = 114)	-1.19	4.34	-6.31	3.92	-0.46	0.65	-0.14
PSYCHLOPS (<i>n</i> = 91)	-1.54	1.98	-4.76	1.67	-0.94	0.35	-0.39
PP analysis							
PHQ9 (<i>n</i> = 92)	-0.68	2.99	-4.66	3.31	-0.33	0.74	-0.11
GAD7 (<i>n</i> = 91)	-0.37	2.75	-4.51	3.78	-0.17	0.86	-0.07
WSAS (<i>n</i> = 88)	-0.97	4.34	-8.83	6.89	-0.24	0.81	-0.11
PSYCHLOPS (<i>n</i> = 74)	-1.04	1.98	-4.83	2.75	-0.54	0.59	-0.26

Note. GAD7 = Generalised Anxiety Disorder Questionnaire; PHQ9 = Patient Health Questionnaire Depression Scale; PSYCHLOPS = Psychological Outcome Profiles; WSAS = Work and Social Adjustment Scale.

^a All *n* given indicate the number of available observations at 6-month follow-up.

4.4.4 Secondary outcome measures: ITT and PP analyses

Table 5 reports ITT and PP analysis of the WSAS and PSYCHLOPs at 6-month follow-up. ITT analyses indicated that the TCC was non-inferior to LI CBT on both the WSAS and the PSYCHLOPs. It was not possible to establish non-

inferiority for both the WSAS and the PSYCHLOPS on the PP analysis, because the upper confidence intervals crossed the non-inferiority margin.

4.4.5 Clinically significant and reliable change

Using an ITT sample, details of those who experienced CSC, RC and recovery for each treatment are reported in Table 6. Baseline levels of those above the cut-off point on each measure are also reported because CSC and recovery can only be achieved if clients are above the cut-off point at baseline.

Table 6. Participants who experienced clinically significant change, reliable change and recovery in the ITT sample.

Measure	Treatment	Above cut-off (%)	CSC (%)	RC (%)	Recovered ^a (%)
PHQ	TCC (<i>n</i> = 76)	63 (83)	21 (28)	25 (33)	18 (24)
	<i>Missing data</i>		16 (21)	16 (21)	16 (21)
	LI CBT (<i>n</i> = 80)	67 (84)	20 (25)	29 (36)	19 (24)
	<i>Missing data</i>		21 (26)	21 (26)	21 (26)
GAD	TCC (<i>n</i> = 76)	59 (78)	17 (22)	23 (30)	15 (20)
	<i>Missing data</i>		16 (21)	16 (21)	16 (21)
	LI CBT (<i>n</i> = 80)	69 (86)	19 (24)	24 (30)	16 (20)
	<i>Missing data</i>		22 (28)	22 (28)	21 (26)

Note. GAD7 = Generalised Anxiety Disorder Questionnaire; PHQ9 = Patient Health

Questionnaire Depression Scale.

^a 'Recovered' entails that patients experienced both CSC and RC

4.5 Discussion

Using ITT analyses, the TCC was found to be non-inferior to individual low-intensity CBT on measures of anxiety and depression symptoms, and a measure of social and other functioning. It was not possible to establish non-inferiority for all outcomes using PP analyses, because the upper confidence intervals crossed the non-inferiority margins. However, this does not entail that TCC is inferior, because the confidence interval is broad and includes zero as well as the non-inferiority margin. The findings provide some support for the effectiveness of transdiagnostic interventions (Newby et al., 2015). Further, this study uniquely indicates that when using ITT analysis a brief group, addressing specifically transdiagnostic mechanisms, is non-inferior for patients with a broad range of common mental health problems within a ‘low-intensity’ primary care setting. It also has a number of strengths including single-blind assessments, pre-specified protocol, conservative non-inferiority margin, accounting for clustering by group within analyses and combining a RCT design with a naturalistic service setting.

4.5.1 Individual verses group therapy

There was no evidence for superiority of either treatment. However, PP analyses were unable to conclusively demonstrate the non-inferiority of TCC. A meta-analysis of CBT for depression indicates that individual therapy can be superior to group therapy with differences in effectiveness present post-treatment, but not at follow-up (Huntley, Araya, & Salisbury, 2012). Evidence is limited by risk of bias and small sample sizes. Comparative studies of patients with anxiety are even more limited, but indicate that an individual format may be more effective (Mayo-Wilson et al., 2014; Tucker & Oei, 2007). However, the current study did not offer optimal delivery of the TCC, which could have influenced results. Due to very

frequent staffing changes, the facilitator team regularly changed and it was generally not possible to arrange timings of the TCC around patient preference (e.g. only one evening course was run). Further, a qualitative study of TCC indicated that many patients strongly endorsed the group format compared to individual treatment, suggesting that it is important to offer patients a choice of modalities (Morris, 2016).

4.5.2 Are recovery levels comparable to other studies?

The percentage of participants who achieved recovery was similar across treatment groups. A RCT of computerised CBT for depression found comparable levels of recovery at 6-months on a depression measure (28.6%) to the current study (TCC 24%; LI CBT 24%) (De Graaf et al., 2009). Uncontrolled studies have found higher recovery rates (Burns, Kellett, & Donohoe, 2016; Delgadillo, McMillan, Leach, et al., 2014; D. A. Richards & Borglin, 2011); including an evaluation of the Stress Control course, which has been found to reduce symptoms of anxiety and depression (e.g. Burns et al., 2016). However, these differ in design, recovery was calculated post-treatment so the duration since initial assessment is not clear and some studies conflate low- and high-intensity CBT interventions. In support of the possible effect of design, a further RCT of computerised CBT for depression found 23% recovery (D. Richards et al., 2015), while a previous cohort study comparing TCC to individual low-intensity CBT found a 44% recovery for either depression or anxiety scores in TCC treatment (27% on depression measure; Morris, 2013).

4.5.3 The effect of number of sessions attended

The relatively low average number of sessions attended (two) across both treatments could also have influenced outcomes. Although attrition levels can be high in similar service contexts (Glover et al., 2010), studies have indicated that attending more sessions can result in better outcomes (Burns et al., 2016; Delgadillo,

McMillan, Lucock, et al., 2014). However, research also indicates that early improvements are associated with recovery (Delgadillo, McMillan, Lucock, et al., 2014) and that sudden gains can account for significant amount of patients' improvement (e.g. 50% in Tang & DeRubeis, 1999) (Aderka et al., 2012). In conjunction with high attrition levels in many primary care studies, it seems possible that patients only access treatment until they have achieved a personally 'good enough' level of change and this could be early in treatment (Barkham et al., 2006). Therefore, the TCC recognises the variation in attendance by offering 'stand-alone' sessions (L. Morris et al., 2015). But it is also recognised that non-attendance would be for a variety of reasons (e.g. high socio-economic deprivation is commonly associated with attrition) (O'Brien, Fahmy, & Singh, 2009), and so the message given to patients remains 'attend if you can'.

4.5.4 Credibility of groups

Individual low-intensity CBT was found to be more credible than TCC prior to treatment. The effect was low, but qualitative data from participants who accessed TCC indicated that patients could have significant concerns regarding group interventions (Morris, 2016). Such concerns did not appear specific to TCC, as they focused upon fears of significant self-disclosure and being with other people. These findings suggest that how groups are introduced is important in allaying fears. For example, within the TCC no self-disclosure is required, it can be more accurately described as a 'course' rather than 'group' format, and the concept of control can be used to explain the overall rationale for the course.

4.5.5 Limitations and future research

In addition to the limitation previously described regarding the non-optimal delivery of TCC, the study had a number of limitations. A key limitation is that

participants were not formally diagnosed. Lack of diagnostic certainty is common within primary care contexts, because accuracy of initial diagnosis by GPs is variable (Mitchell, Vaze, & Rao, 2009). Further, in the UK, few clinicians within primary care psychological services are trained to conduct diagnostic interviews (D. A. Richards et al., 2012). Therefore, limited diagnostic information increases ecological validity, but limits ability to predict the response of those with specific disorders.

Another limit is that the study only recruited from one service and so it is unclear how results would generalise to a population with a different demographic profile. Attrition levels and recruitment difficulties meant the study was slightly underpowered and this is a particular issue for the PP analyses as this necessitated inclusion of a sub-sample; however, sample size for ITT analyses was approximately double that of previous non-inferiority trials comparing transdiagnostic groups to established treatments (Norton, 2012; Norton & Barrera, 2012). PP analysis was also limited by relatively low attendance of treatment sessions across both treatment groups; this is likely to reflect the level of socio-economic deprivation within the recruitment area (O'Brien, Fahmy, & Singh, 2009; L. Morris et al., 2015). Ideally non-inferiority analyses consider findings from both PP and ITT analysis, because it is currently unclear whether ITT analysis increases the chances of concluding non-inferiority as compared to PP analysis (Piaggio et al., 2012). A review concluded that ITT analysis does not lead to an increased chance of concluding non-inferiority (Brittain & Lin, 2005) and given the general statistical issues with PP analysis (Sedgwick, 2015), the ITT analysis within the current study is considered to provide more robust effectiveness data (i.e. data regarding the effectiveness of TCC in a non-ideal, 'real-life' clinical context) (Sedgwick, 2014). All the limits described could be

addressed by a larger trial, which included greater clinician availability, formal diagnoses and multiple sites.

The TCC was deliberately compared with individual low-intensity CBT, as this is the established treatment. However, this entails that there will be differences in format that could influence outcomes. For example, the two treatments differed in the maximum amount of clinician time offered. Maximum attendance time for TCC was 6-hours 15minutes; for individual CBT this was 3-hours (where patients attended the recommended 6-sessions, or up to 4-hours for the 5% who attended over 6-sessions). Clearly this would also be mediated by the ratio of patients to clinician; generally in the TCC there will be more patients per clinician.

Transdiagnostic groups offer a pragmatic response to the prevalence and co-morbidity of common mental health problems, such as greater ease of populating group interventions than recruiting those with a specific disorder (Norton & Barrera, 2012). Furthermore, groups can offer greater cost-effectiveness than individual therapies (Tucker & Oei, 2007). Therefore, cost-effectiveness data on TCC would be useful to add to data regarding service delivery advantages of transdiagnostic groups.

4.5.6 The effectiveness of transdiagnostic groups for common mental health problems

In conclusion, the findings of this non-inferiority RCT provide support for a brief transdiagnostic group as an effective treatment for common mental health problems. However, non-inferiority was only conclusively established using ITT analyses. Findings add to the extant literature by providing the first evidence for the non-inferiority of a brief transdiagnostic group compared to established individual therapy.

CHAPTER 5: Experiences of a transdiagnostic group, the Take Control Course, for clients with common mental health problems: a qualitative study

PREFACE

The paper has been submitted to 'Journal of Clinical Psychology' and it has been prepared in accordance with their requirements. The authors will be: Dr Lydia Morris, Dr Warren Mansell, Rebekah Amos and Dr Dawn Edge

Dr Warren Mansell, Professor Richard Emsley, Professor Karina Lovell and Dr Dawn Edge were the academic supervisory team for the PhD. Dr Warren Mansell and Dr Dawn Edge were the primary supervisors for this aspect of the PhD and provided feedback on the thesis version of this paper. Rebekah Amos was a Masters student who supported qualitative data collection for both treatment groups. However, her primary role was to collect and analyse qualitative data regarding individual low-intensity CBT and this was reported in her thesis

5.1 Abstract

Objectives: Despite the promising effectiveness findings for transdiagnostic groups, studies have not explored clients' experiences. Our aims were to examine whether a brief transdiagnostic group, the Take Control Course (TCC), was acceptable to participants, and to explore participants' perceptions of psychological change.

Methods: Qualitative data were collected via 12 semi-structured, in-depth interviews. Data collection and thematic analysis were concurrent and iterative.

Results: Four superordinate themes were identified: 'Hopes and Fears', 'Style and Format', 'Control', and 'Change'. The flexible group format was appreciated, as participants felt able to engage at their own pace and adapt relevant aspects. Greater clarity regarding what was within participants' control reduced distress and enabled effective pursuit of valued goals.

Conclusions: The transdiagnostic format did not prevent participants experiencing the TCC as individually relevant. The flexibility and consistent theoretical framework seemed to contribute to this. Implications for group therapy include providing flexible delivery where possible.

5.2 Introduction

Common mental health problems, such as anxiety and depression, are often treated exclusively in primary care settings (Aillon et al., 2014). Due to high prevalence, cost-effective psychological therapies are required that can meet such demand (D. A. Richards, 2010). One response has been offering psychological interventions in varied modalities, such as bibliotherapy, computerised and group therapy (e.g. Knowles et al., 2014; Lewis, Pearce, & Bisson, 2012). An example of this is the Improving Access to Psychological Therapies (IAPT) programme in the UK. IAPT follows a stepped care model whereby the ‘least restrictive’ treatment option is offered while still providing a treatment that is likely to lead to significant improvement (Bower & Gilbody, 2005). According to this model, clients with common mental health problems will often be offered brief interventions delivered using varied modalities; described as ‘low-intensity interventions’ (Bennett-Levy et al., 2010). There have been concerns regarding whether low-intensity interventions are acceptable to clients (Chambers, Haim, Mullican, & Stirratt, 2013; Sanders et al., 2012).

Transdiagnostic interventions have also been proposed to contribute to more effective service delivery; for example, by addressing multiple and co-morbid problems (Andersson & Titov, 2014). They target cognitive and behavioural maintenance processes shown to maintain distress across disorders (Mansell et al., 2009). A meta-analytic review of transdiagnostic interventions for anxiety and depressive disorders found large post-treatment reductions in both anxiety and depression symptoms, which were maintained at follow-up (Newby et al., 2015). However, there has been limited qualitative research into transdiagnostic groups. There are a number of qualitative studies of

mindfulness-based interventions, which can be offered in a transdiagnostic format (Newby et al., 2015). But the majority of these qualitative studies focus on disorder-specific groups or clients with severe physical health problems (Malpass et al., 2012), and therefore it is unclear if they generalise to transdiagnostic psychological health samples.

Qualitative studies of ‘low-intensity’ computerised therapy (Knowles et al., 2014) and self-help interventions (Khan, Bower, & Rogers, 2007) indicate that client experiences can be negative. Findings include clients feeling that not enough time was spent discussing their specific problems, and that interventions were not sufficiently tailored to them (Khan et al., 2007; Macdonald, Mead, Bower, Richards, & Lovell, 2007). Positive experiences were also described, such as feeling empowered (Khan et al., 2007; Knowles et al., 2014). A key example of low-intensity groups is the CBT-based Stress Control course for Generalised Anxiety Disorder (White, Keenan, & Brooks, 1992), as recently it has been suggested that this course is transdiagnostic because it works on negative affect (Barlow, Allen, & Choate, 2004; White, 2010). Average satisfaction ratings are high for both Stress Control (Burns et al., 2016) and Take Control Course (TCC; L. Morris et al., 2015), but detailed qualitative understandings of participants’ positive (and negative) experiences are lacking. Therefore, examining acceptability remains important in establishing whether low-intensity and transdiagnostic groups meet the needs of the target population (Ayala & Elder, 2011).

The current qualitative study reports interview data from participants who accessed a brief (6-session, with average session length of 1-hour) transdiagnostic group: the Take Control Course (TCC). The study aims were to examine: a) participants' experience of the course, such as their experience of the modality and

the length of the intervention; b) participants' perceptions of psychological change and which elements of TCC contributed to this. The first research aim reflects the concerns already detailed regarding the acceptability of low-intensity interventions. The second research aim responds to the current lack of qualitative data regarding psychological change processes within transdiagnostic groups. We now turn to the scientific background for this aim.

Despite its transdiagnostic group format, the TCC is adaptive to the particular needs of individual clients. Weekly feedback is collected to facilitate adaptation. The core content of each session is prescribed, but certain techniques re-occur so that subsequent implementation of techniques can be adapted in accordance with feedback. Further, within the majority of sessions, there are optional components that can be delivered if these are of interest to clients and time allows; this also allows flexibility where discussion is proving valuable. Given that the TCC is not diagnosis-specific, it is important to establish whether clients perceive that content is tailored to them.

The TCC is derived from the principles of Perceptual Control Theory (PCT; Powers, 1973). PCT proposes that control is central to well-being (W. T. Powers, 1973). To implement control, current perception is constantly compared to internal references, and actions occur to minimise discrepancies from these references (W. T. Powers, 1973). When important perceptions are not sufficiently close to their desired internal reference, then this is described as 'loss of control' (L. Morris et al., 2016) and can entail psychopathology if control is not restored (Alsawy et al., 2014). Therefore, the TCC focuses on enabling participants to understand the process of control.

PCT also specifies that internal references are arranged hierarchically with

the higher-levels setting the reference values for lower-levels (W. T. Powers, 1973). For example, the higher-level reference ‘be a good friend’, sets the reference ‘keep in regular contact’, which could lead to actions such as texting friends, meeting regularly, etc. Higher-level references often represent longer-term goals and values. Conflict between higher-level references particularly entails loss of control and psychopathology (Alsawy et al., 2014). Awareness of the higher-level conflict is required to regain control. Therefore, the TCC focuses on enabling “awareness of valued higher-level goals (and reasons for change); and awareness of higher-level goal conflict” (Morris et al., 2016, p. 8). TCC specifically targets PCT change mechanisms and therefore it is expected that this would be reflected in participants’ accounts. However, PCT specifies mechanisms of psychopathology and change that are common across disorders and so other therapies are likely to also address these processes to varying degrees (L. Morris et al., 2016).

5.3 Methods

5.3.1 Study context

This exploratory, qualitative study was embedded within a 12-month randomised parallel group trial to establish whether the Take Control Course was non-inferior to individual low-intensity CBT. The study was approved by the North West-Greater Manchester East Research Ethics Committee (Reference number: 14/NW/0160).

5.3.2 Setting

All participants were recruited from Salford (North West of England). Ranked among the 10% most deprived local authority areas in England (Department of Communities and Local Government, 2011), 92% of Salford’s population are of

White ethnicity (Office for National Statistics, 2011).

5.3.3 Participants

Recruitment to the trial was from Salford Six Degrees Social Enterprise⁶. Adults aged 16 and above who were suitable for low-intensity services were recruited. This included individuals with mild-moderate depression and anxiety that emerged within the 12 months prior to referral. However, other mild-moderate problems are addressed within this service context and clinical decision making is according to stepped care models. Other factors that were considered included level of suicidality and the extent to which problems impaired functioning. Sufficient English language skills to understand TCC materials were also required (i.e. the verbal and written language abilities required to read and complete simple worksheets and understand verbal presentations).

Participants' demographic and psychiatric characteristics are reported in Table 7, and are comparable to the overall RCT sample (e.g. average age is the same, both male and female participants are represented in the current sample). Table 8 provides similar characteristics for individual participants. Pseudonyms are used to maintain confidentiality. Specific ages of participants are not detailed to further protect confidentiality and because age had no noticeable influence on the results. Participants' pre-treatment anxiety and depression scores ranged from mild to severe (see Table 7 for severity levels). Participants engaged in one of eight different TCCs and had a range of different levels of improvement at time of interview. Although the entire sample was White, this is representative of the 95% of White participants who accessed the TCC. The average number of sessions attended was higher in the

⁶ Formally the Primary Care Mental Health Team, Six Degrees are the main provider of low-intensity IAPT services in Salford. Their website is: <http://six-degrees.org.uk/six-degrees-help-at-hand/>

current sample ($M = 4.8$) than the RCT sample ($M = 2.2$). Participants who accessed 1-2 sessions were given every opportunity to participate, but all declined. Reasons for non-participation varied, but being “too busy” was most frequently cited.

Table 7: Participants’ demographic and psychiatric characteristics

Variable	Demographic characteristics	
Female, no. female (%)	7 (58.3)	
Ethnicity, no. White British or Irish (%)	12 (100)	
Age, M (SD)	41.5 (14.1)	
Average number of sessions attended, M (SD)	4.8 (1.1)	
	Baseline (prior to TCC)	6-mth follow-up
PHQ9 scores, M (SD)	13 (6.6)	9.7 (9.1)
GAD7 scores, M (SD)	12 (5.4)	8.1 (6.7)

Note. PHQ9 = Patient Health Questionnaire Depression Scale; GAD7 = Generalised Anxiety Disorder Questionnaire

5.3.4 Interview schedule and data collection

Interviews were conducted within GP practices and health centres in Salford. Data were collected by a Masters student and Doctoral student (first author) using a semi-structured interview schedule (Appendix C). The interview schedule was developed based on previous qualitative research with similar aims (e.g. Finucane & Mercer, 2006) and through discussions within the research team. The interview schedule was piloted opportunistically; volunteers who had received a therapeutic intervention in the past gave feedback on the wording and relevance of questions.

Based on feedback from pilot interviews and liaison with the research team, the interview schedule was amended and a final version was developed. Changes made in response to pilot interviews included: changing the structure of the interview schedule to make it easier for researchers to cover all relevant themes, and changing question wording and adding additional prompts (especially where questions could have been answered yes/no, or did not result in relevant answers from volunteers). Interviews ranging between 30 and 60 minutes were conducted and were digitally-recorded. In addition to the questions on the interview schedule, interviewers asked probe questions, which were integral to the interview schedule. These were designed to encourage participants to elaborate on comments and to obtain more details regarding their experience of TCC and perceptions of its impact.

Interviews were conducted shortly after 6-month follow-up wherever possible (average time since follow-up was 39 days)⁷. Participants were interviewed at this time to provide an indication of whether techniques and understandings were used to maintain change after the sessions had finished.

Interviews were conducted until saturation of themes occurred (Guest, Bunce, & Johnson, 2006). Saturation is defined in terms of “the point in data collection and analysis when new information produces little or no change to the codebook” (Guest et al., 2006, p. 65). Data collection and analysis were concurrent and iterative thereby enabling evaluation of whether saturation has been reached (Tuckett, 2004).

⁷ Included in this is one client that was un-contactable at 6-month follow-up, and for this client the measures were taken on the day of their qualitative appointment (9-months after baseline appointment).

Table 8: Individual participants' demographic characteristics and presenting problems

Name (pseudonym)	Gender	Number sessions	PHQ9 scores ^a		GAD7 scores ^a		Presenting problem (Identified by clients prior to therapy)	Individual therapy
			Pre	6-mth	Pre	6-mth		
Sarah	F	3	22 (Severe)	27 (Severe)	19 (Severe)	18 (Severe)	Problems with Mum's health issue and myself feeling depressed and unwell.	Yes (previous)
James	M	5	4 (Sub- clinical)	3 (Sub- clinical)	7 (Mild)	3 (Sub- clinical)	Wanting to go places (holiday) but unable due to anxiety. Expressing feelings to people.	Yes (previous)
Robert	M	3	8 (Mild)	5 (Mild)	12 (Moderate)	10 (Moderate)	Anxiety/Physiological problems deriving from stress. Inability to switch off mentally/concern regarding how others view me.	Yes (previous)
Laura	F	6	20 (Severe)	17 (Moderate- severe)	20 (Severe)	21 (Severe)	Too many tasks, too little time. Lack of support, I help everyone else; they are reluctant to help me.	No previous therapy disclosed

John	M	6	12 (Moderate)	10 (Moderate)	8 (Mild)	4 (Sub- clinical)	Workplace colleague. Having enough work for shop floor.	No
Claire	F	5	10 (Moderate)	6 (Mild)	11 (Moderate)	4 (Sub- clinical)	Menopause. Work: upcoming department restructure.	No
Rachel	F	4	13 (Moderate)	2 (Sub- clinical)	15 (Severe)	4 (Sub- clinical)	Anxiety due to problems with social workers and social services (children taken away). Multiple bereavements.	Yes (previous)
Mike	M	6	25 (Severe)	25 (Severe)	16 (Severe)	15 (Severe)	Depression. Anxiety.	Yes (previous)
Anna	F	5	11 (Moderate)	2 (Sub- clinical)	4 (Sub- clinical)	2 (Sub- clinical)	Unemployed. Feel like a failure due to not being employed.	No
Catherine	F	6	6 (Mild)	14 (Moderate)	5 (Mild)	11 (Moderate)	Relationships with family and friends. Relationship with partner.	Yes (previous)
Christina	F	5	8	2	10	2	Difficulty making friends and family	Yes

			(Mild)	(Sub-clinical)	(Moderate)	(Sub-clinical)	relationships. Anxiety.	(previous)
Dave	M	4	17	3	17	3	Constant worry and overthinking.	Yes
			(Moderate-severe)	(Sub-clinical)	(Severe)	(Sub-clinical)	Feeling as though there is something wrong with me.	(subsequent)

Note. PHQ9 = Patient Health Questionnaire Depression Scale; GAD7 = Generalised Anxiety Disorder Questionnaire

^a The PHQ9 and GAD7 can be used to determine the likely severity levels of depression and anxiety (D. A. Richards & Suckling, 2009). For the PHQ9 these are: not depressed 0–4; mild 5–9; moderate 10–14; moderate-severe 15–19; severe 20–27. For the GAD7 these are: 0–4; mild 5–9; moderate 10–14; severe 15–21 (Richards & Suckling, 2009).

5.3.5 Analytical strategy and procedure

Analysis followed Braun and Clarke's (2006) six-phase approach to Thematic Analysis within a critical realist framework (Creswell, 2009). See Table 9 for details.

Thematic Analysis was conducted by the first author and is described in some detail to provide evidence of the trustworthiness of the study; specifically, the credibility (internal validity) and dependability (reliability) of findings (Shenton, 2004). Methods of establishing reliability and validity used within quantitative research are often not applicable to qualitative data (Creswell, 2009). However, measures can be taken to establish the credibility and dependability of qualitative data (Shenton, 2004). Peer verification, regular debriefing, and member-checking were used to enhance trustworthiness and confirmability. Member-checking confirmed that the themes identified were congruent with participants' experiences (Carlson, 2010). A key informants approach (Onwuegbuzie & Leech, 2007) was used so that feedback could be obtained from participants who gave both positive and critical feedback, and who had a range of improvements in presenting problems.⁸

Criticisms have been made of member checking, such as that themes are abstracted and therefore may not be easily recognisable as participants experience and that participants may have changed their mind since they were interviewed (Angen, 2000; Morse, Barrett, Mayan, Olson, & Spiers, 2002). Further, for non-realist frameworks it is argued that qualitative accounts cannot capture a truth that

⁸ Although there were a range of participant experience represented, there were slightly more people who felt they had benefitted from the course. This was representative of the sample as a whole. However, attempts were made to invite additional participants who provided critical feedback or described not being sure that the course was beneficial to them.

can then be verified with participants (Angen, 2000). However, it is argued that what is being established during member checking is whether participants believe that the themes sufficiently represent their experience. It is suggested that whether participants feel the research represents their experience is of considerable importance because: a) their words and general experience is what is being captured within the research; b) the account is created within an ongoing ‘dialogue’ between participant interviews and researcher interpretations and so if participants have changed their minds this is useful information to capture, and c) in the case of intervention studies, such as this one, the intervention needs to be of relevance to potential clients and so it is helpful if experiential accounts are of relevance to actual clients (Cho & Trent, 2006).

Reflexivity in relation to the researchers’ background experiences and perspectives is useful in order to consider the potential influence of these on interpretation of the data (Carlson, 2010). The first author has greater experience of working within some conceptual frameworks, such as Cognitive Behavioural theories and PCT, and is a Clinical Psychologist. The first and second authors are both involved in research into PCT and developing interventions based on PCT. Both authors therefore have a particular interest in this theory. The first author is a practicing Buddhist and has specifically trained in mindfulness-based interventions.

Table 9: Braun and Clarke’s (2006) six-phase approach to thematic analysis; including detail of how this was implemented and by whom.

Phases	Application of the phases within this study
1. Becoming familiar with the data	The first author conducted the majority of interviews and transcribed the data. Transcripts were repeatedly read, and particular attention was paid to re-reading transcripts of interviews that the first author had not conducted.
2. Generating initial codes	The first author coded the data in a systematic fashion across the entire dataset. All interview data that related to the TCC were coded.
3. Searching for themes	Data were coded using NVivo 10 (QSR International's NVivo 10 Software, 2014) to support data management. All significant patterns in the data were noted and initial table of second-order codes and quotes created. Throughout this and subsequent stages, findings were reviewed for coherence and credibility by Dr Edge and Dr Mansell and the raw data regularly referred to.
4. Reviewing themes	From the initial table of significant second-order codes and discussions with Dr Edge and Dr Mansell, candidate themes were identified. These were then refined by referring back to data and codes, and by creating a detailed thematic map. Candidate themes were examined to establish whether they were coherent, externally heterogeneous, and had explanatory power.
5. Defining and	Through examination of the detailed thematic map and further discussions a more parsimonious list of themes

naming themes were created. These were refined through peer debriefing and verification with Dr Noke, and through a member-checking group. Dr Noke is a qualitative researcher who was not involved in the study team or PCT research.

6. Producing the report
The report was drafted and feedback obtained from Dr Edge and Dr Mansell.

5.3.6 Intervention

A number of techniques and understandings are introduced within the TCC; two of which are detailed here to exemplify how the processes described in the introduction are targeted. One of these is a goal-focused exposure exercise that involves imaginal exposure to an uncomfortable experience (e.g. social situation, feeling of failure), but not one that will be extremely uncomfortable (Carryer & Greenberg, 2010). In initial sessions, participants are strongly encouraged to choose the mildest experience. The way in which this exercise is framed is in the context of meeting important goals in order to promote awareness of goal-conflict. Another technique, which is usually delivered prior to the goal-focused exposure, is brief awareness (including mindfulness meditation). According to PCT, a key reason for using awareness/mindfulness techniques is to develop present moment awareness that can be brought to bear on conflicted goals. Use of such techniques can also support clients to sustain attention on problematic experiences indicative of goal conflict (e.g. during imaginal goal-focused exposure) (Morris et al., 2016).

5.4 Results

Four superordinate themes: ‘Hope and Fears’, ‘Style and Format’, ‘Control’ and ‘Change’, and 13 subordinate themes were identified (See Table 10). These are described in detail below.

Table 10: Superordinate and subordinate themes.

Superordinate theme	Subordinate themes
Hopes and fears	
Style and format	Flexibility, informality and an ‘at ease’ environment Identifying with other attendees Better than one-to-one ‘An hour was spot on’
Control	There are things I can and can’t control Pursuing what really matters ‘Letting go’ of unhelpful responses Facing uncomfortable experiences
Change	Pace of change Practice, integration and consolidation Improved relationships

5.4.1 Hopes and fears

Participants expressed a range of hopes and fears about participating in the TCC. Apprehensions did not appear to affect participants’ ability to benefit, as long as they remained somewhat open to trying the course for a couple of sessions.

Five participants did not express apprehensions, but rather hoped to gain suggestions or strategies to help them manage presenting problems:

“Ways to work round my anxiety a bit and manage it a bit was what I was hoping for.” (Christina)

Five participants identified concerns prior to the TCC. These focused upon apprehensions about public speaking, self-disclosure, and even just being with other people:

“You get told, told that you’re put in a group thing. For a start that rattles you.... when you’ve become so self-contained then by that point and you don’t really want to see anyone.” (John)

Participants expressed specific concerns that the TCC would rely heavily on self-disclosure, such as an Alcoholics Anonymous (AA) group. However, in this regard, both participants who had minor concerns and those with more significant apprehensions generally described that the course exceeded their expectations:

“I didn’t have much hope for it really, cause you have this stigma that you’re all going to be sat in a circle relaying everything, telling all your business. So I was delighted it wasn’t like that.” (Catherine)

It seemed that concerns did not affect participants’ experience as long as they maintained an openness to engage with the material.

“And again the first time I did that [*awareness exercise*] I was thinking, ‘what the hell is going on here?’...but if you allow yourself to go along with it... If you stick along with the Course and just try to stay open with it, certain things work, certain things won’t.” (John)

5.4.2 Style and format

There were a number of aspects of the style and format of the TCC that participants identified as helpful. Participants particularly appreciated the flexibility and 1-hour session length.

Flexibility, informality and an ‘at ease’ environment. The TCC and the facilitators offer a range of strategies and encourage participants to ‘take what is helpful for them’. In addition, the content of the group is adapted around the participants’ needs. Most participants valued this.

“The way it was delivered I think was my favourite part. That we talked about maybe a problem and couple of different ways to deal with it. That’s what really stood out for me was if you didn’t really like one bit, then there was a couple of other options.” (Christina)

Five participants described appreciating the informality of the course. The flexibility seemed to contribute to this as they described finding the focus less intense as “there’s no pressure” as “in a group the spotlights moves around” (Rachel).

“It was very informal, it wasn’t kind of like some AA meeting where you stand up and you’re forced to talk and give your story or anything.” (Anna)

Further, the flexible style was described by some as providing permission for them to become more flexible and to adapt what they learnt to their lives.

“I’ve learnt to integrate the things that we’ve learnt into my life more. Umm, not necessarily exactly how they done on the course but I did feel like that was OK, that it was. Because sometimes you feel, this is the way to do it, don’t do it that way you’re doing it wrong, where as it didn’t feel like, it felt

like take a little bit of anything that you want and if it works for you great.”

(Christina)

Although not all participants made this explicit link, a number described adapting ‘techniques’ in order to apply these more directly to themselves.

“There was a lady there who said that the train thing helped her⁹. Well that didn’t work for me, thinking let them [*thoughts*] pass me by. I had to tell myself ‘no, stop thinking about that now. That was then, this is now.’”

(Catherine)

However, there were two participants (John and Laura) who had reservations about the flexible style and their comments suggested that they would have preferred something more directive. Both accessed the same TCC.

John: There was a lovely lady there, but it just seemed very softly presented.

Interviewer: Hmm, when you say “softly presented”, like it didn’t quite hit home, or?

John: Like, I think it just needed a little bit more telling to the people.

Both participants recognised that the flexible style might have been due to the necessity of accommodating different people:

“That’s the thing though, you’ve got be so careful for everybody’s

individually in a different place.... So you can understand, you’ve got to aim

⁹ The train metaphor is used to exemplify ways of responding to thoughts (and other experiences). The suggestion is that participants can let thoughts pass them by, like train carriages passing through a station. Catherine describes a more proactive attitude to her thoughts, she consciously tells herself to stop thinking these thoughts rather than just letting them pass.

it at everybody and probably by opening it on the softer one, that's what they're trying to do." (John)

Identifying with other attendees. The majority of participants identified that they had benefitted from being with others: feeling able to share without being judged, 'normalisation' of their experience, and hearing the perspectives of others.

"So I thought, 'I'm not going crazy here, that's good'. There are other people who- for various reasons- are going through the same things." (Anna)

However, participants also identified that it was really important that they did not feel "pushed" to share and could do so at their own pace.

"It was helpful cause it wasn't, it wasn't, intrusive.... You didn't have to elaborate on any of your issues really it was just the techniques. Even then you could just say that they were helping... you didn't need to elaborate."
(Catherine)

Better than one-to-one. All participants had accessed at least two individual assessment sessions. Eight of the twelve had accessed individual therapy prior to the qualitative interview. Six participants expressed they preferred the group format and felt that they had made more progress in the group than they would have done in one-to-one.

"Yeah, I don't think that would have benefitted [*from one-to-one*]. It was really nice having other people chip in, not feeling like you had to speak.... Almost have that time to sit there and assess how you feel about it, and for it

to work on you, instead of it being forced out of you, which one-to-one by definition does.” (Anna)

Where they were able to identify a reason for this, they attributed it to aspects of the style of the TCC described in previous themes; for example, that the group felt less formal than individual therapy, and they were able to pace their disclosure and learn from others.

“I think for me, cause of the way of me, being shy and everything. Being in the group it’s more like other people can do the talking and I can take in stuff about what they might have gone through, and how things are helping them as well.” (Mike)

Whilst there was strong support for a group approach, there were two participants who preferred individual therapy; this was generally attributed to the format but also to the nature of the problems that they wanted to work on.

“ I think it was just because I felt it [*one-to-one*] was a bit more personal.”
(Dave)

“And I do think, maybe there is great value for me in a one-to-one environment rather than the group session, not to undermine anyone else's issues, but because of that specific thing that I could see that their issues- I think- were rooted to a specific event that occurred recently.” (Robert)

‘An hour was spot on’. Generally participants liked the hour-long session length. Not all participants gave reasons for this, but those who did said that they

felt an hour enabled them to “work your day around it” and was particularly convenient. Further, it was felt that it would be difficult to concentrate for longer.

The one person who would have liked longer sessions felt that they would have preferred about an extra half-hour. “Just to maybe give the tutors the time to explain what each thing’s about and how it’s meant to work.” (John)

Mostly participants found 6-sessions were enough, although there were three people who would have preferred more sessions (Laura, Anna and Christina). The reasons for this varied including experiencing significant life events during the course and so feeling more support was required, wanting to “hammer home” what had been learnt and to continue the beneficial experience of accessing the course.

5.4.3 Control

An increased understanding of control was a notable feature of nearly all participants’ accounts, and enabled clarification of the things in their lives they could change to meet their goals. Mindfulness was a key tool in enabling them to pursue important goals and manage unhelpful responses more effectively.

There are things I can and can’t control. This understanding was described as helpful by seven participants, and seemed to enable participants to target the things they could control in order to meet their goals. It also seemed to support the majority to ‘let go’ of dwelling on concerns that they could not control.

“Yeah, and I think, going back to when I was thinking about worrying things, I’d think why do I need to worry about that, what can I do about that. Some things you can’t do anything about.” (Claire)

However, there were a few participants who described not being able to ‘let go’ of concerns that they were unable to control. In other words, they did not experience acceptance of this:

“I couldn't say right I’m gonna take control of this, I’m not gonna worry.... I couldn't because when I came out of there my problems were still there.”

(Sarah)

All of these participants described experiencing major life events or significant on-going problems during the TCC; for example, a chronic physical health problem, or being fired from work.

Pursuing what really matters. Nine participants described increased clarity regarding what was really important to them, and an increased perspective on how they could pursue this. This included understanding what areas of their life they could influence (control) to achieve important goals.

“I mean you said then, was it session 3, about (I: long-term goals) umm well, I’d keep doing negative things and I was expecting a different outcome and that’s a waste of time.... And I realised I needed to stop.” (Catherine)

This ability to pursue what mattered to them was reflected in a significant perspective change in some. This could entail both identifying whether a concern or preoccupation was really important, and identifying what could be done to meet important goals.

“Like I say, that upward arrow thing¹⁰, that was just brilliant and the day she went like that, ‘it doesn’t matter’. I just thought, ‘why am I writing this?’ It’s the same thing every week and you’re right on the grand scale of things this doesn’t matter.” (John)

“Umm I think mainly it was being able to break everything down and not having to focus on controlling the bigger picture when you can focus on the smaller parts first, then build it up.” (Rachel)

‘Letting go’ of unhelpful responses. Participants generally used mindfulness to increase their awareness in their day-to-day lives so that they could identify when they were getting into responses that did not help them meet important goals and interrupt these.

“So I could then start to identify when I was getting into this negative thinking so I’d have to... ‘reign myself in really’”. (Catherine)

As well as giving participants a ‘tool’ to enable them to interrupt unhelpful responses, six participants specifically described using mindfulness to work more effectively with difficult experiences. Interestingly, very few participants described still using formal awareness (meditation) practices. This is likely to reflect the emphasis within the TCC on using mindfulness to process and respond to difficult

¹⁰ The ‘upward arrow’ technique physically resembles the downward arrow technique used within CBT (apart from the arrows are progressing upwards instead of downwards). However, the questions fundamentally differ, and therefore the end point is clarifying the goals that are most important to the client. The questions used are: Why is ‘X reason/goal’ important to me, *or why does it help?* (the ‘why is it important question’ is usually more useful but occasionally it makes more sense to ask ‘why it helped’).

experiences. However, it is interesting to consider whether participants would have found it even easier to helpfully respond if they had carried on doing brief meditation practices.

“I mean today a song played at work, and 6 months ago- before the course- I would have had to leave the building, turn it over, be very distraught. It’s got easier and easier, because I don’t get stuck in the negative thinking.... Yeah, I try and then do some mindfulness techniques.... I don’t do any mediation at all.” (Catherine)

However, three participants described difficulties using mindfulness (Robert, Anna and Sarah). These difficulties were particularly described in terms of problems disengaging from unhelpful or distracting thinking, but there were more general difficulties raised:

“Difficult to put into practice on two levels, one because you are dealing with the embedded ways of behaving that are so engrained in you and two, you don't necessarily have the capacity to be able to get any time to step back.” (Robert)

Facing uncomfortable experiences. Some participants identified that facing distressing or feared experiences was an important part of them taking control. Within the TCC, clients undertake a goal-focused imaginal exposure exercise, which they are encouraged to practice ‘in vivo’ (in ‘everyday life’) as appropriate.

“There’s like an high hill with, this little tower on top... it’s quite steep...and I took a photo of it... I’m gonna like tackle it.” (James)

Others described bringing a difficult situation to mind as “tricky”, but as something they received some benefit from:

“Umm, the thinking of a difficult situation, I didn’t really like that.... But I probably did make some progress with them.” (Christina)

However, for some participants, the exposure exercise was something they found difficult or were not sure if they benefitted from.

“I think the only one I struggled with was when they asked me to put myself in a situation where I felt anxious..... I just had to stop, couldn’t go there.”
(Catherine)

For some participants, focusing on a less anxiety-provoking situation helped them to get more out of this exercise, but for one participant (Catherine) they felt unable to do the imaginal exposure exercise for the duration of the course. Catherine expressed “everything was too raw” and bringing these experiences to mind was too challenging. However, she said that having completed the course she would be more able to do this.

5.4.4 Change

Ten participants were still using understandings and techniques from the TCC four- eight months after attending, and it seemed that these offered the potential to equip them to continue to maintain their wellbeing in the future.

Pace of change. Five participants described experiencing gradual, as opposed to sudden, change.

“I feel like a lot of things happened on the course and then I felt that I was quite different at the end, but... it was gradual learning rather than here’s all the information and just take it away.... Yeah it didn’t feel that sudden but still quite profound.” (Christina)

However, three participants described experiences of “light bulb moments” (Laura) or “clicking a switch” (Rachel) that suggest sudden moments of insight.

Practice, integration and consolidation. The majority of participants described continuing to use understandings and techniques from the course. This was made possible by them consciously consolidating the material during the course.

“I do the school run and had the paperwork from the sessions in the car. So I’d go to school, do the school run early and just be sitting reading everything.” (Catherine)

As well as referring to the materials used within sessions, participants described revisiting techniques. They were then able to continue to put understandings into practice once the course had finished.

Interviewer: Is that [*supportive image*]¹¹ something you’ve continued doing after you finished the course?

Mike: Quite a few times, I’ve sat and done something along that line

¹¹ An imagery-based technique that encourages participants to ‘create’ and imagine an image that represents qualities that they value and believe will support them.

Some participants also described a less conscious or effortful integration process.

“And I probably wouldn’t have remembered it happening but I do that an awful lot more now, think ‘really, is this anything to do with me, is there anything I can do?’.... I feel like I’m doing that process with a lot of things.... So that’s obviously very well-integrated cause I wouldn’t have been able to tell you that, that I was doing that.” (Christina)

Improved relationships. Six participants described changes in how they related to other people. These changes were varied and significant. These included “expressing feelings more” (James), getting less irritable with others, engaging in less negative comparisons between themselves and others, and strengthening social networks in other ways.

“And it means that I did become, well I always have been but, I became more compassionate really with people.” (James)

“I don’t know cause, it’s like I got into a new relationship as well.... But umm, whatever clicked, I didn’t go for ones I’d normally go for. Cause I’d normally go for the big bad boys, total complete jerks, umm but no *X [name]* is completely CRB checked, works full time, everything else, completely supportive”. (Rachel)

Based on the previous themes and the benefits that participants identified of being in a group context, it seems possible that the group built confidence in relating

to other people. However, this was not explicitly explored with participants during the interview.

5.5 Discussion

Study aims were to examine: a) participants' experience of the course, such as their experience of the modality and the length; b) participants' perceptions of psychological change and which elements of the course contributed to this. The results indicated that TCC was generally acceptable to participants, as satisfaction and understanding levels were generally high. The 'Style and format' themes indicated that participants valued the flexibility of the TCC and generally liked the brief format. Themes regarding 'Control' suggested that the theoretical threads of control and awareness were understood and utilised by participants. 'Negative cases' were present in most of the themes, which entails that there were one or two participants per theme who expressed a different experience from the majority. Therefore, a minority of participants either: would have preferred a longer or individual format, did not find a greater understanding of control particularly helpful, or did not find awareness techniques useful.

5.5.1 Participants' experience of the course

This is the first qualitative evaluation of the acceptability of a brief transdiagnostic group, targeted at clients with common mental health problems in a 'low-intensity' primary care setting. Qualitative explorations of both transdiagnostic and low-intensity groups are limited; therefore information is lacking as to whether clients experience transdiagnostic groups to be sufficiently tailored to them, or whether they express a preference for longer group interventions.

