

**Evaluating the feasibility and acceptability of Method of Levels therapy for  
people experiencing first-episode psychosis**

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## Thesis Abstract

A thesis submitted to the University of Manchester for the degree of Doctor of Philosophy in April 2019.

Candidate: Robert Griffiths

Title: Evaluating the feasibility and acceptability of Method of Levels therapy for people experiencing first-episode psychosis

Psychological interventions that target the core processes which are proposed to maintain distress across diagnostic categories might have advantages over disorder-specific approaches for people experiencing first-episode psychosis (FEP). This thesis aimed to evaluate the feasibility and acceptability of a transdiagnostic cognitive therapy called Method of Levels (MOL) for people experiencing FEP, and to consider whether adaptations are needed to support its implementation into routine practice. MOL is designed to ameliorate distress, rather than reduce symptoms. A related aim, therefore, was to increase our understanding of the sources of distress for this population. The results of the thesis will be used to inform decision making about the suitability of MOL for further testing in a larger clinical trial.

The thesis comprises three studies described over four papers: (i) a qualitative metasynthesis exploring sources of distress in FEP (Chapter 3); (ii) a feasibility randomised controlled trial (RCT) of MOL for FEP (Chapters 4 and 5); and (iii) a qualitative study exploring experiences of receiving MOL amongst people with FEP (Chapter 6).

The metasynthesis is the first review to address the question of what causes distress in people experiencing FEP from a first-person perspective. Following a systematic review, findings from qualitative studies ( $n = 33$ ) were synthesised using thematic analysis. Sources of distress for this population were found to be diverse and multifaceted. The results suggest that practitioners who pay attention to wider sources of distress will be experienced as more helpful by people experiencing FEP.

Participants ( $n = 36$ ) were successfully recruited to the RCT and randomised to one of two conditions: treatment as usual (TAU) or TAU plus MOL. Retention at final follow up was 97%, substantially higher than the 80% threshold pre-specified as a successful feasibility outcome. This was the first study of its kind and the results provide evidence that it is feasible to recruit and retain participants experiencing FEP in a trial of MOL, suggesting that it is suitable for further testing in a larger trial. It also provides preliminary evidence of MOL's acceptability for this population.

A proportion of participants from the RCT ( $n = 12$ ) were interviewed about their experience of receiving MOL. Results were analysed using thematic analysis. Four superordinate themes were identified: 'The therapist's approach'; 'I was in control'; 'Thinking and talking'; and 'Looking at problems from a different perspective'. Engaging with MOL was predominantly perceived to be a helpful experience. The study provides additional evidence of the acceptability of MOL for people experiencing FEP.

This thesis makes a novel contribution to the literature on psychotherapeutic interventions for people experiencing first-episode psychosis and increases our general understanding of the lived experiences of this population.

## **Declaration**

No portion of the work referred to in the 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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## **The Author**

Robert Griffiths completed a BSc in Psychology in 1998 and subsequently trained as a mental health nurse. After qualifying as a nurse in 2002, he worked as a community mental health nurse and senior practitioner in Assertive Outreach services in Central Manchester. He completed an MSc in individual and family cognitive behavioural therapy for psychosis in 2007, and went onto work as a psychological therapist and clinical lead for Early Intervention in Psychosis services in Salford. During this period, Robert also worked as a trial therapist for the TEAMS (Think Effectively about Mood Swings) study. This was a feasibility randomised controlled trial of a novel cognitive behavioural therapy for bipolar and distressing mood swings. In 2015, Robert was awarded a Clinical Doctoral Research Fellowship by the National Institute of Health Research, which enabled him to undertake this PhD.

## **CHAPTER 1: Introduction**

### **1.1 Introduction and overview**

The primary aims of this thesis were to evaluate the feasibility and acceptability of a transdiagnostic cognitive therapy called the Method of Levels (MOL) for people experiencing first-episode psychosis (FEP). Because MOL specifically aims to reduce psychological distress, a secondary aim was to improve our general understanding of the potential sources of distress amongst people experiencing FEP.

This introductory chapter places the programme of research in context and outlines why developing effective psychological interventions for FEP is a priority for healthcare research. Current psychological interventions for FEP are introduced and the limitations of these approaches are described. The practice of MOL is then outlined, along with the conceptual underpinnings of the approach: a theory of human behaviour called Perceptual Control Theory. Potential advantages of MOL over existing approaches are proposed along with a rationale for evaluating MOL's use for people experiencing FEP. The chapter concludes with a summary of the main research questions to be answered and an outline of the overall structure of the thesis.

### **1.2 Background and context**

A recent report by the British Psychological Society (Cooke, 2014) states that the term “psychosis” encompasses a wide range of experiences including: seeing or hearing things others cannot (hallucinations); holding beliefs that others find unusual or hard to understand (delusions); and difficulties in thinking clearly (thought disorder). People might also experience what are sometimes described as “negative

symptoms”, such as feeling withdrawn, demotivated, or emotionally apathetic.

Psychosis is a relatively common mental health problem. Pooled incidence rates are estimated to be 31.7 per 100,000 person-years (an estimate of rates of developing the health outcome of interest within a cohort during the specified time period), although rates vary considerably depending on a range of other factors, such as age, ethnicity, sex, and geographic location (Kirkbride et al., 2012). Typically, psychosis emerges in adolescence and early adulthood (McGorry, Killackey, & Yung, 2008) and has a significant negative impact on individuals and their families (Lavis et al., 2015; Marshall et al., 2005). The economic impact of untreated psychosis for society is also significant, with total costs estimated to rise to £6.5 billion by 2026 (McCrone, Dhanasiri, Patel, Knapp, & Lawton-Smith, 2008).

### **1.3 Early intervention in psychosis**

The early stages of psychosis are believed to represent a distinct phase (Reading & Birchwood, 2005), and appropriate interventions delivered within the first two to three years after the development of psychotic symptoms lead to improved long-term outcomes for service users (Nordentoft, Jeppesen, Petersen, Bertelsen, & Thorup, 2009). Longer duration of untreated psychosis (DUP) is related to poorer outcomes in terms of symptoms, functioning, and overall quality of life (Marshall et al., 2005). These findings have led to the widespread implementation of Early Intervention in Psychosis (EIP) services (Bertelsen et al., 2008; Craig et al., 2004). A recent United Kingdom Department of Health policy document clearly indicated that improving outcomes for people experiencing first-episode psychosis (FEP) should be a priority for mental health services (NHS England, 2014).

## **1.4 Cognitive behavioural therapy for psychosis**

A key function of EIP services is the delivery of evidence-based psychological interventions such as cognitive behavioural therapy for psychosis (CBTp) (Bird et al., 2010). CBTp has relatively good evidence to support its use with people experiencing psychosis, with most meta-analyses finding effect sizes in the small to moderate range on measures of psychotic symptoms (Jauhar et al., 2014; Turner, van der Gaag, Karyotaki, & Cuijpers, 2014; Wykes, Steel, Everitt, & Tarrier, 2008). The evidence supporting CBTp has been deemed strong enough to justify United Kingdom practice guidelines recommending that everyone experiencing psychosis should be offered at least 16 sessions (National Institute for Health and Care Excellence (NICE), 2014; 2016). As outlined in the next section, however, questions have been raised about the capacity of CBTp to effectively and efficiently meet the complex needs of people experiencing psychosis.

## **1.5 Limitations of existing psychological interventions for psychosis**

### *1.5.1 Problems with implementation*

One longstanding practical difficulty with CBTp is its implementation into routine clinical practice (Berry & Haddock, 2008; Ince, Haddock, & Tai, 2015; Prytys, Garety, Jolley, Onwumere, & Craig, 2011). Partly, this problem is a product of systemic and organisational barriers, including a lack of appropriately trained staff and limited time allocated to the delivery of psychological interventions (Ince et al., 2015). Even amongst service users who are offered CBTp, however, rates of acceptance remain low. A recent audit of EIP found that just 41% of service users had been offered CBTp and, of these, only 51% accepted the offer (Royal College of Psychiatrists, Healthcare Quality Improvement Partnership, & NHS England, 2016).

Leaving aside the question of CBTp's effectiveness, this audit provides evidence that the majority of EIP service users are not offered the intervention. Furthermore, the fact that almost half of all service users who were offered CBTp declined the offer suggests that problems with its delivery are not limited to resource and organisational issues alone.

### *1.5.2 Comorbidity and psychosis*

People experiencing psychosis are also likely to meet diagnostic threshold for a range of other disorders (Buckley, Miller, Lehrer, & Castle, 2009), including problems with depression (Addington, Addington, & Patten, 1998), anxiety (Achim et al., 2011), substance misuse (Barrowclough et al., 2010), and trauma (Berry, Ford, Jellicoe-Jones, & Haddock, 2015). This presents challenges for practitioners attempting to deliver "disorder-specific" interventions, such as CBTp. Where service users prioritise difficulties other than psychosis, CBTp practitioners must draw on related cognitive models and approaches (Morrison, 2017). In situations where service users choose to work on problems with anxiety, for example, practitioners delivering disorder-specific approaches need to be familiar with cognitive models and treatment approaches for five distinct anxiety disorders (panic disorder, health anxiety, social phobia, generalised anxiety disorder, and obsessive compulsive disorder) (Wells, 1997). When the range of other potential difficulties people with psychosis might be experiencing in addition to anxiety is considered, the challenges of adopting this approach to psychotherapy become more apparent. Additionally, providing appropriate training and supervision for practitioners to effectively deliver these interventions has significant efficiency and resource implications for mental health services.