Earlier reviews of qualitative studies of low-intensity interventions (computerised and guided self-help) found common themes that not enough time was spent discussing participants' specific problems, and that interventions were not sufficiently tailored (Khan et al., 2007; Knowles et al., 2014). This was not a common aspect of participant experience within the TCC. It is plausible that this reflects the flexibility that participants valued. However, two participants expressed preferring an individual format and indicated that this was partly (or exclusively) because this was more personalised. The TCC was designed so it could be offered to large groups, but the degree of flexibility would be constrained in this format. It could be that without this flexibility participants might feel the TCC was not sufficiently tailored to them, and this could affect acceptability. Further empirical work would be required to establish whether the individualised worksheets and experiential exercises of the TCC would offset this in a large group.

However, it is also possible that flexibility could be offered in other ways. For example, three participants said that they would have liked more TCC sessions, and this corresponds to increasing evidence that psychological change does not occur within a predictable time frame and that psychological interventions can be offered that respond to differences in 'change trajectory' (Carey & Spratt, 2009; L. Morris et al., 2015). Although TCC sessions cover a range of topics, and will be sufficient for many clients, for others more (or less) therapy may be required. Therefore, clients could be given the option of joining sessions of a future TCC. It is already acknowledged that each individual will not attend every session; clients are provided with advance details of session content and are advised that they can choose not to attend every session.

Some of the aspects that participants valued are unlikely to be specific to the TCC; for example, ‘identifying with other attendees’ and normalisation of experience is common within group sessions (Malpass et al., 2012). However, the fact that that self-disclosure was not required, and could be paced, was also greatly valued.

5.5.2 Participants’ experience of psychological change

If the theoretical premise of the TCC is well-grounded then this should be reflected in participant experience. Furthermore, due to the lack of qualitative studies of transdiagnostic interventions, it is useful to establish if targeting transdiagnostic processes has face validity with clients.

Key themes of the TCC include acting in a flexible manner in order to meet personally important goals, and awareness; these featured strongly within participants’ accounts. For example, participants described taking flexible steps to achieve long-term (higher-level) goals by aiming for short-term achievable goals in pursuit of long-term goals (Morris et al., 2016). Awareness techniques facilitated this process by enabling participants to focus on higher-level goals and to manage thinking/behaviour that was preventing them from pursuing such goals.

Notably, however, references to conflict were generally absent from participants’ accounts. Previous qualitative studies suggest that describing problems in terms of conflict is unusual, whereas describing problems in terms of loss of control is common (reviewed in Alsawy et al., 2014). Further, through identifying and pursuing important higher-level goals despite the consequences of conflict (e.g. distress, intrusive imagery), conflict may be reduced and control regained (Carey, 2011). It is likely that conscious awareness of ‘conflict’ is not always necessary for change (Alsawy et al., 2014). Further, a number of qualitative studies examining

change processes have indicated that participants could identify what changed for them (such as thinking processes and perspectives) and specific techniques that were helpful, but were not able to identify how their distress had been transformed (Marken & Carey, 2014). Despite limited reference to conflict within participants' accounts generally findings indicated that a strong theoretical basis can provide an accessible and consistent therapeutic approach; themes of control and awareness were strongly represented.

A focus on 'control' is central to the TCC and whilst the majority of participants found this helpful a minority expressed difficulties. Participants who found it difficult to 'let go' of 'dwelling on' concerns that they could not control had all experienced significant life events or chronic on-going problems during the TCC. Three out of the four scored in the severe range for both depression and anxiety. However, there were other participants who experienced significant events or chronic problems and did not express difficulties letting go of concerns they could not control. Therefore, it could be that the problems, or low mood/anxiety, experienced by those who struggled were too significant for them to either 'let go' of dwelling upon their problems or take steps to control. In some instances, it seemed that participants were striving for an unachievable level of control, and feeling responsible for things that they could not influence. To further support participants, it could be made even more explicit that they can break down goals that seem difficult to achieve, so they can focus on more achievable sub-goals. Further, a discussion of control prior to the course could help to establish whether clients were aiming for an achievable level of control, and to explore this if not.

Aspects of the 'Control' theme overlapped with themes found in qualitative studies of mindfulness-based groups (Malpass et al., 2012). Themes in such studies

included: letting go of what is outside your control; and responding instead of reacting. Increasing awareness is a significant component of the TCC, and brief mindfulness exercises are used. Further, PCT specifies mechanisms that are common across disorders; TCC targets these mechanisms overtly but other therapies are likely to also address these processes to varying degrees (Morris et al., 2016). Other themes were distinct; for example, the sub-themes of ‘Flexibility, informality and an at ease environment’ and ‘Pursuing what really matters’.

In line with previous studies (Alsawy et al., 2014), participants reported both gradual and sudden changes. Only seven participants commented on this, five described ‘gradual change’ and three ‘sudden change’ (one participant described both). Gradual change was more common and may reflect a PCT account that “changes at the higher level of the hierarchy are accompanied or preceded by changes in lower-order systems that may not lead to significant change on their own” (Higginson & Mansell, 2008, p. 325). However, PCT-based accounts of significant change would generally predict a greater prevalence of reports of sudden changes, or ‘insight moments’, than described in the current study (Gianakis & Carey, 2011). This may be explained by ‘pace of change’ not being a primary focus of the interviews; therefore participants were not consistently asked in detail about this.

5.5.3 Limitations and implications

The primary limitation of this study was that those who attended low numbers of TCC sessions were under-represented and this could mean that those who did not find TCC useful could be under-represented. However, there was some range in the number of sessions that participants attended (three-six) and considerable range in whether their symptoms had improved. Another limitation is that, although two researchers conducted the interviews, only the first author

conducted the coding. Coding was examined by one of the project team (Dr Edge), but formal reliability checks were not conducted. A further possible limit is the sample size. However, the sample was relatively homogenous and saturation of codes occurred early (after the first eight interviews were coded).

Findings suggest some refinements to the TCC: (a) making it even more explicit that participants can break down goals that seem difficult to achieve, so they can focus on more achievable sub-goals; (b) framing the exposure exercise to make it very clear that participants do not have to do this; (c) supporting clients to choose manageable experiences during exposure by providing them with additional opportunities to reflect on the most suitable experience to choose.

The findings also have implications for other group-based interventions of this kind. In particular, the format of the group should be clearly explained in advance owing to concerns that self-disclosure will be required; any components that can be adapted to the individual tend to be valued, and more sessions could be provided where requested.

5.5.4 Conclusions

Results indicated that the TCC was acceptable, and provide an initial indication that transdiagnostic groups are acceptable. The strong theoretical basis seemed to provide an accessible transdiagnostic format.

CHAPTER 6: General discussion

6.1 Introduction and overview

The overall aim of this thesis was to examine the effectiveness and acceptability of a theory-driven group intervention, the Take Control Course (TCC), for clients with common mental health problems. A key specific aim was to establish whether TCC was non-inferior compared to an active control (individual low-intensity Cognitive Behavioural Therapy, CBT). A related aim was to examine participants' experiences of the TCC. The third aim was to examine whether the theoretically-grounded components of TCC, as specified by Perceptual Control Theory (PCT; W. T. Powers, 1973, 2008; W. T. Powers et al., 1960a, 1960b), were accessible and useful to participants. Specific aims and hypotheses of the included papers are detailed in Table 11.

The thesis is presented using 'alternative format'; comprising introductory and methodology chapters and three papers that have either been published (one paper), submitted (one paper) or is in preparation to submit (one paper). This final chapter discusses the contribution of studies within the thesis, recognises the strengths and limitations of the thesis and concludes with recommendations for future research and clinical implications.

Table 11: Overview of papers included within thesis

Paper name	Study type	Chapter	Aims (and hypotheses if appropriate)
The Take Control Course: Conceptual rationale for the development of a transdiagnostic group for common mental health problems	Narrative review	2	<ol style="list-style-type: none"> 1. To explore whether a Perceptual Control Theory (PCT) explanation of psychopathology across disorders is a valid one; 2. To illustrate the process of developing a novel transdiagnostic intervention (Take Control Course; TCC) from a transdiagnostic theory of functioning (PCT).
A brief transdiagnostic group (the Take Control Course) compared to individual low-intensity CBT for depression and anxiety: a randomized non-inferiority trial	Randomised non-inferiority trial	4	<p>To assess whether TCC is non-inferior compared to an active control condition (individual low-intensity CBT).</p> <p>Hypothesis: Participants in both groups will show reductions in symptom scores on measures of anxiety and depression, and outcomes for TCC and low-intensity CBT will be non-inferior.</p>
Experiences of a transdiagnostic group, the Take Control Course, for clients with common mental health problems: a qualitative study	Qualitative interview	5	To explore participants' experiences of the TCC, specifically, to examine what experiences contribute to psychological change.

6.2 Contributions to the literature

Firstly, the narrative review outlined how the development of a transdiagnostic intervention, which targets specific transdiagnostic processes, could provide a particularly efficient way of promoting psychological change. It detailed how a transdiagnostic intervention could be theoretically derived by explicitly describing how the theoretical basis informed the intervention components. Secondly, this thesis found that a specifically transdiagnostic intervention (TCC) was non-inferior to individual low-intensity CBT, and contributes to the literature examining transdiagnostic interventions. Thirdly, qualitative results indicated that the TCC was acceptable, and provided initial evidence that transdiagnostic groups are acceptable. Fourthly, qualitative data indicated that the theoretical premises of the TCC were well grounded; key aspects of PCT, such as flexible goal pursuit and awareness, all featured strongly within participants' accounts. Each of these primary findings will now be discussed in more detail.

6.2.1 Literature review

The literature review indicated that considerable evidence supports certain tenets of PCT. The tenets that perceptions are controlled by behaviours (rather than behaviour being controlled), and that loss of control is a cause of distress were particularly well supported. Further, many studies supported correlational and predictive relationships between elevated goal conflict and psychopathology. However, fewer studies examined whether conflict between higher-level goals was more detrimental than conflict between lower-level goals. There were other areas in which future research is required and these will be discussed in more detail in the subsequent 'On-going and future research' section (6.4).

In addition, the literature review provided a detailed specification of how the PCT basis of the TCC directly informed its style and components. Given that the review was written towards the beginning of the PhD, it is useful to consider to what extent TCC still meets a specific need as this impacts on the overall contribution of research into TCC. Three of the main distinctive features of the TCC were: a) that it is based on a different theoretical model from many of the transdiagnostic groups available (i.e. PCT rather than ‘traditional’ CBT), b) that it offers a theoretically driven and flexible delivery format and c) that it is briefer than available transdiagnostic interventions. These points will be examined.

Arguably the TCC is among the most tightly theoretically specified transdiagnostic groups available (this suggestion will be examined in the next two paragraphs). TCC is based on a different theoretical model from many transdiagnostic groups. The majority of transdiagnostic groups are based on a ‘traditional’ Cognitive Behavioural Therapy (CBT) approach; drawing on a broadly Beckian CBT model (Newby et al., 2015).

Recently, detailed descriptions of how cognitive-behavioural theory could explain common maintenance processes have been provided (Beck & Haigh, 2014). However, the extent to which transdiagnostic CBT groups for anxiety and/or depression draw on such theoretical accounts is often not clear (Clark & Taylor, 2009; Erickson, Janeck, & Tallman, 2009; Norton, Hayes, & Hope, 2004). These interventions sometimes describe targeting specific transdiagnostic processes, such as negative affectivity (Norton et al., 2004; White, 2010) and could be considered pragmatic ways of offering treatments that works to a broader range of clients. However, the theory-driven development of the TCC offers an alternative way of promoting efficient change by focusing all therapy components around specific

transdiagnostic mechanisms. Further, not all clients respond to CBT (e.g. Schindler, Hiller, & Witthöft, 2013; S. Taylor, Abramowitz, & McKay, 2012) and so it would appear beneficial to offer a range of intervention options.

The PCT basis of the TCC continues to be a distinctive feature. Further, the clear specification of the mechanisms targeted within the TCC allows these to be evaluated. For example, the degree to which reduction of higher-level conflict reduces symptoms could be compared to the degree to which intolerance of uncertainty, or increased mindfulness, reduces symptoms (discussed in more detail in 6.5.1 ‘Future research based on the literature review’). Other interventions have been offered transdiagnostically, such as Acceptance and Commitment Therapy (Hayes, Strosahl, & Wilson, 1999) and Mindfulness-Based Stress reduction (Kabat-Zinn, 1982). However, no studies of Acceptance and Commitment Therapy were identified that offer a group intervention to a transdiagnostic sample of clients with common mental health problems (Öst, 2014; M. B. Powers, Zum Vörde Sive Vörding, & Emmelkamp, 2009; Ruiz, 2012). Mindfulness-Based Stress Reduction is commonly offered to groups and has been delivered to transdiagnostically to those with common mental health problems (usually with additional severe physical health problems) (Khoury et al., 2013). But there is no consensus as to which theoretical framework underpins mindfulness interventions. A number of transdiagnostic frameworks have been proposed (Hölzel et al., 2011; Shapiro, Carlson, Astin, & Freedman, 2006), such as those that provide a broad mechanistic and neurobiological account (Y.-Y. Tang, Hölzel, & Posner, 2015; Vago & Silbersweig, 2012), but these have been developed in order to explain the effects of already established mindfulness interventions (practice to theory, rather than theory to practice). An exception to this is the disorder-specific, Mindfulness-Based Cognitive Therapy

(Segal, Williams, & Teasdale, 2002) for depression, which was based on an Interacting Cognitive Subsystems framework (Teasdale, Segal, & Williams, 1995), which has since been applied to a range of other disorders, such as personality disorders, bipolar disorder and anorexia (Duff & Kinderman, 2006; Lomax, Barnard, & Lam, 2009; Park, Dunn, & Barnard, 2011). Therefore, overall the tight theoretical specification of the TCC remains unusual for transdiagnostic groups of clients with common mental health problems, such as anxiety and depression.

Other aspects that distinguished TCC from available interventions included its brief and flexible format. Although other brief groups are available, brief transdiagnostic groups are rare. Only one other transdiagnostic group has been evaluated; the CBT based Stress Control course (White et al., 1992). The early evidence for Stress Control focused upon patients with Generalised Anxiety Disorder, but more recently it has been suggested that it could be transdiagnostic because it targets a general processes of negative affect and ‘stress’ (White, 2010). Stress Control is delivered as part of an innovative model of service delivery, and has been found to reduce symptoms of anxiety and depression (Burns et al., 2016; White, 2010). However, only two studies have used a RCT design (Kitchiner et al., 2009; White et al., 1992); one trial, of primary and secondary care patients, found that Stress Control did not lead to significantly better outcomes than an anxiety management group or waiting list control (Kitchiner et al., 2009). Few studies examining purported mechanisms of Stress Control are available and no qualitative studies were identified. Therefore, additional trial-based efficacy data, acceptability and process evidence for Stress Control is required.

In addition, Stress Control does not offer an explicitly flexible format like the TCC. The flexible format of the TCC is offered by: a) adapting session content

according to weekly client feedback, b) emphasising that clients can adapt techniques to suit them and their context, and c) offering stand-alone sessions so that clients can look at an overall description of the different session themes and choose not to attend a particular session. This flexible format is employed to increase client control over their treatment. Also, it responds to the literature indicating that offering clients flexibility in attending psychological treatments increases effectiveness for services and is valued by clients (e.g. Carey & Spratt, 2009). The qualitative study within this thesis indicated that the majority of participants valued this flexibility, and this appears to remain a unique feature of the TCC (as compared to other group treatments).

Overall, the three main contributions of the TCC that were previously identified remain novel. These were: a) that it is based on a different theoretical model from many of the transdiagnostic groups available (i.e. PCT rather than ‘traditional’ CBT), b) that it offers a strongly theoretically driven and flexible delivery format and c) that it is briefer than most other available transdiagnostic interventions.

6.2.2 Non-inferiority RCT and qualitative study

Use of a mixed-method approach provided different types of data on the TCC, and enabled the course to be examined from different perspectives. Therefore, the relationship between the findings of the RCT and qualitative study will be more directly explored in this section.

The RCT data indicated overall reductions of levels of anxiety and depression symptoms, improved functioning and improvements regarding ratings of idiosyncratic problems. However, the qualitative data provided detailed information regarding how change (or lack of change) was experienced by individuals. For

example, there was one participant in the qualitative study who described considerable benefits from the course but whose anxiety and depression scores had increased, while another participant described feeling they had not improved but their anxiety and depression scores decreased.

As well as providing a more nuanced account of the degree of change experienced than symptom score measures, the qualitative study provided useful information regarding participants' perceptions of which aspects of the TCC contributed to change. This is described in general terms in Chapter 5, which reports findings from the qualitative study. For example, substantial numbers of participants commented on benefits from, or difficulties with, mindfulness and exposure techniques and so these were included within themes in the qualitative paper. However, there were other instances whereby only one or two participants expressed finding a specific technique or way of understanding helpful or unhelpful. This feedback had to be balanced with the feedback from other participants, as different individuals had different perspectives on the same component or technique. For example, a metaphor featuring a dragon is used in Session 1 to introduce an exposure exercise (See Appendix G) and one participant did not feel this was relevant to them. However, the use of cartoons and metaphors (including the dragon story) was really appreciated by some, while one person described this as "childlike" within their sessional evaluation form. It is already stated within the first session of the TCC that the use of stories and metaphors is to aid memory and not to trivialise the problems experienced. Therefore, the best response to this feedback seemed to be to emphasise even more strongly in the first session that a range of techniques would be presented and some would have greater relevance than others.

From both the RCT and the qualitative study, it emerged that participants

could have ‘fears’ and reservations about group-interventions. In the qualitative study this was an explicit aspect of the ‘Hopes and fears’ theme and in the RCT this was implicit in lower credibility ratings of the TCC prior to treatment. The preconceptions and fears expressed within the qualitative study were generally not borne out in participants’ experiences once they started the TCC. For example, they realised that they did not need to self-disclose in detail, as they had feared. Other participants described needing to access a couple of sessions before their fears were allayed. Further, within the RCT, there were no significant differences in treatment credibility once participants had accessed sessions. In addition, levels of attrition and attendance were similar across treatments (with the same average number of sessions attended), which suggests that an ongoing experience of low credibility and subsequent non-attendance was not a specific feature of those randomised to TCC. This indicates that future clients would benefit from additional information regarding the TCC so they could make an informed choice whether to attend.

One way of addressing fears and preconceptions could be by creating an ‘information sheet’, including quotes from the qualitative study, to ensure clients have a clearer sense of what the course entails and to encourage them to attend a couple of sessions before deciding whether to go back again. This sheet could be used before the course or at the first session. The aim of providing such information would not be to coerce clients into attending an intervention that was not helpful for them, but rather to give them accurate information about what they might expect. Although ‘negative’ or ‘inaccurate’ preconceptions can affect client experience of a range of interventions, this theme seems to emerge particularly strongly when a less familiar format is used. For example, findings from qualitative studies of self-help interventions suggest that such preconceptions can arise from lack of familiarity with

the intervention (e.g. clients are less likely to be familiar with self-help interventions than individual therapy, because self-help interventions are not commonly depicted within the media) (Macdonald et al., 2007; Rogers, Oliver, Bower, Lovell, & Richards, 2004). This reinforces the need for providing accessible information to clients to provide them with a sense of the TCC, as it will not be a familiar intervention to most clients.

Findings from both the qualitative study and the RCT indicated that TCC is accessible and acceptable to a broad range of clients. The main source for this is the PSYCHLOPs, which is a measure of idiosyncratic self-determined client problems. The ITT analysis indicated that TCC was non-inferior to low-intensity CBT on the PSYCHLOPs. Within the RCT, clients identified a wide range of problems that “most troubled” them. Given that clients could choose any problem, it is difficult to summarise this data but common examples of problems were regarding relationships and social situations, worry, anger, work stress, and unemployment. A similarly wide range was identified by those who participated in the qualitative study (a summary of this data was included in Table 8, in Chapter 5). The range of presenting problems represented indicates that those with different problems could access the TCC.

Exclusion criteria for the RCT were minimal. For example, generally clients were not excluded based on diagnostic presentation; the only exception to this was if clients needed to be seen by a higher-intensity service. Therefore, it is unlikely that clients with severe obsessive-compulsive disorder, or who were currently experiencing psychotic symptoms were included within the RCT sample. The term ‘unlikely’ is used as one of the disadvantages of a service driven criteria is that is difficult to describe the sample in diagnostic terms. For example, there were

occasions whereby clients were referred to the research project who arguably should not have been seen within a low-intensity context (e.g. with post-traumatic stress symptoms), and it not possible to rule out the inclusion of client groups who would usually be seen in higher-intensity services. However, an advantage of the inclusive service driven criteria is that it indicates that the TCC can be offered to a broad range of clients within a low-intensity primary care setting.

6.3 Strengths and limitations

Before considering the overall conclusions that can be drawn from these findings and the implications of these, it is important to consider the strengths and limitations of the research presented in this thesis. A particular strength of the thesis is the sample size and methodological controls of the RCT. The RCT was single-blind, driven by a pre-specified protocol and combined a conservative pre-specified non-inferiority margin with accounting for clustering by group within analyses. Intention to treat (ITT) analysis was used as the primary analysis, to reduce selection bias and reflect routine practice (where attrition and accessing multiple treatments are common) (Gupta, 2011). The arguments for ITT analysis, and for including ‘protocol-violators’, seem particularly compelling for psychological therapy trials compared to pharmacological trials. This is because it is not common that people take psychiatric medication they have not been prescribed even in routine practice, but it is more common that those accessing psychological interventions will psychologically ‘self-medicate’ (e.g. with a mindfulness app, and/or a self-help book).

Both in sample size and methodological rigor, the RCT was an improvement on previous non-inferiority trials comparing transdiagnostic interventions to

established therapies (Norton, 2012; Norton & Barrera, 2012), and previous TCC research (L. Morris et al., 2015). Attrition levels at follow-up were much lower than the feasibility prospective cohort study of the TCC (L. Morris et al., 2015). All electronic databases for the trial were checked for accuracy against the paper measures (Roberts, Anthony, Madigan, & Chen, 1997).

Furthermore, the trial provided the first evidence for the non-inferiority of a brief transdiagnostic group compared to an established individual intervention. This is important as it supports the use of TCC in routine clinical practice. It also suggests that the brief transdiagnostic format is effective. In addition, the thesis combined both quantitative and qualitative methodology, which contributes to a greater understanding of the TCC. For example, the qualitative study provided data to support the acceptability of the format of the TCC, while the RCT findings indicated that such a brief transdiagnostic intervention contributed to symptoms reductions, and improved functioning.

Further, the qualitative study made a substantial contribution to data available on transdiagnostic groups, as no previous qualitative studies of specifically transdiagnostic groups were identified. Therefore, both the RCT and qualitative study make a substantial contribution to the literature and have implications for clinical practice.

However, there are limitations to the thesis. Limitations of the included papers have already been described in the relevant chapters (Chapters 2, 4 and 5) so these will not be replicated in full here. Only key limitations will be discussed in more detail in this section.

One of the key limitations of the 'thesis version' of the RCT is the inclusion of only 6-month follow-up data. This is because complete 12-month follow-up data

was not available at the time of submission. Furthermore, the cost-effectiveness analysis could not be completed prior to thesis submission, as this requires the 12-month follow-up data. Although both analyses will be included in journal submissions, they cannot inform the conclusions of the thesis. As 6-month follow-up is the primary outcome point, the 6-month data does allow useful conclusions to be drawn regarding the TCC. Further, previous non-inferiority trials comparing transdiagnostic interventions to established therapies have not reported any follow-up data (Norton, 2012; Norton & Barrera, 2012).

Another potential limit of the RCT is the discrepancy between the ITT and Per Protocol (PP) analyses. In the ITT analyses the TCC was non-inferior to low-intensity CBT on all measures, in the PP analyses non-inferiority was not conclusively established on any measure. This is a limitation because it is currently unclear whether ITT analysis increases the chances of concluding non-inferiority, as compared to PP analysis (Piaggio et al., 2012). A review concluded that ITT analysis does not lead to an increased chance of concluding non-inferiority (Brittain & Lin, 2005). But future research is required for definite conclusions (Brittain & Lin, 2005; Porta, Bonet, & Cobo, 2007). Advantages of ITT analyses have been described previously and therefore the results of the ITT analyses give a methodologically reliable indication of non-inferiority.

Further, there are issues with PP analyses, particularly given that TCC does not pre-specify what an adequate dose is. Commonly PP analyses would focus on ‘completers’, but this requires a sessional definition of completion (e.g. attended 6-sessions). Although underpowered and for interest only, the comparative PP analyses were re-run on participants who attended four or more intervention sessions. This was informed by studies in IAPT services indicating that those who

attend more sessions (e.g. four- six) have better outcomes (Burns et al., 2016; Delgadillo, McMillan, Lucock, et al., 2014). The direction of the effect was in favour of TCC, in contrast to the ITT and PP analyses reported in the RCT paper. This points to one issue with PP analyses, which is that it can be defined differently and this can lead to different results (Brittain & Lin, 2005). Another issue is that because PP analysis has to be run on a sub-sample it is often under-powered (Brittain & Lin, 2005; Porta et al., 2007). This is a particular issue for non-inferiority trials (whereby non-inferiority is established using the upper bound of the confidence interval), as small sample sizes generally lead to wider confidence intervals. Given that the difference between treatments was consistently not significant, we decided not to explore ‘drop-out mechanisms’ to try to explain differential results (Porta et al., 2007). This is because the difference between ITT and PP analyses could have occurred by chance, or more likely, due to selection bias (Deeks et al., 2003).

As described in the methodology section, clients were offered a choice between accessing individual low-intensity CBT and accessing the trial. Within the trial clients were not routinely offered treatment as usual (individual CBT). Consequently, at initial assessment eligible clients were offered the choice of continuing with the established intervention (individual low-intensity CBT) or participating in a trial in which they would be randomly allocated to either TCC or individual low-intensity CBT. This could have influenced whether clients agreed to participate in the study, as they were being offered a choice of continuing treatment with a clinician they had already met or participating in a trial. Some clients informed clinicians that the reason they did not participate in the reported RCT was that they did not want to go through a randomisation process. Trial participation entailed additional uncertainty, additional assessments and a slight delay in accessing

treatment (as all clients interested in the trial had to access a research assessment whereby written consent was obtained and baseline measures completed). Therefore, it could be suggested that the sample was not representative if it seemed that individuals with certain motivations or characteristics were accessing the trial. However, a number of reviews indicate that entry into trials (with varied designs) is motivated by a range of factors, and these could influence the representativeness of trials in numerous contexts (i.e. a subsample of the population is represented and certain internal and external factors can influence who participates) (Hughes-Morley, Young, Waheed, Small, & Bower, 2015; McCann, Campbell, & Entwistle, 2013). For example, where trials are introduced by GPs a number of factors can affect who they ask to participate, such as if patients were seen as vulnerable by a particular GP they may not be asked to participate in a trial (Hughes-Morley et al., 2015). Further, other motivations can be salient across trials, such as a desire to help others, so it could be that individuals with such motivations are overrepresented within trials (Jadad & Enkin, 2008; McCann et al., 2013). Overall research indicates that a number of factors can influence whether someone participates in a trial and therefore who is represented within a particular trial; it is unclear whether this was a particular issue within the present trial design.

A further consideration when establishing whether the sample is representative is whether attrition levels were unusually high. It has previously been mentioned that some clients expressed that they did not want to participate in the reported RCT because they would have to be randomised to treatment. Of 1892 clients who were potentially eligible, 156 were randomised; therefore 8% were randomised. Other trials have also experienced seemingly high levels of ‘drop off’. For example, within an evaluation of collaborative care for depression of 7392

potentially eligible clients, 581 were allocated to the trial (8%) (Green et al., 2014); within a trial comparing different therapies for trauma of 1390 potentially eligible clients, 110 were randomised (8%) (Markowitz et al., 2015). However, in other studies the level of ‘drop off’ from initial assessment to trial enrolment is not as high; for example, in a trial comparing behavioural activation to CBT of 1307 potentially eligible clients, 440 were randomised (34%) (Richards et al., 2016). These comparisons are provided as examples, but it is noted that recruitment strategies were different from the RCT reported within this thesis (e.g. some studies screened client notes to identify potential participants instead of screening via a face-to-face assessment) (Markowitz et al., 2015; Richards et al., 2016). Further, there are other differences, such as some studies included clients who would not have immediately accessed a therapy if they had not participated in the project (e.g. they were on a waiting list to access therapy) (Green et al., 2014; Markowitz et al., 2015; Richards et al., 2016). However, overall it seems that it is not uncommon for significant numbers of those who are potentially eligible for a trial not to participate.

A further key limitation was that assessment within the RCT primarily relied on self-report and no diagnostic interviews were conducted. A range of self-report measures were used, including a client-generated measure of problems. Interview and self-report measures were used to inform cost-effectiveness analyses. Process measures were also completed and will be discussed separately (later in this section). Overall this contributed to a substantial assessment battery at baseline and follow-ups. Given the transdiagnostic nature of the intervention multiple of diagnostic assessments would have had to be completed, which would have placed a further time burden on participants. Funding was not available to reimburse participants for their time. However, the lack of diagnostic assessments means that information was

not available regarding which specific anxiety, depressive and other disorders the TCC was effective for.

Another potential limit is the lack of reported process data on the TCC. Process data could have been reported regarding higher-level conflict, awareness, and factors that contribute to reorganisation or inhibit reorganisation. In addition, process data could have been reported on other transdiagnostic processes that were not explicitly targeted within the TCC, in order to examine if these better explained psychological change. Although a number of these process measures were collected during the RCT, these were intended to be examined separately from outcome measures. A parallel project was conducted in conjunction to the main PhD studies, in order to examine mechanisms of change. This will be reported separately from the PhD data, and is described in more detail in 'Future research based on the literature review' (sub-section 6.4.1). Process data is important to clarify the extent to which mechanisms specified by PCT contribute to psychological change. As the TCC targets such mechanisms, it is vital to examine whether this is reflected in measures of these mechanisms. This matter is not explicitly addressed in the current thesis.

However, the qualitative study did give an indication of the kind of change processes participants described. It found significant themes regarding participant understanding of control, including descriptions of being able to control in a more flexible manner. For example, participants described taking flexible steps to achieve long-term (higher-level) goals by aiming for short-term achievable goals in pursuit of such long-term goals. Awareness and goal clarification techniques facilitated this process by enabling participants to focus on higher-level goals and to manage thinking/behaviour that was preventing them from pursuing such goals. This

indicates that psychological change experienced by TCC participants could be in line with PCT mechanisms of change. However, participants made limited reference to resolution of internal conflict as a contributor to change. It is recognised that it can be difficult for individuals to identify exactly how change occurred and this might explain the limited reference to conflict. For example, a number of qualitative studies examining change processes have indicated that participants could identify what changed for them (such as thinking processes and perspectives) and specific techniques that were helpful, but were not able to identify how their distress had been transformed (Marken & Carey, 2014). This provides an additional reason for why process data would be valuable in order to examine whether resolution of internal conflict was occurring but participants were not aware of this, or whether other mechanisms of change better account for the change process.

The primary limitation of the qualitative study was that those who attended low numbers of TCC sessions were under-represented, and this could mean that the views of those who did not find TCC useful were not represented in these findings. There was some range in the number of sessions that participants attended (three-six) and considerable range in whether their symptoms had improved. However, greater information regarding the reasons why participants attended ‘low’ numbers of sessions would have been useful, particularly to inform conclusions regarding how acceptable TCC was. The weekly evaluation forms provide an indication of participants’ initial impressions of the TCC, but they do not provide a detailed understanding of reasons for not attending later sessions. This issue is discussed further in the next section (sub-section 6.4.3 ‘Future research in response to the qualitative study’).

A further limitation is that although two researchers conducted the interviews, only the first author conducted the coding. Coding was examined by one of the project team (Dr Edge), but formal reliability checks were not conducted. There is ongoing debate about the utility of concepts such as 'reliability' in qualitative research. Indeed, Stenbacka (2001) argues that since reliability issues concern measurements then these have no relevance in qualitative research and are irrelevant in the judgement of quality of qualitative research. However, we do strive to establish the overall 'reliability' of our research (as discussed in the methods section, 3.4.1 Rigour in qualitative research), in terms of the construct of 'trustworthiness'. According to Guba and Lincoln (1985), the fundamental question in establishing the trustworthiness of qualitative research is "How can an inquirer persuade his or her audiences that the research findings of an inquiry are worth paying attention to?" (Lincoln & Guba, 1985, p. 290). They conclude that "Since there can be no validity without reliability, a demonstration of the former [validity] is sufficient to establish the latter [reliability]" (p. 316). In this context, oversight of the study by a qualitative methods expert (Dr Edge) together with 'peer validation' (review by independent qualitative methods expert), member checking/participant validation and the auditability of the study provide evidence of its validity and dependability.

6.4 On-going and future research

The limitations discussed above highlight that the findings of this thesis require further extension and also indicate directions for future research. In regards to future research on psychological change mechanisms, as aforementioned, a

parallel project was conducted in conjunction to the main PhD studies that focused upon change mechanisms.

6.4.1 Future research based on the literature review

While the literature review found substantial support for PCT, it identified that further research was required to directly test the relative contribution of some of the PCT mechanisms predicted to underlie psychopathology; for example, whether higher-level conflict is a more significant contributor to psychopathology than lower-level conflict. It also identified that another important area was examining the extent to which the PCT basis of TCC facilitates its effectiveness; for example, the extent to which the resolution of higher-level goal conflict predicts successful exposure. This would facilitate detailed comparison with other explanatory theories and interventions, as the predictive power of higher-level conflict could be compared with the predicative power of other mechanisms.

Addressing both of these gaps requires appropriate measures of the mechanisms specified by PCT. The parallel project conducted during the PhD was to examine the psychometric properties of the Reorganisation of Conflict scale (ROC). Three subscales of the ROC were identified by previous research: ‘inflexible/urgent problem solving’; ‘goal conflict awareness’ and ‘components of goal conflict reorganisation’ (Bird, 2013). Additional work was required regarding the psychometric properties of the ROC because in previous studies only the ‘components of goal conflict reorganisation’ subscale had satisfactory internal reliability (Bird, 2013). The low number of items within the other two subscales could have affected their internal reliability (6 items and 4 items), as alpha is a function of the number of items in a scale (Cortina, 1993). Therefore, within the parallel project additional items were added to the ‘inflexible/urgent problem

solving' and 'goal conflict awareness' in order to establish if this improves the reliability of these subscales.

The ROC was completed longitudinally (alongside measures of mindfulness, intolerance of uncertainty and psychological flexibility) by an analogue sample and participants of the reported RCT. Factor analysis will be conducted on data from both the analogue and RCT samples. In addition to the factor structure, the convergent and discriminant validity (construct validity) and predictive validity will be examined. This will include examining whether scores on the 'goal conflict reorganisation subscale' of the ROC at each session predict greater symptom change at the subsequent session.

While the further development of the ROC will provide a self-report measure of PCT mechanisms, such as factors promoting goal conflict reorganisation, it is recognised that using self-report to measure higher-level conflict can be problematic. Explicit measures of conflict have commonly failed to find a relationship between elevated goal conflict and psychopathology, whereas more implicit measures of conflict indicate a consistent relationship (Kelly et al., 2015). It is suggested that explicit measures assess low-level and therefore more conscious conflicts (Kelly et al., 2015). Such low-level conscious conflicts can be more easily resolved than unconscious conflicts, because once an individual is aware of a conflict between the goals that they are pursuing then they can target one goal over the other (Kelly et al., 2015). Therefore, such lower-level conflicts are less likely to promote psychopathology. This creates a challenge for measures of enduring higher-level goal conflict, because such conflict is unlikely to be fully conscious (both because higher-levels represent values and self-concept goals that are not routinely accessed and because if such conflict was fully conscious it would be more likely to be

resolved). Attempts have been made to address this and measures of higher-level goal conflict include a modified version of the Goal Task (Dickson & MacLeod, 2004) with additional questions to enable participants to access important superordinate (higher-level) goals (Varese et al., submitted). The modified Goal Task paradigm was used in conjunction with ratings of goal interference and facilitation derived from the Strivings Instrumentality Matrix (Emmons & King, 1988). However, measures of higher-level goal conflict require further development and evaluation.

While both a self-report measure of PCT-relevant processes and further development of paradigms to measure higher-level conflict will be useful, PCT also indicates that experimental paradigms should measure a perception that is being controlled. This is because PCT is premised on an ongoing feedback process in which feedback affects the input and output, rather than a stimulus response model (for a more detailed discussion see Marken & Mansell, 2013). Establishing what perception is being controlled can require different paradigms from conventional experimental methodology (Marken & Mansell, 2013). For example, an experimenter might speculate that a socially anxious individual is controlling for a variable (goal) of never being in a crowded environment, but in order to empirically determine this they would need to examine the effects of this goal being disturbed. So if a group of people walked into the room would the individual leave the room, how many people would be required in order to cause them to respond etc.?

Underpinning this methodology is the idea that different individuals will control for different perceptual goals. Furthermore, ideal methodologies are those that enable functional modelling of theoretical components (Mansell, Carey, & Tai, 2015; W. T. Powers, 1973). For example, research using computerised tracking tasks has

provided considerable evidence for the key PCT proposition that perception is controlled through action (Marken & Mansell, 2013). This has been achieved through using tasks that can also be computer modelled. Such methodology allows the investigator to test behavioural data against the specifications of the computerised model to establish whether the model is accurate (Marken & Mansell, 2013). Therefore, a PCT understanding requires reconsideration of the ways in which we conduct psychological experiments (Mansell et al., 2015).

6.4.2 Future research following the RCT

The RCT findings indicated that TCC was non-inferior to individual low-intensity CBT. However, there were limitations to this study that could be addressed by future research. One option would be a similar design to the reported study, but a larger RCT within routine practice in a number of services and with greater resources for training clinicians to deliver the TCC (to account for possible staff turnover). Another option would be a RCT utilising DSM diagnostic assessments and comparing TCC to another group intervention. Again it would be beneficial to recruit from different locations and ensure sufficient numbers of clinicians were trained to deliver the TCC. A multisite study would be important for increased generalizability because Salford has a specific demographic profile (predominantly white, with a high level of deprivation).

Although both of these designs would provide useful information regarding the effectiveness and efficacy of TCC, there are limits to RCT designs. Following a detailed examination of RCTs, which recognises the strengths of such trials, Jadad and Enkin (2008) conclude: “We believe that the still present tendency to place RCTs at the top of the evidence hierarchy is fundamentally wrong.... There is no ‘best evidence’ except in reference to particular types of problem, in particular

contexts” (p. 106). RCT designs are not best suited to answering all questions regarding an intervention. For example, the contribution that qualitative studies make to understanding the nuances of participants’ experiences of an intervention has already been outlined, such as whether the intervention made sense and was acceptable. Further, the first RCT design described in the previous paragraph focused on external (ecological) validity and similarity to routine practice. It could be argued that a multi-site prospective cohort study would provide even greater external validity than a RCT and therefore more effectively answer the question of whether the TCC is beneficial in routine practice. The disadvantages of such a design would be high risk of selection bias and difficulties in directly comparing the two groups, but the advantage would be giving clients a direct choice of intervention. From a PCT perspective, the RCT design has the potential to introduce a conflict (based on not receiving the desired intervention/help) that could influence attendance and outcomes if not reorganised over time.

In addition, larger trials or prospective cohort studies could usefully evaluate the effectiveness of the TCC in both large (e.g. 50+) and smaller groups (e.g. 5-15). An ideal design would be a RCT comparing large group TCC, small group TCC and an established treatment (either individual low-intensity CBT or Stress Control course). The advantage of a comparison with individual low-intensity CBT is that this is the most established treatment within IAPT low-intensity services, and the advantage of comparison with Stress Control would be that there would be a greater similarity and equivalence in treatment format.

Further, the TCC was designed with the view that participants could access sessions of future courses if they wanted to and it would be useful to evaluate the effectiveness of this. The ideal was client-led scheduling and this also informed the

flexible delivery of sessions. However, in the current way that many IAPT services operate this is difficult to fully implement, because clients are discharged from the service once they have completed treatment and have to be re-referred and re-assessed to access future sessions. With a large-group model this could be easier to manage as clients could access sessions in a less formal manner and assessment of risk would be less of an issue as it would not be possible to do a structured risk assessment with 50 people (White, 2010). Client-led scheduling has been used effectively in the delivery of individual therapy, in non-IAPT services, reducing waiting lists and missed appointments (Carey & Spratt, 2009; Carey et al., 2013). Therefore, it would be useful to evaluate the impact of clients being able to easily attend sessions of the TCC having accessed an initial course.

6.4.3 Future research following the qualitative study

Given that the reported study was the first qualitative exploration of an explicitly transdiagnostic group, it is important that other transdiagnostic groups are qualitatively examined. Qualitative explorations of client experience of other brief 'transdiagnostic' groups, such as Stress Control (White et al., 1992), would be particularly useful to follow on from the qualitative study within this thesis. As well as providing information regarding whether other transdiagnostic groups are acceptable, this would provide data on client experience of another brief course that is derived from a different theoretical perspective.

A key area for future qualitative studies of transdiagnostic groups will be to explore the experiences of those who do not attend or only attend a limited number of sessions (Burns et al., 2016). Although certain demographic factors, such as high socioeconomic deprivation (Barrett et al., 2008; O'Brien et al., 2009), are commonly associated with reduced attendance, psychological factors can influence attendance

(Schauman & Mansell, 2012). A range of psychological factors can result in appointment non-attendance, such as fear of stigma, low motivation (Schauman & Mansell, 2012). For example, a prospective study examining psychological predictors of first session non-attendance indicated that concern about self-disclosure was independently predictive of non-attendance (Murphy et al., 2014). It has been convincingly argued that ambivalence regarding therapy attendance is underpinned by a loss of valued control; this model indicates that clients do not attend therapy appointments if they believe that attendance will interfere with their ability to control an important goal (Schauman & Mansell, 2012). For example, if 'being socially acceptable' is a personally-important (valued) goal and it is believed that stigma of attending therapy will undermine this, then therapy will have the potential to interfere with an important goal. Although the loss of valued control model provides a useful model of the factors that contribute to treatment non-attendance, it is important not to underestimate the impact of environmental factors in treatment non-attendance (Barrett et al., 2008; O'Brien et al., 2009). For example, if a client only has limited information about a treatment, then it will make it more difficult for them to know whether the treatment is likely to interfere with a valued goal.

Further, it remains unclear whether clients attend a low number of sessions because they feel they have improved sufficiently or because of other factors. Studies within low-intensity IAPT services have indicated that attending more sessions can result in better outcomes (Burns et al., 2016; Delgadillo, McMillan, Lucock, et al., 2014). However, research also indicates that early improvements are associated with recovery (Delgadillo, McMillan, Lucock, et al., 2014) and that sudden gains, sometimes early in therapy, can account for significant amount of clients' improvement (Aderka et al., 2012).

With clearer information regarding why clients do not attend or attend a 'low' number of sessions it would be easier to address psychological factors that affect attendance. Such factors could be addressed using tailored ways of increasing engagement (Burns et al., 2016; Murphy et al., 2014). For example, the qualitative study indicated that fear of disclosure to a group was particularly concerning for participants, and this could be addressed through use of an information sheet including quotes from the qualitative study (including quotes regarding the lack of necessity for disclosure). Although a qualitative study of those who did not attend or attended low numbers of therapy sessions would be useful, it is acknowledged that some of the factors that would prevent people from attending are likely to also impact upon their desire and ability to attend a qualitative interview.

6.5 Dissemination and impact

This section describes key dissemination activities undertaken during the PhD. However, it does not describe the conference presentations undertaken, training and supervision of Research Assistants, or teaching/training that was not directly related to delivering the TCC.

6.5.1 Service uptake and adaptations

As well as implementation of the TCC by Six Degrees both during and after the research study, a number of other services in the Greater Manchester area are delivering the TCC. Services that have started to deliver the TCC include Stockport, Tameside and Glossop. For example, within Stockport Healthy Minds (who deliver primary care mental health services) eight courses have been delivered with around 6-8 participants per course. Other services and researchers are looking into adapting TCC to different populations, such as adolescents within a Child and Adolescent

Mental Health Service, and clients who have experienced a stroke. Feedback from services delivering TCC has been positive, and within the Stockport service the TCC has been regularly delivered to those with long-term physical health conditions.

In order to support this, training and supervision has been offered. Four training days were delivered by the PhD student (usually with a co-facilitator), as well as a number of half day training sessions and supervision sessions. Regular supervision was delivered as part of the RCT, but in addition to this supervision was offered to clinicians in other services who were delivering the TCC. All clinicians who deliver the TCC are encouraged to access training and supervision in Method of Levels (Carey, 2006; Mansell, Carey, & Tai, 2012) due to the conceptual overlap and similar delivery style.