### *1.5.3 Wider sources of distress*

In addition to research that highlights the prevalence of comorbid difficulties in this population, there is evidence that distress associated with FEP is not limited to psychotic symptoms. For example, many people experiencing FEP rate other problems, such as anxiety and depression, as more distressing than symptoms of psychosis (Vracotas, Schmitz, Jooper, & Malla, 2007). Similarly, when people with lived experience of psychosis were asked to identify factors associated with the concept of “recovery”, statements such as “When the person is able to find time to do the things they enjoy” were rated as more indicative of recovery than those relating to psychotic symptom reduction (Law & Morrison, 2014, p. 1353). This suggests that psychological interventions with a narrow focus on reducing symptoms are unlikely to address broader difficulties experienced by people with FEP. Despite recommendations that psychological interventions for psychosis should focus less on symptom reduction and more on the amelioration of distress (Birchwood & Trower, 2006; Chadwick, 2006), psychotic symptom reduction remains the primary outcome in the majority of trials of CBTp (Greenwood et al., 2010) and research into the wider sources of distress for this population is sparse (Vracotas et al., 2007).

### *1.5.4 Duration of treatment*

Lack of clarity over what constitutes an adequate course of treatment is another factor that potentially limits the ability of CBTp to effectively and efficiently meet the needs of people experiencing psychosis. Treatment guidelines stipulate that CBTp should be delivered over 16 planned sessions (National Institute for Health and Care Excellence (NICE), 2014). The evidence justifying a standardised number of sessions of CBTp, however, is not clear. As Addington and Lecomte (2012) point

out, little agreement exists about what constitutes an adequate “dose” of CBTp, and there is variation between treatment protocols on the issue. For example, one protocol recommends that therapy is delivered over five weeks (Lewis et al., 2002), a second stipulates that 26 weekly sessions is the appropriate amount (Van Der Gaag, Stant, Wolters, Buskens, & Wiersma, 2011), and a third states that the default aim is to deliver 30 hours of therapy over six to nine months (Morrison, 2017). The theoretical or empirical reasons for choosing a certain number of sessions are not stated, despite the fact that there are likely to be significant differences in terms of efficiency between treatment regimes. This issue becomes more problematic when one considers research conducted in primary care that suggests no relationship exists between treatment duration and the amount of change experienced by service users (Stiles, Barkham, Connell, & Mellor-Clark, 2008). Currently, however, decisions about treatment designs appear to be based on the judgement of individual clinicians and researchers, as opposed to being driven by a coherent, empirically supported theoretical framework or the preferences and priorities of service users. The lack of such a framework to guide implementation means that, potentially, CBTp is being delivered inefficiently and in ways which are not attuned to individual needs.

#### *1.5.5 Discontinuing treatment*

Related to the question of how many sessions are required for psychotherapy to be effective is the issue of “treatment dropout”. Dropout is said to occur when, from the perspective of the therapist, a person discontinues therapy without having recovered from the problems for which they first sought help, and prior to completing the requisite number of sessions specified in the treatment protocol (Swift & Greenberg, 2014). A meta-analysis looking at dropout rates in CBT for depression found that 24.6% of people end therapy prior to receiving the planned

number of sessions (Hans & Hiller, 2013). A study that included participants with a variety of presenting problems found CBT dropout rates of 43.8% (Bados, Balaguer, & Saldaña, 2007). So far, there has been limited research that investigates the proportion of people who discontinue CBTp prior to receiving the planned number of sessions. One small-scale study found dropout rates of 46% for psychological interventions for psychosis generally, and 30% for CBTp specifically (Richardson et al., 2017). It seems probable, therefore, that a large proportion of service users are not attending the amount of sessions specified in CBTp treatment protocols. The extent to which this affects outcomes for service users is not clear. At present, the available research does not enable us to distinguish between people who stop attending therapy because they have achieved the results they wanted and those who drop out for other reasons (because therapy was experienced as unhelpful, for example). Even if we assume that significant departures from treatment protocols are not problematic for service users, however, it does suggest that current approaches to delivering therapy are not optimised for efficiency.

#### *1.5.6 Mechanism of change*

Although psychotherapy appears to be helpful for many people, exactly how it effects change is still poorly understood (Kazdin, 2009). The lack of a clear explanation regarding the mechanism of change is a problem affecting all psychological therapies (Kazdin, 2007), including CBTp. Greater understanding of how therapy leads to change would allow us identify the active ingredients of therapy and optimise psychological interventions to meet the needs of people receiving them more effectively and efficiently.



## **1.6 Interim summary**

Although the evidence supporting CBTp is encouraging, indicating that CBTp is helpful for many people, there are problems with its implementation into practice and questions about how effectively it can fully meet the complex needs of people experiencing FEP. Considering the number of service users who are offered CBTp, the numbers who subsequently accept that offer, and the rates of “dropout” prior to completing the recommended amount of sessions, it seems reasonable to conclude that only a very small proportion of people experiencing FEP are accessing CBTp in a way that is consistent with current treatment guidelines. Also, it is not clear that disorder-specific approaches to psychological therapy, such as CBTp, are capable of addressing the wider concerns of this population, particularly given the large numbers of people experiencing FEP who meet diagnostic threshold for other disorders. Finally, the lack of a coherent theoretical framework, with a clearly specified mechanism of change, makes it difficult to optimise CBTp to ensure the most effective elements of therapy are being delivered in the most efficient way possible. One theory that potentially provides such a framework is Perceptual Control Theory (PCT).

## **1.7 Perceptual Control Theory**

Later in this chapter, it is proposed that a transdiagnostic cognitive therapy called the Method of Levels (MOL) has the potential to address some of the limitations inherent in current psychological interventions for people experiencing FEP. MOL is the direct application of an empirically supported theory of human functioning called Perceptual Control Theory (PCT) (Powers, 2005). Therefore, an

outline of PCT and its fundamental principles will be provided before the practice of MOL is described in more detail.

PCT was first expounded by William T. Powers (1926-2013), an engineer who began developing the theory in the 1950s (Powers, Clark, & Farland, 1960a, 1960b). Marken and Mansell (2015) have proposed that PCT can be seen as a third “grand theory” of psychology – after behaviourist and cognitive theories – that offers a radically different perspective on how we understand human behaviour. From a PCT perspective, control is a fundamental property of all living things, one that is essential for survival. Although the term “control” is commonly used in the psychological literature (Marken & Mansell, 2015), PCT offers a precise definition of the term and, through the use of a functional model, provides a mechanistic account of how control is achieved. Distinct from behavioural and cognitive models of human behaviour – which argue that we control our behavioural output – PCT proposes that it is, in fact, our perceptions that are controlled (Powers, 2005). From a PCT perspective, we control perceptual input not behavioural output. Humans have the ability to control a wide range of perceptions; from those that are relatively simple and concrete (e.g. body temperature) to more complex, abstract perceptions (e.g. sense of identity). The process of control is so central to human survival that Carey (2016) has defined health as the state in which important biological, psychological, and social variables are controlled at desired levels.

### *1.7.1 Control*

Control is achieved through the use of a hierarchical and parallel arrangement of negative feedback loops. In an ongoing, dynamic process, current perceptions are compared to internally generated “reference values” (synonymous with “goals”,

“values”, or “just-rights”) specifying the preferred state of those perceptions. Where a difference exists, an “error signal” is produced that specifies the magnitude and direction of error in the control system. The purpose of behaviour is to reduce the amount of error between current and preferred perceptions. In this way, perceptions are maintained in line with reference values, error is minimised, and disturbances that would otherwise disrupt control are counteracted. Multiple experimental studies have now been conducted over several decades that support PCT’s conceptualisation of behaviour as the control of perception, including computer modelling and tracking studies (e.g. Marken, 1980, 2005, 2013; Powers, 1978).

### *1.7.2 Conflict*

Psychological distress is proposed to be a consequence of disrupted or compromised control. Loss of control can occur for a number of reasons. For example, physical illness or overwhelming environmental factors (described in PCT terms as “insuperable disturbances”) can both lead to the loss of control. Amongst people seeking help in the form of psychological therapy, however, the most common source of loss of control is thought to be goal conflict (Carey, Mansell, & Tai, 2015). Conflict is defined as wanting “...two incompatible goals to be realised at once” (Powers, 2005, p. 265). Being in a state of conflict is profoundly disruptive for individuals because efforts to attain one goal actively impede progress towards the other, making both goals unobtainable. From a PCT perspective, symptoms associated with mental health diagnoses – such as anxiety, depression, or schizophrenia – are actually a product of chronic unresolved conflict (Higginson, Mansell, & Wood, 2011).

As Mansell (2005) has pointed out, the assertion that internal conflict leads to psychological distress is not new or unique to PCT. Central to many psychological theories is an assumption that conflict is implicated in the creation and maintenance of distress. To illustrate this point, Mansell (2005) highlights the fact that conflicts about independence versus relatedness are particularly prevalent in several theorists' work (e.g. Beck, Emery, & Greenberg, 1986; Bowlby, 1969; Freud, 1930). What PCT adds to existing theories is a precise and functional account regarding the nature of conflict (Carey, 2008).

In relation to psychotic symptoms, there is some preliminary evidence to support the PCT view that distress connected to these experiences is a product of goal conflict. Varese, Tai, Pearson, and Mansell (2015) found that the content of voices was often thematically linked to voice-hearers' personal goals. They concluded that conflict between voice content and personal goals might be implicated in the maintenance of distress.

### *1.7.3 Reorganisation*

The putative learning mechanism that enables people to resolve conflicts is called "reorganisation" (Powers, 2005). Powers (2005) proposes that the process of reorganisation is analogous to rewiring a computer to alter the operations which it is capable of performing. Reorganisation operates by introducing random trial-and-error changes into a control system and monitoring whether the changes have the effect of increasing or decreasing error. Changes that reduce error persist until the rate of error again begins to increase, at which point another random change is introduced into the system (Carey et al., 2015; Marken & Powers, 1989). The structure of the perceptual hierarchy means that reorganisation of higher level control

systems will have the effect of altering reference values for lower levels.

Reorganisation is believed to take place in areas of the hierarchy where awareness is sustained (Carey, Carey, Mullan, Spratt, & Spratt, 2009; Powers, 2005). Computer modelling studies designed to test the principle of reorganisation have found that the use of trial-and-error behaviour is an efficient means of achieving desired results (Marken & Powers, 1989).