Within Six Degrees, following the research study, all clinicians will be trained to deliver the TCC. This training process has already commenced and two clinicians from within Six Degrees have been supported to independently deliver training. Already three courses have been run since the research courses, with an average group size of eleven.

As described in the literature review because transdiagnostic processes are targeted, the TCC has the potential to be adapted for different populations. Adaptations can be required because there can be differences in the likely content of goal conflicts within different presenting problems (Mansell et al., 2015). For example, if offering the TCC to clients with addictive disorders a number of changes could be made. One change could be to the focus of the session on ‘what blocks our control’ (Session 2) and this could focus on control of urges to partake in substances, e.g. by prioritising other goals and increased awareness, rather than on repetitive thinking (Fujita, 2011; Thomsen, 2015; Webb et al., 2010). However, because

psychological problems would still be underpinned by self-regulation difficulties resulting from goal conflict, much of the intervention content would be similar.

6.5.2 Manual

A complete manual, in a format suitable for publication, was created during the PhD. Feedback was obtained from Dr Mansell, Dr McEvoy and a number of clinicians within Six Degrees and other services. A final draft was completed prior to the trial commencing, and the manual was used to support delivery of the TCC. In addition to this, Tanya Wallwork (Psychological Wellbeing Practitioner within Six Degrees) was supported to obtain formal qualitative feedback on the manual from clinicians within Six Degrees. She interviewed five clinicians who had not accessed previous TCC training. Changes were made to the manual on the basis of this feedback, and in response to the data from the qualitative study (refinements to the TCC were described in the qualitative study, chapter 5, and these were reflected in changes to the manual). An example of a change in response to clinician feedback was that quizzes were developed for each chapter.

6.6 Clinical implications

The studies within this thesis have a number of implications for clinical practice. Specific refinements to the clinical practice of the TCC have been described in the chapter reporting the qualitative study. However, the findings of the qualitative study also have implications for other group-based interventions of this kind; for example, neither Mindfulness-based Cognitive Therapy nor Stress Control rely on extensive self-disclosure (Segal et al., 2002; White, 2010). Therefore, the format of such groups should be clearly explained in advance owing to concerns that self-disclosure will be required. The findings of the qualitative study indicated that participants valued flexible delivery and varied in whether they wanted additional

sessions or not. Consequently, other groups could offer components that could be adapted to individuals, although this would be more difficult for strictly and prescriptively manualised therapies. Other groups could also be delivered in formats where by a range of sessions could be accessed and this would respond to the research suggesting differences in change trajectory.

The RCT added to evidence that transdiagnostic interventions are effective for common mental health problems. The rationale for transdiagnostic interventions has been discussed at a number of points in the thesis and includes pragmatic considerations, such as addressing multiple and co-morbid problems within one intervention (Andersson & Titov, 2014). Further, there are theoretical reasons for the utility of a transdiagnostic approach, such as convergent evidence from neurobiological and cognitive-behavioural research that suggests that current diagnostic categories do not precisely specify the factors that cause and maintain psychopathology (Buckholtz & Meyer-Lindenberg, 2012; S. E. Morris & Cuthbert, 2012). So there are both pragmatic and theoretical reasons for using transdiagnostic interventions in clinical practice. This thesis provides evidence that the TCC is effective and acceptable in a low-intensity context for a range of psychological problems.

6.7 Summary

This thesis presents a substantial and significant contribution to the existing literature on transdiagnostic interventions. The narrative review uniquely described the theoretical development and rationale for a transdiagnostic group. It specifically articulates theory-practice links in a level of detail that is not common for transdiagnostic groups. The RCT was the first to examine non-inferiority of a brief

transdiagnostic intervention as compared to an established treatment. Indeed, studies comparing transdiagnostic interventions to active treatments are still fairly limited (Newby et al., 2015). The qualitative study was the first to explore client experience of an explicitly transdiagnostic group. Qualitative data is particularly important in examining whether transdiagnostic groups are accessible and acceptable to participants. The studies reported in the thesis contribute to data regarding effectiveness and acceptability of TCC, in line with the overall aim to examine these.

REFERENCES

- Aderka, I. M., Nickerson, A., Bøe, H. J., & Hofmann, S. G. (2012). Sudden gains during psychological treatments of anxiety and depression: A meta-analysis. *Journal of consulting and clinical psychology, 80*(1), 93. doi: 10.1037/a0026455
- Aillon, J.-L., Ndetei, D. M., Khasakhala, L., Ngari, W. N., Achola, H. O., Akinyi, S., & Ribero, S. (2014). Prevalence, types and comorbidity of mental disorders in a Kenyan primary health centre. *Social psychiatry and psychiatric epidemiology, 49*(8), 1257-1268. doi: <http://dx.doi.org/10.1007/s00127-013-0755-2>
- Aldao, A., & Nolen-Hoeksema, S. (2012). The influence of context on the implementation of adaptive emotion regulation strategies. *Behaviour research and therapy, 50*(7-8), 493-501. doi: 10.1016/j.brat.2012.04.004
- Aldao, A., Nolen-Hoeksema, S., & Schweizer, S. (2010). Emotion-regulation strategies across psychopathology: A meta-analytic review. *Clinical Psychology Review, 30*(2), 217-237. doi: 10.1016/j.cpr.2009.11.004
- Alexander, C. L., Arnkoff, D. B., & Glass, C. R. (2010). Bringing psychotherapy to primary care: innovations and challenges. *Clinical Psychology: Science and Practice, 17*(3), 191-214. doi: 10.1111/j.1468-2850.2010.01211.x
- Allart-van Dam, E., Hosman, C. M. H., Hoogduin, C. A. L., & Schaap, C. P. D. R. (2003). The Coping with Depression Course: Short-term outcomes and mediating effects of a randomized controlled trial in the treatment of subclinical depression. *Behavior Therapy, 34*(3), 381-396. doi: 10.1016/S0005-7894(03)80007-2
- Alsawy, S., Mansell, W., Carey, T. A., McEvoy, P., & Tai, S. J. (2014). Science and Practice of Transdiagnostic CBT: A Perceptual Control Theory (PCT) Approach. *International Journal of Cognitive Therapy, 7*(4), 334-359. doi: 10.1521/ijct.2014.7.4.334
- Andersson, G., Hesser, H., Veilord, A., Svedling, L., Andersson, F., Sleman, O., . . . Zetterqvist, V. (2013). Randomised controlled non-inferiority trial with 3-year follow-up of internet-delivered versus face-to-face group cognitive behavioural therapy for depression. *Journal of affective disorders, 151*(3), 986-994. doi: <http://dx.doi.org/10.1016/j.jad.2013.08.022>
- Andersson, G., & Titov, N. (2014). Advantages and limitations of Internet-based interventions for common mental disorders. *World Psychiatry, 13*(1), 4-11. doi: <http://dx.doi.org/10.1002/wps.20083>
- Ashworth, M., Robinson, S. I., Godfrey, E., Shepherd, M., Evans, C., Seed, P., . . . Tylee, A. (2005). Measuring mental health outcomes in primary care: the psychometric properties of a new patient-generated outcome

measure, 'PSYCHLOPS' ('psychological outcome profiles'). *Primary Care Mental Health*, 3(4), 261-270.

- Attride-Stirling, J. (2001). Thematic networks: an analytic tool for qualitative research. *Qualitative research*, 1(3), 385-405. doi: <http://dx.doi.org/10.1177/146879410100100307>
- Ayala, G. X., & Elder, J. P. (2011). Qualitative methods to ensure acceptability of behavioral and social interventions to the target population. *Journal of public health dentistry*, 71(s1), S69-S79. doi: <http://dx.doi.org/10.1111/j.1752-7325.2011.00241.x>
- Ballash, N. G., Pemble, M. K., Usui, W. M., Buckley, A. F., & Woodruff-Borden, J. (2006). Family functioning, perceived control, and anxiety: A mediational model. *Journal of Anxiety Disorders*, 20(4), 486-497. doi: <http://dx.doi.org/10.1016/j.janxdis.2005.05.002>
- Barkham, M., Connell, J., Stiles, W. B., Miles, J. N., Margison, F., Evans, C., & Mellor-Clark, J. (2006). Dose-effect relations and responsive regulation of treatment duration: the good enough level. *Journal of consulting and clinical psychology*, 74(1), 160. doi: <http://dx.doi.org/10.1037/0022-006X.74.1.160>
- Barkham, M., Stiles, W. B., Connell, J., & Mellor-Clark, J. (2012). Psychological treatment outcomes in routine NHS services: What do we mean by treatment effectiveness? *Psychology and Psychotherapy: Theory, Research and Practice*, 85(1), 1-16. doi: 10.1111/j.2044-8341.2011.02019.x
- Barlow, D. H., Allen, L. B., & Choate, M. L. (2004). Toward a unified treatment for emotional disorders. *Behavior Therapy*, 35(2), 205-230. doi: [http://dx.doi.org/10.1016/S0005-7894\(04\)80036-4](http://dx.doi.org/10.1016/S0005-7894(04)80036-4)
- Barrett, M. S., Chua, W.-J., Crits-Christoph, P., Gibbons, M. B., Casiano, D., & Thompson, D. (2008). Early withdrawal from mental health treatment: Implications for psychotherapy practice. *Psychotherapy (Chicago, Ill.)*, 45(2), 247. doi: 10.1037/0033-3204.45.2.247
- Beck, A. T., & Haigh, E. A. (2014). Advances in cognitive theory and therapy: The generic cognitive model. *Annual review of clinical psychology*, 10, 1-24. doi: <http://dx.doi.org/10.1146/annurev-clinpsy-032813-153734>
- Bee, P. E., Lovell, K., Lidbetter, N., Easton, K., & Gask, L. (2010). You can't get anything perfect: "User perspectives on the delivery of cognitive behavioural therapy by telephone". *Social Science & Medicine*, 71(7), 1308-1315.
- Bennett-Levy, J., Richards, D., & Farrand, P. (2010). Low intensity CBT interventions: a revolution in mental health care. In J. Bennett-Levy, D. Richards, P. Farrand, H. Christensen, K. Griffiths, D. Kavanagh, B. Klein, M. A. Lau, J. Proudfoot, L. Ritterband, J. White & C. Williams (Eds.), *Oxford guide to low intensity CBT interventions* (pp. 3-18). Oxford: Oxford University Press

- Bird, T. (2013). *An investigation of transdiagnostic processes and interventions in clinical and non-clinical settings*. (Unpublished doctoral thesis). University of Manchester, Manchester, UK.
- Boudreaux, M. J., & Ozer, D. J. (2013). Goal conflict, goal striving, and psychological well-being. *Motivation and Emotion*, 37(3), 433-443. doi: <http://dx.doi.org/10.1007/s11031-012-9333-2>
- Bower, P., & Gilbody, S. (2005). Stepped care in psychological therapies: access, effectiveness and efficiency Narrative literature review. *The British Journal of Psychiatry*, 186(1), 11-17. doi: <http://dx.doi.org/10.1192/bjp.186.1.11>
- Brady, A., & Raines, D. (2009). Dynamic hierarchies: a control system paradigm for exposure therapy. *The Cognitive Behaviour Therapist*, 2(01), 51-62. doi: 10.1017/S1754470X0800010X
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative research in psychology*, 3(2), 77-101. doi: <http://dx.doi.org/10.1191/1478088706qp063oa>
- Brittain, E., & Lin, D. (2005). A comparison of intent-to-treat and per-protocol results in antibiotic non-inferiority trials. *Statistics in medicine*, 24(1), 1-10. doi: <http://dx.doi.org/10.1002/sim.1934>
- Brockmeyer, T., Grosse Holtforth, M., Krieger, T., Altenstein, D., Doerig, N., Friederich, H.-C., & Bents, H. (2013). Ambivalence over emotional expression in major depression. *Personality and Individual Differences*. doi: 10.1016/j.paid.2012.12.002
- Buckholtz, J. W., & Meyer-Lindenberg, A. (2012). Psychopathology and the human connectome: toward a transdiagnostic model of risk for mental illness. *Neuron*, 74(6), 990-1004. doi: 10.1016/j.neuron.2012.06.002
- Bullis, J. R., Fortune, M. R., Farchione, T. J., & Barlow, D. H. (2014). A preliminary investigation of the long-term outcome of the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders. *Comprehensive psychiatry*, 55(8), 1920-1927. doi: <http://dx.doi.org/10.1016/j.comppsy.2014.07.016>
- Burns, P., Kellett, S., & Donohoe, G. (2016). "Stress Control" as a Large Group Psychoeducational Intervention at Step 2 of IAPT Services: Acceptability of the Approach and Moderators of Effectiveness. *Behavioural and Cognitive Psychotherapy*, 44(04), 431-443. doi: <http://dx.doi.org/10.1017/S1352465815000491>
- Butler, A. C., Chapman, J. E., Forman, E. M., & Beck, A. T. (2006). The empirical status of cognitive-behavioral therapy: a review of meta-analyses. *Clinical psychology review*, 26(1), 17-31. doi: 10.1016/j.cpr.2005.07.003

- Cameron, I. M., Crawford, J. R., Lawton, K., & Reid, I. C. (2008). Psychometric comparison of PHQ-9 and HADS for measuring depression severity in primary care. *The British Journal of General Practice*, 58(546), 32. doi: 10.3399/bjgp08263794
- Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A. L., Sandercock, P., Spiegelhalter, D., & Tyrer, P. (2000). Framework for design and evaluation of complex interventions to improve health. *BMJ: British Medical Journal*, 321(7262), 694. doi: 10.1136/bmj.321.7262.694
- Cape, J., Whittington, C., Buszewicz, M., Wallace, P., & Underwood, L. (2010). Brief psychological therapies for anxiety and depression in primary care: meta-analysis and meta-regression. *BMC medicine*, 8(1), 1. doi: <http://dx.doi.org/10.1186/1741-7015-8-38>
- Carey, T. A. (2006). *The method of levels: How to do psychotherapy without getting in the way*: Living Control Systems Publ.
- Carey, T. A. (2008). Perceptual Control Theory and the Method of Levels: Further Contributions to a Transdiagnostic Perspective. *International Journal of Cognitive Therapy*, 1(3), 237-255. doi: 10.1521/ijct.2008.1.3.237
- Carey, T. A. (2011). Exposure and reorganization: The what and how of effective psychotherapy. *Clinical Psychology Review*, 31(2), 236-248. doi: 10.1016/j.cpr.2010.04.004
- Carey, T. A., Carey, M., Mullan, R. J., Spratt, C. G., & Spratt, M. B. (2009). Assessing the Statistical and Personal Significance of the Method of Levels. *Behavioural and Cognitive Psychotherapy*, 37(3), 311-324. doi: 10.1017/s1352465809005232
- Carey, T. A., Mansell, W., & Tai, S. (2014). A biopsychosocial model based on negative feedback and control. *Frontiers in Human Neuroscience*, 8, 1-10. doi: <http://dx.doi.org/10.3389/fnhum.2014.00094>
- Carey, T. A., Mansell, W., Tai, S. J., & Turkington, D. (2014). Conflicted control systems: the neural architecture of trauma. *The Lancet Psychiatry*, 1(4), 316-318. doi: [http://dx.doi.org/10.1016/S2215-0366\(14\)70306-2](http://dx.doi.org/10.1016/S2215-0366(14)70306-2)
- Carey, T. A., & Mullan, R. J. (2007). Patients taking the lead. A naturalistic investigation of a patient led approach to treatment in primary care. *Counselling Psychology Quarterly*, 20(1), 27-40. doi: <http://dx.doi.org/10.1080/09515070701211304>
- Carey, T. A., & Mullan, R. J. (2008). Evaluating the method of levels. *Counselling Psychology Quarterly*, 21(3), 247-256. doi: <http://dx.doi.org/10.1080/09515070802396012>
- Carey, T. A., & Spratt, M. B. (2009). When is enough enough? Structuring the organisation of treatment to maximise patient choice and control. *The*

Cognitive Behaviour Therapist, 2, 211–226. doi:
10.1017/S1754470X09000208

- Carey, T. A., Tai, S. J., & Stiles, W. B. (2013). Effective and efficient: Using patient-led appointment scheduling in routine mental health practice in remote Australia. *Professional Psychology: Research and Practice*, 44(6), 405. doi: 10.1037/a0035038
- Carlson, J. A. (2010). Avoiding traps in member checking. *The Qualitative Report*, 15(5), 1102.
- Carryer, J. R., & Greenberg, L. S. (2010). Optimal levels of emotional arousal in experiential therapy of depression. *Journal of consulting and clinical psychology*, 78(2), 190. doi: 10.1037/a0018401
- Carver, C. S., & Scheier, M. F. (1998). *On the self-regulation of behavior*. Cambridge: Cambridge University Press.
- Chambers, D. A., Haim, A., Mullican, C. A., & Stirratt, M. (2013). Health information technology and mental health services research: a path forward. *General hospital psychiatry*, 4(35), 329-331. doi:
<http://dx.doi.org/10.1016/j.genhosppsy.2013.03.006>
- Chiesa, A., Calati, R., & Serretti, A. (2011). Does mindfulness training improve cognitive abilities? A systematic review of neuropsychological findings. *Clinical psychology review*, 31(3), 449-464. doi: 10.1016/j.cpr.2010.11.003
- Chorpita, B. F., & Barlow, D. H. (1998). The development of anxiety: The role of control in the early environment. *Psychological bulletin*, 124(1), 3. doi: 10.1037/0033-2909.124.1.3
- Clark, D. A., & Taylor, S. (2009). The Transdiagnostic Perspective on Cognitive-Behavioral Therapy for Anxiety and Depression: New Wine for Old Wineskins? *Journal of Cognitive Psychotherapy*, 23(1), 60-66. doi: 10.1891/0889-8391.23.1.60
- Cortina, J. M. (1993). What is coefficient alpha? An examination of theory and applications. *Journal of applied psychology*, 78(1), 98. doi:
<http://dx.doi.org/10.1037/0021-9010.78.1.98>
- Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). *Developing and evaluating complex interventions: new guidance* Retrieved from www.mrc.ac.uk/complexinterventionsguidance
- Crane, C., Barnhofer, T., Hargus, E., Amarasinghe, M., & Winder, R. (2010). The relationship between dispositional mindfulness and conditional goal setting in depressed patients. *British Journal of Clinical Psychology*, 49(3), 281-290. doi: <http://dx.doi.org/10.1348/014466509X455209>

- Crane, C., Winder, R., Hargus, E., Amarasinghe, M., & Barnhofer, T. (2012). Effects of mindfulness-based cognitive therapy on specificity of life goals. *Cognitive therapy and research*, 36(3), 182-189. doi: <http://dx.doi.org/10.1007/s10608-010-9349-4>
- Craske, M. G., Bunt, R., Rapee, R. M., & Barlow, D. H. (1991). Perceived control and controllability. *Journal of anxiety disorders*, 5(4), 285-292. doi: 10.1016/0887-6185(91)90029-S
- Creswell, J. W. (2009). *Research design: Qualitative, quantitative, and mixed methods approaches*: SAGE Publications, Incorporated.
- De Graaf, L., Gerhards, S., Arntz, A., Riper, H., Metsmakers, J., Evers, S., . . . Huibers, M. (2009). Clinical effectiveness of online computerised cognitive-behavioural therapy without support for depression in primary care: randomised trial. *The British Journal of Psychiatry*, 195(1), 73-80. doi: <http://dx.doi.org/10.1192/bjp.bp.108.054429>
- Deeks, J., Dinnes, J., D'amico, R., Sowden, A., Sakarovich, C., Song, F., . . . Altman, D. (2003). Evaluating non-randomised intervention studies. *Health technology assessment (Winchester, England)*, 7(27), iii-x, 1-173. doi: <http://dx.doi.org/10.3310/hta7270>
- Delgadillo, J., McMillan, D., Leach, C., Lucock, M., Gilbody, S., & Wood, N. (2014). Benchmarking routine psychological services: a discussion of challenges and methods. *Behavioural and cognitive psychotherapy*, 42(01), 16-30. doi: <http://dx.doi.org/10.1017/S135246581200080X>
- Delgadillo, J., McMillan, D., Lucock, M., Leach, C., Ali, S., & Gilbody, S. (2014). Early changes, attrition, and dose-response in low intensity psychological interventions. *British Journal of Clinical Psychology*, 53(1), 114-130. doi: <http://dx.doi.org/10.1111/bjc.12031>
- Dell'Osso, B., Altamura, A. C., Allen, A., Marazziti, D., & Hollander, E. (2006). Epidemiologic and clinical updates on impulse control disorders: a critical review. *European archives of psychiatry and clinical neuroscience*, 256(8), 464-475. doi: <http://dx.doi.org/10.1007/s00406-006-0668-0>
- Deville, G. J., & Borkovec, T. D. (2000). Psychometric properties of the credibility/expectancy questionnaire. *Journal of behavior therapy and experimental psychiatry*, 31(2), 73-86. doi: [http://dx.doi.org/10.1016/S0005-7916\(00\)00012-4](http://dx.doi.org/10.1016/S0005-7916(00)00012-4)
- Dickson, J. M., & MacLeod, A. K. (2004). Approach and avoidance goals and plans: Their relationship to anxiety and depression. *Cognitive Therapy and Research*, 28(3), 415-432. doi: <http://dx.doi.org/10.1023/B:COTR.0000031809.20488.ee>

- Dijksterhuis, A., & Aarts, H. (2010). Goals, attention, and (un) consciousness. *Annual review of psychology*, *61*, 467-490. doi: <http://dx.doi.org/10.1146/annurev.psych.093008.100445>
- Duff, S., & Kinderman, P. (2006). An interacting cognitive subsystems approach to personality disorder. *Clinical Psychology & Psychotherapy*, *13*(4), 233-245. doi: <http://dx.doi.org/10.1002/cpp.490>
- Dures, E., Kitchen, K., Almeida, C., Ambler, N., Cliss, A., Hammond, A., . . . Hewlett, S. (2012). "They didn't tell us, they made us work it out ourselves": Patient perspectives of a cognitive-behavioral program for rheumatoid arthritis fatigue. *Arthritis care & research*, *64*(4), 494-501. doi: <http://dx.doi.org/10.1002/acr.21562>
- Egan, S. J., Wade, T. D., & Shafran, R. (2011). Perfectionism as a transdiagnostic process: A clinical review. *Clinical Psychology Review*, *31*(2), 203-212. doi: [10.1016/j.cpr.2010.04.009](https://doi.org/10.1016/j.cpr.2010.04.009)
- Elliott, R., Fischer, C. T., & Rennie, D. L. (1999). Evolving guidelines for publication of qualitative research studies in psychology and related fields. *British journal of clinical psychology*, *38*(3), 215-229.
- Emmons, R. A., & King, L. A. (1988). Conflict among personal strivings: immediate and long-term implications for psychological and physical well-being. *Journal of personality and social psychology*, *54*(6), 1040. doi: [10.1037/0022-3514.54.6.1040](https://doi.org/10.1037/0022-3514.54.6.1040)
- Erickson, D. H., Janeck, A. S., & Tallman, K. (2009). Transdiagnostic group CBT for anxiety: Clinical experience and practical advice. *Journal of Cognitive Psychotherapy*, *23*(1), 34-43. doi: <http://dx.doi.org/10.1891/0889-8391.23.1.34>
- Fernandez-Serrano, M. J., Perez-Garcia, M., & Verdejo-Garcia, A. (2011). What are the specific vs. generalized effects of drugs of abuse on neuropsychological performance? *Neuroscience and Biobehavioral Reviews*, *35*(3), 377-406. doi: [10.1016/j.neubiorev.2010.04.008](https://doi.org/10.1016/j.neubiorev.2010.04.008)
- Finucane, A., & Mercer, S. W. (2006). An exploratory mixed methods study of the acceptability and effectiveness of mindfulness-based cognitive therapy for patients with active depression and anxiety in primary care. *BMC psychiatry*, *6*(1), 14. doi: [10.1186/1471-244X-6-14](https://doi.org/10.1186/1471-244X-6-14)
- Fjorback, L., Arendt, M., Ørnbøl, E., Fink, P., & Walach, H. (2011). Mindfulness-Based Stress Reduction and Mindfulness-Based Cognitive Therapy—a systematic review of randomized controlled trials. *Acta Psychiatrica Scandinavica*, *124*(2), 102-119. doi: <http://dx.doi.org/10.1111/j.1600-0447.2011.01704.x>

- Foa, E. B., Huppert, J. D., & Cahill, S. P. (2006). Emotional Processing Theory: An Update. In B. O. Rothbaum (Ed.), *Pathological anxiety: Emotional processing in etiology and treatment* (pp. 3–24). New York: Guilford Press
- Follette, W. C., & Beitz, K. (2003). Adding a more rigorous scientific agenda to the empirically supported treatment movement. *Behavior Modification, 27*(3), 369-386. doi: 10.1177/0145445503027003006
- Forgeard, M. J., Haigh, E. A., Beck, A. T., Davidson, R. J., Henn, F. A., Maier, S. F., . . . Seligman, M. E. (2011). Beyond Depression: Toward a Process-Based Approach to Research, Diagnosis, and Treatment. *Clinical Psychology: Science and Practice, 18*(4), 275-299. doi: <http://dx.doi.org/10.1111/j.1468-2850.2011.01259.x>
- Fujita, K. (2011). On conceptualizing self-control as more than the effortful inhibition of impulses. *Personality and Social Psychology Review, 15*(4), 352-366. doi: 10.1177/1088868311411165
- Fujita, K., & Carnevale, J. J. (2012). Transcending Temptation Through Abstraction The Role of Construal Level in Self-Control. *Current Directions in Psychological Science, 21*(4), 248-252. doi: <http://dx.doi.org/10.1177/0963721412449169>
- Gaffney, H., Mansell, W., Edwards, R., & Wright, J. (2013). Manage Your Life Online (MYLO): A Pilot Trial of a Conversational Computer-Based Intervention for Problem Solving in a Student Sample. *Behavioural and cognitive psychotherapy, 1*-16. doi: 10.1017/S135246581300060X
- Gianakis, M., & Carey, T. A. (2011). An interview study investigating experiences of psychological change without psychotherapy. *Psychology and Psychotherapy: Theory, Research and Practice, 84*(4), 442-457. doi: 10.1111/j.2044-8341.2010.02002.x
- Glaser, B., & Strauss, A. (1967). *The Discovery of Grounded Theory: Strategies for Qualitative Research*. Chicago, IL: Aldine.
- Glover, G., Webb, M., & Evison, F. (2010). Improving access to psychological therapies: a review of the progress made by sites in the first roll-out year. *North East Public Health Observatory*. <http://www.iapt.nhs.uk/silo/files/iapt-a-review-of-the-progress-made-by-sites-in-the-first-roll8208-out-year.pdf>
- Gotlib, I. H., & Joormann, J. (2010). Cognition and depression: current status and future directions. *Annual review of clinical psychology, 6*, 285. doi: <http://dx.doi.org/10.1146/annurev.clinpsy.121208.131305>
- Grafton, S. T., & Hamilton, A. F. (2007). Evidence for a distributed hierarchy of action representation in the brain. *Human movement science, 26*(4), 590-616. doi: <http://dx.doi.org/10.1016/j.humov.2007.05.009>

- Grawe, K. (2007). *Neuropsychotherapy : how the neurosciences inform effective psychotherapy*. Mahwah, NJ ; London: Lawrence Erlbaum Associates.
- Guest, G., Bunce, A., & Johnson, L. (2006). How many interviews are enough? An experiment with data saturation and variability. *Field methods*, 18(1), 59-82. doi: <http://dx.doi.org/10.1177/1525822X05279903>
- Guillaud, E., Simoneau, M., & Blouin, J. (2011). Prediction of the body rotation-induced torques on the arm during reaching movements: Evidence from a proprioceptively deafferented subject. *Neuropsychologia*, 49(7), 2055-2059. doi: <http://dx.doi.org/10.1016/j.neuropsychologia.2011.03.035>
- Gupta, S. K. (2011). Intention-to-treat concept: A review. *Perspectives in clinical research*, 2(3), 109. doi: <http://dx.doi.org/10.4103/2229-3485.83221>
- Harvey, A. G., Watkins, E., Mansell, W., & Shafran, R. (2004). *Cognitive behavioural processes across psychological disorders: A transdiagnostic approach to research and treatment*: Oxford University Press, USA.
- Hayes, S. C., Strosahl, K., & Wilson, K. G. (1999). *Acceptance and commitment therapy : an experiential approach to behavior change*. New York ; London: Guilford Press.
- Higginson, S., & Mansell, W. (2008). What is the mechanism of psychological change? A qualitative analysis of six individuals who experienced personal change and recovery. *Psychology and Psychotherapy-Theory Research and Practice*, 81, 309-328. doi: 10.1348/147608308x320125
- Higginson, S., Mansell, W., & Wood, A. M. (2011). An integrative mechanistic account of psychological distress, therapeutic change and recovery: The Perceptual Control Theory approach. *Clinical Psychology Review*, 31(2), 249-259. doi: 10.1016/j.cpr.2010.01.005
- Hirsh, J. B., Mar, R. A., & Peterson, J. B. (2012). Psychological entropy: A framework for understanding uncertainty-related anxiety. *Psychological review*, 119(2), 304. doi: 10.1037/a0026767
- Hofmann, S. G. (2013). Bridging the Theory-Practice Gap by Getting Even Bolder with the Boulder Model. *Behavior Therapy*, 44(4), 603-608. doi: 10.1016/j.beth.2013.04.006
- Hofmann, S. G., Asnaani, A., Vonk, I. J., Sawyer, A. T., & Fang, A. (2012). The efficacy of Cognitive Behavioral Therapy: a review of meta-analyses. *Cognitive therapy and research*, 36(5), 427-440. doi: <http://dx.doi.org/10.1007/s10608-012-9476-1>
- Hofmann, S. G., & Smits, J. A. (2008). Cognitive-behavioral therapy for adult anxiety disorders: a meta-analysis of randomized placebo-controlled trials. *The Journal of clinical psychiatry*, 69(4), 621. doi: <http://dx.doi.org/10.4088/JCP.v69n0415>

- Hölzel, B. K., Lazar, S. W., Gard, T., Schuman-Olivier, Z., Vago, D. R., & Ott, U. (2011). How does mindfulness meditation work? Proposing mechanisms of action from a conceptual and neural perspective. *Perspectives on Psychological Science*, 6(6), 537-559. doi: 10.1177/1745691611419671
- Huntley, A. L., Araya, R., & Salisbury, C. (2012). Group psychological therapies for depression in the community: systematic review and meta-analysis. *The British Journal of Psychiatry*, 200(3), 184-190. doi: 10.1192/bjp.bp.111.092049
- Hyland, M. E. (1987). Control Theory Interpretation of Psychological Mechanisms of Depression: Comparison and Integration of Several Theories. *Psychological Bulletin*, 102(1), 109-121. doi: <http://dx.doi.org/10.1037/0033-2909.102.1.109>
- Jacobson, N. S., Roberts, L. J., Berns, S. B., & McGlinchey, J. B. (1999). Methods for defining and determining the clinical significance of treatment effects: description, application, and alternatives. *Journal of consulting and clinical psychology*, 67(3), 300. doi: <http://dx.doi.org/10.1037/0022-006X.67.3.300>
- Jacobson, N. S., & Truax, P. (1991). Clinical significance: A statistical approach to denning meaningful change in psychotherapy research. *Journal of consulting and clinical psychology*, 59(1), 12-19. doi: 10.1037/0022-006X.59.1.12
- Jadad, A. R., & Enkin, M. W. (2008). Bias in randomized controlled trials. *Randomized Controlled Trials: Questions, Answers, and Musings, Second Edition*, 29-47.
- Johnson, R. (2009). The intrapersonal civil war. *Psychologist*, 22(4), 300.
- Jönsson, B. (2009). Ten arguments for a societal perspective in the economic evaluation of medical innovations. *The European Journal of Health Economics*, 10(4), 357-359. doi: <http://dx.doi.org/10.1007/s10198-009-0173-2>
- Kabat-Zinn, J. (1982). An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: Theoretical considerations and preliminary results. *General hospital psychiatry*, 4(1), 33-47. doi: [http://dx.doi.org/10.1016/0163-8343\(82\)90026-3](http://dx.doi.org/10.1016/0163-8343(82)90026-3)
- Kelly, R. E., Mansell, W., & Wood, A. M. (2011). Goal conflict and ambivalence interact to predict depression. *Personality and Individual Differences*, 50(4), 531-534. doi: 10.1016/j.paid.2010.11.018
- Kelly, R. E., Mansell, W., & Wood, A. M. (2015). Goal conflict and well-being: A review and hierarchical model of goal conflict, ambivalence, self-discrepancy and self-concordance. *Personality and Individual Differences*, 85, 212-229. doi: <http://dx.doi.org/10.1016/j.paid.2015.05.011>

- Kennaway, J. (1999). Control of a multi-legged robot based on hierarchical perceptual control theory. *J. Perceptual Control Theory*, 1(1).
- Kessler, R. C., Demler, O., Frank, R. G., Olfson, M., Pincus, H. A., Walters, E. E., . . . Zaslavsky, A. M. (2005). Prevalence and treatment of mental disorders, 1990 to 2003. *New England Journal of Medicine*, 352(24), 2515-2523. doi: 10.1056/NEJMsa043266
- Khan, N., Bower, P., & Rogers, A. (2007). Guided self-help in primary care mental health Meta-synthesis of qualitative studies of patient experience. *The British Journal of Psychiatry*, 191(3), 206-211. doi: <http://dx.doi.org/10.1192/bjp.bp.106.032011>
- Khoury, B., Lecomte, T., Fortin, G., Masse, M., Therien, P., Bouchard, V., . . . Hofmann, S. G. (2013). Mindfulness-based therapy: a comprehensive meta-analysis. *Clinical psychology review*, 33(6), 763-771. doi: <http://dx.doi.org/10.1016/j.cpr.2013.05.005>
- Kitchiner, N. J., Edwards, D., Wood, S., Sainsbury, S., Hewin, P., Burnard, P., & Bisson, J. I. (2009). A randomized controlled trial comparing an adult education class using cognitive behavioural therapy (“stress control”), anxiety management group treatment and a waiting list for anxiety disorders. *Journal of Mental Health*, 18(4), 307-315. doi: 10.1080/09638230802052153
- Knowles, S. E., Toms, G., Sanders, C., Bee, P., Lovell, K., Rennick-Egglestone, S., . . . Kessler, D. (2014). Qualitative meta-synthesis of user experience of computerised therapy for depression and anxiety. *PLoS one*, 9(1), e84323. doi: <http://dx.doi.org/10.1371/journal.pone.0084323>
- Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9: Validity of a brief depression severity measure. *Journal of General Internal Medicine*, 16(9), 606-613. doi: 10.1046/j.1525-1497.2001.016009606.x
- Levin, M. E., Hildebrandt, M. J., Lillis, J., & Hayes, S. C. (2012). The impact of treatment components suggested by the psychological flexibility model: A meta-analysis of laboratory-based component studies. *Behavior therapy*, 43(4), 741-756. doi: 10.1016/j.beth.2012.05.003
- Lewin, S., Glenton, C., & Oxman, A. D. (2009). Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study. *Bmj*, 339, b3496.
- Lewis, C., Pearce, J., & Bisson, J. I. (2012). Efficacy, cost-effectiveness and acceptability of self-help interventions for anxiety disorders: systematic review. *The British journal of psychiatry*, 200(1), 15-21. doi: <http://dx.doi.org/10.1192/bjp.bp.110.084756>
- Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic inquiry*. Beverly Hills, CA: Sage.

- Loh, J. (2013). Inquiry into issues of trustworthiness and quality in narrative studies: A perspective. *The qualitative report*, 18(33), 1.
- Lomax, C. L., Barnard, P., & Lam, D. (2009). Cognitive processing in bipolar disorder conceptualized using the Interactive Cognitive Subsystems (ICS) model. *Psychological medicine*, 39(05), 773-783. doi: <http://dx.doi.org/10.1017/S003329170800425X>
- Macdonald, W., Mead, N., Bower, P., Richards, D., & Lovell, K. (2007). A qualitative study of patients' perceptions of a 'minimal' psychological therapy. *International journal of social psychiatry*, 53(1), 23-35. doi: <http://dx.doi.org/10.1177/0020764006066841>
- Maia, A. C. C., Braga, A. A., Nunes, C. A., Nardi, A. E., & Silva, A. C. (2013). Transdiagnostic treatment using a unified protocol: application for patients with a range of comorbid mood and anxiety disorders. *Trends in Psychiatry and Psychotherapy*, 35(2), 134-140. doi: <http://dx.doi.org/10.1590/S2237-60892013000200007>
- Malpass, A., Carel, H., Ridd, M., Shaw, A., Kessler, D., Sharp, D., . . . Wallond, J. (2012). Transforming the perceptual situation: a meta-ethnography of qualitative work reporting patients' experiences of mindfulness-based approaches. *Mindfulness*, 3(1), 60-75. doi: <http://dx.doi.org/10.1007/s12671-011-0081-2>
- Mansell, W. (2010). Bipolar Disorders. In A. Grant, M. Townend, R. Mulhern & N. Short (Eds.), *Cognitive Behaviour Therapy in Mental Health Care, 2nd Edition*. London, UK: SAGE Publications Ltd.
- Mansell, W. (2011). Core processes of psychopathology and recovery: "Does the Dodo bird effect have wings?". *Clinical Psychology Review*, 31(2), 189-192. doi: 10.1016/j.cpr.2010.06.009
- Mansell, W., & Carey, T. (2012). Dissociation: Perceptual Control Theory as an Integrative Framework for Clinical Interventions. In F. Kennedy, H. Kennerly & D. Pearson (Eds.), *Cognitive behavioural approaches to the understanding and treatment of dissociation* (pp. 221–235). London: Routledge
- Mansell, W., Carey, T., & Tai, S. (2015). Classification of psychopathology and unifying theory: The ingredients of a Darwinian paradigm shift in research methodology. *Psychopathology Review*, 2, 129-153.
- Mansell, W., & Carey, T. A. (2009). A century of psychology and psychotherapy: Is an understanding of 'control' the missing link between theory, research, and practice? *Psychology and Psychotherapy-Theory Research and Practice*, 82(3), 337-353. doi: 10.1348/147608309x432526

- Mansell, W., Carey, T. A., & Tai, S. J. (2012). *A Transdiagnostic Approach to CBT Using Method of Levels Therapy: Distinctive Features*. New York: Routledge.
- Mansell, W., Harvey, A., Watkins, E., & Shafran, R. (2009). Conceptual foundations of the transdiagnostic approach to CBT. *Journal of Cognitive Psychotherapy*, 23(1), 6-19. doi: 10.1891/0889-8391.23.1.6
- Marken, R. S. (2009). You say you had a revolution: Methodological foundations of closed-loop psychology. *Review of General Psychology*, 13(2), 137. doi: <http://dx.doi.org/10.1037/a0015106>
- Marken, R. S. (2014). Testing for controlled variables: a model-based approach to determining the perceptual basis of behavior. *Attention, Perception, & Psychophysics*, 76(1), 255-263. doi: <http://dx.doi.org/10.3758/s13414-013-0552-8>
- Marken, R. S., & Carey, T. A. (2014). Understanding the Change Process Involved in Solving Psychological Problems: A Model-based Approach to Understanding How Psychotherapy Works. *Clinical psychology & psychotherapy*. doi: 10.1002/cpp.1919
- Marken, R. S., & Mansell, W. (2013). Perceptual Control as a Unifying Concept in Psychology. *Review of General Psychology*. doi: 10.1037/a0032933
- Marken, R. S., Mansell, W., & Khatib, Z. (2013). Motor control as the control of perception. *Perceptual and motor skills*, 117(1), 1278. doi: <http://dx.doi.org/10.2466/24.23.PMS.117x15z2>
- Mason, O., & Hargreaves, I. (2001). A qualitative study of mindfulness-based cognitive therapy for depression. *British Journal of Medical Psychology*, 74(2), 197-212. doi: <http://dx.doi.org/10.1348/000711201160911>
- Mataix-Cols, D., Cowley, A. J., Hankins, M., Schneider, A., Bachofen, M., Kenwright, M., . . . Marks, I. M. (2005). Reliability and validity of the Work and Social Adjustment Scale in phobic disorders. *Comprehensive Psychiatry*, 46(3), 223-228. doi: 10.1016/j.comppsy.2004.08.007
- Matthews, J. N. (2006). *Introduction to randomized controlled clinical trials*: Chapman & Hall/CRC Boca Raton, FL.
- Mayo-Wilson, E., Dias, S., Mavranouzouli, I., Kew, K., Clark, D. M., Ades, A., & Pilling, S. (2014). Psychological and pharmacological interventions for social anxiety disorder in adults: a systematic review and network meta-analysis. *The Lancet Psychiatry*, 1(5), 368-376.
- McClelland, K. (2004). The collective control of perceptions: constructing order from conflict. *International journal of human-computer studies*, 60(1), 65-99. doi: 10.1016/j.ijhcs.2003.08.003

- Mcglynn, F. D., Rose, M. P., & Lazarte, A. (1994). Control and attention during exposure influence arousal and fear among insect phobics. *Behavior modification*, 18(4), 371-388. doi: 10.1177/01454455940184001
- McHugh, R. K., & Barlow, D. H. (2010). The dissemination and implementation of evidence-based psychological treatments: a review of current efforts. *American Psychologist*, 65(2), 73. doi: 10.1037/a0018121
- McHugh, R. K., Murray, H. W., & Barlow, D. H. (2009). Balancing fidelity and adaptation in the dissemination of empirically-supported treatments: The promise of transdiagnostic interventions. *Behaviour Research and Therapy*, 47(11), 946-953. doi: 10.1016/j.brat.2009.07.005
- McLeod, B. D., Weisz, J. R., & Wood, J. J. (2007). Examining the association between parenting and childhood depression: A meta-analysis. *Clinical psychology review*, 27(8), 986-1003. doi: 10.1016/j.cpr.2007.03.001
- McManus, F., Shafran, R., & Cooper, Z. (2010). What does a 'transdiagnostic' approach have to offer the treatment of anxiety disorders? *British Journal of Clinical Psychology*, 49, 491-505. doi: 10.1348/014466509x476567
- Mechsner, F., Stenneken, P., Cole, J., Aschersleben, G., & Prinz, W. (2007). Bimanual circling in deafferented patients: Evidence for a role of visual forward models. *Journal of neuropsychology*, 1(2), 259-282.
- Miller, W. R., & Rose, G. S. (2009). Toward a theory of motivational interviewing. *American psychologist*, 64(6), 527. doi: <http://dx.doi.org/10.1037/a0016830>
- Mitchell, A. J., Vaze, A., & Rao, S. (2009). Clinical diagnosis of depression in primary care: a meta-analysis. *The Lancet*, 374(9690), 609-619. doi: [http://dx.doi.org/10.1016/S0140-6736\(09\)60879-5](http://dx.doi.org/10.1016/S0140-6736(09)60879-5)
- Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., . . . Wight, D. (2015). Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*, 350, h1258. doi: <http://dx.doi.org/10.1136/bmj.h1258>
- Morris, L. (2013). *A pilot evaluation of a transdiagnostic group intervention for mental health problems in primary care* (Unpublished doctoral thesis). University of Manchester, Manchester, UK.
- Morris, L., Mansell, W., Emsley, R., Bates, R., Comiskey, J., Pistorius, E., & McEvoy, P. (2015). Prospective cohort feasibility study of a transdiagnostic group intervention for common mental health problems: The Take Control Course. *Psychology and Psychotherapy: Theory, Research and Practice*.
- Morris, L., Mansell, W., & McEvoy, P. (2016). The Take Control Course: Conceptual rationale for the development of a transdiagnostic group for common mental health problems. *Frontiers in Psychology*, 7, 99. doi: 10.3389/fpsyg.2016.00099