#### *1.7.4 PCT and psychosis*

Tai (2009) has argued that PCT provides a useful means of understanding experiences of psychosis. From a PCT perspective, what are generally described as symptoms of mental disorders are better understood as the manifestation of underlying problems of control. In the case of psychosis, it can sometimes be difficult for observers to make sense of behaviour that seems bizarre or inexplicable. However, even in these cases, PCT proposes that the symptoms and unusual behaviour associated with psychosis are produced by problems of control. This view is supported by the wider literature on psychosis, which is replete with references to control and loss of control.

For example, Campbell and Morrison (2007) conducted a qualitative study exploring the experience of paranoia in a group of participants with a diagnosis of schizophrenia-spectrum disorders compared to another group with no psychiatric diagnosis who had experienced paranoid thoughts. The key difference between the two groups was that the diagnosed group felt controlled by their ideas, whereas the non-diagnosed group did not. A study by Birchwood, Mason, Macmillan, and Healy (1993) found that the perceived controllability of psychotic symptoms was a powerful discriminator between depressed and non-depressed participants with a

diagnosis of schizophrenia. Additionally, individuals' strategies for controlling symptoms of psychosis, such as avoidance, worrying, or rumination, can have the unintended effect of maintaining distress (Morrison, 2001; Morrison & Wells, 2007). A more externalised locus of control – defined as a predisposition to believe that events in peoples' lives are the result of external forces – is associated with fewer periods of recovery and lower mood amongst people who have experienced psychosis (Harrow, Hansford, & Astrachan-Fletcher, 2009). Conversely, greater perceived control has been identified as an important aspect of recovery from psychosis (Pitt, Kilbride, Nothard, Welford, & Morrison, 2007).

The research cited above suggests that the phenomenon of control is implicated in the creation and maintenance of distress connected to psychosis. When considered in isolation, however, it can be hard to appreciate the ways in which different studies about psychosis, distress, and control relate to each other. What PCT provides is a functional model that enables us to integrate the findings of apparently disparate strands of research on these topics.

## **1.8 Method of Levels**

### *1.8.1 The practice of MOL*

MOL takes the PCT principles described above and directly applies them to the practice of psychotherapy. The aim of MOL is to help people resolve conflicts in order to improve wellbeing and reduce psychological distress. To achieve this, therapists delivering MOL have two main goals. The first is to encourage the person to talk about whatever is currently on their mind. Ideally, the person should feel free to discuss their thoughts openly, without screening or filtering the content prior to expression. Typically, a therapist would start an MOL session by asking something

along the lines of “Is there something you would like to talk about today?” While the person is talking freely, the therapist shifts to the second goal: to pay attention for “disruptions” and ask about these when they occur. Disruptions are thought to be signs that the person’s awareness has momentarily shifted from the topic of conversation onto potentially relevant background thoughts. Examples of disruptions can include changes in facial expression or body posture, disruptions to the flow of speech, or evaluative comments (e.g. “It sounds strange when I say it like that”). The purpose of asking about disruptions is to help shift the person’s awareness above the source of the conflict and facilitate the reorganisation of higher level goals. The therapist continues to follow these two goals iteratively for the duration of the MOL session.

### *1.8.2 Service user-led scheduling*

One novel feature of MOL is its use of service user-led appointment scheduling (Carey et al., 2015). Many approaches to psychotherapy stipulate the number and frequency of sessions that people should attend for a course of treatment to be considered adequate. As mentioned previously, current treatment guidelines for CBTp recommend that people should attend at least 16 sessions (National Institute for Health and Care Excellence (NICE), 2014). However, MOL is based on the principles of PCT, which assumes that change is non-linear and idiosyncratic. Therefore, it is not possible to specify exactly how many sessions of therapy individuals will require in order to achieve the changes they want. Instead, it is expected that the exact number of sessions will vary between people. The right amount of sessions can only be determined from the perspective of the person attending therapy. As such, MOL maximises service users’ control over appointment

booking, encouraging people to choose the number, frequency, and duration of sessions that is right for them.

There is evidence that this approach to scheduling therapy appointments is appreciated by service users and has the potential to use mental health resources more efficiently. Carey and Mullan (2007) evaluated service user-led scheduling in a large (approximately 10,600 patients and six GPs) general practice setting. Two therapists provided a total of 16 psychotherapy appointments per week. Patients referred for therapy by their GPs were informed of the availability of psychotherapy sessions and told they could book appointments as required. No restrictions were placed on the frequency or duration of appointments. Patients were also free to book sessions with either therapist. This system was viewed favourably by both patients and GPs at the practice. After implementing the system, the practice no longer needed to operate a waiting list to manage access to psychotherapy appointments.

Carey, Tai, and Stiles (2013) evaluated the use of service user-led scheduling in a secondary care mental health service operating in a remote Australian town. Here, a single therapist operated a clinic for two mornings each week, with four MOL therapy appointments available in each session. Over the two year period of the study, 92 service users were referred to the clinic by psychiatrists and case managers. Service users in the study generally achieved good therapeutic outcomes despite attending relatively small numbers of sessions (mean = 3.6; median = 3; range = 2–11). Rates of appointments cancelled (mean = 0.4) or not attended (mean = 1.1) were very low. The results also showed a high degree of variability between service users in their patterns of attendance. This is consistent with the principles of PCT, which would predict that service users will require varying numbers of appointments to achieve the changes they want.