- Morris, S. E., & Cuthbert, B. N. (2012). Research Domain Criteria: cognitive systems, neural circuits, and dimensions of behavior. *Dialogues in clinical neuroscience, 14*(1), 29.
- Mundt, J. C., Marks, I. M., Shear, M. K., & Greist, J. M. (2002). The Work and Social Adjustment Scale: a simple measure of impairment in functioning. *The British Journal of Psychiatry, 180*(5), 461-464. doi: 10.1192/bjp.180.5.461
- Murphy, E., Mansell, W., Craven, S., & McEvoy, P. (2014). Approach-Avoidance Attitudes Associated with Initial Therapy Appointment Attendance: A Prospective Study. *Behavioural and cognitive psychotherapy, 1-5*. doi: <http://dx.doi.org/10.1017/S135246581400023X>
- Nanda, M. M., Kotchick, B. A., & Grover, R. L. (2012). Parental psychological control and childhood anxiety: The mediating role of perceived lack of control. *Journal of Child and Family Studies, 21*(4), 637-645. doi: <http://dx.doi.org/10.1007/s10826-011-9516-6>
- Newby, J. M., McKinnon, A., Kuyken, W., Gilbody, S., & Dalgleish, T. (2015). Systematic review and meta-analysis of transdiagnostic psychological treatments for anxiety and depressive disorders in adulthood. *Clinical psychology review, 40*, 91-110. doi: <http://dx.doi.org/10.1016/j.cpr.2015.06.002>
- Newman, M. G., Szkodny, L. E., Llera, S. J., & Przeworski, A. (2010). A review of technology-assisted self-help and minimal contact therapies for anxiety and depression: Is human contact necessary for therapeutic efficacy? *Clinical Psychology Review, 31*, 89-103. doi: 10.1016/j.cpr.2010.09.008
- Nieuwsma, J. A., Trivedi, R. B., McDuffie, J., Kronish, I., Benjamin, D., & Williams, J. W. (2012). Brief psychotherapy for depression: a systematic review and meta-analysis. *The International Journal of Psychiatry in Medicine, 43*(2), 129-151. doi: <http://dx.doi.org/10.2190/PM.43.2.c>
- Nolen-Hoeksema, S., & Watkins, E. R. (2011). A Heuristic for Developing Transdiagnostic Models of Psychopathology Explaining Multifinality and Divergent Trajectories. *Perspectives on Psychological Science, 6*(6), 589-609. doi: <http://dx.doi.org/10.1177/1745691611419672>
- Nolen-Hoeksema, S., Wisco, B. E., & Lyubomirsky, S. (2008). Rethinking rumination. *Perspectives on psychological science, 3*(5), 400-424. doi: 10.1111/j.1745-6924.2008.00088.x
- Norton, P. J. (2008). An open trial of a transdiagnostic cognitive-behavioral group therapy for anxiety disorder. *Behavior Therapy, 39*(3), 242-250. doi: <http://dx.doi.org/10.1016/j.beth.2007.08.002>
- Norton, P. J. (2012). A randomized clinical trial of transdiagnostic cognitive-behavioral treatments for anxiety disorder by comparison to relaxation

training. *Behavior Therapy*, 43(3), 506-517. doi:
<http://dx.doi.org/10.1016/j.beth.2010.08.011>

- Norton, P. J., & Barrera, T. L. (2012). Transdiagnostic versus diagnosis-specific CBT for anxiety disorders: a preliminary randomized controlled noninferiority trial. *Depression and Anxiety*, 29(10), 874-882. doi:
<http://dx.doi.org/10.1002/da.21974>
- Norton, P. J., Hayes, S. A., & Hope, D. A. (2004). Effects of a transdiagnostic group treatment for anxiety on secondary depression. *Depression and Anxiety*, 20(4), 198-202. doi: 10.1002/da.20045
- Norton, P. J., & Philipp, L. M. (2008). Transdiagnostic approaches to the treatment of anxiety disorders: A quantitative review. *Psychotherapy*, 45(2), 214-226. doi: 10.1037/0033-3204.45.2.214
- O'Brien, A., Fahmy, R., & Singh, S. P. (2009). Disengagement from mental health services. *Social psychiatry and psychiatric epidemiology*, 44(7), 558-568. doi: 10.1007/s00127-008-0476-0
- Onwuegbuzie, A. J., & Leech, N. L. (2007). Sampling designs in qualitative research: Making the sampling process more public. *The qualitative report*, 12(2), 238-254.
- Öst, L.-G. (2014). The efficacy of acceptance and commitment therapy: an updated systematic review and meta-analysis. *Behaviour research and therapy*, 61, 105-121. doi: <http://dx.doi.org/10.1016/j.brat.2014.07.018>
- Ottaviani, C., Shapiro, D., & Couyoumdjian, A. (2013). Flexibility as the key for somatic health: From mind wandering to perseverative cognition. *Biological psychology*, 94(1), 38-43. doi:
<http://dx.doi.org/10.1016/j.biopsycho.2013.05.003>
- Park, R. J., Dunn, B. D., & Barnard, P. J. (2011). Schematic models and modes of mind in anorexia nervosa I: A novel process account. *International Journal of Cognitive Therapy*, 4(4), 415-437.
- Pellis, S. M., & Bell, H. C. (2011). Closing the circle between perceptions and behavior: A cybernetic view of behavior and its consequences for studying motivation and development. *Developmental Cognitive Neuroscience*, 1(4), 404-413. doi: <http://dx.doi.org/10.1016/j.dcn.2011.07.010>
- Peters, S. (2010). Qualitative research methods in mental health. *Evidence-based mental health*, 13(2), 35-40. doi: <http://dx.doi.org/10.1136/ebmh.13.2.35>
- Piaggio, G., Elbourne, D. R., Pocock, S. J., Evans, S. J., Altman, D. G., & Group, C. (2012). Reporting of noninferiority and equivalence randomized trials: extension of the CONSORT 2010 statement. *Jama*, 308(24), 2594-2604. doi: <http://dx.doi.org/10.1001/jama.2012.87802>

- Pierre, J. M. (2010). The borders of mental disorder in psychiatry and the DSM: Past, present, and future. *Journal of Psychiatric Practice, 16*(6), 375-386. doi: <http://dx.doi.org/10.1097/01.pra.0000390756.37754.68>
- Pitman, R. K. (1987). A cybernetic model of obsessive-compulsive psychopathology. *Comprehensive Psychiatry, 28*(4), 334-343. doi: [http://dx.doi.org/10.1016/0010-440X\(87\)90070-8](http://dx.doi.org/10.1016/0010-440X(87)90070-8)
- Porta, N., Bonet, C., & Cobo, E. (2007). Discordance between reported intention-to-treat and per protocol analyses. *Journal of clinical epidemiology, 60*(7), 663-669.
- Powers, M. B., Zum Vörde Sive Vörding, M. B., & Emmelkamp, P. M. G. (2009). Acceptance and commitment therapy: A meta-analytic review. *Psychotherapy and psychosomatics, 78*(2), 73-80. doi: 10.1159/000190790
- Powers, W. T. (1973). *Behavior : the control of perception*. Chicago, Ill.: Aldine.
- Powers, W. T. (1999). A model of kinesthetically and visually controlled arm movement. *International Journal of Human-Computer Studies, 50*(6), 463-479. doi: <http://dx.doi.org/10.1006/ijhc.1998.0261>
- Powers, W. T. (2005). *Behavior: The Control of Perception*: Benchmark Press.
- Powers, W. T. (2008). *Living Control Systems III: The fact of control*. Bloomfield, NJ: Benchmark Publications Inc.
- Powers, W. T., Clark, R., & Mc Farland, R. (1960a). A general feedback theory of human behavior: Part I. *Perceptual and motor skills, 11*(1), 71-88. doi: <http://dx.doi.org/10.2466/pms.1960.11.1.71>
- Powers, W. T., Clark, R., & Mc Farland, R. (1960b). A general feedback theory of human behavior: Part II. *Perceptual and Motor Skills, 11*(3), 309-323. doi: <http://dx.doi.org/10.2466/pms.1960.11.3.309>
- Pyszczynski, T., Holt, K., & Greenberg, J. (1987). Depression, self-focused attention, and expectancies for positive and negative future life events for self and others. *Journal of personality and social psychology, 52*(5), 994. doi: <http://dx.doi.org/10.1037/0022-3514.52.5.994>
- Reinholt, N., & Krogh, J. (2014). Efficacy of transdiagnostic cognitive behaviour therapy for anxiety disorders: A systematic review and meta-analysis of published outcome studies. *Cognitive behaviour therapy, 43*(3), 171-184. doi: <http://dx.doi.org/10.1080/16506073.2014.897367>
- Richards, D., Timulak, L., O'Brien, E., Hayes, C., Vigano, N., Sharry, J., & Doherty, G. (2015). A randomized controlled trial of an internet-delivered treatment: Its potential as a low-intensity community intervention for adults with symptoms of depression. *Behaviour research and therapy, 75*, 20-31.

- Richards, D. A. (2010). Access and organization: putting low intensity interventions to work in clinical services. In J. Bennett-Levy, D. A. Richards, P. Farrand, H. Christensen, K. Griffiths, D. Kavanagh, B. Klein, M. A. Lau, J. Proudfoot, L. Ritterband, J. White & C. Williams (Eds.), *Oxford Guide to Low Intensity CBT Interventions* United States, New York: Oxford University Press
- Richards, D. A., & Borglin, G. (2011). Implementation of psychological therapies for anxiety and depression in routine practice: Two year prospective cohort study. *Journal of affective disorders*, *133*(1), 51-60. doi: 10.1016/j.jad.2011.03.024
- Richards, D. A., Bower, P., Pagel, C., Weaver, A., Utley, M., Cape, J., . . . Leibowitz, J. (2012). Delivering stepped care: an analysis of implementation in routine practice. *Implement Sci*, *7*(3). doi: 10.1186/1748-5908-7-3
- Richards, D. A., & Suckling, R. (2009). Improving access to psychological therapies: phase IV prospective cohort study. *British Journal of Clinical Psychology*, *48*(4), 377-396. doi: 10.1348/014466509X405178
- Roberts, B. L., Anthony, M. K., Madigan, E. A., & Chen, Y. (1997). Data management: cleaning and checking. *Nursing research*, *46*(6), 350-352. doi: <http://dx.doi.org/10.1097/00006199-199711000-00010>
- Rogers, A., Oliver, D., Bower, P., Lovell, K., & Richards, D. (2004). Peoples' understandings of a primary care-based mental health self-help clinic. *Patient education and counseling*, *53*(1), 41-46. doi: [http://dx.doi.org/10.1016/S0738-3991\(03\)00114-9](http://dx.doi.org/10.1016/S0738-3991(03)00114-9)
- Rose, M. P., McGlynn, F. D., & Lazarte, A. (1995). Control and attention influence snake phobics' arousal and fear during laboratory confrontations with a caged snake. *Journal of anxiety disorders*, *9*(4), 293-302. doi: [http://dx.doi.org/10.1016/0887-6185\(95\)00010-L](http://dx.doi.org/10.1016/0887-6185(95)00010-L)
- Rosen, G. M., & Davison, G. C. (2003). Psychology should list empirically supported principles of change (ESPs) and not credential trademarked therapies or other treatment packages. *Behavior Modification*, *27*(3), 300-312. doi: 10.1177/0145445503027003003
- Ruiz, F. J. (2012). Acceptance and commitment therapy versus traditional cognitive behavioral therapy: A systematic review and meta-analysis of current empirical evidence. *International Journal of Psychology and Psychological Therapy*, *12*(3), 333-358.
- Sanders, C., Rogers, A., Bowen, R., Bower, P., Hirani, S., Cartwright, M., . . . Hendy, J. (2012). Exploring barriers to participation and adoption of telehealth and telecare within the Whole System Demonstrator trial: a qualitative study. *BMC health services research*, *12*(1), 220. doi: <http://dx.doi.org/10.1186/1472-6963-12-220>

- Schauman, O., & Mansell, W. (2012). Processes Underlying Ambivalence in Help-Seeking: The Loss of Valued Control Model. *Clinical Psychology: Science and Practice, 19*(2), 107-124. doi: <http://dx.doi.org/10.1111/j.1468-2850.2012.01277.x>
- Schindler, A., Hiller, W., & Witthöft, M. (2013). What predicts outcome, response, and drop-out in CBT of depressive adults? A naturalistic study. *Behavioural and cognitive psychotherapy, 41*(03), 365-370. doi: <http://dx.doi.org/10.1017/S1352465812001063>
- Schultz, P., & Searleman, A. (2002). Rigidity of thought and behavior: 100 years of research. *Genetic, social, and general psychology monographs, 128*(2), 165-207.
- Schwandt, T. A. (1996). Farewell to criteriology. *Qualitative Inquiry, 2*(1), 58-72. doi: <http://dx.doi.org/10.1177/107780049600200109>
- Seale, C. (1999). Quality in qualitative research. *Qualitative inquiry, 5*(4), 465-478. doi: <http://dx.doi.org/10.1177/107780049900500402>
- Segal, Z. V., Williams, J. M. G., & Teasdale, J. D. (2002). *Mindfulness-based cognitive therapy for depression : a new approach to preventing relapse*. New York ; London: Guilford Press.
- Shafran, R., Clark, D., Fairburn, C., Arntz, A., Barlow, D., Ehlers, A., . . . Ost, L. (2009). Mind the gap: Improving the dissemination of CBT. *Behaviour Research and Therapy, 47*(11), 902-909. doi: <http://dx.doi.org/10.1016/j.brat.2009.07.003>
- Shapiro, S. L., Carlson, L. E., Astin, J. A., & Freedman, B. (2006). Mechanisms of mindfulness. *Journal of clinical psychology, 62*(3), 373-386. doi: <http://dx.doi.org/10.1002/jclp.20237>
- Shenton, A. K. (2004). Strategies for ensuring trustworthiness in qualitative research projects. *Education for information, 22*(2), 63-75.
- Skinner, E. A. (1996). A guide to constructs of control. *Journal of personality and social psychology, 71*(3), 549. doi: <http://dx.doi.org/10.1037/0022-3514.71.3.549>
- Smith, J. A. (2004). Reflecting on the development of interpretative phenomenological analysis and its contribution to qualitative research in psychology. *Qualitative research in psychology, 1*(1), 39-54.
- Smith, J. A., Jarman, M., & Osborn, M. (1999). Doing interpretative phenomenological analysis. In M. Murray & K. Chamberlain (Eds.), *Qualitative health psychology* (pp. 218-239). London: Sage

- Sobell, M. B., & Sobell, L. C. (2000). Stepped care as a heuristic approach to the treatment of alcohol problems. *Journal of consulting and clinical psychology*, 68(4), 573.
- Spitzer, R. L., Kroenke, K., Williams, J. B. W., & Lowe, B. (2006). A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of Internal Medicine*, 166(10), 1092-1097. doi: 10.1001/archinte.166.10.1092
- StataCorp. (2011). *Stata Statistical Software: Release 12*. College Station, TX: StataCorp LP.
- Stenbacka, C. (2001). Qualitative research requires quality concepts of its own. *Management Decision*, 39(7), 551-555
- Tai, S. J. (2009). Using Perceptual Control Theory and the Method of Levels to work with people who experience psychosis. *The Cognitive Behaviour Therapist*, 2(03), 227-242. doi: 10.1017/S1754470X09990134
- Tamayo-Sarver, J. H., Albert, J. M., Tamayo-Sarver, M., & Cydulka, R. K. (2005). Advanced statistics: how to determine whether your intervention is different, at least as effective as, or equivalent: a basic introduction. *Academic emergency medicine*, 12(6), 536-542. doi: <http://dx.doi.org/10.1111/j.1553-2712.2005.tb00897.x>
- Tang, T. Z., & DeRubeis, R. J. (1999). Sudden gains and critical sessions in cognitive-behavioral therapy for depression. *Journal of consulting and clinical psychology*, 67(6), 894. doi: <http://dx.doi.org/10.1037/0022-006X.67.6.894>
- Tang, Y.-Y., Hölzel, B. K., & Posner, M. I. (2015). The neuroscience of mindfulness meditation. *Nature Reviews Neuroscience*.
- Taylor, M. (1999). Editorial: Perceptual control theory and its application. *International journal of human-computer studies*, 50(6), 433-444. doi: <http://dx.doi.org/10.1006/ijhc.1998.0262>
- Taylor, S., Abramowitz, J. S., & McKay, D. (2012). Non-adherence and non-response in the treatment of anxiety disorders. *Journal of anxiety disorders*, 26(5), 583-589. doi: <http://dx.doi.org/10.1016/j.janxdis.2012.02.010>
- Teachman, B. A., Joormann, J., Steinman, S. A., & Gotlib, I. H. (2012). Automaticity in anxiety disorders and major depressive disorder. *Clinical psychology review*, 32(6), 575-603. doi: <http://dx.doi.org/10.1016/j.cpr.2012.06.004>
- Teasdale, J. D., Segal, Z., & Williams, J. M. G. (1995). How does cognitive therapy prevent depressive relapse and why should attentional control (mindfulness) training help? *Behaviour Research and therapy*, 33(1), 25-39. doi: [http://dx.doi.org/10.1016/0005-7967\(94\)E0011-7](http://dx.doi.org/10.1016/0005-7967(94)E0011-7)

- Thomsen, K. R. (2015). Measuring anhedonia: impaired ability to pursue, experience, and learn about reward. *Frontiers in psychology, 6*.
- Trope, Y., & Liberman, N. (2010). Construal-level theory of psychological distance. *Psychological review, 117*(2), 440. doi: <http://dx.doi.org/10.1037/a0018963>
- Tucker, M., & Oei, T. P. (2007). Is group more cost effective than individual cognitive behaviour therapy? The evidence is not solid yet. *Behavioural and Cognitive Psychotherapy, 35*(1), 77. doi: 10.1017/S1352465806003134
- Tuckett, A. (2004). Qualitative research sampling: the very real complexities. *Nurse Researcher, 12*(1), 47. doi: <http://dx.doi.org/10.7748/nr2004.07.12.1.47.c5930>
- Uithol, S., van Rooij, I., Bekkering, H., & Haselager, P. (2012). Hierarchies in action and motor control. *Journal of cognitive neuroscience, 24*(5), 1077-1086. doi: http://dx.doi.org/10.1162/jocn_a_00204
- Vago, D. R., & Silbersweig, D. A. (2012). Self-awareness, self-regulation, and self-transcendence (S-ART): a framework for understanding the neurobiological mechanisms of mindfulness. *Frontiers in human neuroscience, 6*.
- van der Leeden, R., Meijer, E., & Busing, F. M. (2008). Resampling multilevel models. In J. Leeuw & E. Meijer (Eds.), *Handbook of multilevel analysis* (pp. 401-433): Springer
- Watkins, E. (2008). Constructive and unconstructive repetitive thought. *Psychological bulletin, 134*(2), 163. doi: 10.1037/0033-2909.134.2.163
- Watkins, E. (2011). Dysregulation in level of goal and action identification across psychological disorders. *Clinical Psychology Review, 31*(2), 260-278. doi: <http://dx.doi.org/10.1016/j.cpr.2010.05.004>
- Watts, S., Mackenzie, A., Thomas, C., Griskaitis, A., Mewton, L., Williams, A., & Andrews, G. (2013). CBT for depression: a pilot RCT comparing mobile phone vs. computer. *BMC psychiatry, 13*(1), 1. doi: <http://dx.doi.org/10.1186/1471-244x-13-49>
- Webb, T. L., Sniehotta, F. F., & Michie, S. (2010). Using theories of behaviour change to inform interventions for addictive behaviours. *Addiction, 105*(11), 1879-1892. doi: <http://dx.doi.org/10.1111/j.1360-0443.2010.03028.x>
- White, J. (1998). " Stress control" large group therapy for generalized anxiety disorder: Two year follow-up. *Behavioural and Cognitive Psychotherapy*.
- White, J. (2010). The STEPS model: a high volume, multi-level, multi-purpose approach to address common mental health problems. In J. Bennett-Levy, D. Richards, P. Farrand, H. Christensen, K. Griffiths, D. Kavanagh, B. Klein, M. A. Lau, J. Proudfoot, L. Ritterband, J. White & C. Williams (Eds.),

Oxford Guide to Low Intensity CBT Interventions United States, New York:
Oxford University Press

White, J., & Keenan, M. (1990). Stress control: A pilot study of large group therapy for generalized anxiety disorder. *Behavioural Psychotherapy*, *18*(02), 143-146. doi: 10.1017/S0141347300018267

White, J., Keenan, M., & Brooks, N. (1992). Stress control: a controlled comparative investigation of large group therapy for generalized anxiety disorder. *Behavioural Psychotherapy*, *20*(2), 97-113. doi: 10.1017/S014134730001689X

Wilamowska, Z. A., Thompson-Hollands, J., Fairholme, C. P., Ellard, K. K., Farchione, T. J., & Barlow, D. H. (2010). Conceptual background, development, and preliminary data from the unified protocol for transdiagnostic treatment of emotional disorders. *Depression and Anxiety*, *27*(10), 882-890. doi: <http://dx.doi.org/10.1002/da.20735>

APPENDIX A

RCT Protocol

1. **Primary Care Trial of Efficacy of Alternative Modalities (PCTEAM):** A 12-month randomized parallel group trial to establish whether the take control course is non-inferior to low intensity interventions in primary care mental health services

2. ISRCTN TRIAL REGISTRATION NUMBER: 27529354

3. Protocol version 1.0

Date: 14th January 2014; Revised 1st July 2014

Authors: Lydia Morris, Karina Lovell, Phil McEvoy, Richard Emsley, Dawn Edge, Ian Jacob, Warren Mansell.

Protocol prepared in accordance with the SPIRIT guidelines, which recommend standard protocol items for interventional trials (Chan et al., 2013).

4. Funding

This study is funded through a North West Doctoral Training College CASE Studentship Award to the principal investigator. Salford Six Degrees Social Enterprise (SDSE) will provide treatment costs and facilities for the interventions being compared.

5. Study Team

Lydia Morris (PI): is a clinical psychologist and has a number of years' experience working within primary care. She has experience of managing research studies and leading quantitative and qualitative projects, including evaluations of psychological interventions. *Contribution:* overall management of the trial, development and delivery of training and supervision.

Warren Mansell: is a reader in clinical psychology, an experienced health care researcher, clinical psychologist and cognitive behaviour therapist. He has substantial experience of managing research into psychological processes and interventions. *Contribution:* methodological, design and analysis, theoretical background; development and delivery of training and supervision.

Phil McEvoy: is a specialist mental health nurse and experienced researcher in the field of service evaluation, with over 20 peer-reviewed publications. He is the managing director of Six Degrees Social Enterprise (which offers NHS funded primary care services). *Contribution:* site lead; theoretical background to project; development of training and supervision.

Karina Lovell: is a professor of mental health, an experienced health care researcher and cognitive behaviour therapist. She has led on and contributed to previous clinical trials of psychological intervention studies. *Contribution:* methodological, design and analysis, policies and procedures for the trial.

Dawn Edge: is an experienced qualitative researcher. She has led on and contributed to a number of studies of service user experience of mental health services. *Contribution:* Qualitative methods: design and analysis.

Richard Emsley: is a statistician and health sciences researcher. He has significant expertise in trial design and analysis. He has contributed to a number of previous clinical trials of psychological intervention studies. *Contribution:* design and statistical input

Ian Jacob: is a health economist. He has expertise in economic evaluation and mathematical modelling. *Contribution:* Health economics.

Rachel Bates: is a Gateway Worker with many years' experience of working in primary care services. *Contribution:* integration of project into service; development of training and supervision.

Jody Comiskey: is a Gateway Worker with many years' experience of working in primary care services. *Contribution:* integration of project into service; development of training and supervision.

Chloe Preston: is a Gateway Worker with many years' experience of working in primary care services. *Contribution:* integration of project into service; development of training and supervision.

6. Introduction and Scientific Background

Anxiety and depressive disorders are common. In the Adult Psychiatric Morbidity Survey UK (2007) 16.2% of adults met the diagnostic criteria utilized for depression or anxiety; more than half of these people presented with mixed anxiety and depressive disorder (9.0%) (Jenkins et al., 2009). A number of large community surveys indicate that many people do not receive psychological treatment for these common mental health problems (Alonso et al., 2004; Wang et al., 2007; Wang et al., 2005; Young, Klap, Sherbourne, & Wells, 2001). This indicates that there is a need for greater access to timely evidence based psychological interventions.

Research has shown that some cognitive and behavioural processes contribute to psychological distress in one particular disorder; for example, a heightened attention to experiences that can be perceived as threatening, such as social situations, contributes to anxiety (e.g. Bogels & Mansell, 2004; Schultz & Heimberg, 2008). However, more and more research has shown that many of these processes contribute to psychological distress across a range of disorders (Clark & Taylor, 2009; Mansell, 2011; Nolen-Hoeksema & Watkins, 2011); for example, worry and other repetitive thinking occurs across anxiety and depressive disorders (Harvey, Watkins, Mansell & Shafran, 2004). Interventions that target processes that are common across disorders (or transdiagnostic processes) may be more flexible to use and teach than interventions based on disorder-specific models (Clark & Taylor, 2009; McManus, Shafran, & Cooper, 2010). For example, instead of learning a new protocol to deal with a complex new presentation of client symptoms a clinician would be able use transdiagnostic knowledge and skills to target common processes. So transdiagnostic interventions may offer implementation advantages.

If certain intervention modalities demonstrate greater cost-effectiveness, as well as equivalent clinical effectiveness, then they offer the potential to be more widely delivered. Overall the majority of studies have found that groups are more cost-effective than individual therapy; however, these findings must be considered in light of the limitations of the available literature (Huntley, Araya, & Salisbury, 2012; Tucker & Oei, 2007). Although a number of studies have compared the cost-effectiveness of group and individual psychological interventions, only a minority of studies have included broader societal costs and there is variation as to which costs have been factored into comparisons (Tucker & Oei, 2007). For example, the majority of studies have focused on costs to healthcare providers and few have factored in the costs to clients that could be incurred from missing work to attend fixed time group sessions (Tucker & Oei, 2007; Wolff, Helminiak, & Tebes, 1997). Further the evidence that groups are as effective as individual interventions is not consistent (Huntley et al., 2012; Lockwood et al., 2004; Tucker & Oei, 2007). Therefore, whether groups are equally effective and more cost-effective than individual interventions requires more investigation.

Even if groups are not more cost-effective, offering interventions in a variety of formats increases client choice. A number of studies indicate that participants can derive benefits from engaging in group interventions in terms of normalisation of experience and interpersonal support [for example, Finucane & Mercer (2006) and Mason & Hargreaves (2001)].

Although initial effectiveness data for transdiagnostic groups is promising (e.g. Norton & Philipp, 2008), the groups available involve a significant time commitment (e.g. 10 weekly 2-hour sessions) (Maia et al., 2013; Norton & Philipp, 2008). The current study investigates the efficacy and cost-effectiveness of the Take Control Course (TCC), which offers a brief 6-session format. The TCC is aimed at clients in primary care settings, such as clients with mild to moderate anxiety or depressive disorders. There is considerable evidence that briefer

interventions are effective for this client group (Newman, Erickson, Przeworski, & Dzus, 2003; Newman, Szkodny, Llera, & Przeworski, 2010; Richards & Borglin, 2011). The TCC offers flexibility in that clients can look at an overall description of the different session themes for the TCC and choose not to attend a session if they do not think it is relevant. Furthermore, in delivering the intervention, TCC is adapted according to weekly client feedback. Initial research indicates that greater autonomy, defined as the ability self-organise and act according to one's sense of sense, within groups is related to improved outcomes (Dwyer, Hornsey, Smith, Oei, & Dingle, 2011).

The TCC is derived from Perceptual Control Theory (PCT: Powers, 1973). PCT is a transdiagnostic theory that proposes generic mechanisms that account for psychological distress across disorders (Higginson, Mansell, & Wood, 2011; Mansell, 2005). PCT is based on the idea that people 'control' perceptions in order to ensure our experience is a certain way. For example, this applies to basic things like how warm or cold we want to be, through to more complex life goals, such as having a good relationship with a partner. There is substantial evidence that problems with control of the external environment and internal events (e.g. thoughts, impulses) are associated with low-wellbeing and psychopathology (e.g. Chopita & Barlow, 1998; Harrow, Hansford, Astrachan-Fletcher, 2009; Teachman, Joormann, Steinman, Gotlib, 2012). Furthermore, there will be conflicts between the goals people are trying to achieve. Evidence supports a second important tenant of PCT, which is that circumstances in which this conflict is enduring can result in psychopathology (Brockmeyer et al., 2013; Emmons & King, 1988; Michalak, Heidenreich, & Hoyer, 2004; Porter, Keefe, Lipkus, & Hurwitz, 2005).

The effectiveness and feasibility of the TCC has previously been examined in a prospective cohort study comparing TCC with a non-randomised control group of clients accessing individual low-intensity interventions (LII) (Morris, 2013). The primary outcomes were depression and anxiety scores. For the TCC group, changes on all pre-post outcomes were significant with moderate effect sizes. The interaction effects of two treatments over time were not significant. This study did not provide data to suggest that superiority of TCC would be established in the RCT. Therefore, a non-inferiority analysis will be conducted, as even if the TCC is only equal in effectiveness to LII it should still be more cost-effective (Tucker & Oei, 2007). Further, there are other justifications for having a brief evidence-based group intervention available in primary care, such as offering choice to clients.

The Randomised Controlled Trial (RCT) design of the current study will reduce potential confounding variables. Further, a more robust method of collecting follow-up data than postal return and a longer follow-up period will enable more substantive conclusions to be drawn regarding the long-term outcomes of the TCC. Qualitative data would be valuable to ascertain how the TCC works from the perspective of participants (Mason & Hargreaves, 2001). Furthermore, for any psychological intervention that has multiple components, it is important to assess the theorised mechanism of change to establish that the intervention works through the mechanisms proposed. A self-report measure (RoC; Reorganisation of Conflict scale, Higginson, 2007) has been developed and validated for this purpose. The RoC assesses awareness of the causes of psychological distress, psychological mechanisms that facilitate long-term problem solving, and those that may inhibit dealing with them.

7. Aims and hypotheses

Study aims:

1. To examine whether TCC is non-inferior to a control condition in a randomised controlled trial with long-term follow-up.
2. Further examination of the reliability, and convergent and predictive validity of the RoC measure.
3. Qualitative component: To explore participants' experiences of the Take Control Course (TCC) and individual low-intensity interventions (LII), specifically, to examine what experiences contribute to psychological change.

Study hypotheses:

1. Participants in both groups will show reductions in symptom scores on measures of anxiety and depression and outcomes in the TCC group and individual LII will be non-inferior.
2. Scores on the 'goal conflict reorganisation subscale' of the ROC at each session will predict greater symptom change at the subsequent session.

8. Overall study design

The PCTEAM study is designed as a randomised open two parallel group non-inferiority trial comparing TCC and LII with outcomes of depression and anxiety measured at baseline, 6 months and 12 months post baseline. Randomisation will be performed as block randomisation with a 1:1 allocation.

A nested qualitative study will be conducted using semi-structured interviews with 20-24 clients from both conditions. Clients will be contacted after they have attended their 6-month follow-up assessment. The study will utilise a purposive sampling approach in order to obtain a maximum variation sample of participants who attended a range of numbers of sessions, i.e. those who attended one session through to six sessions.

9. Study setting

The study will be conducted amongst clients accessing services from Salford Six Degrees Social Enterprise (SDSE). They provide the low-intensity Primary Care Mental Health Service (PCMHS) in Salford, UK.

10. Eligibility criteria:

Inclusion criteria are:

- A) Adults aged 16 and above.
- B) Suitability for low-intensity services. This includes individuals with mild-moderate depression and anxiety that has emerged within the 12 months prior to referral (i.e. the problem is not a chronic and enduring one). However, other mild to moderate problems can be addressed within this service context and clinical decision making is according to stepped care models, i.e. other factors that are considered are level

of suicidality (see exclusion criteria) and the extent to which problems impair functioning.

C) Sufficient English language skills to understand material (i.e. verbal and written language abilities required to read and complete simple worksheets and understand verbal presentations).

Exclusion criteria are:

A) Clients under 16.

B) Suitability for higher intensity services that is primarily determined after first assessment with the service; for example, clients with Post Traumatic Stress Disorder or severe Obsessive Compulsive Disorder; clients with persistent self-injury requiring clinical management or who were potentially intent on and/or planning suicide; clients who are currently experiencing psychotic symptoms; have current substance dependence; or have an organic brain impairment, such as dementia.

C) Literacy or language difficulties that will preclude them from reading simple worksheets or from conversing with a healthcare professional.

11. Interventions

Take Control Course (TCC)

The TCC consists of six weekly sessions (the first session is 1 hour 15 minutes and all other sessions are 1 hour). See Morris (2013) for further details of the sessional content and regarding the development of the TCC. Each session has a theme and includes videos of clients who have accessed either previous interventions within the service or earlier TCC. These provide opportunities for the group to hear other people's experiences of distress and recovery, as relevant to the session theme. The TCC is not focused on client self-disclosure and discussion, but rather emphasises experiential learning, videos, facilitator presentations and worksheets. Specific homework tasks are not given, but at the end of each session time is allocated for participants to reflect on what they are taking from the session and to set themselves a specific task, if appropriate. Sessional evaluation forms are filled in and session content can be slightly adapted in response to feedback. For example, although the core content of each session is prescribed, certain techniques re-occur and so later implementation of techniques can be adapted in accordance with feedback. 'Satisfaction and evaluation' forms will be collected anonymously.

Control is the basis of this course. In accordance with the PCT theoretical account, targeted throughout the TCC are: 1) understanding the process of control, including the degree to which one can, and desires, control over various aspects of one's life; 2) awareness of valued higher-level goals (and reasons for change); 3) awareness of higher-level goal conflict; 4) encouragement of flexible ways to control and reduction of processes (including rules, habits, routines and mental processes) that block valued goals. See Mansell (2005) for an overview of PCT.

Maintaining treatment fidelity and assessing competence: Training will be delivered to all new facilitators. Five clinicians within SDSE have already been trained and have facilitated the TCC. Three other clinicians have accessed training, but have not facilitated the TCC. The PI (a Clinical Psychologist) will offer supervision and deliver training. Initial training is a day long and supervision will provide additional opportunities to develop skills; half day booster sessions will be offered according to demand and depending on any training needs identified by the adherence and competence checklist. Training focuses on familiarisation with the content of the TCC and on addressing group process issues, e.g. what to do if a

client becomes distressed during a TCC session. The adherence and competence checklist will be used to assess delivery of sessions. This competence checklist was used in the pilot prospective cohort study (Morris, 2013). Two sessions will be other-rated for each facilitator. In addition, all facilitators will self-rate their adherence for each session, using the same checklist. This checklist will be used for supervision purposes and to identify any training needs. During each TCC all facilitators will access two half hour peer supervision sessions every week. In addition, one hour of external supervision will be offered after session 2 (by the PI and Dr Warren Mansell).

Low-intensity interventions (LII)

The LII delivered within the service are based on principles of CBT. All clinicians have a minimum first degree and have received specific training to deliver low-intensity treatments. The interventions offered include aspects, such as psycho-education and cognitive and behavioural strategies; for example, behavioural activation, cognitive restructuring, sleep management and problem solving. Emphasis is on participant self-help and participants are often given homework tasks to do between sessions (Richards & Borglin, 2011; Richards & Suckling, 2009). Sessions last 30 minutes and participants are generally offered up to six sessions.

Maintaining competence: all clinicians receive weekly supervision. Supervision sessions include skill monitoring and development using audio recordings of sessions.

12. Outcomes

Primary outcomes:

- Depression: Patient Health Questionnaire Depression Scale (PHQ9; Kroenke, Spitzer, & Williams, 2001). A 9-item measure of depression with scores from 0 to 27. The PHQ9 has been validated in a UK depressed population (Cameron, Crawford, Lawton, & Reid, 2008; Gilbody, Richards, & Barkham, 2007) and has good psychometric properties; Cronbach's alpha 0.89 (Kroenke et al., 2001).
- Anxiety: Generalised Anxiety Disorder Questionnaire (GAD7; Spitzer, Kroenke, Williams, & Lowe, 2006). A 7-item measure with scores from 0-21. The GAD7 has not been validated in a UK population but has good psychometric properties from studies in the US- Cronbach's alpha 0.92.

Secondary outcomes:

- Functioning: Work and Social Adjustment Scale (WSAS; Mundt, Marks, Shear, & Greist, 2002).
- Client's self-rated idiosyncratic problem: PSYCHLOPS (Ashworth et al., 2005; Ashworth et al., 2004).
- Health-related quality of life (EQ5D; Kind et al., 1996).
- Adult Service Use Schedule (AD-SUS; Byford et al., 2003).

Process measures:

- Re-organisation of Conflict Scale (RoC; Higginson, 2007; Bird, 2014).
- Acceptance and Action Questionnaire-2 (AAQ-2; Bond et al., 2011).
- Intolerance of Uncertainty Scale, Short form (IUS-12; Carleton, Norton, et al., 2007).
- Toronto Mindfulness Scale- trait version (TMS; Davis, Lau & Cairns, 2009).
- Credibility/Expectancy Questionnaire (CEQ; Devilly, Borkovec, 2000).

- Satisfaction and evaluation measure (Morris, 2013). There is a sessional version of this for the TCC group only and a more detailed post-treatment version for both groups.

When the measures are completed:

Measure	Baseline Pack 1	Sessional Pack 2 (TCC) Pack 3 (LII)	6-month & 12-month follow-up Pack 4
PHQ9	✓	✓	✓
GAD7	✓	✓	✓
WSAS	✓	✓	✓
PSYCHLOPS	✓		✓
EQ5D	✓		✓
AD-SUS	✓		✓
ROC	✓		✓
Goal conflict reorganisation subscale (from ROC)		✓ TCC group only	
AAQ-2	✓		✓
IUS-12	✓		✓
TMS	✓		✓
CEQ			✓
Satisfaction and evaluation		✓ TCC group only	
Satisfaction and evaluation: post-treatment			✓

13. Participant timeline (see participant flow diagram at end of document)

Clients will initially predominantly be referred to SDSE by their GP but may also be referred by other healthcare professionals. They will also be able to self-refer to the service. Clients will be offered an initial assessment with a service clinician to discuss treatment options; the appointment letter will include a brief information sheet about the research study. The Service, rather than the research team, will send out letters in order that service users' names and addresses are not accessed without their consent.

The information provided within this letter will make clear that group allocation is random, and if they wish to take part in the study they will have a 50% chance of being assigned the TCC condition and a 50% chance of accessing the service's standard treatment (individual low intensity interventions, LII). In a minority of GP practices, GPs book clients directly into clinicians' diaries. Therefore, these clients would not receive an initial appointment letter. However, the study will be advertised using posters and flyers and these clients will have the opportunity to discuss all their options at their generic initial assessment.

At the generic initial assessment with a SDSE clinician clients will be able to discuss participation and request further information if needed. At this appointment, clients who meet the inclusion criteria will be informed of the study alongside the service's other treatment options and will be given the research information sheet if they are interested. They will be able to give verbal consent to participate at this time. Clinicians will fill in and initial a form, which indicates via tick boxes that the

project has been discussed with the client and whether client is excluded with the reason for this (the three reasons will be: not meeting inclusion criteria; declined to participate; other reasons). Clients will also sign the form to show that the research has been discussed and that they are clear regarding the next stage, i.e. whether they will be contacted regarding the research or not.

Clients who give verbal consent to be involved in the research will be offered the option of attending a face-to-face 'baseline' appointment to fill in baseline measures (or by phone if face-to-face is not possible for the client, with consent forms being sent out by the direct clinical team and returned by the client prior to the interview). This appointment will be offered a minimum of 24 hours after giving verbal consent and will be conducted by a research assistant. During this appointment the research study will be discussed in more detail and it will be made clear what participants will be expected to do. Clients will be given the option to consent to participate in the RCT, but to withhold consent to be contacted about the qualitative study. There will be a highlighted box on the consent form that they will be able to leave blank if they do not want to be contacted about the qualitative study. If the client still wants to participate then they will initial the relevant boxes and sign the consent form in order to provide written consent. After informed written consent is obtained, clients will complete the baseline self-report measures.

Formal written consent for the qualitative study will be obtained after the 6-month follow-up appointment for participants in both conditions. Participants will only be contacted if they have previously provided consent to be contacted. It will be made clear on the earlier general consent form that participants can consent to be contacted about the qualitative study, but then chose not to participate at a later stage. Participants will initially be contacted by phone to arrange a convenient appointment time and then will be sent an email, letter or text confirmation of this appointment (depending on their preferred method of communication). Participants who have provided consent to be contacted will be offered an appointment where the qualitative study will be explained in more detail and at this appointment they will be provided with the qualitative study participant information sheet and be able to provide informed written consent for the qualitative study. As long as they still wish to participate, they will have the option to complete the interview at this point. This will be made clear in the letter inviting them to participate. This is in order to reduce the burden on participants of multiple appointments and given that they will have been given information about the qualitative study at the baseline assessment and in the letter inviting them to participate in the qualitative study. Therefore they will have had multiple opportunities to consider whether they want to participate.

After written consent to participate in the RCT is provided the randomisation process will be completed. An administrator within SDSE will randomise the client using a computerised randomisation programme. The randomisation programme is called Sealed Envelope and in order to randomise the client, only their participant ID and the study password is required. An automatic email is sent once the client has been allocated. The administrator will then inform the client of the group that they have been allocated to and arrange their first intervention session.

All participants will be asked to attend a face-to-face follow-up appointment 6-months and 12-months from baseline when an appointment will be arranged for them to complete Questionnaire Pack 4. Participants will be contacted at least 1 month before the follow-up point to ensure that a convenient date can be arranged. Participants may be contacted even further in advance towards the end of the trial to ascertain that they can attend a follow-up appointment within the trial duration. It is possible that some participants would have gone on to receive further treatment before the final follow-up. We would hope to control for any effect by obtaining information about ongoing treatment with co-operation from the service, and with consent from the clients.

All research assistants (RAs) will be trained in obtaining informed consent and risk management procedures. They will have access to support from a Clinical Psychologist who has training and experience in risk management. All RAs will have an honorary contract with the University of Manchester and will have a valid, up-to-date, enhanced Disclosure Barring Service (DBS) check. They will have completed Good Clinical Practice Training.

14. Sample size calculation

Power calculations for the primary hypothesis were based on a non-inferiority trial design comparing two groups, with equal numbers in each group. In line with the Extension of the CONSORT statement (Piaggio, Elbourne, Altman, Pocock, & Evans, 2006; Piaggio, Elbourne, Pocock, Evans & Altman, 2012) this is being stated explicitly so that the non-inferiority margin is clear from the outset. Power calculations indicate 63 participants per group would have 80% power to detect a significant (0.025 level, as non-inferiority analyses are one-tailed) effect of 0.5 (Tamayo-Sarver, Albert, Tamayo-Sarver, & Cydulka, 2005).

The value of 0.6 was originally considered as the non-inferiority margin based on previous non-inferiority studies (Hedman et al., 2011; Lovell et al., 2006; Norton, 2012; Norton & Barrera, 2012), in two of these studies the non-inferiority margin was based on previous meta-analyses (Hofmann & Smits, 2008; Norton & Price, 2007). Margins of non-inferiority in these trials, ranged from $\Delta = 0.50$ to 0.67 *SD* below the mean effect of the established treatment arm for each measure (Mean $\Delta = 0.59$, rounded up to 0.6). However, the effect size of 0.6 corresponds to approximately 4 points on the PHQ9 and approximately 3.5 points on the GAD7. These values were considered too high to be a reliable non-inferiority margin, i.e. a value that is not clinically significant and therefore the treatment can genuinely be considered non-inferior. For example, only 5-points on the PHQ9 differentiates clients with the highest score in the mildly depressed category from clients with the highest score in the moderately depressed category (Richards & Suckling, 2009). Therefore, the value of 0.5 was chosen because this was the lowest non-inferiority margin found in the non-inferiority studies aforementioned (Hedman et al., 2011; Lovell et al., 2006; Norton, 2012; Norton & Barrera, 2012). The margin of 0.5 corresponds to 3 points of the PHQ9 and 2.5 points on the GAD7 (Richards & Borglin, 2011).

The calculation indicates a sample size of 126. Additional participants will be recruited to allow for attrition at 27%. This figure is an average of the attrition levels within a meta-analysis of individual CBT treatments by Hofmann & Smits (2008), two RCTs of group interventions by Allart-van Dam et al. (2007) and Andersson et al. (2013) and the pilot study of the TCC (the groups RCTs were chosen because they provided information on attrition for group interventions and because they were relatively similar in design, e.g. they did not include a delayed treatment arms). Consequently we aim to recruit 173 participants. However, the trial team will take proactive measures to reduce attrition; for example, checking the best contact means for individual clients.

In line with the extension of the CONSORT statement, superiority analysis will be conducted if the TCC is found to be non-inferior (Piaggio, Elbourne, Pocock, Evans & Altman, 2012) and if a significant treatment effect, at $p = 0.05$ or greater, is found in favour of the TCC. Power calculations for the primary hypothesis for a superiority trial design comparing two groups, with equal numbers in each group are provided so that it can be demonstrated that the study will be sufficiently powered to conduct the analysis. It is possible that attending a particular course of TCC could affect the results; for example, one particular course could include clients who are willing to share inspirational stories that could influence the outcomes for others

within this course. This was accounted for using intra-cluster correlations within the power calculations (intra-cluster correlations for TCC group = 0.01). The sample size calculation indicates that a sample size of 60 per group would have 83% power to detect an effect size (standardised mean difference) of 0.6, with a significance level of 0.05 and a common standard deviation of 6.67. This indicates a sample of 120 clients.

15. Recruitment

On average (based on 6mths of figures) each month SDSE received 456 referrals and 159 clients received treatment (more than 1 session plus the initial assessment). Even allowing for clients choosing not to participate, and attrition at 95% from referral to first TCC session, over an 18mth period it would be possible to recruit 173 participants. During the feasibility cohort study 109 participants agreed to participate and 77 attended more than one session across both groups. This was achieved from 11 months of recruitment. We aim to recruit over 16 months from July 2014.

16. Randomisation

Participants will be randomly assigned to either TCC or LII group with a 1:1 allocation using a computer generated randomisation schedule with randomly permuted block sizes to ensure allocation concealment.

17. Blinding

Due to the nature of the interventions neither clients nor research clinicians can be blinded to random allocation. Assessors will be blinded to treatment allocation at all assessment time points. The trial statistician will be blind to the status of the TCC and LII groups until the primary analysis has been conducted.

18. Statistical analysis

All primary analysis will follow the intention-to-treat principle, and participant flow throughout the trial will be reported according to the extension of the CONSORT guidance for non-inferiority and equivalence trials (Piaggio, Elbourne, Altman, Pocock, & Evans, 2006; Piaggio, Elbourne, Pocock, Evans & Altman, 2012). All analysis will be performed using Stata version 13.1 (StataCorp, 2011).

The two primary outcome measures are the PHQ-9 (depression) and GAD-7 (anxiety). To test hypothesis 1 (that participants who are randomly allocated to TCC will experience non-inferior reductions in separate anxiety and depression symptom scores than participants randomly allocated to LII) we will use multilevel models including a random allocation by time interaction as an indication of the treatment effect. These results will be examined to establish whether treatment effect (and 95% confidence interval around the parameter) for the TCC differs by more than 0.6SD (the non-inferiority value) from the LII. If non-inferiority is established then whether TCC is superior to LII will be ascertained (Piaggio et al., 2012); to account for this re-testing only p-values less than, or equal to, 0.01 would be considered significant for these analyses.

The data has two-level structure consisting of responses at different time points (level 2) nested within individuals (level 1). The two treatment groups will also be compared at baseline, 6 and 12 months. Bootstrapping will be used where outcomes are non-normal (van der Leeden, Meijer, & Busing, 2008). The models will be estimated using maximum likelihood estimation, which accounts for missing outcomes assuming a missing at random mechanism.

A per protocol (PP) analysis will also be conducted as this is a method more

commonly recommended for non-inferiority than superiority trials. Intention to treat (ITT) analysis may increase the risk of falsely claiming non-inferiority and therefore it is recommended that both ITT and PP analyses are conducted (Piaggio et al., 2012). An ITT analysis will be conducted as primary because non-compliance and attendance are very likely in routine clinical practice (Gupta, 2011). Participant data will be included in the PP analysis if participants have attended one or more sessions of the randomised treatment. It is anticipated that clients may only access one session of the TCC (and may still benefit); further in routine clinical practice where LII interventions are offered it is common that clients do not attend the full six sessions offered (Glover, Webb, & Evison, 2010; Richards & Borglin, 2011).

As a secondary analysis the relationship between dose (number of sessions) and response will be examined.

Clinically significant change (CSC) and Reliable Change (RC) will be calculated with the commonly used formula of Jacobson & Truax (1991). For the PHQ9, RC required an improvement of 6 points or more and CSC required a person to score 8 or above pre-treatment and 7 or below post-treatment. The corresponding figures for the GAD7 are: a pre- to post- treatment improvement of 5 points or more (RC) and a move from 7 or above pre-treatment to 6 or below post-treatment (CSC). The number of clients achieving these cut-offs will be reported.

To test hypothesis 2 that sessional scores on 'Components of goal conflict reorganisation subscale' from the ROC will predict greater sessional symptom change, multilevel models will be used with 'goal conflict reorganisation' score at previous session as a predictor and symptoms at current session as the dependent variable, across all sessions. For example, does 'Components of goal conflict reorganisation' score at session 1 predict symptoms at session 2 and so on. Bootstrapping will be used where outcomes are non-normal (van der Leeden, Meijer, & Busing, 2008).

19. Qualitative data analysis

All interviews will be recorded and transcribed verbatim prior to coding. Thematic analysis (TA) will be used to analyse the interview data. We plan to interview 10-12 participants in each group based on previous research indicating that it is possible to achieve data saturation (when no new themes emerge) with this sample size (after 12 interviews in this study) (Guest, Bunce, & Johnson, 2006). However, as we shall be exploring the data for similarities and differences between groups, data saturation might be achieved with approximately with 20 interviews across both conditions (Guest, Bunce, & Johnson, 2006). NVivo (QSR International Pty Ltd, Version 10, 2012) computer package will be used to facilitate data management and analysis. To establish the reliability of the codes, Dr Dawn Edge (Supervisor and Lecturer in Qualitative Methodology) will code a subset of interviews (10%). Emergent themes will be reviewed by a qualitative methods expert independent of the study (peer verification). Member checking will be used to verify the trustworthiness and potentially to refine key themes, i.e. participants will be asked whether the themes that the researcher derives reflect their experiences and perspectives. Themes will be presented to a subset of key informants on an individual basis. Key informants are those who are particularly representative of the sample as a whole (Anfara, Brown & Mangione, 2002; Marshall, 1996).

20. Economic analysis

The proposed economic evaluation will take a societal perspective. Data will be collected on the use of all hospital and community health and social services, productivity losses and costs to patients. This information will be obtained via a resource use instrument. To the authors' knowledge, no specific tool for measuring use of services and other resources in clients with anxiety and/or depression in primary care exists. Instead, the Adult Service Use Schedule (AD-SUS) as applied in previous mental health populations (Bower, Byford et al., 2000; Byford et al., 2007; Kuyken, Byford et al., 2008) will be used and adapted to ensure it adequately captures resources appropriate to this client group. The AD-SUS will initially be adapted through review of relevant literature and discussions with the clinical team.

Calculations will require unit cost data on clinicians' salaries, including appropriate overheads and employers' oncosts (national insurance and superannuation), working time and estimates of the ratio of direct face-to-face to indirect time. Costs will also include any room booking changes and clinician time in locating appropriate rooms, plus purchase of additional equipment (if required). For all other health and social services, nationally applicable unit costs will be applied (Curtis, 2012; Department of Health, 2010; Joint Formulary Committee & Royal Pharmaceutical Society of Great Britain, 2012). Productivity losses will be calculated using the human capital approach, which involves multiplying days off work due to illness by the national average salary (Rice and Cooper 1967, Drummond et al. 2007, Sculpher 2005). Resource use data will then be valued using the unit costs identified above to provide estimates of overall costs for individual and group therapy.

The cost analysis has three phases: 1) identifying resources (healthcare, wider society and the patient); 2) measuring these resources; and 3) valuing these resources. The relevant resources have been identified and included in the resource use instrument and the valuation will use the identified sources (e.g. NHS Reference Costs, BNF). Cost-effectiveness will be explored in terms of incremental cost per quality adjusted life years; calculated using the EQ-5D measure of health related quality of life. The perspective of the analysis will be societal. The Take Control Course will be compared to brief individual interventions in the management of clients at 12 month follow up.

Nonparametric bootstrapping from the costs and effectiveness data will be used to generate a joint distribution of incremental mean costs and effects for the two arms. This will then be used to calculate the probability that each of the treatments is the optimal choice, subject to a range of possible maximum values (ceiling ratio) that a decision maker might be willing to pay for a unit improvement in outcome. Cost-effectiveness acceptability curves are presented by plotting these probabilities for a range of possible values of the ceiling ratio (Fenwick, Claxton, & Sculpher, 2001). These curves are a recommended decision-making approach to dealing with the uncertainty that exists around the estimates of expected costs and expected effects associated with the interventions under investigation (Claxton, 1999).

21. Data monitoring

We anticipate no clear risks inherent in the interventions under evaluation that would allow us to set an a priori stopping criteria. Both interventions have been offered previously, although LII are more established (Richards & Borglin, 2011; Richards & Suckling, 2009). No serious adverse effects have been identified in previous studies. If serious adverse effects are identified at any point during the study, the study will be stopped. A data monitoring committee will not be convened, as issues of toxicity or high mortality do not apply in this trial.

22. Risk management procedures

A risk assessment will always be conducted at the generic initial assessment (by trained clinicians) and clients who are actively suicidal or describe repeated self-harm requiring on-going clinical management will be excluded from the research. During the baseline appointment, risk of suicide or self-harm will be identified from Question 9 of the PHQ9 (*Thoughts that you would be better off dead or of hurting yourself in some way*) or any other information that indicates that such a risk is present. Any risk of suicide or self-harm will be followed up using a list of specific questions to establish the severity of the risk, for example, Do you know how you would harm or kill yourself? Have you made any actual plans harm yourself or end your life? Depending on the responses to these questions the research assistant will contact the clinical lead and appropriate action will be taken, for example, informing the participants GP.

23. Research ethics approval

The study has been approved by the NRES Committee North West-Greater Manchester East Ethics Committee (ref. 14/NW/0160)

24. Protocol Amendments

The REC will be informed of any substantive protocol amendments. Amendments will be registered with the ISRCTN (trial registry).

25. Informed consent:

A clinician from Six Degrees Social Enterprise (SDSE) will offer a 30-minute appointment to anybody referred to the service. Clinicians will be provided with training and information regarding how to explain the project in a non-coercive way. All clinicians will be provided with a recruitment advice document that emphasises the importance of not influencing clients' choices. One of the functions of this appointment will be to help clients to decide what treatment option they want to choose. Potential participants will be presented with the full Participant Information Sheet at the 30-minute appointment and will be able to provide verbal consent to participate in the research. There will be a minimum period of 24 hours between a client providing verbal consent to participate and the appointment to provide written consent and complete baseline measures. Written consent to participate in the RCT will be discussed and obtained prior to the completion of any baseline measures. Thus clients will have a number of opportunities to consider their treatment options over at least a 24-hour time period. See participant timeline section (13) for further details.

26. Confidentiality and data management:

All participants will be allocated a unique study number for study participation. From then on the participant information will only be identified by this number. The only exception to this will be that participants will be asked to initial the sessional questionnaires that are collected within both conditions; this is to ensure that the information can be matched to the correct person. All participant information, such as questionnaire data, will be kept in a locked filing cabinet. Identifiable information (e.g. full names, addresses) will be kept separate from data. All written communication to clients will be sent from the clinical base, meaning that identifying information will not need to be transported and will be protected by NHS confidentiality arrangements. Confidentiality of information will only be broken when a participant is at risk to themselves or other people. They will be informed of this procedure, which is standard good practice within the NHS.

Home/ personal computers may be used in the analysis of the data. However, any data analysed or saved on a home computer will be completely

anonymised so that it is not personally identifiable. There will be a log on facility to open the home computer.

27. Declaration of interests

The authors wish to confirm that there are no known conflicts of interest associated with this research project and there has been no significant financial support for this work that could have influenced its outcome.

28. Access to data

Members of SDSE, the Principal Investigator (Lydia Morris) and their main supervisor, Dr Warren Mansell, will have access to participant data. The Principal Investigator and Dr Mansell are outside the direct care team and it is made clear on the consent form that members of the research team will access their records to obtain specific information.

29. Dissemination plans:

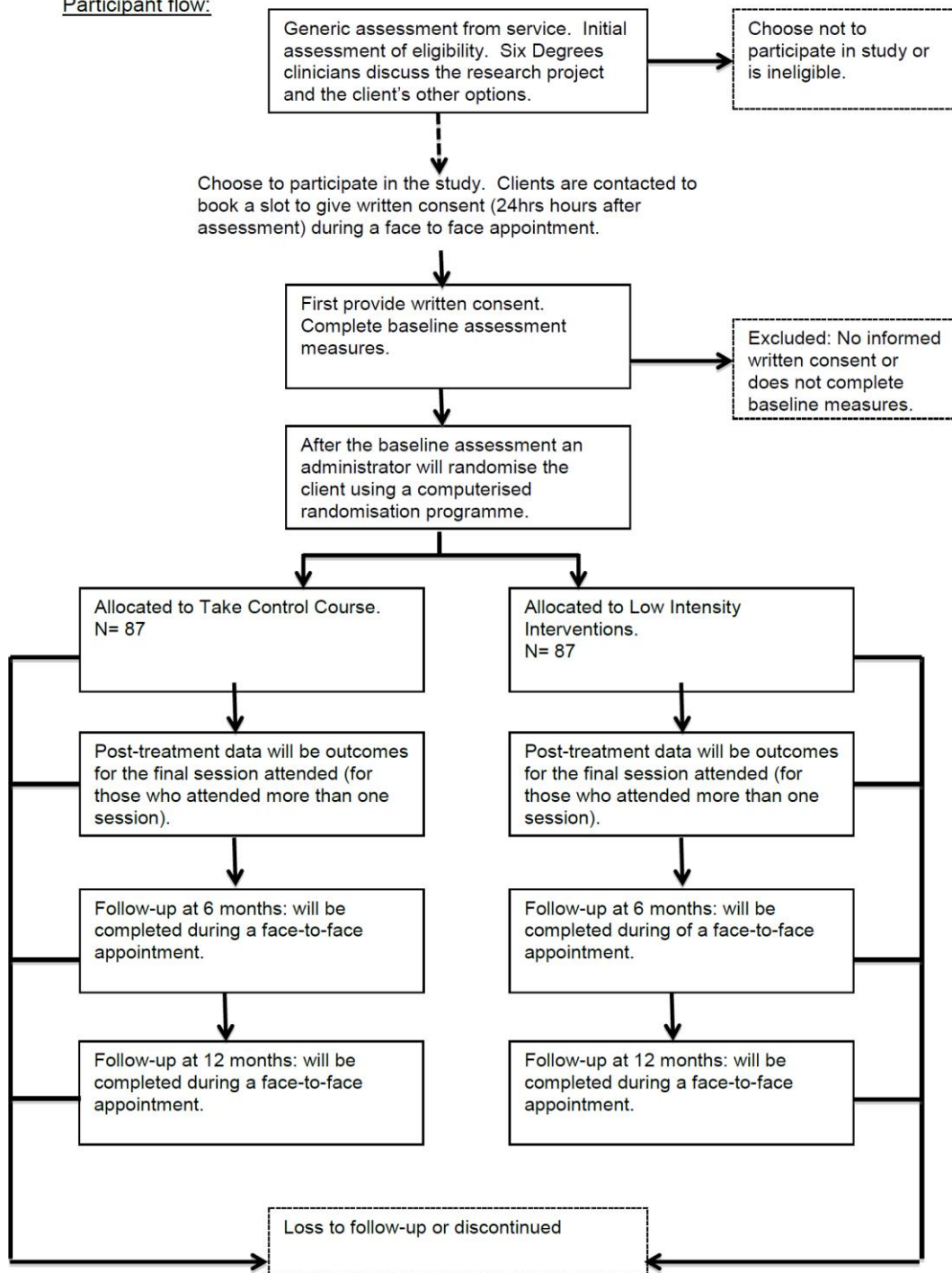
A plain English summary of the study and the findings will be made available for participants after the report has been completed. Participants will be provided with the SDSE website details where a brief summary of the project will be made available for free download. We will post of copy of the findings to those that prefer this option.

The research would be presented at conferences for academic and clinical attendees; for example, British Association of Behavioural and Cognitive Psychotherapies (BABCP) conferences have multidisciplinary delegates. The research will be published in peer-reviewed journals. The TCC has the potential to be offered as an intervention package that is commissionable by private and NHS services. As have been previously outlined there are potential implementation advantages to a transdiagnostic group format.

Key references

- Ashworth, M., Shepherd, M., Christey, J., Matthews, V., Wright, K., Parmentier, H., . . . Godfrey, E. (2004). A client-generated psychometric instrument: The development of 'PSYCHLOPS'. *Counselling and Psychotherapy Research, 4*(2), 27-31.
- Guest, G., Bunce, A., & Johnson, L. (2006). How many interviews are enough? An experiment with data saturation and variability. *Field methods, 18*(1), 59-82.
- Huntley, A. L., Araya, R., & Salisbury, C. (2012). Group psychological therapies for depression in the community: systematic review and meta-analysis. *The British Journal of Psychiatry, 200*(3), 184-190. doi: 10.1192/bjp.bp.111.092049
- Morris, L. (2013). *A pilot evaluation of a transdiagnostic group intervention for mental health problems in primary care*. (Unpublished Clinical Psychology Doctorate thesis). The University of Manchester, England.
- Mansell, W. (2005). Control theory and psychopathology: An integrative approach. *Psychology and Psychotherapy-Theory Research and Practice, 78*, 141-178. doi: 10.1348/147608304x21400
- Mansell, W. (2007). *Coping with fears and phobias : a step-by-step guide to understanding and facing your anxieties*. Oxford: Oneworld.
- Mansell, W., Harvey, A., Watkins, E., & Shafran, R. (2009). Conceptual foundations of the transdiagnostic approach to CBT. *Journal of Cognitive Psychotherapy, 23*(1), 6-19
- Newman, M. G., Szkodny, L. E., Llera, S. J., & Przeworski, A. (2010). A review of technology-assisted self-help and minimal contact therapies for anxiety and depression: Is human contact necessary for therapeutic efficacy? *Clinical Psychology Review, 31*, 89-103. doi: 10.1016/j.cpr.2010.09.008
- Norton, P. J. (2012). A randomized clinical trial of transdiagnostic cognitive-behavioral treatments for anxiety disorder by comparison to relaxation training. *Behavior Therapy, 43*(3), 506-517.
- Norton, P. J., & Philipp, L. M. (2008). Transdiagnostic approaches to the treatment of anxiety disorders: A quantitative review. *Psychotherapy, 45*(2), 214-226. doi: 10.1037/0033-3204.45.2.214
- Norton, P. J., & Price, E. C. (2007). A meta-analytic review of adult cognitive-behavioral treatment outcome across the anxiety disorders. *The Journal of nervous and mental disease, 195*(6), 521-531. doi: 10.1097/01.nmd.0000253843.70149.9a
- Powers, W. T. (1973). *Behavior : the control of perception*. Chicago, Ill.: Aldine.
- Richards, D. A., & Borglin, G. (2011). Implementation of psychological therapies for anxiety and depression in routine practice: Two year prospective cohort study. *Journal of affective disorders, 133*(1), 51-60. doi: 10.1016/j.jad.2011.03.024
- Tucker, M., & Oei, T. P. (2007). Is group more cost effective than individual cognitive behaviour therapy? The evidence is not solid yet. *Behavioural and Cognitive Psychotherapy, 35*(1), 77. doi: 10.1017/S1352465806003134

Participant flow:



APPENDIX B

Approval of Ethics re-submission



NRES Committee North West - Greater Manchester East

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11 April 2014

Dr Lydia Morris, PhD student
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Dear Dr Morris

Study title: Primary Care Trial Efficacy of Alternative Modalities
(PCTEAM)
REC reference: 14/NW/0160
IRAS project ID: 147212

Thank you for your letter of 28 March 2014 and email of 11 April 2014. I confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 21 March 2014

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Participant Information Sheet: Long RCT	2	28 March 2014
Participant Information Sheet: Brief RCT	2	28 March 2014

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Advertisement	Poster v 1	14 January 2014
Advertisement	Leaflet v 1	14 January 2014
Covering Letter		02 March 2014

APPENDIX C

Semi-structured interview guide

This meeting today is to discuss you how found the take control course/ brief one-to-one sessions. To help us improve the therapy I'll be asking you questions to find out if there were parts you found useful and to find out if there was anything less useful.

Before we begin have you got any questions?

Attendance/Client experience of sessions or course

1. Just thinking back to when you did the take control course/one-to-one sessions, how many did you come to?
2. What did you hope to get out of the course/ one-to-one session?
3. Do you remember any particular topics that were covered?
Prompt: if cannot remember the TCC sessions show them the structure of sessions.
4. How did you find the course/one-to-one session?

Helpful and unhelpful aspects of sessions/course

5. Was there anything about the sessions/course you found helpful?
Potential follow-up questions: what aspects did you find helpful? What made it 'helpful'?
6. It sounds like you found xxxx helpful what was it like using xxx?
*Potential follow-up question: How much have you used xxx? (daily, weekly, rarely)?
Have you used xxx to deal with problems that have arisen for you in the past 6 months?*
7. Was there anything that wasn't helpful?
Potential follow-up questions: What aspects did you not find helpful? What made it 'unhelpful'?

Changes in thinking

8. Has anything changed in the way you deal with problems in your day to day life?

*Potential follow-up questions: in what way do you deal with things now?
How has the way you deal with problems stayed the same? 'Has anything changed in how you are with people'?*

Session Length/Research study

9. What did you think about the amount of time the sessions lasted for?

Potential follow-up questions: How long would you have liked? Did you feel you had enough sessions?

10. Do you think it would have made a difference if you went to the course/ one-to-one session?

Potential follow-up questions: How different do you think it might have been if you had gone to the course/one-to-one session?

Research Study

I've been asking about the course/one-to-one session and would like to know more about your experience being part of a research project, do you remember being part of a research study?

11. How was it taking part in a research project?

*Follow-up questions: Do you remember how you ended up in the group/one-to- one sessions? What do you think of the way that happened?
Could it have been done differently?*

APPENDIX D

Take Control Course Manual Contents page and Chapters 1-5

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Part A

Chapter 1: Introduction to this book and the Take Control Course

Introduction to this book

This book describes a group-based intervention called the Take Control Course. The first three chapters provide background to the development Course and information about how to set up a Course. Subsequent chapters provide a detailed overview of each of the six sessions of the Course.

Why have we developed the Take Control Course?

There are many Cognitive Behavioural interventions already available, with a substantial number of research studies showing that these are effective (Butler, Chapman, Forman, & Beck, 2006; Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012; Hunsley & Lee, 2007; Stewart & Chambless, 2009). However, a number of large surveys indicate that many people do not receive psychological treatment even for common mental health problems, such as anxiety and depression (Alonso et al., 2004; Wang et al., 2007; Wang et al., 2005; Young, Klap, Sherbourne, & Wells, 2001). This suggests that there needs to be greater access to evidence-based psychological interventions. Psychological interventions need to be cost-effective in order to make it more likely that they can be made readily available. One of the reasons for the way we have developed the Take Control Course is on the basis of pragmatic reasons, such as cost-effectiveness, but there are a number of other equally important theoretical reasons why the Take Control Course has been developed in the way that it has. These reasons are summarised in this chapter.

Because some clients can get 'added value' from groups

A number of studies indicate that some clients can derive particular benefits from engaging in group interventions. For example, these include normalisation of experience, 'other people are having the same struggles as me', and interpersonal support, 'finding that the group context helped me to keep trying out techniques and persevering' [for example, Finucane & Mercer (2006) and Mason & Hargreaves (2001)]. Clearly this does not mean that groups are the best option for everyone, but groups can offer a useful alternative to individual interventions.

To target common processes across disorders

Until fairly recently many of the Cognitive Behavioural interventions available have been offered, as a manualised protocol, to clients with one specific disorder. For example, specific protocols have been developed to be offered to clients with Social Anxiety Disorder, which is characterised by a fear of social situations and being around people (Clark et al., 2003; Stangier, Heidenreich, Peitz, Lauterbach, & Clark, 2003; Wells, 1997). These target cognitive and behavioural processes that have been found to contribute to psychological distress and problematic symptoms in this disorder. For example, some interventions for social anxiety target the way in which clients can focus on themselves in social situations

and can miss positive external cues because this has been shown to contribute to problematic symptoms (Hirsch & Mathews, 2000; Hofmann, 2007).

However, more and more research has shown that a substantial number of these processes contribute to psychological distress across a number of disorders; for example, worry and other repetitive thinking occur in a number of anxiety and depressive disorders (Harvey, Watkins, Mansell, & Shafran, 2004; Nolen-Hoeksema & Watkins, 2011). Processes that occur across a number of disorders are described as transdiagnostic. In addition to this support for the transdiagnostic nature of such processes, often when people seek help for distressing symptoms it is possible to describe their symptoms using more than one disorder label (described as comorbidity) (e.g. Jenkins et al., 2009). Conversely, sometimes it is hard to give people a specific disorder label, as their symptoms do not fit neatly under a particular label. Therefore, researchers have started to design and research transdiagnostic interventions because such interventions can target the processes that contribute to symptoms that could be categorised under different disorder labels. Such interventions offer the potential to develop generalisable clinician skills; for example, using conceptualisations and techniques that are readily adapted for clients with comorbid or unusual problems (Alexander, Arnkoff, & Glass, 2010; McHugh & Barlow, 2010; Richards & Bower, 2011; Shafran et al., 2009).

There are a number of journal articles and other resources that describe the evidence base and rationale for a transdiagnostic approach (e.g. Harvey et al., 2004; Mansell, Harvey, Watkins, & Shafran, 2009; Nolen-Hoeksema & Watkins, 2011). For those who are interested, there are a number of articles that provide neuro-scientific research that supports a transdiagnostic approach (e.g. Buckholtz & Meyer-Lindenberg, 2012; Goschke, 2014).

To offer more cost-effective interventions

Overall the majority of research studies that have compared individual and group interventions have found that groups are more cost-effective than individual therapy; however, there are limits to the available studies (Tucker & Oei, 2007). Although a substantial number of studies have compared the cost-effectiveness of groups and individual psychological interventions, only a minority of studies have included broader societal costs (Tucker & Oei, 2007). For example, the majority of studies have focused on costs to healthcare providers and few have factored in the costs to clients that could be incurred from missing work to attend fixed time group sessions (Tucker & Oei, 2007; Wolff, Helminiak, & Tebes, 1997). We have focused particularly heavily on the research basis in regards to this because it seems to make intuitive sense that groups would be more cost-effective (as you can see more people at once). In particular, the Take Control Course is designed to be delivered to large groups, as it does not rely on interactions between members of the group.

To allow clients to attend sessions in a flexible way

An explicit emphasis of the Take Control Course is that clients can choose which sessions they attend; for example, they might choose not to attend a session that does not seem so relevant to their problems. There is increasing evidence that psychological change occurs at a different pace and in a varied way for different people. For example, there is evidence that some clients can experience 'sudden gains' (can be described as eureka/aha moments, insights etc.) that contribute a significant amount to their improvement by the end of the intervention (Aderka, Nickerson, Bøe, & Hofmann, 2012; Norton, Klenck, & Barrera, 2010; Tang & DeRubeis, 1999). Adele Hayes and colleagues review a number of different strands of research that illustrate psychological change that is not linear and gradual. For example, studies suggest that anxiety and distress levels can increase before symptoms improve (A. M. Hayes, Laurenceau, Feldman, Strauss, & Cardaciotto, 2007). Another example is from the research looking at responses to traumatic events. Some people

experience post-traumatic stress disorder (PTSD), others could experience personal growth (in terms of changes in life priorities and greater personal strength etc.), while others could experience both PTSD and personal growth (Tedeschi & Calhoun, 2004)!

Clinicians and researchers commonly offer clients a set number of sessions, e.g. 6 or 8 or 15. Such clinical practice is often informed by research studies, but generally the number of sessions offered in research studies is not based on what is most effective. For example, demonstrating that 12 weekly sessions are an effective time frame does not demonstrate that this is the most effective time frame or that 12 sessions is actually required. It is understandable that treatments are often specified in this way, but in routine clinical practice clients often do not attend the specified number of sessions (Barkham et al., 2006; Glover, Webb, & Evison, 2010). It is possible that clients are 'voting with their feet' and letting us know that the prescribed number of sessions is not always what they find most useful. This makes sense given the research indicating that change happens at a different pace for different people. It has been suggested that, in clinical practice, clients and clinicians regulate their treatment attendance on an ongoing basis and continue treatment until they have achieved a personally "good enough" level of change (Barkham et al., 2006; Stiles, Barkham, Connell, & Mellor-Clark, 2008).

One of the concerns about allowing clients to choose the number of sessions that they attend is that people will attend an unmanageable number. However, a number of studies (across different clinical settings) that have allowed clients to choose the sessions they attend have found that clients generally attend a low average number of sessions, such as between four and six (Mansell, Carey, & Tai, 2012). Although a few clients may access a larger number, the majority attend a small number (T.A. Carey, 2005; T.A. Carey, Tai, & Stiles, 2013). Dramatic improvements in waiting times, access to services and missed/cancelled appointments have been observed using this 'client-led' approach (e.g. T.A. Carey & Spratt, 2009).

Accessible format and style

The theoretical framework that underpins the course allows us to focus on a small number of simple concepts that we have found ring true with clients. Naturally, the key tenet is 'control'. Clients are very familiar with their struggles to control aspects of their lives and they tend to find the tasks around understanding control very engaging. In contrast, some clients struggle to label their thoughts and feelings, especially at the start of a psychological intervention. The Take Control Course does not necessarily require participants to label their thoughts, feelings, behaviour, attitudes and assumptions, as might be necessary for a classic CBT course. The interpersonal style of the facilitators also promotes accessibility because they are attuned to the importance of helping group members maintain adequate control and feel safe in the group setting.

Key Points

- Some people seem to get added value from groups.
- Groups have generally been found to be more cost-effective than individual interventions.
- Increasing research suggests that disorder categorisations may not be the most helpful way to understand psychological distress.
- Transdiagnostic interventions are ones that target processes that maintain psychological distress across disorders.
- Enabling clients to choose how many sessions they attend can be beneficial for the clients and the service.

Further Reading

Harvey, A. G., Watkins, E. R., Mansell, W., & Shafran, R. (2004). *Cognitive Behavioural Processes Across Psychological Disorders: A Transdiagnostic Approach to Research and Treatment*. Oxford, UK: OUP. [provides a systematic review of the research literature which supports a transdiagnostic account]

Mansell, W., Harvey, A., Watkins, E., & Shafran, R. (2009). Conceptual foundations of the transdiagnostic approach to CBT. *Journal of Cognitive Psychotherapy*, 23(1), 6-19. [provides an update of transdiagnostic research, considers theoretical accounts that could explain the empirical data]

Chapter 2: Conceptual and theoretical background

The Take Control Course draws understanding from three main strands of research. It draws on research into cognitive behavioural therapy (CBT) and particularly research into the underlying processes that contribute to psychological distress. It is also influenced by research that suggests that some processes contribute to psychological distress and problematic symptoms across a number of different psychological disorders. Finally it draws on research into Perceptual Control Theory (PCT; Powers, 1973), which is a theory that provides a framework for understanding psychological functioning as a whole and for understanding what contributes for psychological distress.

Common processes across disorders

As described in the previous chapter, increasing research has found that certain cognitive and behavioural processes can contribute to psychological distress across psychological disorders. These processes, which are problematic across disorders, are described as transdiagnostic processes.

The Take Control Course (TCC) is derived from Perceptual Control Theory (PCT; Powers, 1973). PCT is a transdiagnostic theory that proposes generic mechanisms that account for psychological distress across disorders (Higginson, Mansell, & Wood, 2011; Mansell, 2005). These mechanisms are unique to the theory and provide a fundamental ethos for how to provide an intervention. PCT provides an explanation of why certain processes that are proposed by other theories are actually a problem for the individual (described in more detail in the next section). Therefore, the TCC is a transdiagnostic intervention because it targets generic mechanisms according to PCT.

Introduction to Perceptual Control Theory (PCT)

PCT was developed in the 1950s and 1960s and is informed by the field of control engineering (Powers, 1973; Powers, Clark, & McFarland, 1960a, 1960b). This section provides a brief overview of PCT and Table 1 provides a summary of key terms.

Many of you will not be familiar with PCT, although you may have come across some of the theories and understandings that it has influenced. For example, self-regulatory theories, such as that of Carver and Scheier, have been strongly influenced by PCT (Carver & Scheier, 1990; Carver & Scheier, 1998). Other theorists and theories that have been influenced by PCT include Robin Vallacher in his work on Action Identification and Klaus Grawe in his work on integrating psychological therapies (Grawe, 2007; Vallacher & Wegner, 1987). Further a number of theorists have used PCT to understand some of the components of CBT that are effective across disorders. For example, Carey (2011) provides an understanding of exposure based on PCT, which is described in more detail in this and later chapters. Other writers have considered how concepts of PCT resonate with other therapeutic approaches, such as essential principles of person centred therapy of therapist genuineness (therapist authentic within the therapy relationship), unconditional positive regard (therapist not disapprove of aspects of client's experience) and empathic understanding (understanding of the individual clients' internal world) (Higginson et al., 2011). These principles are characteristics associated with low therapist interpersonal control and have influenced a range of therapeutic approaches. As is explained in more detail in this chapter, PCT based interventions emphasize the importance of the client's perceived control, with it being less important that the therapist feels in control particularly in situations where increased therapist control would limit client control.

However, PCT provides a distinctive set of understandings and these are outlined in this chapter. This chapter is written with healthcare professionals in mind, so it includes clinical examples where possible.

Living is control

PCT is based on the idea that all living beings, including humans, control their perception to ensure their experience is a certain way. This applies to basic things, such as how warm or cold we want to be, through to more complex life goals, such as having a good relationship with a partner (Higginson et al., 2011). One way of thinking about this is that we have a set of 'just rights' in our head, 'just rights' being representations of how we want the world to be (T.A. Carey, 2006). When our experience within the world matches up to our 'just rights' then we act to keep things happening this way, but when conditions change and things are no longer 'just right' we act to bring things back to the way that we want them to be.

This approach makes PCT highly distinctive. Sometimes other therapies consider control to be a problem; for example, Steven Hayes who developed Acceptance and Commitment Therapy has stated: "control is the problem" (S. C. Hayes, 2004, p.653). Yet, PCT would propose that if we did not control a multitude of things every day, we would become increasingly overwhelmed by our environment – not washing, dressing, talking, travelling, working – all of these are sophisticated processes of control in action. A PCT approach would suggest that we are aware of our attempts at control mainly when we are finding it difficult, whereas most control happens automatically and without thought. It is this kind of automatic flow of control that we are helping clients to try to restore in their lives. Control is implemented through a process known as a negative feedback loop, which is explained in detail in Part B, Chapter 2 (which details session 2).

Control is managed over many hierarchical levels

PCT suggests that our goals are organised hierarchically, this means that goals are represented at different levels. Higher-level, long-term goals lead to the setting of sub-goals that in turn regulate lower-level, shorter-term goals. For example, a higher-level goal of 'being a good friend' could lead to the setting of sub-goals, such as 'to be helpful' and this in turn could lead to the setting of lower-level goals, such as 'to contact a friend'. The theory itself describes in detail eleven different levels in a hierarchy, but the most important principle to be aware of is that for any goal or problem that is being discussed there are likely to be successively higher levels that indicate why this is important, and lower levels that describe how to implement actions to achieve the goal.

Loss of control causes distress and conflict undermines control

Sometimes we cannot bring things back to the way we want them to be, we cannot get the world to match up to our 'just rights' and can experience loss of control. A number of reviews support a relationship between control and well-being, and between lack of control and psychological distress (e.g. Chorpita & Barlow, 1998; Fitzsimons & Fuller, 2002; Grawe, 2007; Mansell, 2005). It is common that things do not quite go the way that we want them to and this in itself is not the problem. What is suggested to be problematic is when we have important goals that remain in conflict. Carey (2008) gives the example of a client, with symptoms of anxiety, who had an on-going conflict between 'wanting to let her daughter do normal things' and 'wanting to keep her safe'. As well as leading to anxiety these goals informed certain actions at lower-levels, which were problematic for the client; for example, trying to stop her daughter going out of the house.

According to Carey, the principle of conflict being at the heart of psychological distress is rather like a theory of 'relativity' for psychology. For example, the negative thought 'I will make a fool of myself and other people with laugh at me' is only a problem for someone who wants to come across as competent and serious – in other words, it creates conflict (Timothy A Carey, Mansell, & Tai, 2015). The same thought has an opposite implication for a stand-up comedian or a clown, whose goal is exactly to act foolish and make other people laugh. The same principle can be applied to any behaviour or process – it is only a problem if it creates or maintains conflict.

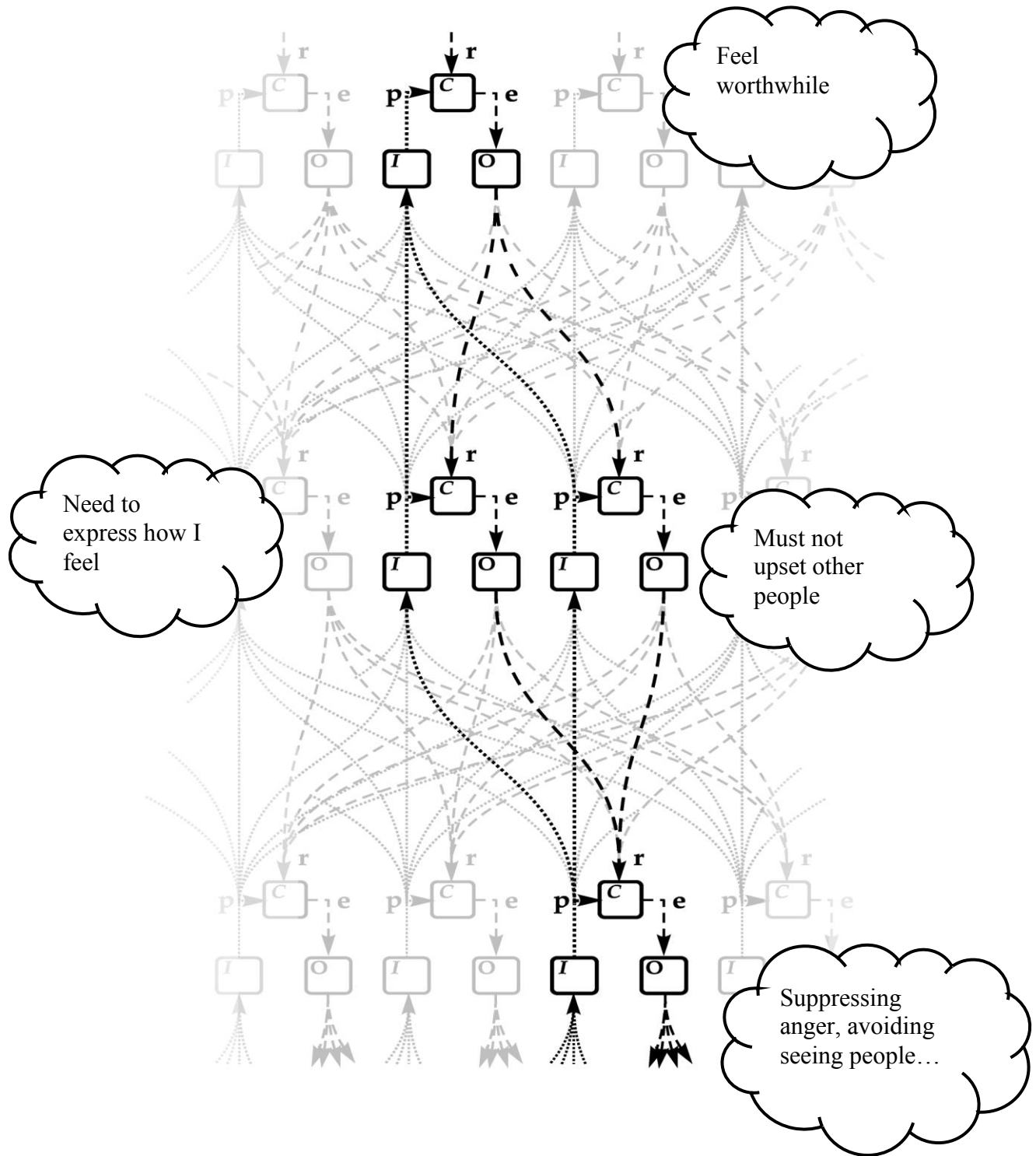
Conflicts between higher-level goals cause greater problems than conflicts at lower-levels

According to PCT, it is when important, higher-level, goals remain in conflict that we experience psychological distress and unwanted symptoms. One of the reasons for this is the higher-levels goals set the goals for the levels below – they are longer term and more definitional to the self. One way of thinking of this is that the higher-level systems that set the conflicted goals are the root of the problem. Without change at the root of the problem any other changes will not fully address the issue. Although problematic symptoms and behaviours can be highly distressing, they are generally not the 'root' of the problem, unless it is these symptoms and behaviours that are blocking awareness of conflicted goals, or conflicting with goals themselves. For example, when people engage in rumination or worry over long periods of time about everyday stresses, this could prevent attention being directed to where the more significant problems lie. On the other hand, targeted worry about an important concern (e.g. recently being attacked in the street) may have a beneficial effect in seeking help or engaging in actions to prevent more serious outcomes.

An example to illustrate the importance of higher-level conflict is a client who has a higher-level goal conflict between 'I need to express how I feel in relationships' and 'I must not upset other people'. This conflict led to a range of problems because as soon as she thought about telling other people how she felt, she became so concerned that she would upset them that she suppressed the feelings and avoided meeting them. Over time, this led to greater feelings of anger and frustration with other people, and even more avoidance of seeing them. She found that when she tried to force herself to express her feelings, this only led her to feel more guilty and concerned about the impact on other people. So, shifting the lower-level goals merely perpetuated the conflict. However, the more she became aware that she was in a conflict between expressing her feelings and not upsetting other people, the more she realised that both sides were a normal part of feeling worthwhile (the overarching goal that drove the conflict) and she needed to change the way she balanced these two goals in different situations. See Figure 1 for a diagrammatic representation of this.

For those who are familiar with a traditional CBT framework, it could be interesting to consider how the concept of higher-level goals relates to the concept of core beliefs (Higginson et al., 2011). Certainly, it appears that accessing this level of cognition is of benefit in CBT. However, in contrast, a PCT approach regards "I want to feel worthwhile" as the goal to discuss; the belief of 'I am worthless' is merely be the result of long periods of not achieving a feeling of being worthwhile owing to the kinds of conflict we have discussed. Thus, a PCT approach has the capacity to reframe a core belief as the consequence of difficulties with a normal, dynamic, positively orientated goal that can be openly discussed and better understood.

Figure 1. Conflict model with a clinical example mapped onto it. Based on the diagram in *A Transdiagnostic Approach to CBT using Method of Levels Therapy*, by Warren Mansell, Timothy A. Carey and Sara Tai.



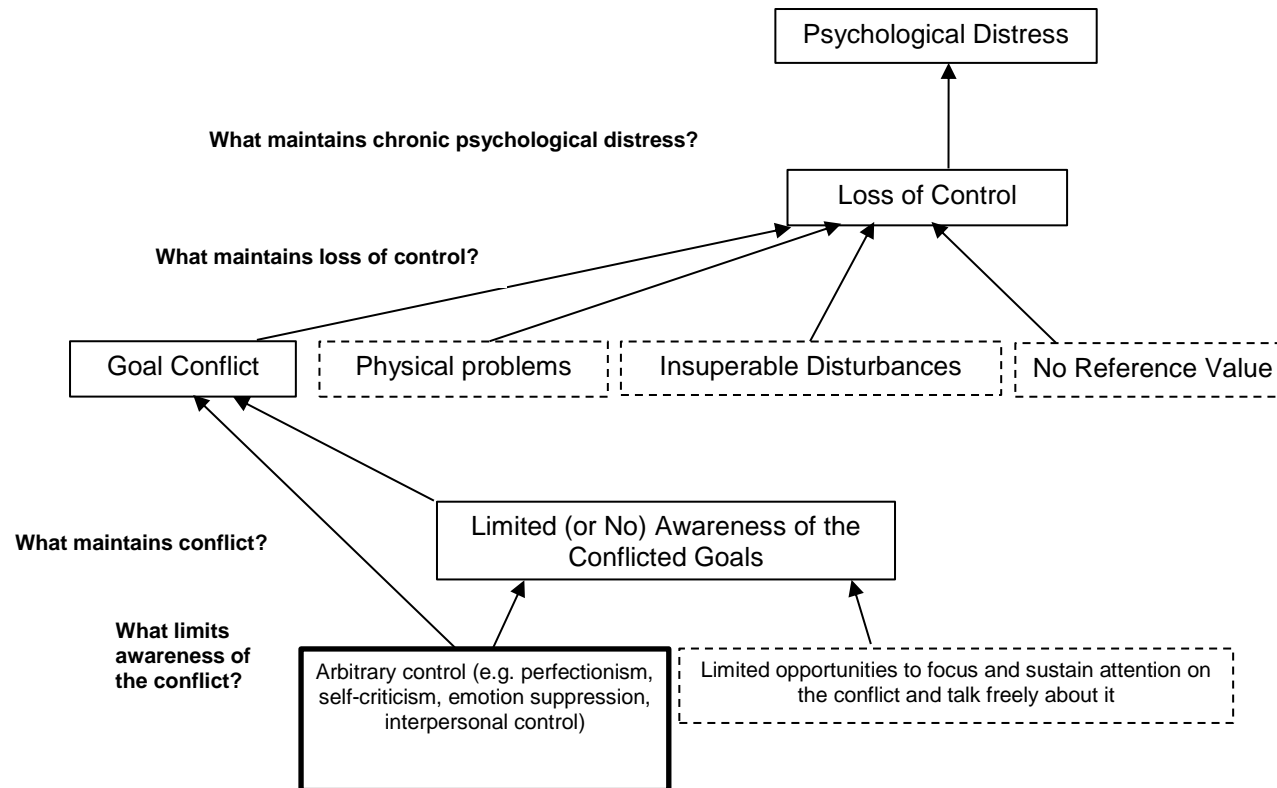
Control without awareness can exacerbate conflict

Within PCT there is an important role for awareness because without awareness of conflicted goals then conflicts will not be resolved. Lack of awareness of all relevant goals (or reference values) makes it more likely that a goal will be pursued without taking into account another goal that is also controlling this experience. Within PCT, this process of pursuing one goal without taking into account another relevant goal is referred to as '*arbitrary control*' (Powers, 1973).