These studies suggest that service user-led scheduling is a promising means of using limited health resources efficiently, in a way that is tailored to meet the individual needs of service users, without compromising outcomes. Further research into the application of service-user scheduling is warranted.

### *1.8.3 Current evidence for MOL*

A number of pragmatic studies conducted in a variety of practice settings have found relatively large effect sizes for MOL. Carey and Mullan (2008) found that MOL led to statistically significant reductions in levels of depression and anxiety as measured on the Depression and Anxiety Stress Scale (DASS21; Crawford & Henry, 2003) for participants ( $n = 44$ ) attending more than one session. They also found that no relationship existed between the amount of change experienced and the number of MOL sessions attended.

Carey et al. (2009) conducted a larger study ( $n = 120$ ) of MOL across primary and secondary care settings. This study also found significant effects of MOL on participants' DASS21 scores and self-reported levels of distress. Again, no relationship was found between number of sessions attended and levels of change experienced by participants. This study also included a qualitative component. Participants were invited to tell the researchers how they felt about their levels of distress after receiving MOL and for any comments they had about the therapy they had received. The results showed that participants judged MOL to be a generally helpful experience.

A study conducted by Carey et al. (2013) in a remote Australian secondary mental healthcare setting assessed the efficiency of MOL against alternative psychotherapeutic approaches by calculating an "efficiency ratio". This is the ratio of

effect size to mean number of sessions attended. They found that, when benchmarked against equivalent practice-based studies, MOL was equally effective but significantly more efficient.

Tai (2009, 2016) has outlined how MOL can be delivered to people experiencing psychosis and has used the approach in a variety of practice settings, although no systematically collected data were obtained (Tai, 2018). Tai has suggested that MOL is an acceptable and effective intervention for this population (Tai, 2016). However, currently, no studies have specifically investigated the use of MOL with people experiencing psychosis. Also, although the study conducted by Carey et al. (2009) contained a qualitative component, no in-depth qualitative studies have so far been conducted that explore the subjective experience of receiving MOL, either amongst people experiencing psychosis or in other populations.

### **1.9 Potential advantages of the Method of Levels**

MOL has several potential advantages over existing psychological interventions for people experiencing FEP.

#### *1.9.1 A transdiagnostic approach*

Firstly, because MOL is a transdiagnostic approach, it is applicable whatever diagnosis the person may have received. This is the case even in situations where people have multiple diagnoses or no diagnosis at all (Carey et al., 2015). Given the high levels of comorbidity amongst people having experienced psychosis (Buckley et al., 2009), interventions that can be applied across a range of diagnoses are likely to be advantageous. MOL is also believed to be helpful when service users present with multiple problems simultaneously, obviating the need for practitioners to apply

multiple disorder-specific models over the course of therapy. In circumstances where service users report multiple concerns, therapists delivering MOL continue to adhere to the two main goals of MOL: encourage the person to talk freely and ask about disruptions.

### *1.9.2 Efficiency and cost-effectiveness*

Secondly, MOL's applicability to a range of problems and disorders means that it has potential advantages in terms of the training and ongoing supervision of practitioners delivering psychological intervention. Instead of training staff in the application of multiple disorder-specific approaches, it is likely to be more cost-effective for staff to be proficient in the delivery of a single therapy that can be applied in multiple contexts and across a diverse range of presenting problems. Additionally, compared to therapy protocols that stipulate how many sessions constitute a course of treatment, evidence suggests that when service users have control over appointment booking, on average, they attend substantially fewer sessions and this does not lead to a reduction in the effectiveness of therapy (Carey et al., 2013). This suggests that MOL has the potential to be significantly more efficient and cost-effective compared to current approaches.

### *1.9.3 Increased service user control*

Thirdly, MOL aims to give service users greater control over the psychological interventions they access. Empowerment has been identified as central to the process of recovery from psychosis (Pitt et al., 2007; Wood, Price, Morrison, & Haddock, 2010). The concept of empowerment has been defined as "control over one's life and the recovery process or the efforts to achieve more control and self-efficacy" (Castelein, van der Gaag, Bruggeman, van Busschbach, & Wiersma, 2008,

p. 1338). Therefore, therapeutic approaches that maximise service user control, such as MOL, might have advantages over highly protocolised methods of service delivery. Service user-led appointment scheduling enables people to access therapy in a way that is tailored to meet their individual needs. Additionally, MOL's focus on helping people regain control and reduce distress, as opposed to symptom reduction, is consistent with the aims of the recovery movement. This movement, which has been growing in influence over the last two decades, emphasises control over one's life as being more important than having control over specific psychiatric symptoms (Jacob, 2015).