For example, after a traumatic accident an individual may have recognised the need to discuss their experiences with other people because they recognise it will give them support and help them understand how to cope better. However, they might struggle to talk about these experiences due to a second goal they hold which is to 'make sure other people don't think I'm crazy'. In practice they may switch between wanting to talk about their problems and wanting to avoid other people. This avoidance then constitutes arbitrary control because they do it despite the impact it has on achieving a goal that is important to them. In PCT, rather than regarding avoidance, or any other 'safety seeking behaviour' as a problem per se, we recognise that it is only a problem to the extent that it causes conflict or keeps it outside awareness. There may be all kinds of benefits to these behaviours as well. Therefore, we help people fully explore the costs and benefits of their behaviour, and work out for themselves how to reduce the negative impact they have. Sometimes this might involve gaining better control of when they engage in the behaviour and when to not use it.

According to PCT, *arbitrary control* between individuals is a very important to consider because it creates conflict. For example, the criticism of a highly critical friend or family member could interfere with that person's goal of 'feeling good about myself'. This criticism blocks an important personal goal and so it constitutes arbitrary control. But even what seem to be quite innocuous behaviours on the surface can have the same damaging effects. For example, ignoring a family member when they express their needs, or applying one's own expectations of what is a good achievement to other people. Figure 2 illustrates how arbitrary control maintains the loss of control involved in psychological distress via its effect on blocking important personal goals.

Figure 2. A diagram to illustrate how arbitrary control contributes to goal conflict, which in turn contributes to chronic loss of control and psychological distress. Reproduced with permission from *A Transdiagnostic Approach to CBT using Method of Levels Therapy*, by Warren Mansell, Timothy A. Carey and Sara Tai.



Change occurs when awareness is brought to enduring higher-level conflicts, for long enough to allow their successful reorganisation

Awareness of conflicted goals is important within a PCT account, as it is suggested that goals cannot change until we have some awareness of them. PCT suggests that changes to our goals occur at the point within the control system at which we are currently aware. The proposed change mechanism within PCT is known as reorganisation (Powers, 1973). When there is a loss of control (or error) within the control system then the reorganisation process begins to make random changes (Powers, 1973). Trial-and-error changes in the properties of the control systems continue until loss of control (error) is reduced (Carey, 2011; Powers, 1973). The clinical implications of this include explaining the findings that sudden psychological change (gains, insights or aha moments) within therapy can result in lasting symptom change because these would be examples of successful reorganisation (Aderka et al., 2012). Reorganisation can be experienced as things suddenly making sense, being resolved, or seeing what needs to change etc.

A vital implication of this for psychological interventions is that awareness must be directed to the higher-level goals that are setting the conflicted goals so that these can be reorganised. There are a few ways that this process is facilitated within the TCC. Firstly awareness or mindfulness techniques are used within the Course. From a PCT perspective, the main reason for using awareness techniques is to develop a 'window' of awareness that can be brought to bear on the thoughts, feelings and behaviours involved in conflicted goals. As a result of this emphasis, awareness techniques used in the TCC are shorter than those delivered in some other approaches; for example, Mindfulness Based Cognitive Therapy (Segal, Williams, & Teasdale, 2002).

It is important that awareness is directed to problematic feelings or thoughts in a sustained manner because it can take time for awareness to 'settle' on the higher-level conflict driving the problem. Awareness of higher-level conflict is a precursor for this to be reorganised; however, reorganisation is a trial and error process and may not always hit on the best solution first. For example, a client may experience a heightening of distress and symptoms before they experience positive change.

Another way in which awareness is directed to the higher-level goals that are setting the conflicted goals is through the way that exposure is delivered. Exposure in the TCC is designed to help people hold perceptual conflict in mind and establish a new organisation of goals that allows them to regain overall control. An example of a perceptual conflict is between the desire to give a presentation and the fear of looking incompetent, or a conflict between avoiding a past distressing memory and the desire to bring this to mind to make sense of it. So, in the TCC, exposure exercises are client-driven and framed in such a way that they are guided by clients' life goals to promote sustained attention on personally relevant conflicts.

Summary

This section aims to give a brief overview of key components of PCT, but for more comprehensive accounts of PCT and the evidence base for its components see (Mansell & Carey, 2009; Mansell et al., 2012; Marken & Mansell, 2013). Also Morris, Mansell and McEvoy (2016) give a more detailed summary of PCT and the ways in which PCT has informed the Take Control Course (TCC). Box 1 provides a summary of key PCT concepts. We are aware that many readers will not be very familiar with PCT so key theoretical points will be revisited as we introduce the material covered in each session. The next section provides a brief overview of the TCC and an introduction to the PCT basis of each session.

Box 1: Summary of key PCT concepts (informed by Powers, 1973 and Morris, Mansell & McEvoy, 2014)

1. **Living is control.** PCT is based on the idea that all living beings control their perceptions in order to make their experience a certain way. We all have internal standards, a sense of how we'd like our experience to be, and we act on our environment to make our experience match these standards.
2. **Control is managed over many hierarchical levels.** People's goals are organised over a number of different levels. Goals are arranged in a hierarchy with higher-level, more general, goals setting the goals for lower-levels.
3. **Loss of control causes distress.** When people are unable to control their experiences over a period of time, then they experience distress. Significant loss of control can be a really frightening and disorientating experience and it is not surprising that it can result in a range of distressing symptoms.
4. **Conflict undermines control.** Conflicts will regularly arise between the goals people are trying to achieve; however, when these conflicts are enduring they can result in psychological distress and unwanted symptoms.
5. **Conflicts between higher-level goals cause greater problems than conflicts at lower-levels.** Chronic conflicts at higher-levels result in greater psychological distress than conflicts at lower-levels. A specific conflict between 'doing a presentation' and 'wanting to avoid giving a presentation' does not undermine control to the same extent as a conflict between 'being a good employee' and 'I can't cope in social situations'.
6. **Control without awareness can exacerbate conflict.** If control is applied to an experience in order to meet a goal and does not take into account a competing goal, then one of the goals will be 'blocked'. This causes conflict as only one of the goals is achieved. For example, one might avoid presentations to prevent anxiety without thinking about how much one wants to present to demonstrate this capability and potentially improve career progression.
7. **Change occurs when awareness is brought to enduring higher-level conflicts, for long enough to allow their successful reorganisation.** Change occurs through a process called reorganisation and reorganisation occurs at the point in the hierarchy that the person is aware. Given the importance of higher-level goal conflicts within a PCT account it is vital that awareness is brought to the higher-level systems driving the enduring conflict that is creating distress.

Key points

- Perceptual Control Theory (PCT) is a transdiagnostic theory that proposes generic mechanisms that account for psychological distress across disorders.
- A key focus is recognising that we 'control' our experiences to make our experiences a certain way.
- Enduring conflicts cause people to perceive that they have lost control and to experience distressing symptoms.

Further Reading

Carey, T. A. (2011). Exposure and reorganization: The what and how of effective psychotherapy. *Clinical Psychology Review*, 31(2), 236-248. [Presents a PCT account of exposure]

Higginson, S., Mansell, W., & Wood, A. M. (2011). An integrative mechanistic account of psychological distress, therapeutic change and recovery: The Perceptual Control Theory approach. *Clinical Psychology Review*, 31(2), 249-259. [An overview of PCT and discussion of how concepts within PCT integrate with different psychological approaches].

Morris, L., Mansell, W., & McEvoy, P. (2016). The Take Control Course: Conceptual Rationale for the Development of a Transdiagnostic Group for Common Mental Health Problems. *Frontiers in Psychology*. doi: 10.3389/fpsyg.2016.00099
<http://journal.frontiersin.org/article/10.3389/fpsyg.2016.00099/abstract>

Chapter 3: PCT within psychological interventions

PCT provides an account of the causes, and maintenance, of psychological distress. Such an understanding has been applied across a wide variety of presentations, such as phobias (Mansell, 2005), obsessive-compulsive disorder (Pitman, 1987), depression (Hyland, 1987), bipolar disorder (Mansell, 2010), addiction (Webb, Sniehotta, & Michie, 2010) and dissociative disorders (Johnson, 2009; Mansell & Carey, 2012). Although the conflicted goals might be different in each presentation (e.g. facing versus avoiding a specific object in phobia, or conflicting self-states in dissociative identity disorder), the underlying cause of the distress is the same process of prolonged goal conflict outside of awareness. Given the broad application of PCT and both qualitative and quantitative studies providing empirical support, a comprehensive account is not possible here- for a more detailed summary of the evidence for PCT as an account of psychological distress and recovery see (Alsawy, Mansell, Carey, McEvoy, & Tai, 2014).

PCT applied within individual interventions

An individual CBT therapy has been developed based on the principles of PCT. This is called Method of Levels (MOL) (T.A. Carey, 2006) and aims to help clients to become aware of higher-level goals and facilitate the process of reorganisation, in order to resolve goal conflicts (T.A. Carey, 2006, 2008). This is achieved by encouraging the client to talk about their problem and by asking about 'disruptions'. Disruptions can be a smile or a shake of the head, hand gestures etc. These are important because they indicate a shift in a person's awareness, which could be a shift to higher-level thoughts or understandings of the topic being discussed (Powers, 1998). Curious questions are asked about the problem being discussed and the disruptions in order to direct the client's awareness to their present-moment experience of the problem. An example of such a curious questioning style is provided in 'Chapter 4, Part A' as we recommend the use of this within interactions during the Take Control Course.

There are manuals available that describe, in detail, the use of PCT in individual therapy. These are included in the further reading list at the end of this chapter.

There have been a number of evaluations of MOL in uncontrolled trials. These have shown significant reductions in symptoms on standardised measures of psychological distress after MOL, with moderate to large effect sizes, for clients experiencing a range of problems including depression, bereavement, anxiety disorders (e.g. social anxiety disorder, post-traumatic stress disorder), relationship breakdowns and anger management (T.A. Carey, 2005; T.A. Carey, Carey, Mullan, Spratt, & Spratt, 2009; T.A. Carey & Mullan, 2007, 2008). A study of MOL with clients in secondary care calculated an efficiency ratio, which was in order to examine the magnitude of symptom change in relation to the number of sessions attended. As is common in studies of MOL, clients were able to attend the number of sessions that they perceived would be helpful. The improvements demonstrated in this study were of a similar level to other therapies and the efficiency ratio was higher in this study than in all the comparison studies, which included a range of different therapies (T.A. Carey et al., 2013). This indicates that letting clients chose the sessions that they attend does not make therapy inefficient, on the contrary this client-led approach makes it more efficient. A pilot RCT has been conducted in a primary care psychology service (Bird, Tai, Hamilton, & Mansell, 2013) where MOL was compared to control (waiting list or regular CBT treatment). Significant improvements were found on ratings of anxiety and depression in both conditions and there were larger improvements in the MOL condition for ratings of anxiety.

General information and resources regarding applying PCT to mental health problems can be found at: <http://www.pctweb.org/psy/mental.html>, and the MOL website is <http://www.methodoflevels.com.au>.

Research focusing on the Take Control Course

The effectiveness and feasibility of the Take Control Course (TCC) was examined in a prospective cohort study comparing TCC with a non-randomised control group of clients accessing individual low-intensity CBT (Morris et al., 2015). Individual low-intensity CBT (LI CBT) includes guided self-help and other brief clinician-facilitated interventions. The primary outcome was a composite depression and anxiety score. Comparison points were 1-month post-baseline (TCC $n = 26$; LI CBT $n = 14$) and 3-months follow-up (TCC $n = 12$; LI CBT $n = 7$). For the TCC group, changes on all pre-post outcomes were significant with moderate effect sizes. The between group effect was not statistically significant; although TCC showed lower mean scores at 1-months and 3-months compared to control. Also understanding and satisfaction ratings were taken every TCC session ($N = 186$) and the median understanding rating was 9/10 ($IQR = 2.38$) and the median satisfaction rating was 8/10 ($IQR = 3$). However, this study was not a Randomised Controlled Trial (RCT) and so there are of sources of bias, e.g. differences between the two treatment groups, which could have influenced the results obtained.

Research is ongoing in order to evaluate the TCC in a more rigorous study. This uses a RCT design, comparing TCC to individual low-intensity interventions (LII), and uses a more robust method of collecting follow-up. Also this has a longer follow-up period, which will enable more substantive conclusions to be drawn regarding the long-term outcomes of the TCC. Qualitative data will be collected within this study to find out in more detail how the TCC, and LII, work from the perspective of participants. For example, to understand which elements of TCC are particularly helpful for participants in order to make valued changes and any elements they did not find helpful.

Components of the Take Control Course (including the rationale based on PCT)

There is a strong emphasis on client self-direction and flexible control within the TCC, which reflects the evidence base that psychological change (or gains) happen at different time for different people. Also promoting client control as much as possible aims to make it more likely that they are meeting their own goals, rather than being heavily influenced by the clinician's goals. Therefore, clients are given information regarding the content of each session and are advised that they do not have to attend a session if they do not think it is relevant. Specific homework tasks are not given, but at the end of each session participants reflect on what they are taking from the session and are encouraged to write down a specific task if relevant. Sessional evaluation forms are filled in and session content can be slightly adapted in response to feedback. Although the core content of each session is prescribed, certain techniques re-occur and so later implementation of techniques can be changed or explained differently in response to feedback. Furthermore, there is an emphasis on experiential learning (trying things out) in order to promote individual clients to consider the relevance, and application, of techniques to themselves.

Each session includes videos of clients who have accessed either previous interventions within the service or earlier TCC. These provide opportunities for the group to hear accounts of other people's experiences of distress and the things that helped them gain more control, as relevant to the session theme. Some opportunities are provided for

participants to share their personal experience, but it is strongly emphasised that clients do not have to share these experiences if they do not want to.

In accordance with the PCT theoretical account, targeted throughout the TCC are: 1) understanding the process of control, including the degree to which one can, and desires, control over various aspects of one's life; 2) awareness of valued higher-level goals (and reasons for change); 3) awareness of higher-level goal conflict; 4) encouragement of flexible ways to control and reduction of processes (including rules, habits, routines and mental processes) that block valued goals.

The following is a description of key themes of the six sessions with a brief explanation of the PCT rationale. See Appendix A for the list of session themes that we provide to clients. If you want a more detailed account of how the PCT basis has informed individual sessions, please see Morris, Mansell and McEvoy (2016). The themes will be revisited when individual sessions are described and more detail will be given!

Session one: 'Thinking about control'. Control is the basis of this course. The overall theme in this session is to understand control and to encourage clients to consider the things that they can, and want to, have more control over. Exercises also support clients to consider which of their habits/responses get in the way of them achieving the things that are important to them.

Session two: 'What blocks our control? Addressing negative thinking: self-critical voice, worry and dwelling on things'. A key message here is that individual thoughts, even negative ones, are not a problem. Even worry, self-criticism and rumination are normal processes that most people engage in. They are a problem only to the extent that they get in the way of important life goals, or they limit a person's awareness of them. This message is both normalising and empowering, giving clients the opportunity to think carefully about how and why they do these things, rather than feeling they must stop doing something that has been part of their way of being for many years.

Session three: 'Feeling in control short-term vs getting control of your life'. The principle of a hierarchy provides a key basis of this session. A fundamental message of the session is that sometimes our attempts to control our emotions, avoid distress or keep safe can actually get in the way of us doing things that are really important to us. This encourages clients to focus on their longer-term (higher-level) goals and to consider how to prioritise these over short-term goals that are getting in the way.

Session four: 'Taking control of the things around you'. A unique theme of PCT is that we are designed to control our environment for our own purposes. There are many things in our environment that we can change in order to make our world more like we want it to be. However, there are also some things that, objectively, we will have limited control over. Part of our world is other people. This session focuses on helping people take a wider perspective on their own needs and balancing them with those of people who are important to them.

Session five: 'Building on strengths, qualities and resources'. The focus of the session is to encourage participants to recall the strengths, qualities and resources they have, especially at times when things are difficult for them. These are the things inside themselves and within their social world that will help them take control of their lives.

Session six: 'Moving forward: what gets me stuck? What helps?'. The focus of the session is on consolidating what has been learnt and planning for the future. Clients are encouraged to choose elements of the TCC that they want to revisit. Allowing choice in the material covered, and encouraging clients to reflect on what works for them and when, encourages flexible control. Planning for the future uses what PCT describes as the 'imagination mode' and the theory behind this is detailed in 'Chapter 6, Part B', which is the chapter covering session six.

In the next chapter we will describe how to set up a Take Control Course and go into more detail regarding the overall style of the course.

Key Points

- Perceptual Control Theory (PCT) has been used effectively to inform psychological interventions.
- An individual therapy called Method of Levels (MOL), based on PCT, has been found to be a useful transdiagnostic intervention.
- PCT based interventions emphasize key 'PCT relevant' themes, such as maximising client control.

Further Reading

Morris, L., Mansell, W., & McEvoy, P. (2016). The Take Control Course: Conceptual Rationale for the Development of a Transdiagnostic Group for Common Mental Health Problems. *Frontiers in Psychology*. doi: 10.3389/fpsyg.2016.00099

Morris, L., Mansell, W., Emsley, R., Bates, R., Comiskey, J., Pistorius, E. & McEvoy, P. (2015). Prospective cohort study of a transdiagnostic group intervention for common mental health problems: the Take Control Course. *Psychology and Psychotherapy- Theory Research and Practice*. doi: 10.1111/papt.12070

Therapy manuals for PCT in individual therapy:

Carey, T. A. (2006). *The method of levels: How to do psychotherapy without getting in the way*. Hayward, USA: Living Control Systems Publ.

Carey, T. (2008). *Hold that thought! Two steps to effective counseling and psychotherapy with the Method of Levels*. Chapel Hill, NC: New View Publishing.

Mansell, W., Carey, T. A., & Tai, S. J. (2012). *A Transdiagnostic Approach to CBT Using Method of Levels Therapy: Distinctive Features*. New York: Routledge.

Useful websites:

<http://www.pctweb.org/psy/mental.html>

<http://www.methodoflevels.com.au>

Chapter 4: How to use this book

In this chapter we will give an overview of how to make use of the book. We will detail the clients it is most likely to be helpful for. We will then give an overview of the Take Control Course (TCC) and the material in this book, including the overall format of the course and how to set up and organise courses.

Who is the Take Control Course for?

The Take Control Course (TCC) is a transdiagnostic intervention. This means that it is aimed at clients with a range of problems, including symptoms of anxiety and depression (see Chapters 1-2, for more details regarding transdiagnostic approaches). Although the TCC is transdiagnostic, the format of the TCC is fairly brief (six sessions). Therefore, the research so far has looked at how effective it is in primary care services, as there is a stronger evidence base for brief interventions within such services (e.g. Richards & Borglin, 2011). We expect that the course will be relevant to a much wider range of clients, but there may need to be adaptations and regular monitoring and feedback from clients to ensure that the TCC is meeting their needs; see Part B, Chapter 7 for more discussion of this (Morris, Mansell, & McEvoy, 2016). Consequently, if you are interested in providing the course beyond primary care, we would encourage you to contact us and work together on adapting it.

Like any psychological intervention the TCC should be offered to clients on the basis of their goals and preferences. For example, if a client specifically wants to 'talk things over' in some detail then the TCC is unlikely to be the best option for them. Similarly if a client really does not want to access an intervention delivered in a course format then the TCC is not going to be the best option. While always being sure to respect clients' wishes it is often worth ensuring that clients are clear about what the format of the TCC is. It can be helpful to explicitly say that the Course is not at all like the stereotype of AA meetings, where everyone gets up and talks about their problems! This is not done to persuade clients that they should attend the Course if they do not want to, but to help make sure that they do not miss out because they think it is something it is not.

It is also possible that some clients might need an alternative approach or more than one psychological intervention. Again, this is common to all psychological interventions and can not be entirely prevented even through use of careful clinical assessment.

Using this book

Structure of the book

The book is laid out so that every chapter (after this one) describes a single session of the TCC. The full TCC is six sessions, the first session is an hour and a quarter and the other five sessions are 1-hour each. As well as describing the session, relevant theoretical points will be briefly covered- we are aware that PCT will be new to some people!

Worksheets are included for each session in the relevant chapter. The extra worksheets that we give people at the end of certain sessions are included in appendices.

Session ‘overviews’

Each chapter includes an overview of the components of the relevant session. A summary of these is provided in a format that is easy to print out and use during the session. Although some of the overviews contain scripts of what to say, we don't expect these to be learnt by heart. They are provided to give a clear illustration of the kind of language and explanation used. Facilitators will have different styles and as you become more familiar with the material it is likely that you'll adapt the style and language used to suit your style and the group that you are addressing.

Using a Perceptual Control Theory style

The theoretical understanding of Perceptual Control Theory (PCT; Powers, 1973) is critical to the style of delivery. The aim is to encourage clients to control in the broadest sense. Recall that effective control is driven by people's higher-level goals – i.e. their ideals, values and long-term aspirations. The facilitator of the group is therefore aware that there will always be reasons behind any question asked, and behind any particular behaviour that a person engages in. They may not be aware of these or their impact at the time. Arbitrary control is the opposite of this overarching control because it does not take into account all of a client's important goals. Therefore, the kind of flexible control promoted takes into account all of a client's important goals and how these are related. One important implication of this is that a behaviour is only seen as a problem if it is incompatible with achieving another goal that is important to the client. For example, worry would only be a problem if it conflicts with another important goal, such as 'having a happy life' or 'resolving my current problems'.

Another important implication, which follows on from the worry example, is that it really important for the clinician to encourage a client to make sense of whether a behaviour is problematic for them: is it always problematic? Would it still be problematic if they did it less? It is important not to assume that a particular behaviour (or cognitive process) is automatically problematic, but to check this out or encourage clients to check this out. Many behaviours and cognitive processes that characterise psychological disorders are also common in the general population; for example, worry and intrusive thoughts have been found to be common (e.g. Eriksen, Svendsrod, Ursin, & Ursin, 1998; Fullana et al., 2009). Such processes can be highly problematic for some people, but the important thing is not to assume.

Overall, each client is treated as a unique individual with their own goals, values and beliefs, which are respected. The problems the client describes are seen as a potentially understandable consequence of the kind of life the client is experiencing, and the challenges inherent in managing conflicting values, beliefs and goals.

Curious questioning style

This style of 'not assuming' leads to a curious questioning style, which is directed towards an understanding of a client's present moment experience and the personal meaning of what they are raising. For example, such a questioning style maybe used to develop and understand comments or questions within the group. Clearly it is important to tailor the response to the question asked, if a client asked a very factual question (e.g. when does the session finish) it is unlikely to be appropriate to ask them in detail about their present moment experience! Also given the group context it is important to be sensitive to what and how much you ask people, as it is not an individual therapy session and individuals will vary as to how comfortable they feel sharing with a group. Facilitators could check with clients whether they are comfortable to be asked some questions; for example, "is it OK if I ask you a few questions about that?" An example of a curious questioning style is given in Box 4.1; in this example the client leads the dialogue by asking the facilitator questions. However, the facilitator could still check out with the client whether they are feeling

comfortable with the dialogue; for example, “is it OK for you to talk about this now?” or “how is it going talking about this?” This is especially important if the facilitator picks up any cues that the client is uncomfortable, such as reduced eye-contact, slow responses, but it is useful to check even if there are no visible cues of discomfort.

As mentioned, the focus of this questioning style is to encourage clients to elaborate problems and concerns that they are experiencing and the personal significance of these. Ultimately focusing on personally salient aspects of the conversation facilitates clients to bring awareness to conflicts and deeper values or higher-level goals. For example, the facilitator may ask about words that seem to have a particular salience, or emotional charge, for the client, such as “normal” in the example box 4.1. The facilitator may also ask the client, “does that bother you?” or “why is that important to you?” to clarify the meaning of events, behaviours and experiences for the individual client. Questions such as these are an important part of ‘not assuming’. This style of questioning can constitute a therapeutic intervention in itself and has been termed empathic curiosity (McEvoy, Baker, Plant, Hylton, & Mansell, 2013; McEvoy & Plant, 2014). The established intervention based on this sort of questioning style is called Method of Levels (MOL). A much more detailed account of ‘PCT-style’ questioning and MOL is provided in Mansell, Carey & Tai (2013).

For those clinicians familiar with CBT, this questioning style has some similarities to Socratic Questioning as described by some leading writers (e.g. Padesky, 1993). However, summarising or interpretative questioning is not common in a ‘PCT-style’ of questioning. Also, questions are focused particularly around the present moment.

Box 4.1: An example of an exchange using a curious questioning style

Client: Is it normal to think about things over and over again?

Clinician: What does normal mean to you?

Client: Like does everyone think over and over about certain things? Is it healthy to do this?

Clinician: Can I just check with you - you mentioned both 'normal' and 'healthy' there. Would you say normal and healthy are the same or different?

Client: Different.

Clinician: Is one more important to you?

Client: I think being healthy is more important because different people do all kinds of different things. I suppose I'm worried that it is not healthy to keep thinking about things.

Clinician: And what do you have in mind when you say 'healthy'?

Client: Well, physically ok- not damaging myself.

Clinician: So, are you concerned you're damaging yourself?

Client: Yes by dwelling on things and making myself feel bad.

Clinician: OK, so would it make sense for you if we do some work in this session on describing the bad things about dwelling too much, but also maybe look at what people get out of dwelling on things too?

The clinician would have a number of options as to how they wanted to further respond to this and this would depend on client preference, where they were up to with the sessions, the potential relevance to other clients and previous feedback from the group. They might continue the discussion, or bring some psychoeducative materials to the next session, or offer the client opportunity to discuss this with them after the session, or refer to a relevant section of the materials covered in more detail etc.! Given the format of the sessions it is always necessary to balance individual and group discussion with covering the core components; for example, some groups will feedback that they find the opportunity to explore and ask questions particularly helpful, but others will feedback that they would prefer to focus on the worksheets and core session components.

Evaluation form (provided in Appendix B)

A one-page evaluation form has been developed and should be handed out at the end of every session. This should be completed anonymously as the purpose is to get honest feedback on what elements of the session clients are finding helpful/less helpful. Although people will give verbal feedback, the evaluation form gives everyone the opportunity to express their perspective.

In line with the focus on maximising client's flexible control, the responses to the evaluation form should be used to inform the next session. Although the core content of each session is prescribed, certain techniques re-occur and so later implementation of techniques can be changed or explained differently in response to feedback. It is necessary to be pragmatic in response to feedback; for example, if one person doesn't respond to a certain exercise but everyone else really likes the exercise then you wouldn't want to totally remove that element. However, what you could do is explain the exercise in a different way or even acknowledge that the anonymous evaluation forms have indicated that someone is not finding a particular aspect very helpful and giving them the opportunity to discuss this at the end of the session.

Stories and metaphors

While explaining certain techniques, and ways of understanding, we use stories and metaphors. This is to make the material more engaging and because sometimes a story can be much easier to remember than a load of concepts! We suggest you explain this at some point, just to make clear why you're delivering some of the material in this way. However, we have not had any negative feedback about the use of stories and metaphors and some people have said how much they like this element.

Imagery and metaphor have been found to be useful intervention components (Holmes, Arntz, & Smucker, 2007; Holmes & Mathews, 2010; Ng, Krans, & Holmes, 2013). A useful resource is the Oxford Guide to metaphors as this gives examples of metaphors in many different contexts (Stott, Mansell, Salkovskis, & Lavender, 2010). This book goes some way to explain the function and mechanism of metaphors, drawing on PCT.

Hand-outs

There are hand-outs for each session. You may photocopy these to give to group members. The main session worksheets are included in each chapter and supplementary sheets (which are given to clients at the end of some sessions) are included in the appendices. Most of the hand-outs are ones that clients will be asked to complete during the session, this follows on from the emphasis on trying out techniques, and ways of thinking about things, in order to encourage flexible control. Some slides and session sheets are described as 'reference' this is used when the slide or sheet is provided for a visual reference but clients do not need to refer to or complete these.

PowerPoint slides

There are slides for each session. These include the videos of previous clients' experiences. A print out of the slides is available in each chapter. *The actual slides and videos are available on request by following the link listed at the end of the book.*

Condensed session sheets and session guides

Condensed session sheets and session guides are provided for each session. The condensed session sheets provide a brief overview of what will be covered in the sessions. The session guides provide more detail; they list the main session components and provide a summary of the key points. The session guides can be useful for newer facilitators as they provide prompts as to key utterances and actions. The session guides can also be used to note which facilitator is taking a lead on which section.

How to organise a course

Room layout

We arrange the room a bit like a classroom, i.e. with desks in rows and people sitting at the desks. This is to emphasise that the TCC is not a group that focuses on self-disclosure and also to provide clients with some privacy when they are filling in worksheets. At the front is the projector screen and the facilitators will stand or sit at the front during most of the exercises. It can be helpful to put the relevant worksheets out on tables or by the door so that people can pick them up as they come in.

Facilitator roles

Courses generally run with two facilitators. It is possible to run a session with one person, e.g. if one facilitator is off, but generally it is better to have two facilitators. Having two facilitators generally means that the group will get the best experience and it helpful for the facilitators also! For example, one facilitator can be delivering material while the other can keep an eye on whether anyone in the group looks like they aren't following the material or seems upset etc. Also facilitators can support each other by providing examples, or clarification of sections that have not been presented clearly.

We would suggest that you agree before the session who is doing what (see 'Preparation for the sessions' section) and would generally divide up the material fairly evenly. Generally we are guided by facilitator preference in dividing up the material; if someone particularly wants to introduce a certain section then we'd encourage them to do so.

Preparation for the sessions: each week

Before each session you will need to meet with your co-facilitator to discuss who is doing what during the next session. Ideally this is done a few days to a week before the next session to allow you time to practice any aspects that you feel you need to work on. You will also need to agree who is preparing what, e.g. who is printing out the session worksheets for the session.

Group processes

This section offers some general pointers regarding working with groups and different group dynamics. The same general stance, described previously, applies in dealing with different interpersonal interactions, which is that each client is treated as a unique individual with their own goals, values and beliefs. Given that the group consists of a number of different individuals then these varied individuals need to be taken into account.

Responding to different opinions. If what the person is saying is not overtly offensive to anyone in the group (e.g. racist comments) explore what they are saying. You can thank them for their opinion/ honesty. If someone continues to express the opinion to the extent that it is affecting others in the group then 'move on'; for example, agree to differ. If comments are offensive then please follow the relevant service policy, as offensive comments are not appropriate.

Refocusing. This may be necessary if you feel discussion has gone off track. We want to be responsive to group members; however, each individual is not the only person in

the group and people will often get frustrated/ disinterested if they feel one person is dominating the group.

Try to relate what is being discussed to themes/ content of group. If you feel that you need to move on, use phrases like: “thank you for sharing that with, we are going to need to move on or there won’t be enough time to cover everything”. “We’re going to need to move on now but I’m interested in what you are saying, you can talk to me after the session if you want to”.

Dealing with distress. If client gets very distressed, panicky etc. you can normalise the response; allow other group members to support. Do not ignore it or explore it too deeply. Give the person the option to leave the room with one of the facilitators. Find a private space and allow them what they need to feel they want to return to group. Usually it makes most sense for whoever is less involved in leading the section to go out. Again the emphasis is on checking out what is best for the individual and enabling them to maintain control. Although many facilitators will also be trained clinicians, supporting distressed clients in this context will be different from a therapy session. For example, the emphasis is more on supporting the client through this particular experience than on providing a discrete psychological intervention (at times there may be some overlap).

Equipment

Different rooms have very different facilities. It is important to check what facilities are on offer; e.g. do they have a projector, or computer that could connect to a projector, which you could use? If you are using a computer the does not belong to the service it is important to check for potential issues **before the first group session**, such as the presentations not being compatible with the system or the videos not playing. It is worth checking how loud the videos are in advance and bring speakers if they are too quiet.

Below are the materials for every session; these are also listed prior to the session plan for each individual session. Facilitators may find it easier to have a bag/other storage in which you keep the materials that are needed repeatedly, e.g. pens, post it notes. It can also be useful to have a file(s) to keep the worksheets and clinical measures organised.

Materials required every session

Projector to show PowerPoint
Laptop or computer (to use with projector)
Speakers
USB containing PowerPoint slides
Pens
Clipboards
Spares of previous session worksheets
Evaluation form
Clinical measures: e.g. IAPT measures (PHQ9, WSAS etc.).
Session plans and materials
Record of attendance

Adherence rating

Although rating adherence is not compulsory, it can be helpful to do in order to establish if there are any areas of facilitation that can be improved. The checklist can be used by each facilitator to self-rate their own performance, or it can be used by an observer or co-facilitator to other-rate.

The *Adherence checklist* was developed for use in the initial effectiveness, feasibility and acceptability study of the Take Control Course (TCC) and is partly based on CTS-R (Blackburn et al., 2001). The manual should be used to inform ratings made using the *Adherence checklist*, as it describes the content of the intervention and the underlying theoretical stance in more detail than was possible for the checklist itself. The checklist and more detail on the items included can be found in Appendix C.

In the next chapter we will describe the first session.

Key points

- Take Control Course is a transdiagnostic intervention.
- An understanding of Perceptual Control Theory (PCT) is essential to the style of delivery.
- It is important that facilitators do not assume that a particular behaviour (or cognitive process) is automatically problematic. A curious questioning style helps with this.
- When responding to the group it is important to check out what is best for individual group members and enable them to maintain control.

Further reading

Stott, R., Mansell, W., Salkovskis, P., & Lavender, A. (2010). *Oxford guide to metaphors in CBT: Building cognitive bridges*: Oxford University Press.

Mansell, W., Carey, T. A., & Tai, S. J. (2012). *A Transdiagnostic Approach to CBT Using Method of Levels Therapy: Distinctive Features*. New York: Routledge.

Article link (Padesky, 1993)

<http://padesky.com/newpad/wp-content/uploads/2012/11/socquest.pdf>

Part B

Chapter 1: Session 1

Thinking about control

Overview

In this session we welcome participants to the Course and introduce the key elements of the course. This session also introduces a number of components that come up throughout the course, and so it is more comprehensive than later chapters. Although we encourage TCC participants to choose which sessions they want to attend, we advise everyone to attend this first session.

The first part of the chapter details the overall theoretical basis of the session and key session sections. Then each session section is detailed, including the materials required for each section. A list of all the materials for the whole session is provided after the session sections. A condensed session plan is provided after the list of all the session materials.

Key session focus

The overall theme in this session is to understand control and to encourage clients to consider the things that they can, and want to, have more control over. Exercises also support clients to consider which of their ways of coping get in the way of them achieving the things that are important to them.

Overall rationale

The key message of this session is that it is normal to try to control aspects of our lives – in fact, to live is to control. We are often unaware of how many things in our lives we control quite naturally. Yet, many clients are fully aware of the fact that they have lost control over aspects of their lives since their mental health difficulties began. They may well see this as an all-or-nothing change – that they no longer have control over their lives. Therefore, this session includes various methods to help people understand that control is relative, even for the simplest experience. For example, we cannot control whether it is going to rain outside, but we can control how much we get wet – by carrying an umbrella. Similarly, one might not be able to control whether a family member is being critical, but one can control how much one listens to this criticism.

The PCT focus of the session also ensures that the facilitators are interested in what experiences or perceptions are being controlled *by* behaviour. When clients are perplexed by their actions, or those of other people, PCT can help illuminate a reason for the behaviour. This in itself can be very normalising. For example, anxious clients may report tensing their muscles. Simple questioning can reveal that this is an attempt to feel less shaky and therefore less anxious. Depressed clients may isolate themselves from other people, and yet criticise themselves for doing so. Questioning often reveals that social withdrawal serves to try to keep them away from people who they think might criticise or reject them. This makes their own behaviour more understandable and acceptable. According to PCT, every behaviour has a purpose – often one that rings true with the client. This is the case whether or not it achieves that purpose successfully, or leads to other difficulties.

Sometimes, facilitators and clients may struggle with the term 'control' because they see it as a bad thing. For example, a 'control freak' is a term commonly used to describe someone who tries to dictate to others how everything should be done. A control freak may be regarded as 'rigid' or 'inflexible' in the standards they set for other people. In turn, other people may become frustrated with them and either refuse to do what the control freak says, or oblige and yet resent the infringement on their freedom.

From the perspective of PCT, someone who is called a 'control freak' is clearly not controlling effectively, for the very reasons that we see above – they create conflict with other people through their inflexible ways of applying control. According to PCT, we ultimately control *our own perceptions*; we can attempt to manipulate other people to do this (e.g. "if other people do what I say it means I am a worthwhile person'), but it can be met with conflict when other people's goals are not considered. This is called arbitrary control (Powers, 1973) and it ultimately reduces control because of the conflict it causes. Thus, in the session, where people suggest that control is a problem, the facilitator will ask curious questions to elucidate what they mean, considering that conflict is likely to lurk round the corner when control is not working effectively. See Box 1.1 for an example.

Box 1.1: An example of an exchange using a curious questioning style

Client: I'm not sure about being controlling. I picture my ex-husband screaming at our daughter.

Clinician: Can I just check- what does being controlling mean to you?

Client: Well, I don't want to be like my ex-husband. He was really controlling. He wanted too much control.

Clinician: Would you say that 'control' and being controlling are the same or different?

Client: They are a bit different I suppose. When I'm being controlling I tend to yell at my daughter and go on at her about needing to get a job.

Clinician: And what is it like when you're 'in control'?

Client: I don't think I am in control that much, its like I'm either controlling or other people are controlling me.

Clinician: How does that work for you?

Client: Its rubbish- when I'm controlling I really upset everyone and when other people control me I feel really down and can't be bothered to do anything.

Clinician: How far apart are being controlling and being controlled by others?

Client: They seem miles apart.

Clinician: Is there anything in the middle?

Client: I think that being in control is in the middle, but I don't really know what that looks like.

The clinician would have a number of options as to how they wanted to further respond to this. They can ask themselves: how relevant the discussion could be to others in the group? Whether there is a section that could be missed to allow for more discussion? Whether they could link it into the session theme or components covered within the session? For example, session four discusses being 'in control' with other people and looks at being assertive as a mid-point between 'being controlled' or 'being controlling'.

As discussed in Chapter 4, Part A, it is always necessary to balance individual and group discussion with covering the core components. The evaluation forms and verbal feedback are really useful in understanding what the group is finding most helpful.

This session demonstrates conflict in more detail through exercises and discussion. It is important to note that clients may not use the word 'conflict' explicitly. Clients may describe the experience of conflict in more subtle and idiosyncratic ways. For example, they may describe having problems with another person, they may experience 'being stuck', being in 'two minds' about something, or having 'two sides within themselves'.

PCT rationale for the Brief Awareness Technique and Imaginal Goal-focused Exposure

PCT proposes that problematic conflict is maintained by a lack of awareness of one of the goals that is causing the conflict. An example may illustrate this. Sarah had a goal of 'being independent' and another goal, which she was unaware of, of 'being cared for by others'. Partly in order to fulfil her goal of being independent she became a very successful business woman, yet at the same time her need for being cared for became more distant. She felt increasingly isolated and low, but could not quite put her finger on why. Sarah's example illustrates how conflict can remain implicit, continuing to contribute to problems, until it is brought into awareness.

PCT suggests that changes to our goals occur at the point within the control system at which we are currently aware. Therefore, bringing awareness to problematic conflicts is really important. The proposed change mechanism within PCT is known as reorganisation (Powers, 1973). It is a fundamental process of learning common to all living organisms and so it operates directly on what we are currently perceiving – it is not a logical or intellectual process. This may explain why effective exposure is commonly described as 'experiential', i.e. learning through experience. When there is a loss of control (or error) within the control system then the reorganisation process begins to make random changes at the point in the system where awareness is focused (Powers, 1973). If the changes result in reducing the error, then these changes will persist. If these changes do not reduce the error, then another change is generated (Powers, 1973). Because reorganisation is a trial-and-error process and therefore the first changes may not resolve the problem, it takes a period of time to begin to work. This may explain why successful exposure is 'sustained' on an experience for a period of time.

If you are reading about PCT for the first time, it may well feel as if you are still 'getting to grips' with this understanding of how change works. You may have noticed the implications of such a process in clinical practice; for example, change that happens suddenly, but is still significant and lasting. Or initial changes that do not seem like the most helpful ones (due to the random nature of the process)- e.g. sudden strong outbursts of anger as someone tries to be more assertive.

You may also remember from Chapter 2, Part A, the importance of reorganisation occurring at the 'root' of the conflict. We gave the example of a client, called Gemma, who has a higher-level goal conflict between 'I need to express how I feel in relationships' and 'I must not upset other people'. She suppressed feelings of anger and dissatisfaction with others and avoided meeting them. She found that when she tried to force herself to express her feelings, this only led her to feel more guilty and concerned about the impact on other people. So, shifting the lower-level goals merely perpetuated the conflict. It was only when Gemma became aware of the 'root' conflict that she realised that both sides were a normal part of feeling worthwhile. For reorganisation to occur at the 'root' of conflict, awareness has to be directed there. This may explain why exposure in psychological therapy is carried out within the context of client goals, even though this may not be explicit. For example, the graded hierarchy would be used to help the client move towards something they need or want to face. Generally clinicians would also spend time discussing the value of the exposure process, as 'moving towards' a feared or avoided experience is often not immediately appealing. This might often involve discussing what the client might be able to achieve if they can learn to face these experiences in the future. When conducting goal-focused exposure in PCT, the client's most important life goals are explored in depth to help the changes that occur during exposure to be clearly directed to serve the client's real needs.

Within the TCC course, both the Brief Awareness Technique and Goal-focused Exposure are offered to help clients bring awareness to problematic conflicts. Although the brief awareness and exposure techniques are separate sections, they are closely linked because they attempt to reproduce the processes that are active in Method of Levels therapy – sustaining attention on a topic and shifting it to thoughts that are more

fundamental to the problem. The Brief Awareness Techniques is designed to help the clients to develop a 'window' of awareness that can be brought to bear on the thoughts, feelings and behaviours involved in conflicted goals. Therefore, the Brief Awareness Technique is delivered prior to the exposure exercise and is shorter than those delivered in some other approaches; for example, MBCT (Segal et al., 2002).

In turn, the Imaginal Goal-focused Exposure then specifically involve encouraging clients to direct attention to experiences and situations in which their most important life goals are blocked. This is likely to involve the kinds of experiences that they normally avoid, but only to the extent that the avoidance blocks important goals (T.A. Carey, Kelly, Mansell, & Tai, 2012). For avoidance –to be a problem, there will always be an 'approach goal' or reason why it is worthwhile for that person to face the avoided experience. For example, someone might avoid presentations for many years, but this would become problematic if they needed to deliver presentations in a new job. Therefore, the focus on goals during exposure enables clients to bring awareness to the most important conflicts. By holding the conflict in mind, this helps the client to establish a new organisation of goals that allows them to regain overall control.

We can return to the example of Gemma to illustrate this process. She had a conflict between 'I need to express how I feel in relationships' and 'I must not upset other people'. Ultimately, she realised that both sides were a normal part of feeling worthwhile, and she was then able to be more flexible about meeting these goals and balancing them in different situations. In practice, Gemma managed to generate an image that involved a conflict between her two goals. It was an image of a discussion with a friend in which Gemma had to express some dissatisfaction. She was prompted to remind herself of her goal to be able to feel worthwhile as she held the image in mind. She found that the image changes spontaneously so that she was able to visualise herself being assertive in a way that did not entail upsetting her friend; in fact she found that her friend was empathising with her. Not everyone will experience such spontaneous changes in their imagery, but the typical process does involve a change in the hear-and-now experience as the exposure proceeds.

This exposure technique is described as 'goal focused' in order to emphasise that the function is to promote awareness of higher-level goals and the conflict that is preventing these being achieved. This differs from behavioural or cognitive-behavioural approaches, in which the explicit functions of exposure are generally to habituate the client to a feared experience, or to promote reappraisal (Clark, 1986; Foa, Huppert, & Cahill, 2006; Foa & Kozak, 1986; Salkovskis, Clark, Hackmann, Wells, & Gelder, 1999). Both of these outcomes may nevertheless arise from the technique even within this context, but they are not the reason for the technique.

It is important during the exposure exercise that clients feel in control. An experience of being really out of control during this exercise is unlikely to be helpful, as it would perpetuate such feelings and corresponding distress. Also it is likely that the 'approach goal', the reason why the client is facing the experience, would be obscured by the short-term experience of extreme distress. For example, the person who is bringing an image to mind of a presentation in front of a huge audience and feels really out of control could find it difficult to maintain their 'approach goal' to give a presentation at work. Consequently, the goal-focused exposure technique is framed to encourage clients to choose an experience that provides a personally relevant challenge, but is not so challenging and uncomfortable that they feel really out of control. Also the exposure exercise is self-directed prompts are offered, but clients are in control of the experience they bring to mind. In support of this stance most research studies have found that having greater perceived control during exposure exercises reduces anxiety and distress levels (Craske, Bunt, Rapee, & Barlow, 1991; McGlynn, Rose, & Lazarte, 1994; Rachman, Craske, Tallman, & Solyom, 1986; Rose, McGlynn, & Lazarte, 1995).

Before the session

- Set up the room as described in Chapter 4, Part A.
- Print out the relevant session handouts (listed before the condensed session plan on p. 49)
- Bring the relevant materials (listed before the condensed session plan on p. 49).
- Put up the continuum.
- Put up the 'posters of opposing goals'

Session sections

Each major element of the session is described below; wherever relevant we detail linking to previous sections, take home messages and interactive elements. The 'linking between sections' is detailed when it may not be apparent how one section relates to the previous one.

The take home messages are what we broadly want to get across during the section. Individual participants may have their own personally useful take home message. If they express this then this can be useful to explore with curious questioning (see Chapter 4, Part A). When clients are filling in worksheets it is useful for facilitators to offer them support as required; for example, let clients know that they can make eye contact with the facilitators or gesture them over if they want to clarify something.

Most session sections have a corresponding PowerPoint slide and section on the worksheet (although this won't always be a section that clients need to fill in). Readers may find it helpful to have the session worksheets in front of them (or periodically refer to them) while reading through the sections. We include examples of worksheets and slides in the main body of the chapter. This is to make clear how these elements fit together, as appreciating this will be vital to smoothly run the Course. Worksheets for this session are at the end of this chapter. The slides for each session are included in the appendices; this session's slides are included in Appendix D. Some slides and session sheets are described as 'reference' this is used when the slide or sheet is provided for a visual reference but clients do not need to refer to or complete these. The slides are numbered according to the session, step and slide that they relate to; for example, 1.1.1 would be session 1, step 1, slide 1; 1.2.4 would be session 1, step 2, slide 4. The sheets to give out at the end of the session are described as 'additional session sheets' and are included in Appendix E.

Overview of session

This introduces the theme of the Course and gives a brief overview of what will be covered during this session. The key theme is control and facilitating people to establish more control over things that are important to them. In doing so, the session also touches upon what blocks control, when attempts at control are problematic and considerations of what would be more helpful on these occasions. As mentioned earlier, it is important not to assume that a particular behaviour (or cognitive process) is automatically problematic, but to check this out or encourage clients to check this out. This message can be both normalising and empowering, giving clients the opportunity to think carefully about how and why they do these things, rather than feeling they must stop doing something that has been part of their way of managing for many years.

Below is an example of the way that this session is introduced. As we mentioned earlier, you don't have to follow what we say to the letter, as you will develop your own style, but having a suggested wording can be useful.

“This course is about how to get back in control of your life. During the course we’ll talk about different ways to get more control.

We’ll run through eight different steps during this session, looking at different strategies and ways of thinking about things. At the end we’ll ask you which bits seemed helpful and less helpful. We can change the things we do next week, so we do more of the things you find helpful. The reason we do this is because we are all different, we will all find different things helpful at different times. It is like we are all experts. We (clinicians) are experts in techniques that can be helpful for people, but you all are experts in your own individual situation and life.

The session will last an hour and a quarter; there won’t be a break but if you really need to nip out you can.”

Course Ground Rules

The course ground rules are important to establish early so that people are clear what is expected. We also emphasise clients considering their own level of control within a session so that they feel comfortable. We acknowledge that sometimes it is helpful for people to step outside their ‘comfort zone’, but suggest that this should be done in a way that doesn’t make the individual feel really out of control. The ground rules described below are detailed on a PowerPoint slide, but we also give people the opportunity to suggest other rules if they think there are other important ones.

Below is an example of the sort of thing that you could say- as mentioned previously, these are examples not strict scripts!

“You don’t have to share personal experiences, only speak if and when you want to. Anything that a group member says within the session is private and should not be shared with anyone else. Please turn phones off or to silent wherever possible. Encourage you to feel in control of what occurs for you during the sessions, for example, how much you say. You may want/need to slightly step out of your personal comfort zone, but you are in control of whether you do so and by how much.”

Session 1 - Step 1: How much control do I have? A Continuum of control

Materials

‘Step 1- how much control do I have?’ reference sheet in worksheets pack

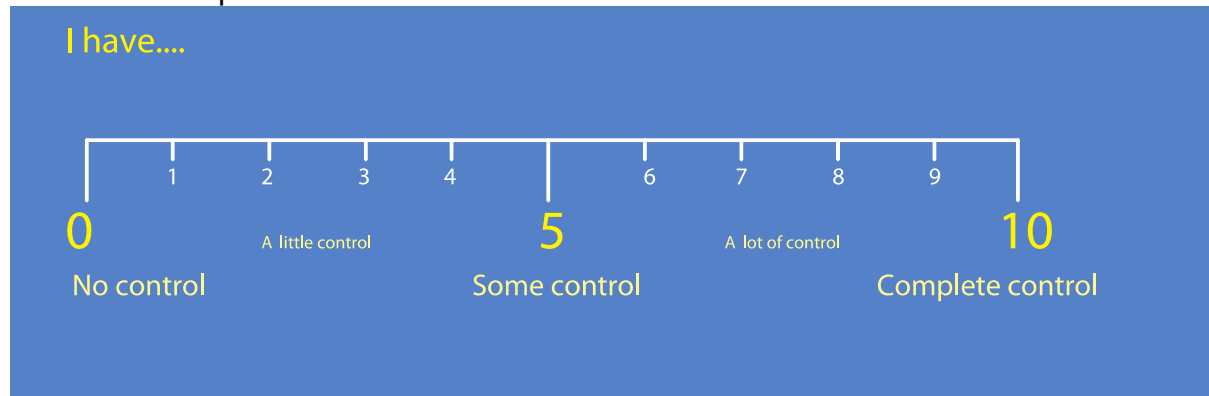
Continuum poster

Pack of large post-it notes

Slide 1.1.3 ‘how much control do I have’.

This first exercise can involve each person producing their own material. People will still be settling into the group, and so it allows for minor to no participation from group members. A PowerPoint slide shows the continuum and this is reproduced on a large piece of paper for the interactive demonstration. Box 1.2 shows a blank continuum at the start of a session.

Box 1.2: Example of a blank continuum of control



This section starts simply. The facilitator explains that we all have different degrees of control over different things in our life; this exercise helps to consider how much control we have and which things we can gain more control of. Ideally it is useful if the key ‘take home messages’ emerge from discussions after the exercises. Individual participants may have their own personal take home message.

Take home message: Control is on a continuum or scale. We have different degrees of control over different things. We can all identify things we have little control over, some control over, and a lot of control over. This process of understanding the amount of control we have over different things helps us to manage our lives more effectively.

Interaction and Feedback: This section begins with the facilitators reading their own examples. They use post-it notes to denote the amount of control they have over different things in their life. Ideally this would be a ‘personal’ example, e.g. worry, self-criticism, work deadlines. Facilitators can also give a neutral example; e.g. I don’t have control over the weather, but can control the impact the weather has on me/ how I respond to different conditions, I can wear a coat, check the forecast etc.

Next, the facilitators ask clients to write down different experiences/situations in their lives and provide a rating on the continuum of how much control they have over this. Again, it is preferable if clients choose examples of things that they want more control over but they can use neutral examples if this makes them more comfortable at this stage. The clients are prompted **not** to include their names. The facilitators ask each client for their permission to put the post-it notes on the continuum that is displayed on the wall. The post-its are put up next to the relevant rating, e.g. if worry is rated as a ‘3’ then the facilitator would stick that post-it next to the number 3 on the continuum. As each post-it note is placed on the continuum at different locations, this should reveal examples of the full range. Facilitators may decide to add more of their own examples to ensure that the full range is illustrated. See Box 1.3 for a completed example of a continuum with a variety of post-it notes of suggestions from facilitators and clients.

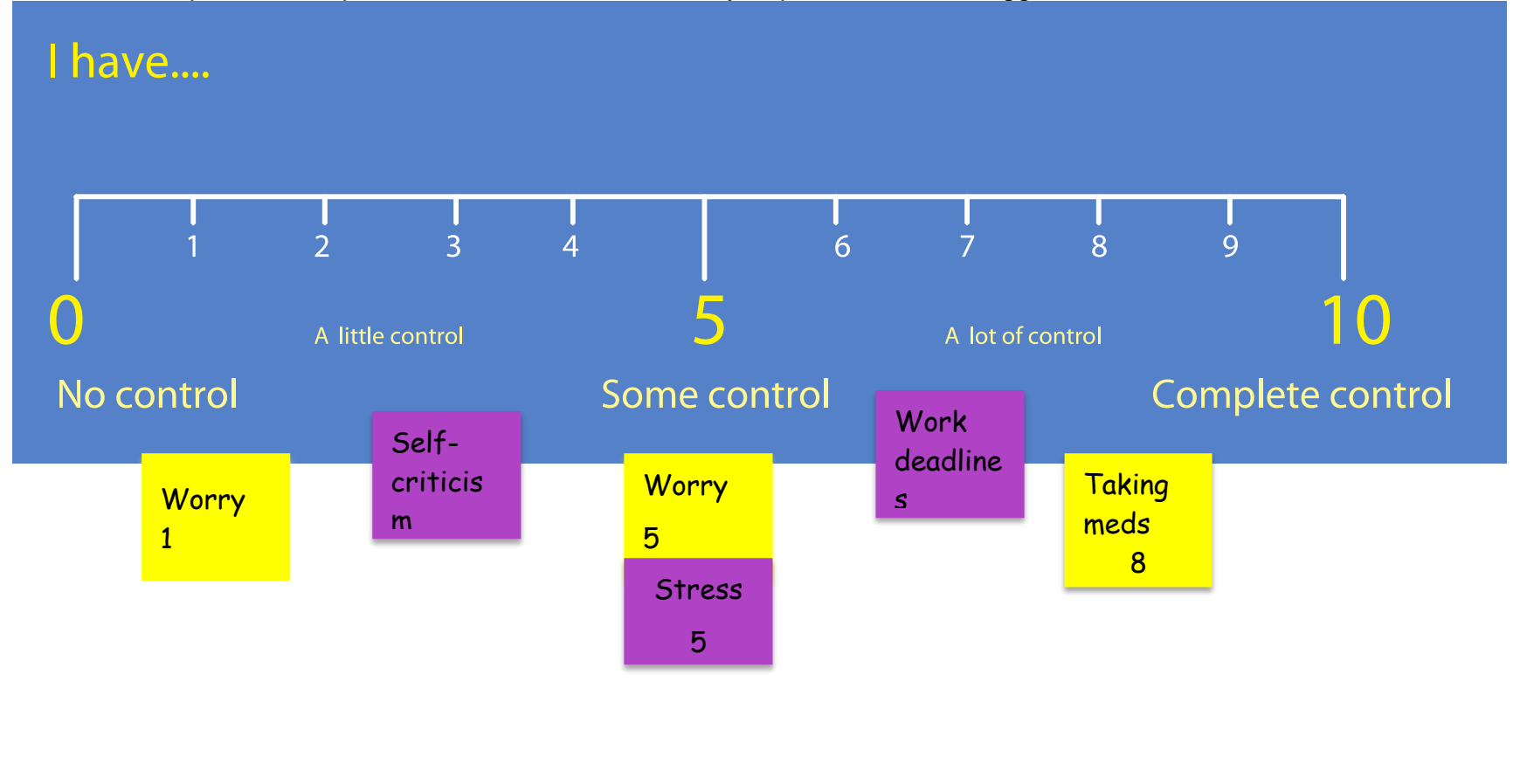
Discussion. This task is followed by the opportunity for discussion, which may cover a number of areas. A common topic of discussion is how clients’ ratings compare to one another. Often, several clients include the same experience on their post-it, but give it a different rating. For example, ‘worry’ may be rated as 2,4 and 5 by different people. These discrepancies provide a valuable opportunity to invite clients to explain their choice of rating. Typically, the differences between ratings, and reasons for ratings prompts clients to reflect

on their perceptions of control, which is the aim of the task. For example, worry can be perceived as a choice by some people, but as an uncontrollable habit by others. The facilitators can then explore the reasons with the clients in more detail. It is important to convey that no particular rating is 'wrong' or 'right'. Rather, it is intriguing that the same process can be felt so differently by different people. The facilitators may also mention that the second session explicitly focuses on ways of thinking that can become problematic for people, such as worry and self-criticism.

It can also be helpful for the facilitator to link relevant client comments to the take home message or session themes. For example, it seems to me that what you said relates to our earlier discussion of...? However, it is important to clarify the client's idiosyncratic experience and understanding first by using curious questioning. Otherwise the risk is that the link you suggest will be irrelevant to the client or based on assumption. See Box 1.1 (p. 29) for an example of curious questioning.

Another possible discussion theme can be how clients can respond if they perceive they have no control over an aspect of their life that they would like to change. Again if someone brings this up, it is important to clarify specific experience and respond appropriately. But a useful suggestion could be to make it explicit that participants can break down goals that seem difficult to achieve, so they can focus on more achievable sub-goals. Further, clients may be able to change how they respond to a particular aspect of their life or experience even if they are unable to change the external aspect of their life.

Box 1.3: Completed example of a continuum with a variety of post-it notes of suggestions from facilitators and clients



Session 1- Step 2: Why do I want to take control of my problems?

Materials:

'Step 2- Why do I want to take control of my problems?' worksheet.

Slides (1.2.4 'why I want to take control', *examples*; 1.2.5 'what is important to me'; 1.2.6 'what is important to me, for example').

The purpose of this exercise is to encourage clients to consider what their goals are for attending the sessions and gaining more control of their current problems. This is used as a basis to help people consider their goals more broadly and particularly to explore whether these goals are informed by 'deeper' values.

Take home message: There are personally important reasons we can all identify for taking control of our problems. It can be helpful to consider what things are really important, as these key goals (or values) drive nearly everything we do. We experience some of our most pressing problems when we are not meeting these important life goals.

Application and practice:

We think it is critical to help clients become aware of, and articulate, their main life goals. Therefore, this step includes three consecutive stages that are used to help people elicit them.

1. Examples and first worksheet section. The facilitator begins by reading an anonymised list of examples of common reasons that other clients have cited for needing to take control and to manage their problems better. These are shown in slide 1.2.4. It can help to let clients know that the word 'problems' is just a term. They might have a more personally meaningful word for what they are experiencing, such as stress, difficulties, or worries. Next, the facilitator asks the clients to fill in their worksheet (Step 2a: 'Why do I want to take control of my problems?')

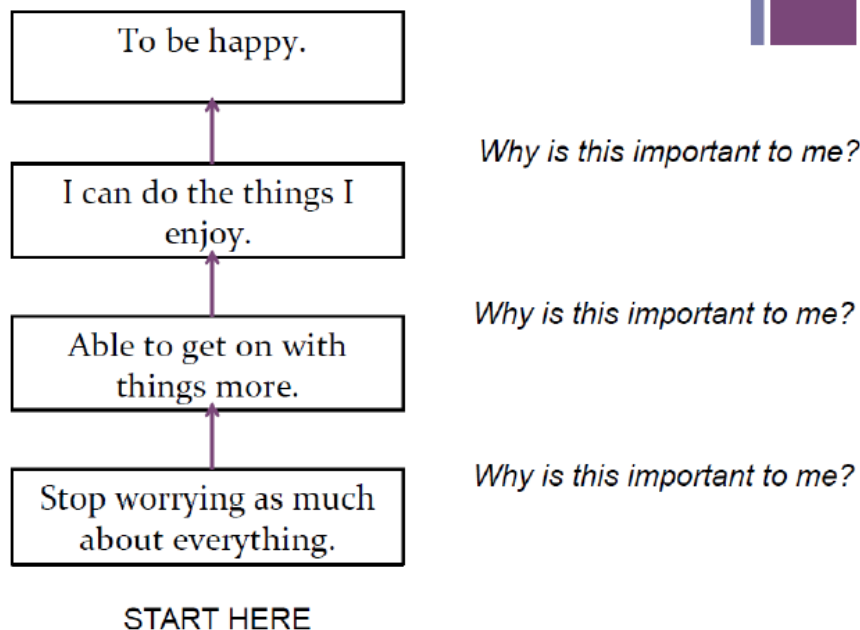
2. Upward arrow. In order to encourage clients to explore their goals in more depth, an 'upward arrow' technique is used. Slide 1.2.6, demonstrated in Box 1.4, illustrates an example that the facilitators may use at this point. Below is an example of how you could introduce the technique:

"This is an example of one way to clarify the things that are more important to you, we'll give you a sheet at the end in case you want to try this at home. This example is of Kaitlin who wants to stop worrying as much as she is and what is really important to her about taking control of this. This example is based on what clients who are accessing psychological support have said".

3. Clients fill in second worksheet section. Having seen a completed example, clients are now asked to complete the second section on their worksheet (Step 2b; 'What things are important to me? What type of person do I want to be?'). We have found that it is helpful to suggest that clients consider the things in their life they value most. For example, the roles that are most important to them, such as being a parent, a friend, or an employee. Offer clients support in completing the worksheets if required; for example, let clients know that they can make eye contact with the facilitators or gesture them over if they want to clarify something.

Box 1.4 example of the upward arrow on session slides.

+ 2. What is important to me? For example....



Session 1- Step 3: What causes us problems and blocks our control?

Materials:

'Step 3- What causes us problems and blocks our control?' reference sheet in worksheets pack.

Elastic bands (fairly big).

Posters that represent opposing goals.

Slides (1.3.7 'what causes us problems and blocks our control'; 1.3.8-10 'what causes us problems', *examples of anger, stress and sadness*).

This section is about conflict. It introduces the idea that being "stuck between two things" can block control. The experience of being stuck may be experienced in very different ways by people. Some people have described it as "knowing what I need to do but not doing it" and as being "pulled around". Being "pulled around" seems to commonly represent the experience of switching between different habits without feeling fully in control or feeling that these habits are helpful. For example, Sonia had an overall higher-level goal of 'being loved by others'. She strived to achieve this socially by going out and drinking extensively with work colleagues. This was only a problem because she also wanted to be highly professional and yet she often found herself becoming overfamiliar in these situations, which led her to worry and ruminate extensively about her conduct. Thus, her ultimate life goal of being loved entailed conflict between the goals of 'being intimate' and 'being professional'. She felt "pulled around" and unable to stay in control. The following exercise demonstrates how conflict can be experienced.

Three clinical examples are prepared and clients can choose which example is focused upon within the below demonstration.

Take home message: Sometimes we experience problems when we are stuck between two goals or aims. We can feel pushed and pulled, but don't always know exactly what is pulling us. What we can notice is that we feel stressed and stretched.

Interaction and Feedback:

1. Introduction

“Sometimes we experience problems when we are stuck between two different impulses, or two different sides of ourselves. We can feel pushed and pulled, but don't always know exactly what is pulling us. We're going to demonstrate how this feeling of being pushed and pulled might play out, in regards to a feeling we might have experienced to some extent. We'd like you to choose whether we focus on anger, stress or sadness, by a show of hands. Please can you put your hand up if you want....”

2. Setting up the demonstration

Facilitators conduct the elastic band demonstration with the most popular experience. To put the demonstration in context, an example is provided for each experience. Please read out the relevant example (below), depending on what clients have chosen, before completing the elastic band demonstration.

Anger example: *Jo has always tried not to be angry. Trying not to be angry has not been too much of a problem for him, but now he is being bullied at work. He still tries to stop himself feeling and expressing anger, through pushing out his thoughts, criticising himself and using alcohol. But he sometimes finds himself intensely angry and believes his anger is justified. He both does and doesn't want to feel and express anger and we're going to demo how this can work out.*

Stress example: *Susan has had a number of stressful experiences recently. She doesn't think she should be getting stressed and anxious; she feels she must not worry or let things bother her. However, she also feels she needs to work everything out and manage everything. She moves between distracting herself, drinking alcohol and trying not to feel any stress and spending hours working things out and feeling stressed.*

Sadness example: *Beth has recently broken up with her boyfriend. She misses him, but feels that she shouldn't miss him and should just move on. She tries never to cry or feel upset, but finds she sometimes 'crashes' and spends hours dwelling on the breakup.*

3. The demonstration

The demonstration uses visual representations of the goals (or reference points) described in the above examples. These are on the slides (See Box 1.5), but, for the purpose of the demonstration, facilitators will also need to have them written/printed on paper. See Box 1.6 for a representation of the paper version of Jo's goals, the 'anger example'. There is also a recording of the demonstration on YouTube (NOT CURRENTLY AVAILABLE). Two elastic bands knotted together are used to demonstrate the affect of trying to meet both goals at once. The elastic band is used as a visual metaphor for the experience of being pulled in two ways by a goal conflict. But it can also suggest the feeling of being stuck because while the elastic band is pulled in two directions it cannot move in any other direction.

One facilitator will represent one of the goals and the other facilitator will represent the other. The elastic band consists of two elastic bands knotted together and one facilitator will hold a pen in one of the elastic bands and the other facilitator will hold a pen in the other elastic band. See Box 1.7 for a picture of how the elastic band is used in this demonstration.

Before doing the demonstration please identify which role you and the other facilitator will play e.g. "I'll represent the goals that lead to 'no anger', Jody will represent the goals that lead to 'high anger'".

To make it clear that the two facilitators represent the conflict within one person, suggest that participants imagine themselves as the knot. Make the link between the

thoughts and goals listed on the slides and the relevant feeling; e.g. reading out the goals for no anger, I must be completely calm, I must not lash out etc. It can also be helpful to read the relevant goals while the two facilitators are conducting the demonstration.

Box 1.5: Slide depicting the example of Jo, the 'anger example'.

+

3. What causes us problems?

High anger

I must assert myself.
I must not be a doormat.
I must be understood.

No anger

I must not lose control.
I must be completely calm.
I must not lash out.

Box 1.6: Representation of the paper version of Jo's goals, the 'anger example'.

No anger

High anger

4. Feedback

As is appropriate after most the session sections, give participants the opportunity to ask questions or comment. Introduce the idea of checking on their internal elastic band (if this does not emerge from the discussions). The 'internal elastic band' can be a useful indicator of how tense, stressed or upset someone is. It can be used to represent the stress that people experience as tension between conflicting goals, or opposing sides of themselves. This can help clients to shift from seeing distressing feelings and experiences as 'symptoms' to seeing them as markers of the difficulties resolving important goals they have in their lives. Also it can help explain how the 'markers', the distressing feelings and experiences, can change while the problem still remains unresolved. For example, a client could be engaging in rumination regarding feeling under pressure at work- with an underlying conflict 'My work must be perfect' and 'I must complete all my work fast'. After some time of wrestling with rumination they became adept at pushing away their ruminative thoughts using distraction. However, they still felt stressed, flat in mood and the issue that they were dwelling upon remained unresolved. So, even though the 'symptoms' may change, the underlying conflict remains. The symptoms are ultimately relieved when they can bring the original problem to their awareness, and explore the two goals openly.

Box 1.7: Picture of how the elastic band is used in the demonstration.

How to take control (Step 4 onwards)

The remaining sections of this session focus on approaches and techniques that people can use to take greater control over their lives. They focus on raising awareness of their life goals and how the conflict between them undermines their control.

How to take control: video

Materials:

1.4.11 Video within slides.

The videos depict real people talking about their experiences of various aspects of the problems they were facing or their recovery. They are either people who accessed previous therapy or previous Take Control Courses and have given permission for their accounts to be used in this way. As this is the first video shown, it is worth mentioning that these are real people who have accessed psychological interventions.

Linking with previous section: There are ways that we can increase our control over our experiences and move towards our goals. We'll be discussing these in the next few exercises in the group.

Video: This is a video of Sarah who talks about how she began to get more control over things in her life.

Session 1- Step 4: How to take control: The Three Knights and the Dragon

Materials:

'Step 4- How to take control: the dragon story' reference sheet in worksheets pack.

Reference slide 1.4.12 'How to take control: dragon'.

Facilitators may want to refer to the 'additional session sheets' as this details the full metaphor (provided in Appendix E).

As mentioned earlier, the PCT rationale suggests that it is critical for clients to be able to shift and sustain their awareness to their own personal problems for effective change to occur. We have found that a rationale is necessary to justify this to clients in the group. The most accessible way to convey the rationale has been to use a metaphorical story.

The dragon metaphor aims to convey that sometimes it is necessary to 'move toward/observe' the things that cause us problems. Avoidance of experiences can cause problems when it conflicts with an important 'approach' goal'. For example, avoidance of anxiety provoking social experiences can conflict with goals of maintaining relationships, progressing at work etc. The metaphor draws out the potential goal conflicts that those in the story had. It suggests that flexibility in meeting goals can be helpful when addressing problems. The dragon story also provides a rationale for the subsequent goal-focused exposure exercise.

The story is detailed below; it is informed by a similar story described in (Stott et al., 2010):

"Once there was a village at the bottom of a large mountain. There was a fierce dragon lurking in the hills around the village and it has been attacking people. Clearly something has to be done, and so three knights volunteer to help.

Without hesitation, the first knight gets hold of a huge sword and charges in and attacks the dragon. Unfortunately the dragon is too strong for him and frightens him away and he flees the village never to be seen again.

The second knight is really terrified by the first knight's experience and so stays at home. He thinks that he will never be able to defeat the dragon.

The third knight decides he needs more information about the dragon and so he watches the dragon's lair over a number of weeks to find out when the dragon is awake and when the dragon is asleep. He finds out that the dragon goes to sleep at 9pm every night in the corner of his lair. He also asks another knight for help and eventually they are able to sneak up on the dragon and capture it."

Take home message and linking with previous sections: We are suggesting that one way achieving what we want, and dealing with any problems that arise, is by approaching and/or observing the things that cause us difficulties.

If we think of the elastic band exercise, the first knight could have had the two goals of being brave and being safe. It seems that the goal of trying to be brave won out against the safety goal! For the second knight the safety goal won out, but the third knight seems to have managed to balance and meet both goals.

Both avoiding problems and going at them full force can be ways we are trying to keep safe. They may not always be the most effective ways of resolving an issue, because it seems that when we have a problem it is helpful to give time and attention.

Application and practice: After facilitators have told the story, they can ask clients: Do you think the third knight and the village were safe after he captured the dragon?; Do you think the first two knights were trying to keep safe? Invite questions or comments, if people want to comment. Then let clients know what the take home messages were if these have not already emerged from the discussion.

Explain the use of examples and stories is not intended to trivialise problems, but sometimes these can be much easier to remember than a lot of concepts!

Session 1- Step 5: How to take control: The Brief Awareness Technique

Materials:

'Step 5- How to take control: The Awareness exercise' reference sheet in worksheets pack
Facilitator 'Awareness prompt sheet'

Reference slide 1.5.13 'How to take control: awareness'

The awareness technique is a brief exercise that is focused on attending to sounds. A prompt sheet is provided towards the end of the chapter (before the worksheets). If facilitators have not previously led or experienced awareness/mindfulness based practices it is recommended that they listen to examples of these and practice leading the exercise using the prompt sheet. There are a number of examples of mindfulness and awareness practices freely available online; for example, on <http://www.freemindfulness.org/download>. A metaphor of a train is used to illustrate the 'mindful mindset'. The theoretical rationale for this, and the subsequent goal-focused exposure technique, were explained in detail towards the beginning of this chapter (p.30- 31).

Linking with previous section: In the previous section we talked about the importance of giving time and attention to the things that cause us problems. This is not always an easy thing to do and in the next section we'll practice an exercise that can help us move towards/ face problems or difficult experiences. The awareness exercise develops a 'mindful mindset' that can help move towards/ face difficult experiences.

Take home message: We can make a step toward our important life goals by choosing to face an experience that we have *some* control over right now. This involves facing the experience in a 'mindful' way for a period of time where you neither let the experience overwhelm you (losing control completely) nor suppress it completely (try to have complete control over it).

This 'mindful mindset' can help you notice what is getting in the way of you taking control. You may notice thoughts, worries or uncomfortable physical experiences are getting in the way of you doing what you want to do. The 'mindful mindset' gives you some space to notice the experiences that are getting in the way, without being caught up in the experience or pushing it away.

Application and practice: Ask clients to pay attention to sounds in the room, or one particular sound, using the prompt sheet (provided at the end of the chapter). The prompts on the prompt sheet should not be read out like a list, but mentioned with appropriate amounts of space between each prompt.

Please give clients the option of closing their eyes if they want; this can aid concentration but clients need to decide if they feel comfortable with this. Then, after the exercise, ask what they noticed.

Then lead clients through imagining the train, bringing the image to mind (again they can close their eyes). The metaphor models one way of interacting with thoughts/experiences, by noticing and letting thoughts go past.

“Imagine you are waiting on a platform of a small station watching non-stopping goods trains go by.

Each of your thoughts or sensations is like the carriage of a train passing through the station.

There is no point in trying to stop the train or climbing aboard, just be a bystander and watch your thoughts.”

If it does not emerge from the discussion, facilitators can explicitly mention that 'paying attention' to an experience is unlikely to be the same as worrying about or dwelling upon a problem. Although such thinking may arise, the instruction is to gently bring attention back to the object of focus. From a PCT perspective, processes that limit awareness of problematic experiences (and related goal conflict) can prevent the process of reorganisation and resolution of problems. Both suppression and worry/rumination have the potential to limit awareness (See Session 2). Therefore, in this exercise we are encouraging clients to notice and watch their thoughts and experiences, rather than suppressing these or thinking extensively about them. These ideas are discussed in more detail in the next session, which specifically focuses on thinking that clients are finding problematic.

Session 1- Step 6 and 7: Goal-focused exposure technique

There are two sections that apply to the exposure technique. The first helps participants to identify an appropriate experience to use in the second section, which is an imaginal goal-focused exposure exercise. It is important that clients feel in control of the imaginal exposure exercise and do not choose an experience that is so uncomfortable that it will be highly distressing and overwhelming. Therefore, we ask clients to consider the physical sensations associated with the experience as these can influence how distressing an experience is. The theoretical rationale for these sections is explained in detail towards the beginning of this chapter.

Step 6: Choosing an experience

Materials:

'Step 6- Choosing an experience I want to take control of' worksheet.

Two slides 1.6.14-15 'Choosing an experience I want to take control of'.

Linking with previous section: A bit like the third knight, in this section we will be getting to understand more about our problems. We will be mapping out the territory and observing a problematic experience. Like the third knight, we may have to observe the problem more than once to help us change it.

Take home message: We are suggesting that it can be useful to give our problems time and attention, and to observe problematic experiences. Sometimes we have to observe a problematic experience more than once- this is a step towards resolving the problem. We are going to consider what experience/ imagined situation you want to observe as the first step. Generally problematic experiences cause us difficulties because they prevent us from achieving a goal that we value. We will consider which problematic experience/situation is most preventing you from achieving the goals that you value. This can help you decide which experience/situation is the most important one to face as the first step.

Application and practice: Slides and worksheets are used to help clients identify the experience/ situation that they want to take control of. See Box 1.7 for the slides. Clients are asked to choose an experience that they find somewhat uncomfortable and that is getting in the way of them achieving their valued goals/the things that are important to them. This is an important component and clients can refer back to the goals that they identified in the Step 1 worksheet. It is useful to emphasize that the exercise will be most helpful if clients do not choose an experience that is so uncomfortable that it will be highly distressing and overwhelming.

The slides provide examples of the sorts of experiences clients may want to face, such as feeling of failure, social situations, or a specific recurrent worry. *If facilitators think it will be helpful for their group they can explicitly describe the important goals that these experiences could block (e.g. feeling of failure blocks applying for promotion at work; avoiding social situations blocks building strong relationships; recurrent worry blocks 'having peace of mind').*

In order to complete the worksheet (see Box 1.8 for the worksheet), clients consider what physical sensations they might expect when bringing this experience to mind, such as, 'heart beats really fast', 'can't breathe properly', 'feel really upset and tired'. Clients rate the level of comfort for the experience they have chosen and consider if it is manageable. Clients also remind themselves of why they want to face the experience, such as 'I want to be able to enjoy going out', 'I want to get back to the normal me'. Clients will have considered this earlier in the exercise when they identified the experience/situation that they want to take control of.



6. Choosing an experience I want to take control of...



The Experience

Think of an 'uncomfortable experience' that is really stopping you from achieving important aims/goals.

Experience: **Feeling I've failed at something.**

Social situations. Worrying about Jim having an accident.

What kinds of physical sensations might you expect? What kinds of things would you expect to pop into your head during this experience?

Heart beat fast, can't breathe properly. Stomach pain.

Feel really upset and tired.



6. Choosing an experience I want to take control of.... (continued)



How long do I think I can face this experience?

Will vary from person to person, depending on the experience.

How comfortable does thinking about this right now make you feel?

0 = "extremely uncomfortable" and 10 = "extremely comfortable".

How comfortable? 0 1 2 3 4 5 6 7 8 9 10

Remind yourself why it might help you to be able to face this experience

I want to be able to enjoy going out. I want to get back to the normal me. I want to feel more relaxed.

Box 1.8: 'Choosing an experience I want to take control of' worksheet

Step 6
Choosing an experience I want to take control of



The Experience

Think of an experience that would make you feel uncomfortable, but that you feel you could deal with.

Experience

.....
.....
.....

What kinds of physical sensations might you expect? What kinds of things would you expect to pop into your head during this experience?

Examples include: images, memories, feelings, sounds, impulses and thoughts:

.....
.....
.....

How long do I think I can face this experience?

.....

How comfortable does thinking about this right now make you feel?
0 = "extremely uncomfortable" and 10 = "extremely comfortable".

How comfortable? 0 1 2 3 4 5 6 7 8 9 10

If the answer is 3 or less you may need to think of a smaller step, or a less uncomfortable, less anxiety-provoking, experience. It can be as simple as looking at a certain object or picture for a certain amount of time.

Remind yourself why it might help you to be able to face this experience

.....
.....



Step 7: Taking control in imagination

Materials:

'Step 7: Taking control in imagination' reference worksheet.

Reference slide 1.7.16 'Taking control in imagination'.

Facilitator prompt sheet: 'Guided exposure in imagination'.

Take home message: Bringing to mind a problematic experience/situation can help us to start to see this differently. Facing these experiences in imagination can also help prepare to face them at other times as this can develop understanding of how in control you might feel and any barriers. By staying with an experience, sometimes we feel a bit different about the experience. This process can enable us to move more fully towards the valued goals that we want to achieve.

Application and practice: This exercise involves leading the clients through the imaginal exposure exercise using the relevant prompt sheet (this is provided towards the end of the

chapter; before the worksheets; p 52). It is important to make it clear that clients can choose not to do the exercise if the experience they have chosen causes them too much distress. This should be framed by first encouraging clients to try to stay with the previous 'manageable' experience that they have chosen, but recognising that this is the first session and it can be difficult to decide what experience to choose.

Do invite comments or questions about the experience and offer an opportunity for the clients to talk to one of the group facilitators after the sessions as occasionally clients have found this more distressing than they had expected.

It is useful to again consider the internal process that may occur within this exercise to gain a fuller appreciation of why we frame the exercise as we do. We encourage clients to identify a problematic experience/situation that is getting in the way of them achieving an important goal. Therefore, this will result in clients choosing an experience/situation that they are in conflict about, i.e. one that means they cannot achieve all of their important goals. For example, Roger chose to focus on 'anxiety in social situations', as this was blocking his important goal of 'Getting a good job'. As a first step, he decided to focus on a meeting between six people because this was something he felt a medium level of discomfort regarding. When the TCC facilitator prompted him to consider how he would like the image to be he brought to mind an image of himself 'holding the floor' in a confident manner. Although there was no obvious shift in perspective for him this session, in a later TCC session when he repeated this exercise he realised he did come across confidently at this type of meeting. He remembered a couple of recent examples when he had 'held the floor' in meetings. After this, he brought to mind more and more challenging social situations during exposure exercises.

Session 1- Step 8: Summary: Thinking about the week ahead

Materials:

'Step 8- Thinking about the week ahead' worksheet.

Reference slide 1.7.17 'Thinking about the week ahead'.

At the end of each session a brief summary of the session is given. It is also suggested that clients consider what they want to do during the week in order to consolidate the session.

Take home message: It can be helpful to give the things that cause us problems time and attention. This can help us notice whether we are being pulled in two different directions, which can help us feel more in control of what is going on in our lives. Keeping your goals in mind is important because goals keep us motivated to deal with problems. Also we can experience problems when we are not meeting our goals.

During the week you may want to move further towards facing your problems in some way, for example, doing the awareness exercise at home or facing a situation identified for real.

Application and practice: Give participants time to look through session worksheets to facilitate them to identify what they want to do at home. We encourage participants to reflect on whether the thing that they have chosen to do will be realistic. We ask them to consider some way of reminding themselves. For example, they might want to set a specific time aside or remind themselves using post-its.

Give out evaluation form and additional sheets

At the end of each session, it is important we give participants the sessional evaluation form and emphasise the importance of feedback. For example, we use the

feedback to adapt our style and to shape the content of future sessions. Make the 'session 1 additional sheets' available for people to take if they want to (included in Appendix E).

Provide the overall session themes (in Appendix A) and remind people that they can choose not to attend a session if it does not seem appropriate to the problems that they are working on.

All materials required

Worksheets required:

Session 1 worksheet pack

Session 1 additional sheets (to make available at the end of the session)

Session themes (to make available at the end of the session)

Facilitator prompts required:

Awareness exercise prompts

Guided exposure in imagination prompts

Other materials required:

Continuum control & Post- it notes

Elastic bands (fairly big)

Posters that represent opposing goals

Pens

Projector to show powerpoint slides and videos

Laptop (to use with projector)

Speakers

Powerpoint presentation

Clinical measures: IAPT measures (PHQ9, WSAS etc.)

Optional:

Session 1 guide (in Appendix F)

Don't forget!

- Use curious questioning to help clients develop understanding.
- Try to let 'take home' messages emerge from client comments/discussion.
- When responding to the group try to check out what is best for individual group members to enable them to maintain control.
- Be yourself. You, as an individual, will develop your own style of facilitating.

Condensed session plan: Session 1

Measures	Give participants the clinical measures prior to the session.
Overview of Session 5mins	Introduce the theme of the Course and give a brief overview of what will be covered during this session.
Course ground rules 2mins	Explain Course Ground Rules: these are on the slides. Give clients the opportunity to add more rules if they think any have been missed.
STEP 1. How much control do I have? 5-10mins	Continuum of control exercise.
STEP 2. Why do I want to take control of my anxieties/ problems? 5-10mins	Includes: <ul style="list-style-type: none"> - Reasons for taking control on slides - Clients filling in the first section on their worksheet: Step 2 - Example of 'upward arrow' on slides - Clients filling in the second section on their worksheet: Step 2
STEP 3. What causes us problems and blocks our control? 5-10mins	Includes: <ul style="list-style-type: none"> - Rationale: experience of being stuck between two things, pushed & pulled - Introduction: demo how feeling pushed & pulled play out. Ask clients to choose focus on anger, stress or sadness - Provide relevant example, depending on client choice - Demo: elastic band; both facilitators will be involved in the demo
How to take control: video. 2mins	These are videos of real people who have accessed 'therapy.' Video of Sarah- how she began to get more control over things in her life. SHOULD BE AT LEAST HALFWAY THROUGH
STEP 4. How to take control: dragon metaphor. 5mins	Dragon story. Qus to prompt discussion: Do you think the third knight and the village were safe after he captured the dragon? Do you think the first two knights were trying to keep safe?
STEP 5. How to take control: awareness exercise. 5mins	Includes: <ul style="list-style-type: none"> - Brief introduction: 'mindful mindset' - Awareness exercise - Train metaphor
STEP 6. Choosing an experience I want to take control of 5-10mins	Help clients to choose a manageable experience that they sometimes avoid or are having problems with.
STEP 7. Taking control in imagination 8-10mins	Use 'Guided exposure in imagination prompts' to lead.
STEP 8. Summary: Thinking about the week ahead 5-10mins	Brief summary of the session. Clients identify what they want to do at home.
Evaluation form and additional sheets	Emphasise the importance of feedback. Provide 'session 1 additional sheets' & 'overall session themes'.

Awareness exercise prompts

Lead through awareness exercise for 3mins. Note: the below are prompts which are not intended to be read out like a list but intended to be 'dropped into' the practice at appropriate intervals.

You may want to close your eyes, you don't have to, the reason I suggest it is that it can make it easier to focus on what you have chosen to focus on.

- Become aware of the sensation of contact with the chair
- Try to listen to the sounds inside and outside the room.
- There is no need to listen to particular sounds, you can notice sounds from all directions: sounds that are near or far, in front or behind of you
- If you notice that your mind has wandered bring your attention back to the sounds in the room
- You may also notice the space between the sounds, the silence
- If you notice that you have started to think about other things bring your attention back to the sounds
- In a few moments we'll be drawing this practice to a close, so just being aware of this.

Guided exposure in imagination prompts

Lead through awareness exercise for 3mins. Note: the below are prompts which are not intended to be read out like a list but intended to be 'dropped into' the practice at appropriate intervals.

As before you may want to close your eyes.

- Can you bring an image of the situation or experience to mind.
- If it is difficult to bring an image to mind, you may be able to get a sense of how you'd feel or you could even try bringing a memory to mind.
- How vivid and real does it feel? If it doesn't feel very vivid you make want to try and imagine sounds or smells if appropriate, or focus on the colours and details within the image.
- Notice what effect imagining this experience is having on you, on your bodily experiences, on your thoughts. How comfortable do you feel?
- You may need to move the image forward if you have chosen an experience that will change over time and the image is not unfolding naturally.
- If you can you can begin to imagine how you'd like the image to be, an ideal experience. Notice what feelings or sensations come with this ideal image or experience.
- Again if this ideal image doesn't feel real you can imagine colours, sounds and other details.
- In a few moments we are going to end this practice, so you might want to bring your awareness to the contact of your legs against the chair.

And if you've got your eyes closed, open your eyes

APPENDIX E

PCTEAM

**RESEARCHER STANDARD OPERATING
PROCEDURES (SOPs)**

The SOPs outlined in this document are to be followed throughout the PCTEAM trial.

The SOPs/documents included are as follows:

- | | |
|--|------|
| 1. Booking baseline interview – Checklist | pg2 |
| 2. Booking baseline interview – Protocol | pg3 |
| 3. Baseline interview – Checklist | pg5 |
| 4. Baseline – Protocol | pg7 |
| 5. Booking follow-up interview – Checklist | pg10 |
| 6. Follow-up interview – Checklist | pg11 |
| 7. Follow-up interview – Protocol | pg12 |
| 8. Risk protocol | pg17 |
| 9. Risk Form - suicide and self-harm | pg22 |
| 10. Risk Form - not suicide and self-harm | pg23 |
| 11. GP risk letter | pg24 |
| 12. Distress Protocol | pg25 |
| 13. Researcher Blinding Protocol | pg27 |
| 14. Researcher FU Interview Unblinding Report Form | pg28 |

If you have any queries please contact Lydia Morris (Clinical Lead and Chief Investigator):

Email: lydia.morris-2@postgrad.manchester.ac.uk

Ph: 07807 102 865 (personal mobile)

Please ensure that these SOPs are used alongside your own University/Trust lone working guidance and procedures.

Booking Baseline Interview - Checklist

Please tick to confirm you have performed these checks

Participant ID -

[Lydia will provide you with the Participant ID]

<ul style="list-style-type: none"> • Check patient details correct. Check preferred means of communication & whether consents to contact by email or text. 	<input type="checkbox"/>
<ul style="list-style-type: none"> • ASKED – if patient is currently taking any psychotropic medications (antidepressants, anti-anxiety medication, medications for sleep) <p>Yes/No*</p> <ul style="list-style-type: none"> • Ask them to bring their medication/ prescription to session if possible. 	<input type="checkbox"/>
<ul style="list-style-type: none"> • Explain purpose/length of 1st interview (baseline) 	<input type="checkbox"/>
<ul style="list-style-type: none"> • Confirm location/time of interview 	<input type="checkbox"/>
<ul style="list-style-type: none"> • Provide researcher contact telephone number/email 	<input type="checkbox"/>
<ul style="list-style-type: none"> • Inform patient that they will be sent a confirmation text, email or letter stating the time and location of the interview (NB if letter inform them that this may not arrive prior to the interview) 	<input type="checkbox"/>
<ul style="list-style-type: none"> • Send patient interview confirmation communication 	<input type="checkbox"/>

Booking Baseline Interview - Protocol

1. What You Need To Check

Before you arrange the interview you need to check:

1. What preferred contact medium they indicated at the initial assessment.

During the phone call to arrange the interview you need to check:

2. If they are currently taking antidepressants, anti-anxiety medication, medications for sleep

Yes/No

2. Organising the Baseline Interview: Lydia will coordinate this

Advise the patient that the interview will last about 45 minutes (but may take longer). That they'll have a further opportunity to discuss the research and they'll be given some forms to fill in. Make an interview date and time and ensure that you have their correct contact details. Ask them to bring their medication or prescription with them, if possible.