#### *1.9.4 Addressing the problems of treatment duration and dropout*

Fourthly, service user-led scheduling, informed by the principles of PCT, has the potential to answer questions that currently exist regarding what constitutes an adequate course of therapy and how the issue of "treatment dropout" can be resolved. From a PCT perspective, the correct number and frequency of sessions can only be determined from the perspective of the person attending therapy. An expectation that people attend a specific number of sessions is predicated on the assumption that change occurs at the same rate for everyone. However, reorganisation, the proposed mechanism of change in MOL, is a random trial-and-error process. This means that it is not possible to predict how many sessions of therapy an individual will need in order to adequately resolve goal conflict. Similarly, the concept of treatment dropout appears to be based on the assumption that people will require a certain "dose" of therapy for it to be effective. However, if we assume that people will attend therapy until they reach a "good enough" level of change (Stiles et al., 2008), and this level could be reached at any point, the concept of treatment dropout becomes redundant.

### *1.9.5 Bridging the theory-practice gap*

Fifthly, because MOL explicitly applies the principles of PCT to the practice of psychotherapy, it has the potential to bridge the theory-practice gap that has been identified as an impediment to the dissemination of evidence based psychological treatments (Dobson & Beshai, 2013; Reese, Rosenfield, & Wilhelm, 2013). The developers of MOL have explicitly advocated moving away from the development of ever more psychotherapeutic techniques and practices, proposing instead that the field would be better served if we were able to identify empirically supported principles of effective psychotherapy (Carey et al., 2015). They argue that three principles derived from PCT – control, conflict, and reorganisation – are sufficient to develop a flexible therapy that can be applied across a range of problems and clinical settings. MOL’s adherence to these key principles minimises the risk that a theory-practice gap will emerge and guides its implementation in routine clinical practice.

Given the potential advantages of MOL over existing psychological interventions for FEP, further research into its use with this population is justified.

### **1.10 Aims of the thesis**

Broadly, this thesis aims to investigate the feasibility and acceptability of MOL for people experiencing FEP. Because MOL explicitly aims to reduce psychological distress, the thesis also aims to contribute to our wider understanding of the sources of distress amongst people who have experienced FEP. Currently, research on this topic is sparse (Vracotas et al., 2007), so it is not clear what this population says causes them distress. Understanding this topic better would support

the development of interventions, such as MOL, that aim to ameliorate distress in people experiencing FEP. The specific research questions this thesis aims to address are as follows:

- (1) What are the self-reported sources of distress amongst people who have experienced FEP?
- (2) Is it feasible to recruit and retain people experiencing a first-episode of psychosis in a randomised controlled trial of Method of Levels (MOL)?
- (3) Is it feasible to deliver MOL to people experiencing FEP?
- (4) Is MOL an acceptable psychological intervention for people experiencing FEP?
- (5) Are adaptations necessary to overcome problems or barriers to the implementation of MOL in EIP services?

### **1.11 Overview of the thesis**

This thesis is comprised of three main studies described across four papers: a systematic review and qualitative metasynthesis, a feasibility randomised controlled trial (RCT), and a qualitative study.

*Chapter 2* describes the overall methodology used in the thesis and provides a rationale for using a mixed methods approach to answer the research questions.

*Chapter 3 (paper 1, study 1)* is a systematic review and qualitative metasynthesis that investigates the self-reported sources of distress amongst people who have experienced FEP.

*Chapter 4 (paper 2, study 2)* outlines the rationale, design and baseline data for a feasibility RCT of MOL for people experiencing FEP.

*Chapter 5 (paper 3, study 2)* reports the results of a feasibility RCT of MOL for people with FEP.

*Chapter 6 (paper 4, study 3)* describes a qualitative study that investigates experiences of receiving MOL amongst participants of the feasibility RCT.

*Chapter 7* provides a general discussion of all four papers. This chapter highlights the novel contributions made to the literature by this thesis, along with the implications for practice, future research directions, and the strengths and limitations of the thesis.

### **1.12 How the programme of research addresses the overall research questions**

The individual studies that comprise the thesis address the overall research questions in the following ways. Study 1 (Chapter 3) specifically aims to address the first research question: what are the self-reported sources of distress amongst people who have experienced FEP? Study 2 (Chapters 4 and 5) addresses the question of whether it is feasible to recruit and retain participants with FEP in an RCT of MOL. Study 2 also aims to answer the question of whether it is feasible to deliver MOL to people experiencing FEP, and provides some indication of MOL's acceptability for this population. The question of MOL's acceptability for people experiencing FEP is then addressed from a qualitative perspective in study 3 (Chapter 6). Studies 2 and 3 both contribute to answering the question of whether adaptations are needed to overcome barriers to the implementation of MOL in EIP services.

### **1.13 Personal contribution**

The personal contributions of the PhD student to the research programme are outlined in the methodology chapter and in the preface for each of the four papers that comprise the thesis.



## **CHAPTER 2: Methodology**

### **2.1 Introduction**

The purpose of this chapter is to outline the methodology of the thesis. After providing a general rationale for using a mixed methods approach, each of the three studies will be discussed in turn. The particular research questions that each study aimed to address are outlined. A rationale for the methods used in each study is provided, along with a justification for their use over possible alternative methods. Practical details regarding the conduct of each study are discussed, and the relative contribution made to the three studies by the PhD student, supervisors, and collaborators are described. Specific details about the methods used in each of the three studies are available in the preface of the relevant chapters.