It is preferred that the interview is conducted **face-to-face**, especially for the baseline interview. If this is impossible (or under exceptional circumstances), arrange a time that you can call them

Face-to-face interviews

We would normally expect the interview to take place at Willow Tree Centre (94 Littleton Road, M7 3SE), Blackfriars Medical Practice (138 Chapel Street, M3 6AF) and Chapel Medical Centre (220 Liverpool Road, Irlam, M44 6FE). However, it maybe possible to offer an appointment at other locations, particularly the Angel Centre; you will need to tell the client that you'll check and back to them if they require this. Confirm with the patient their preferred location, confirm the address and their contact details with them and make sure they have a contact number for you, in case they need to postpone.

Inform the patient that they will be sent out a confirmation text, email or letter with details of the time, date and location of the baseline interview.

Telephone interviews

Arrange with the patient a suitable time to conduct the telephone interview. This would include the questions regarding eligibility and, if appropriate, the following baseline measures- AD-SUS-Interview and PHQ9.

Post the patient an appropriate cover letter confirming the appointment. Also post two copies of the consent form with the baseline measures (excluding the PHQ9 and the AD-SUS-Interview) along with a freepost envelope. **These will have to be returned prior to conducting the interview.**

Please ensure that you leave at least 3 working days for the baseline interview measures and consent forms to arrive (if possible).

Declining participation prior to randomisation

If at any stage during the initial phone call/email contact, they decide they do not want to participate, thank them for their time and record on the database that they no longer wish to participate. You can do this on the 'Manage Participants page of the database. In the 'Status' section click on 'Refused to Continue'. Please add a brief explanation of their reason for not participating in the 'Notes' section.

Notes Section of Database (enter on SPSS database and Excel database at each clinical base)

Please use the notes section for each patient to provide information for future reference/other site researchers/site leads and the trial managers about the following:

- if any difficulties contacting participants (this may be useful when contacting patients at follow-up)
- if questionnaires have had to be sent by you due to inability to contact or participant preference

Baseline Interview - Checklist

Please tick to confirm you have completed these steps

Patient ID –

<ul style="list-style-type: none"> Consent given for reminders by text/ email or other (please state _____). 	<input type="checkbox"/>
<ul style="list-style-type: none"> Consent given to leave voicemail (please state Yes/No _____). 	<input type="checkbox"/>
<ul style="list-style-type: none"> Patient given opportunity to discuss trial and ask questions (use main RCT Participant information sheet) 	<input type="checkbox"/>
<ul style="list-style-type: none"> Consent forms completed *ensure you insert the patient ID at the top 	<input type="checkbox"/>
RISK SCREENING:	
<ul style="list-style-type: none"> PHQ9 suicide risk checked & risk protocol followed if necessary 	<input type="checkbox"/>
<ul style="list-style-type: none"> Clinical Lead (Chief Investigator) informed if risk present, according to protocol 	<input type="checkbox"/>
IF ELIGIBLE (RISK NOT SIGNIFICANTLY HIGH, see protocol):	
<ul style="list-style-type: none"> Measures completed 	<input type="checkbox"/>
<ul style="list-style-type: none"> Patient informed of next steps (e.g. will contact them to let them know which intervention they'll access) 	<input type="checkbox"/>
<ul style="list-style-type: none"> Biju informed whether patient eligible so can randomise the eligible patients. Send required info (see main guide) to GMCSU.randomisation@nhs.net 	<input type="checkbox"/>
<ul style="list-style-type: none"> Once data entered into database return baseline booklet to Lydia at the UoM. This data will be stored in Lydia's office. You must return the consent forms to the nearest Six Degrees office (Southwood House or Irlam Office) on the day of the assessment. 	<input type="checkbox"/>
IF INELIGIBLE:	
<ul style="list-style-type: none"> Thank for patient for their time and inform them of next steps. 	<input type="checkbox"/>

Baseline Interview - Protocol

1. Face-to-face interview

Before the Interview

Assemble *recruitment interview pack*, consisting of;

- 2 consent forms
- Questionnaire pack

*Ensure that you insert the Participant's ID number on the questionnaire

You will also need to ensure that you have:

- Relevant researcher SOP and checklist
- Distress protocol and sources of support sheet
- Risk protocol
- Copy of the main RCT participant information sheet

Remember to follow your employing institution's lone worker protocol (University or NHS).

Introduction

- Introduce yourself to the patient and thank them for agreeing to see you
- Check best contact details; try to obtain an alternative contact details e.g. email address for the patient (if not already provided). When is the best time to call between 9-5? Ask clients if they'd prefer reminders (for the follow-up sessions etc.) by text or email (or another modality, which one?).
- Use the patient information sheet to explain the research. Give the patient time to ask any questions.
- If during the interview (but before they have been randomised), they decide they do not want to participate, thank them for their time and record on the PCTEAM database that they no longer wish to participate. [You can do this on the 'Manage Participants' page of the database under 'status'. As prior to randomisation you would select the 'Refused to Continue' option. Please add a brief explanation of their reason for not participating in the 'Notes' section of baseline interview contact].

Assessing for Eligibility

- AT ROUTINE SERVICE INITIAL ASSESSMENT: The primary assessment for eligibility will be conducted with a service clinician at the routine initial assessment appointment that all clients have when they

access the service. Clinicians will have established, during the routine assessment: whether clients need to access higher-intensity services (including whether they are dependent on drugs or alcohol), whether clients have any thoughts of suicide and if so the severity of these, and whether clients are able to understand spoken and written English. Clients will be excluded from the trial at this stage if their treatment needs cannot be met within low-intensity services, they are dependent on drugs or alcohol, they engage in persistent self-injury requiring clinical management or are potentially intent on and/or planning suicide, or they are unable to understand spoken and written English sufficiently to read and complete simple worksheets and understand verbal presentations.

- Although somewhat unlikely, it is possible that clients' circumstances will have changed to the extent that they are no longer eligible for the project between the routine initial assessment and the baseline appointment. For example, they might be intent on suicide in the baseline assessment, having had no intention in the routine initial assessment. Therefore, explain that prior to enrolling them in the trial we are going to double check that trial will be suitable for them.
- Ask them to sign and date the consent forms – you need to then sign and date them also. Ask the patient to sign **two** copies (*one for them to retain and one for the research team*). Please ensure you insert the patient ID number at the top of the consent form.

If the patient refuses to consent:

Thank them for their time and advise them to continue seeing their GP as normal. Enter information of refusal of consent into PCTEAM database. [You can do this on the 'Manage Participants' page of the database under 'status'. As prior to randomisation you would select the 'Refused to Continue' option. Please add a brief explanation of their reason for not participating in the 'Notes' section of baseline interview contact].

If the patient gives consent ask them to complete the following Eligibility measures:

- 1 PHQ-9 (see below for RISK monitoring)

PHQ-9 as a measure of RISK

If the patient has indicated a positive score (1 or more) for question 9 on the PHQ-9 then you should follow the risk protocol. If the score is 2 or more and/or the client has active plans to end their own life, inform the patient that you will be letting their GP and service know about their response to this question (see protocol for more details). It will also be important to check if they need more immediate help. Ask them whether they have made any actual plans to end their life. If they have, you need to ask whether they have made any preparations to carry out those plans. If they have, we would class them as "actively suicidal" and they would need immediate help. Stay with the patient and immediately contact the Clinical Lead, if unavailable, one of the other nominated contacts. Contact numbers are at the end of the risk protocol.

A client would be ineligible only if they had a significant level risk. You will ascertain level of risk by following the risk assessment protocol. If there is no immediate risk or you're unsure if level risk will mean the client is ineligible continue with baseline measures. You can briefly excuse yourself from the office to phone Lydia (Clinical Lead), while the client is completing baseline measures, if you need to check whether level of risk will confer ineligibility or if you want to discuss the level of risk for any other reason.

Ineligible Patients

If the patient is **ineligible** on the basis of risk, then this will be agreed with the Clinical Lead and an action plan will be agreed. This action plan will be conveyed to the patient.

Eligible Patients

- If the patient is **eligible** continue with the baseline measures.
- One of the first measures you should complete with clients is the Credibility/Expectancy Questionnaire (CEQ). You'll need to explain the two interventions using the script on this measure.
- Indicate to them that the other measures you've given them are designed to be completed by them, but if they have any difficulties or queries that you would be happy to assist them.
- Often the first item on the WSAS causes problems so it is worth clarifying to clients that they should complete the first item if they are working (and NOT tick the box). Make sure they have the WSAS in front of them when you explain this.
- Check client's ethnicity using the categories on p2 of PSYCHLOPS. You don't have to fill anything else in on p2.
- Once clients have completed each measure, please check thoroughly that they have completed all items. Please ask them to complete any missed items, even if they are a bit unsure of the answer. Tip: often participants miss items if the item is not clear to them so clarify if necessary.
- Score the measures as you go along.

Baseline Measures:

- 1 CEQ
- 2 GAD-7 (Generalised Anxiety Disorder)
- 3 IAPT Employment Status questions A13-A15 (Improving Access to Psychological Therapies)
- 4 WSAS (Work and Social Adjustment Scale)
- 5 EQ5D (EuroQol)
- 6 PSYCHLOPS (CLIENT ONLY COMPLETES P1,BUT you need to check ethnicity using p2)
- 7 ROC (Re-organisation of Conflict Scale)
- 8 AAQ-2 (Acceptance and Action Questionnaire-2)
- 9 IUS-12 (Intolerance of Uncertainty Scale, Short form)
- 10 TMS (Toronto Mindfulness Scale- trait version)

- 11 AD-SUS Interview (Adult Service Use Schedule) [As this is interview based, don't hand this out to patients]
- 12 AD-SUS self-complete *

*Ensure that you insert the Patient's ID number on the questionnaire

While the patient is filling in the questionnaire then you could check through already completed questionnaires for any missing/incomplete data and begin to score the questionnaires.

Randomisation Procedure

Towards the end of the session inform the patient that they will automatically be allocated to one of the two interventions. Let them know that as you have to remain unaware (blinded) to the group that they have been allocated to, but that they will be contacted shortly and told which group they have been allocated to. See overleaf for script for explaining blinding. They will be given details of the intervention session that they are offered. **In case they get allocated to the Take Control Course group, check whether they would prefer to attend a venue in Central Salford or nearer Irlam.**

End of Recruitment Interview

- Check if they are going away in the next few weeks. We need to know in order to establish how easy it will be to convey information to them about which treatment they have been allocated to, i.e. if they are going away and are un-contactable this could delay us conveying the information to them.
- Discuss arrangements for obtaining follow-up data and explain what the follow-ups will involve. Inform them that you will see them at 6-monthly intervals over the next year (at 6 and 12 months). Inform the patient that you will call them in approximately 5 months (1 month prior to when the follow-up interview is due) to arrange the next interview.
- *Remind the patient that it is important for you to not know which group they have been allocated to. See blinding script (p. 9).
- Thank client for their time. Ensure they have a copy of the consent form and full patient information sheet to keep.

Script for explaining blinding

As we've discussed, you have an equal chance of getting allocated to either the one-to-one sessions or the course. I will not know which one you get allocated to, and neither will any of the people doing these assessments. So please don't let me know any information about whichever intervention you are attending. If I knew which intervention you attend then this could affect the questions that I ask or how I interpret your answers and this would make the information less reliable. Thanks a lot for your help with this, it is really appreciated. If you have any queries about the intervention it is best to ask the clinician you are seeing and they will be able to help you.

2. Telephone interview

NB preferred method of data collection is face-to-face

You will have sent out the all measures and the consent forms (excluding the PHQ9 and the AD-SUS-Interview). **These will have to be returned prior to conducting the interview.**

Procedure would be as above but AD-SUS interview and PHQ9 (to check for risk) will need to be completed over the phone (any queries about this please contact Lydia). You should have received the completed

consent forms back in the post prior to this interview taking place. Please use this opportunity to complete any items that were missing in the measures that were returned to you.

All measures completed by the patient would have to taken to Lydia at the UoM. This data will be stored in Lydia's office. You must return the consent forms to the nearest Six Degrees office (Southwood House or Irlam Office) or the University on the day of the assessment; the location will depend on where you are phoning from and what is most convenient.

3. After the Baseline Interview

You must return the consent forms to the nearest Six Degrees office (Southwood House or Irlam Office) on the day of the assessment.

Email Biju (who is conducting the randomisation procedure) at the end of your assessment interviews for that day. The email address is: GMCSU.randomisation@nhs.net. Please send him a list of names and **the corresponding researcher ID** for each client- also for each client send him: Text permission Y/N; Voicemail permission Y/N; Location Central or Irlam.

Please input the data as soon as is possible, the database will be a shared one that is accessible from your University account.

Once data entered into database return baseline booklet to Lydia at the UoM. This data will be stored in Lydia's office.

Booking Follow-up Interview - Checklist

Please tick to confirm you have performed these checks

Patient ID -

Approximately 4 weeks before a follow-up interview is due **Lydia will coordinate contacting the patient to arrange the follow-up interview date, time and location.** She may ask you to assist with sending letters and contacting patients.

*From the outset remind the patient that you are to remain BLINDED to the arm of the trial that they have been randomised to

<ul style="list-style-type: none">• Explain purpose/length of follow-up interview	<input type="checkbox"/>
<ul style="list-style-type: none">• Confirm location/time of interview	<input type="checkbox"/>
<ul style="list-style-type: none">• Provide researcher contact telephone number/email	<input type="checkbox"/>
<ul style="list-style-type: none">• Inform patient that they will be sent a confirmation text/email stating the time and location of the interview	<input type="checkbox"/>
<ul style="list-style-type: none">• Input details of appointment to PCTEAM database	<input type="checkbox"/>

Approximately 1-2 days (or longer if you're sending a letter) prior to the interview date contact the patient to confirm that the date and time is still suitable.

<ul style="list-style-type: none">• Inform them that you will re-send the confirmation letter or text/email them (check contacts up to date).	<input type="checkbox"/>
<ul style="list-style-type: none">• Re-iterate the importance of you remaining blinded	<input type="checkbox"/>
<ul style="list-style-type: none">• If necessary re-send confirmation letter or text/email as client prefers.	<input type="checkbox"/>

Contacting participants for follow-up interviews

There may be occasions where it is difficult to get in touch with participants to arrange their follow-up interview.

- For 4 weeks try to contact the participant each week using the contact details that they have provided (e.g. home phone/mobile/email) – telephone contact is preferable at the outset (unless the participant has indicated that they do not wish to be contacted in this way). Contact the client at different times, unless they have specified that a particular time is best for them. If voicemail consent is provided, and it is appropriate, please leave a voicemail stating who you are and when you'll phone back. If an email address is provided, after 2-weeks of being unable to contact the participant, then please contact them by email and post out the PHQ9, GAD7 and WSAS.
- When arranging face to face/postal follow-up assessments please let the client know that we are now able to give them £20 high street vouchers after they've completed the full follow-up assessment (either by post or on the phone)- as a thank you for their time. These vouchers can be spent at over 20 000 high street stores (<http://www.highstreetvouchers.com/gift-vouchers/love2shop>). They can actually 'claim' these vouchers for either 6-month or 12-month follow-up (not both), but we really want to encourage them to complete the 6-month so I'd generally only mention this if there is some strong reason that they can't/won't do the 6-month follow-up.
- Please remember to fill in the dates that you contacted clients in the 'CONTACTED TO BOOK 6MTH Follow-up' column on the follow-up database, also update the other relevant sections as you manage to contact people.
- When you manage to get hold of someone on the phone, as well as booking them in for a face-to-face or postal follow-up, please say 'I just got a few quick questions to ask now, it should only take a few minutes?' If they are OK to answer some questions at the time then please ask them the PHQ9, GAD7 and WSAS. If it is taking a long time, then it is fine to just do the PHQ9 and GAD7. If they indicate risk on question 9 on the PHQ9 then you would need to briefly go through the risk protocol. As ever, if there are any concerns regarding risk or you feel that they would benefit from a longer discussion then you can advise that Lydia will contact them.
- If they opt for postal follow-up please advise that we need the measures to be returned within 2-weeks (this will generally be 2-weeks from completing the phone part of the follow-up interview, but in cases where a date isn't booked for the phone part this would be 2-weeks from sending the measures out).
- If no contact/response after 4 weeks then Lydia will send a letter to the participant in the post *Follow-up interview contact letter* and *Follow-up interview response form* (first class with a reply slip and first class prepaid envelope and containing contact details)
- If the patient does not get in touch (approximately a week and a half later), Lydia will re-send out the PHQ9 and GAD7 and WSAS if appropriate.

The letter and response form can be found in Appendix 1

Follow-Up Interview - Checklist

Please tick to confirm you have completed these steps

Patient ID -

<ul style="list-style-type: none"> • Patient details correct 	<input type="checkbox"/>
<ul style="list-style-type: none"> • Patient given opportunity to discuss trial and ask questions They are provided with the PIS Interview Study. 	<input type="checkbox"/>
<ul style="list-style-type: none"> • FU Measures completed (according to FU time point) 	<input type="checkbox"/>
<ul style="list-style-type: none"> • PHQ9 suicide risk checked (risk protocol followed if necessary – PCTEAM Risk Protocol) 	<input type="checkbox"/>
<ul style="list-style-type: none"> • Patient completes the AD-SUS (self-report) on their own. 	<input type="checkbox"/>
<ul style="list-style-type: none"> • Patient informed of next steps (i.e. will contact in approx 5mths to arrange next interview or if last follow-up interview that thank them for their time as their involvement in the research is complete). 	<input type="checkbox"/>
<ul style="list-style-type: none"> • Data entered into PCTEAM database ASAP including unblinding form 	<input type="checkbox"/>
<ul style="list-style-type: none"> • All measures completed by the patient would have to taken to Lydia at the UoM. This data will be stored in Lydia's office. 	<input type="checkbox"/>

Please note below, if applicable, why all procedures not carried out

Follow-up Interview - Protocol

There are 2 main ways to collect follow-up data from trial patients at 6 and 12 months. These are

- Meeting with the patient face-to-face (preferred method)
- Interviewing the patient over the telephone for PHQ9 and AD-SUS Interview and sending out additional measures by post

You will have contacted the patient approximately 1 month prior to the follow-up interview to agree a date and a time. You will have sent a text (or letter/email if preferred) to the patient confirming the agreed date and time of the follow-up interview. Please try to avoid booking patients in more than 3-weeks prior to their projected follow-up date. It is worth contacting the patient a few days beforehand via text or email (whichever is their preferred method of contact) to check that they are still happy with this day and time to avoid wasted visits. This is also a good opportunity to double-check contact details. If you have not already done so, it is a good opportunity to get an alternative contact from the patient.

If the patient states that they would no longer like to see you face-to-face but would still like to take part and complete the follow-up questionnaires by post then you will need to send out the outcome measures to them. Confirm the address that you will be sending them to and let them know when they should expect to receive them. Stress the importance of completing all the measures on the same day – you will also have to arrange a time to contact them to complete the AD-SUS-Interview over the phone (preferably on the day or as close to it as they intend to complete the measures).

Please note that if you are having trouble getting agreement to complete follow-up measures, it is possible to offer the patient the option of just completing the PHQ9 and GAD7 over the telephone. It is important to try to make an appointment to obtain the rest of the measures, but obtaining these measures is better than getting no data at all.

NB Irrespective of the way that a patient is being followed-up it is important to stress at the outset the need for you to **remain blinded** to the treatment that they are receiving. See blinding script (p. 9).

1. Face- to- Face Interviews

Beforehand

Assemble *interview pack*, consisting of;

- Questionnaire pack

You will also need to ensure that you have:

- Distress protocol and sources of support sheet
- Risk protocol (make sure you have the latest version)
- Copy of the patient information sheet
- Qualitative interview PIS

Remember to follow your employing institution's lone worker protocol.

At the Interview

Introduce yourself to the patient and thank them for agreeing to be interviewed again. Check that the patient contact details are correct (this may be more applicable if you were not the person who arranged the appointment). Explain what will happen in the interview and give the patient time to ask any questions.

- Inform them that they will have to complete a number of measures that they completed the last time.
- Once again indicate to them that the measures are designed to be completed by them but if they have any difficulties or queries that you would be happy to assist them.
- Again check they understand the first item on the WSAS, this item often causes confusion. As appropriate, it is worth clarifying to clients that they would only NOT complete the first scale (i.e. tick the box) if they aren't working. Make sure they have the WSAS in front of them when you explain this.
- Once clients have completed each measure, please check thoroughly that they have completed all items. Please ask them to complete any missed items, even if they are a bit unsure of the answer.
- Score the measures as you go along.

Follow-up Measures:

- 1 GAD-7 (Generalised Anxiety Disorder)
- 2 WSAS (Work and Social Adjustment Scale)
- 3 IAPT Employment Status questions A13-A15 (Improving Access to Psychological Therapies)
- 4 CEQ: 2-item
- 5 EQ5D (EuroQol)
- 6 PSYCHLOPS - Post therapy; first page only
- 7 ROC (Re-organisation of Conflict Scale)
- 8 AAQ-2 (Acceptance and Action Questionnaire-2)
- 9 IUS-12 (Intolerance of Uncertainty Scale, Short form)
- 10 TMS (Toronto Mindfulness Scale- trait version)
- 11 AD-SUS Interview (Adult Service Use Schedule)
- 12 AD-SUS self-complete *to be completed at the end by the patient on their own
- 13 Evaluation form *to be completed at the end by the patient on their own

*to be completed at the end by the patient on their own (if they have not already done so) and ask them to put into an envelope without showing you the contents.

Please ensure that you insert the Patient's research ID number on the questionnaire **before** they fill it in and put the ID number onto the envelope once they've handed it back to you.

PHQ-9 as a measure of RISK

If the patient has indicated a positive score (1 or more) for question 9 on the PHQ-9 then you should follow the risk protocol [PCTEAM Risk Protocol] i.e. inform the patient that you will be letting their GP and service know about their response to this question. It will also be important to check if they need more immediate help. Ask them whether they have made any actual plans to end their life. If they have, you need to ask whether they have made any preparations to carry out those plans. If they have, we would class them as “actively suicidal” and they would need immediate help. Stay with the patient and immediately contact your site’s designated support contact for further advice or, if unavailable, one of the other nominated contacts. Contact numbers are at the end of the risk protocol. If you are not able to contact them, contact the designated person from another site. Failing this, contact any of the other co-investigators, or the Trial Manager.

After the interview, thank the patient for their time, and discuss arrangements for the next scheduled follow-up (i.e. the research team will be in contact in 5-months and check that contact details are unlikely to change during this time). If this is the 12 month follow-up interview you can inform the patient that their participation in the trial is now over and thank them for all their help. Ask if they want to receive a summary of the results and inform them that these will be available on the Six Degrees Social Enterprise Website (<http://six-degrees.org.uk/>).

At the end of the interview

Whilst detailed in the information sheet for the main trial we would like to ensure that participants are aware that they may be contacted to take part in a qualitative interview about their experiences of the interventions received. We would also like to stress at this point that this interview is different to those they have completed so far and that they will only be invited to participate in one of these interviews if they initially gave consent to be contacted. The following script can be used at the end of the 6-month interview to remind participants of the possibility of this:

Script for Qualitative Interviews

In addition to the questionnaires we complete with you at the beginning of the study and at 6 and 12 months, we are also interested in finding out peoples’ experiences and how they have found being part of this study.

We will be contacting people, who provided consent to be contacted, to take part in a separate interview to talk about their experiences. These interviews are an opportunity for you to tell us how you have found being part of the trial. Check if they would like to be contacted about this, having previously said they didn’t (this will update the previous decision).

In the near future you may receive a phone call, inviting you to take part in this additional study.

2. Interviewing the patient over the telephone

Beforehand

Post the patient an appropriate cover letter confirming the appointment. Also post the follow-up measures (excluding the PHQ9 and the AD-SUS-Interview) along with a freepost envelope addressed to Lydia Morris, 1 St Philips Place, Salford, M3 6FA. Enter the patient ID number and the date of posting on ALL the questionnaires.

Call client to confirm that they are still happy with the date and time that you have agreed to call them. Before the interview, it's a good idea to assemble copies of the risk protocol in case you need it.

Please ensure that you leave at least 3 working days for the measures to arrive (if possible).

The Interview

Introduce yourself on the phone to the patient and thank them once again for agreeing to be interviewed. Check that the patient contact details are correct. Explain what will happen in the interview and give the patient time to ask any questions.

Complete AD-SUS interview and the PHQ-9 (to check for risk). Please use this opportunity to complete any items that were missing in the measures that were returned to you.

PHQ-9 as a measure of RISK

If the patient has indicated a positive score (1 or more) for question 9 on the PHQ-9 then you should follow the risk protocol. If the score is 2 or more and/or the client has active plans to end their own life, inform the patient that you will be letting their GP and service know about their response to this question (see protocol for more details). It will also be important to check if they need more immediate help. Ask them whether they have made any actual plans to end their life. If they have, you need to ask whether they have made any preparations to carry out those plans. If they have, we would class them as "actively suicidal" and they would need immediate help. Ask them to stay on the phone and immediately contact the Clinical Lead, if unavailable, one of the other nominated contacts. Contact numbers are at the end of the risk protocol.

After the interview, thank the patient for their time. Ask the patient if they have received the additional measures in the post and stress the importance of completing and returning them asap (if they have not already done so). Ask them to return these within 2-weeks and let them know that they need to return within 2-weeks to be eligible to receive the vouchers. **If this is the 12 month follow-up** interview you can inform the patient that their participation in the trial is now over and thank them for all their help. Ask if they want to receive a summary of the results and inform them that these will be available on the Six Degrees Social Enterprise Website.

Following the telephone interview you will need to input the questionnaire data into the database.

If measures aren't returned

If the questionnaires are not returned after 1-2 weeks, contact the patient using their preferred contact method and/or send the appropriate reminder letter with a further set of questionnaires. If the questionnaires are not returned after a second set has been posted, it is worth contacting the patient by telephone or email to see what has happened.

Once the completed measures have been received the patient will be sent an appropriate letter with a reminder of when they will receive the next set of questionnaires. If these are their final set, receipt of measures will be acknowledged and they will be thanked for their participation in the trial. Ask if they want to receive a summary of the results and inform them that these will be available on the Six Degrees Social Enterprise Website (if they don't express that they want the summary this won't be sent).

Missing Data: if any of the questionnaires are incomplete, you will need to telephone the patient for clarification. We do warn patients about this possibility in the cover letter. Fill in the missing data on the questionnaire in a different colour to the one the patient has used and initial and date each new entry. Write a note on the questionnaire to indicate that you have completed missing data after speaking to the patient. This is important to provide a clear audit trail for the information. Also make a note in the Notes section of the database.

Withdrawal

If at anytime during the trial the patient indicates that they would like to withdraw from the study, it is important to check what they mean by this. It is often the case that they don't want to complete any more of the intervention. *It is hoped that the patient would discuss this with clinician who is delivering their treatment as discussion with a researcher is likely to cause unblinding. If they discuss this with you please inform Lydia as soon as is possible.

There are three ways which a patient may wish to withdraw:

- 1 ***Full withdrawal from trial*** – if the patient wishes to withdraw from treatment and is not willing to be followed-up. This will be recorded on the database in the 'Status' section for the patient.
- 2 ***Withdrawal from follow-up*** - this would be appropriate if the patient wanted to continue treatment (or already had completed treatment), but did not want to be followed up. This will be recorded on the database in the 'Status' section for the patient.
- 3 ***Withdrawal from treatment only*** *this would still be considered as **Full Participation** - They may only wish to withdraw from treatment (it is likely that they will inform their clinician about this). If they withdraw from treatment they may still be willing to complete the follow-up measures. If they let you know this during the follow-up appointment advise them that it is best if they let the clinician/facilitator they are seeing know and check that they are still OK to complete the follow-up data.

3. After the Follow-up Interview

Please input the data into the database, including the unblinding form, as soon as you can.

All measures completed by the patient would have to taken to Lydia at the UoM. This data will be stored in Lydia's office.

12 month follow-up Interviews

Qualitative interview invitation

At the end of the 12mth follow-up interview we would like to ensure that as many participants as possible have been offered the opportunity to take part in a qualitative interview about their experiences of the interventions.

Please see the Script for Qualitative Interviews on pg14.

If participants have not participated in a qualitative interview, and are interested or would like to find out more, please provide them with the qualitative interview PIS.

PROTOCOL FOR ASSESSING AND REPORTING RISK IN RESEARCH INTERVIEWS

The following principles and procedures govern risk assessment and reporting in the PCTEAM study. The PCTEAM study does not include routine management of people at acute risk of suicide/self-harm by trial clinical workers or research assistants.

General procedures

All Research Assistants and will have received the PCTEAM risk training.

A risk assessment will always be conducted at the generic initial assessment and clients who are actively suicidal or describe repeated self-harm requiring ongoing clinical management will be excluded.

Whenever any significant risk is identified research assistants will contact the clinical lead. A risk assessment will be completed by the clinical lead as soon after the assessment as possible and she will ensure appropriate supportive actions are completed.

Any significant, but not imminent risk will be reported to the client's GP by the clinical lead and through Six Degrees Social Enterprise's (SDSE) duty system.

Any imminent risk should lead to the immediate involvement of the appropriate emergency health services. Research Assistants will be fully informed and competent to follow the procedures.

When the clinical lead is away they will arrange appropriate cover for any risk issues that might arise in their absence.

Exploring Risk for Research Assistants

There are six questions to be used following any indication of risk from questionnaire items of Q9 of the PHQ9 (Thoughts that you would be better off dead or of hurting yourself in some way), responses to interview questions or any other sources. Any report of suicide/self harm as determined by a positive score (i.e. a score of 1 or more) on the PHQ9 for question 9 should be followed up as indicated in this protocol.

Ask the Exploring Risk in Research Interviews questions and then look at answers from the sheet to determine the level of risk, A B or C:

Exploring Risk in Research Interviews

THOUGHTS

"I see that you've said / you mentioned that..... These are thoughts / feelings that people suffering from low mood/ experiencing problems often have, but it's important to make sure you are receiving the right kind of support. So if it's OK, I would now like to ask you some more questions that will explore these feelings in a little more depth."

PLANS

1 Do you know how you would harm or kill yourself? Yes / No

If **yes** – details

2 Have you made any actual plans harm yourself or end your life? Yes / No

If **yes** – details

ACTIONS

3 Have you made any actual preparations to harm or kill yourself? Yes / No

If **yes** – details

4 Have you ever attempted to harm or kill yourself in the past? Yes / No

If **yes** – details

PREVENTION

5 Is there anything stopping you killing or harming yourself

at the moment?

Yes / No

If **yes** – details

6 Do you feel that there is any immediate danger that you

will harm or kill yourself?

Yes / No

If **yes** – details

Researcher Risk Protocol

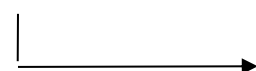
Actions by Researcher

Tell Participant

All answers 'no' apart from Q5 'yes':



A

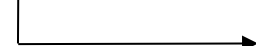


I can see that things have been very difficult for you, but it seems to me these thoughts about death are not ones you would act on – would this be how you see things? (if they say yes) I would advise you to make an appointment to see your GP to talk about these feelings.

'Yes' for any **one** of Qs 1-3; plus 'yes' for Q5 and 'no' for Q6



B



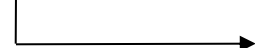
Things seem to be very hard for you right now and I think it would help if you were to speak to your GP about these feelings. My Supervisor will be speaking or writing to your GP, and a colleague within the service, to tell them that you have been here today and have been having some troubling thoughts. I would also advise you to make an appointment to see your GP to talk about these feelings.
Inform clinical lead (Lydia) she will contact the duty officer at SDSE. She will contact the GP.

NB A participant may be considered actively suicidal and may be excluded. This decision will be made by the clinical lead. Contact Lydia during the session (e.g. when client completing measures) to ascertain whether client is excluded.

Scoring 'no' to Q5 or 'yes' to Q6



C Actively Suicidal



*I am very concerned about your safety at this moment. I am not qualified to deal with this on my own as I am not a therapist but I am going to talk to my line manager now. Participant needs immediate help – **do not leave them alone.** Follow the chain of clinical contact and enact immediate risk procedure (phone for ambulance).*

NB a participant would be excluded on the basis of this.

Exploring other risk areas

Other areas of risk which may arise in the interviews, but that are not directly asked about, are: risk to others, risk from others and self neglect. **These will always be asked about and identified in the generic initial assessment and will be covered in greater detail in the risk training. However, any concerns, please contact the clinical lead (Lydia).**

Risk from others

Risk from others includes events such as domestic violence. If risk from others is detected contact the clinical lead.

Risk to vulnerable others

- This could include risk to children, risk to older adults or risk to individuals with learning disabilities. A definition of a vulnerable adult is an individual “who is or may be in need of community care services by reason of mental or other disability, age or illness; and who is or may be unable to take care of him or herself, or unable to protect him or herself against significant harm or exploitation” (No Secrets, DoH, 2000)
- Actions that would be considered to pose a risk to others include physical, psychological, financial or sexual abuse; neglect.

Self neglect

This would include an individual neglecting to attend to their basic needs, such as personal hygiene, appropriate clothing, feeding, or tending appropriately to any medical conditions that they have. Although vigilance is important, significant self neglect is unlikely within those accessing low-intensity services, as it is more common within people with a greater severity of mental health needs than those commonly seen within this setting (Lauder & Roxburgh, 2012; Poythress, Burnett, Naik, Pickens, & Dyer, 2007).

Actions

If the researcher detects any of the above risks contact the clinical lead and discuss. Clinical lead contacts are as follows:

Lydia Morris: 0161 275 2555 or on 07807 102 865.

The clinical lead will then perform the following actions:

Contact Six Degrees Social Enterprise duty system and inform GP or complete other relevant risk management actions. Document the discussions and actions taken on the electronic record system.

Telephone Chain

In the first instance contact the clinical lead by phone and if no reply then text stating that you need to speak to them urgently. Clinical lead is Lydia Morris: 0161 275 2555; 07807 102 865.

If your clinical lead is not immediately available you can contact the relevant Six Degrees Social Enterprise office and ask to speak to the duty officer, which will either be the Southwood House office (0161 212 4981) or the Irlam office (0161 775 7757). However, this should only be used as a back-up and you should always contact the clinical lead first.

In the third instance, if neither of the previous contacts is available, you can contact the:

Patient's GP surgery

Accident and Emergency Services.

No assessments will be conducted out of hours.

PCTEAM Risk for suicide and self harm form

The participant below has been identified at risk using Q9 on the PHQ 9 which triggers the PCTEAM exploring questions as indicated in the risk protocol and their responses have enacted the risk protocol

PCTEAM ID:

Date participant seen:

Score on PHQ-9, item 9:

Assessed risk as A B or C

Copy of 'PCTEAM 'exploring questions attached

Outcome of this assessment:

Clinical lead contacted Y / N

Date

Instructions given:

Actions taken

.....
Researcher Name

.....
Signed

.....
Date

PCTEAM Risk for risks not including suicide and self harm form

The participant below has been identified at risk other than suicide or self harm – this triggers contacting the clinical lead and their responses will enact the risk protocol

PCTEAM ID:

Date participant seen:

Risk identified:.....

Outcome of this assessment:

Clinical lead contacted Y / N

Date

Instructions given:

Actions taken

.....
Researcher Name

.....
Signed

.....
Date

GP Risk Letter

Surgery Address

Date

Dear Dr _____

Re: [Participant Name] _____

As part of their treatment with Six Degrees Social Enterprise, [PATIENT NAME], is taking part in our trial of a group and an individual psychological intervention (called PCTEAM). As part of this research I meet with him/her on a number of occasions to assess his/her wellbeing and depressive symptoms. I am writing to update you about our meeting today.

As part of the assessment we carry out we asked PATIENT NAME to fill out a PHQ-9, as you know this questionnaire asks if the patient has had *“Thoughts that you would be better off dead or of hurting yourself in some way”* (Question 9). [PATIENT NAME] response to this was that in the past 2 weeks he/she has had these thoughts more than half the days/nearly every day. [INSERT ANY POSITIVE SCORE]

As a result of this I carried out a further risk assessment and determined that whilst I do not believe [PATIENT NAME] to be in immediate danger, I feel they would benefit from talking to you about these thoughts. I have recommended that they arrange to make an appointment to come and see you to discuss this further.

It is part of our study protocol to inform you of such risks, so that you can take account of them in your care plan.

Yours sincerely,

[Site Researcher]

Cc: Participant

Distress Protocol

If a patient appears to become distressed, the researcher will:

1. Encourage the patient to take a break from completing forms and answering questions.
2. Acknowledge that talking about problems can be distressing.
3. Offer support by reassuring patient that they do not need to answer a question(s) if they do not wish to.
4. Ask if they would like to continue with the interview or prefer to stop.

If they prefer to stop then:

5. Finish the interview and offer to return at another time.
6. If the patient withdraws their consent to participate (either from follow-up or entire trial) then this must be communicated to Lydia and the procedures outlined on pages 15-16 followed.

If the interview continues:

7. Take time at the end of the interview to talk informally, and encourage patients to access further support dependant on their level of distress. This may be to visit their GP or mental health service provider.
8. If the patient has any questions or requires reassurance about the research they should be encouraged to contact Lydia (her details are on the PIS).
9. If the participant still appears to be distressed when the interview is over offer to phone back in a couple of days to ensure the distress has not escalated and to reiterate the sources of support.
10. If the participant becomes more distressed, as appropriate, follow the risk protocol.

Sources of support

Anxiety UK

If you would like to speak to someone about anxiety, ring our helpline on **08444 775 774**. Our helpline operates from 9:30-5:30, Monday to Friday. The helpline is staffed by volunteers with personal experience of anxiety so you will be speaking with someone who has been there.

Mind infoline

Mind infoline team provide information on a range of topics including:

- types of mental distress
- where to get help
- drug and alternative treatments
- advocacy

They aim to provide details of help and support for people in their own area.

Contact Mind infoline on 0300 123 3393 or email info@mind.org.uk

Rethink Mental Illness

Call Rethink, Monday to Friday, 10am - 1pm on **0300 5000 927**

Calls cost the same as the cost of a local call (and if local calls free on your tariff, the call will be free). Rethink are not open on Bank Holidays.

Researcher Blinding Protocol

Risks to blinding

Research Workers are at risk of being unblinded via several channels and points in the PCTEAM study:

- from the participants
- from discussions with clinical staff at sites

Communication with Participants & Clinical staff

Accidental unblinding through communication with participants and clinical staff is a significant risk. The most likely is in discussions with participants at follow-up interviews or if they call between interviews.

Timepoint	Who, what, when
Introducing the PCTEAM study	<p>Although the CI will do the majority of this, there may be times where you contact the clinical site. In such circumstances:</p> <ul style="list-style-type: none"> - Explain the RCT and the importance of the blinding process to staff. - Explain that the RAs should not know which intervention group the participant is allocated to. - If any of the clinical staff at the site have any queries please direct them to the CI who will not be fully blinded.
Initial phone call/Baseline assessment	<ul style="list-style-type: none"> - RAs to explain the randomisation and blinding process to the participant as part of consent process - Emphasise to the participant that they should try to remember not to talk to you about the interventions - Remind them that if they have any queries about the intervention they have been allocated to that they can discuss these with their PWP or the CI
Participants who phone up in between intervention sessions	<ul style="list-style-type: none"> - This is primarily relevant to the RA who is based at the Six Degrees base. - If they identify that the person phoning up is involved in the research study they should ideally try to pass the call to an appropriate colleague. If this is not possible and they become unblinded them they'd need to notify CI (Lydia).
Follow-up Research Assessment	<ul style="list-style-type: none"> - One month before the follow-up assessment is due, contact the participant to arrange the follow-up interview (as per follow-up interview protocols). Remind them at this point that you are to remain blinded.

	- Remind participant at beginning of all contacts to not discuss intervention
--	---

Researcher Follow-up Interview Unblinding Report Form

Please complete this form to indicate if you have been unblinded during this follow-up interview

Name of RA/CSO: _____

Site: _____

Participant ID: _____

FU Interview Time point: 6month 12month

Interview Outcome: Blinded Unblinded

If **Unblinded** please complete the following questions:

1. point at which this occurred: At the start at the end during the appointment

2. measure being completed at the time: _____

Appendix 1

Unable to contact letters and response forms

1. CtoC follow-up response form
2. Follow-up appointment contact letter

[Date]

Dear

Primary Care Trial Efficacy of Alternative Modalities (PCTEAM)

About [X months] ago you completed some questionnaires with [me/researcher name] and joined our trial. You should by now have started your allocated treatment.

As we discussed with you we would like to meet with you at 6 and 12 months following our first meeting to ask you to complete some more questionnaires. Each of these appointments will be about 45-minute to 1-hour long. The interview could take place face-to-face or by telephone. I have recently tried to contact you to arrange the [6/12] month appointment. Unfortunately I have not been able to contact you. For your information, we are now able to offer £20 of vouchers as a thank you for completing either a 6 or 12 month follow-up appointment.

If you can return the enclosed contact sheet in the pre-paid envelope provided to indicate if you would like to continue, and if so your preferred means of contact, we would be extremely grateful.

Alternatively, you can contact the study coordinator directly using the contact details below. Please leave a message if she does not answer, and she will call you back.

Email: lydiamorris@nhs.net

Phone: 0161 212 4981

I look forward to hearing from you soon.

Yours sincerely

[researcher name]

PCTEAM: Primary Care Trial Efficacy of Alternative Modalities

Follow-up Interview Response Form

Please tick the relevant box below to indicate if you would still like to participate in the PCTEAM trial

1. I am still interested in participating in the trial and am happy for a researcher to contact me to arrange a follow-up interview to complete some questionnaires.

Please provide contact details in the form below.

OR

2. I no longer wish to meet with a researcher from the PCTEAM trial to complete the questionnaires at [6 and 12 months].

If you have indicated that you are still interested in meeting with a researcher a member of the research team will contact you to talk to arrange your follow-up interview. Your participation is voluntary and you are free to withdraw at any time without giving any reason, without your medical care or legal rights being affected.

If you would prefer to talk to the research team direct, please call:

Lydia Morris, PCTEAM Study Coordinator

Ph: 0161 212 4981

email: lydiamorris@nhs.net

Participant ID	[researcher to complete]
Name	
Address	
Post Code	
Telephone	
Mobile	
Email	
How would you prefer to be	Telephone/ Mobile/ Email

contacted? (please circle)	
What time of day is best to contact you? (please circle)	Morning/Afternoon/ Evening/ Don't Mind

APPENDIX F

Baseline and 6-month follow-up means for all RCT outcome measures

Measure	Baseline, <i>M (SD)</i>		6-month, <i>M (SD)</i>	
	TCC	LI CBT	TCC	LI CBT
PHQ9	13.76 (6.32)	14.66 (5.64)	10.18 (7.17)	9.75 (6.38)
GAD7	12.37 (6.00)	13.33 (4.96)	9.03 (6.16)	9.31 (5.76)
WSAS	17.72 (9.15)	17.24 (8.26)	14.91 (11.53)	13.04 (9.97)
PSYCHLOPS	13.99 (4.07)	14.35 (3.85)	10.91 (5.22)	9.39 (5.04)

Note. GAD7 = Generalised Anxiety Disorder Questionnaire; PHQ9 = Patient Health Questionnaire Depression Scale; PSYCHLOPS = Psychological Outcome Profiles; WSAS = Work and Social Adjustment Scale.

APPENDIX G

Details of 'dragon metaphor'

How to take control: The Dragon story

Once there was a village at the bottom of a large mountain. There was a fierce dragon lurking in the hills around the village and it has been attacking people. Clearly something has to be done, and so three knights volunteer to help.

Without hesitation, the first knight gets hold of a huge sword and charges in and attacks the dragon. Unfortunately the dragon is too strong for him and frightens him away and he flees the village never to be seen again.

The second knight is really terrified by the first knight's experience and so stays at home. He thinks that he will never be able to defeat the dragon.

The third knight decides he needs more information about the dragon and so he watches the dragon's lair over a number of weeks to find out when the dragon is awake and when the dragon is asleep. He finds out that the dragon goes to sleep at 9pm every night in the corner of his lair. He also asks another knight for help and eventually they are able to sneak up on the dragon and capture it.



What is the point of the story?

We are suggesting that one way achieving what we want, and dealing with any problems and worries that arise, is by observing the things that cause you problems. This can help you understand more how best to approach these problems, in order to deal with them.

Another thing that the story is highlighting is that both avoiding problems and going at them full force can be ways we are trying to keep safe. They may not always be the most effective ways of resolving an issue, but it makes sense that we try to deal with problems in this way.