### **2.2 Mixed methods research**

#### *2.2.1 Rationale for using a mixed methods approach*

A mixed methods approach was used to fully answer the research questions of the thesis. The term mixed methods refers to the use of both quantitative and qualitative methods to investigate a research topic (Yardley & Bishop, 2015). Advocates argue that mixed methods represent a distinct third research paradigm that enables researchers to draw on the relative strengths of both quantitative and qualitative approaches (Johnson & Onwuegbuzie, 2004; Johnson, Onwuegbuzie, & Turner, 2007). Doyle, Brady, and Byrne (2016) state that healthcare researchers might use mixed methods, as opposed to purely quantitative or qualitative methods, for a number of reasons. For example, to examine the same phenomenon using different methods (known as “triangulation”), to answer different research questions

within a single study, or to provide a more complete picture of the phenomenon of interest than would be possible through the use of a single method alone (Doyle et al., 2016).

In the context of clinical trials, incorporating qualitative methods into the study design can be a particularly helpful way of understanding more about the acceptability of an intervention (Cooper et al., 2014). The following quote from Braun and Clarke (2014) supports the view that mixed methods research in healthcare can generate insights which could not be achieved through the use of quantitative methods alone:

Qualitative research offers rich and compelling insights into the real worlds, experiences, and perspectives of patients and health care professionals in ways that are completely different to, but also sometimes complimentary to, the knowledge we can obtain through quantitative methods (Braun & Clarke, 2014, p. 1).

This view is supported by guidance from the United Kingdom Medical Research Council (MRC) (Craig et al., 2008), which states that a combination of quantitative and qualitative methods is advantageous when evaluating complex interventions.

### *2.2.2 Epistemological assumptions of mixed methods research*

One challenge for researchers using mixed methods is reconciling the opposing ontological and epistemological assumptions that underpin qualitative and quantitative research paradigms (Symonds & Gorard, 2010). Quantitative research has traditionally been associated with positivism and, as such, is aligned with a

realist world view. This perspective assumes that an independent “reality” exists which can be objectively described and measured by researchers who aim to study it. In contrast, the roots of qualitative research lie in constructivism, which assumes that our subjective perceptions are the only means of knowing ourselves and the world (Symonds & Gorard, 2010). From this perspective, reality cannot be objective and value-free because it is constructed by our own minds (Slevitch, 2011).

Johnson and Onwuegbuzie (2004) argue that one way to resolve these epistemological differences is to take an approach characterised by *pragmatism*. Rather than focusing on the epistemological differences between quantitative and qualitative research paradigms, pragmatism argues that it is more productive to concentrate instead on the practical consequences of using a particular method. Pragmatism has been described as taking the view that “the end justifies the means” when it comes to selecting the most appropriate research methods (Doyle et al., 2016, p.178). This position acknowledges that qualitative and quantitative methods both have significant strengths and limitations. What is important is that researchers select the method, or combination of methods, best placed to answer their specific research question.

Morgan (2007) outlines how pragmatism has the potential to reconcile many of the intractable epistemological differences that exist between qualitative and quantitative paradigms. Morgan (2007) argues, for example, that apparently incompatible ideas around subjectivity and objectivity can legitimately be resolved by using the concept of *intersubjectivity* instead. From this perspective, it is reasonable to simultaneously accept the existence of an objective “real world”, while still acknowledging that people experience that world subjectively, in ways which

are unique to them. This makes it possible to move beyond the traditional dualism that has characterised debates around research paradigms.

The position stated above is consistent with a philosophy of science called *critical realism*, which aims to integrate elements of realist and constructivist epistemologies (Cresswell & Plano Clark, 2011). Critical realism rejects both the positivist view that reality is limited to that which can be known empirically, and the constructivist perspective that reality is entirely constructed by human minds (Fletcher, 2017). It can be thought of as positioned somewhere between realism and constructivism. Both pragmatism and critical realism are consistent with the ontological and epistemological assumptions of Perceptual Control Theory (PCT) (Powers, 2005). Specifically, they are in accord with the assumption that a single reality exists independently of our thinking, but that it is only possible to know this reality through our subjective perceptions of the world. This is the theoretical perspective adopted by the thesis.

### *2.2.3 Use of mixed methods in the thesis*

Some of the research questions this thesis aimed to answer were better approached using either quantitative or qualitative methods alone. For example, qualitative methods were more suitable for understanding the self-reported sources of distress amongst people experiencing FEP. However, some questions could be answered more comprehensively using a combination of qualitative and quantitative methods. These included questions relating to the feasibility and acceptability of MOL for people experiencing FEP, and whether adaptations were required to deliver MOL in EIP services. In determining MOL's acceptability for people experiencing FEP, for example, it was possible to take quantitative data in the form participants'

scores on the Session Rating Scale (Duncan et al., 2003) and compare this with participants' detailed accounts of receiving MOL gathered in semi-structured qualitative interviews. The strength of this mixed methods approach was that – by drawing on multiple perspectives – it produced a more complete picture of the topic of interest.

Researchers using mixed methods face a number of decisions about the sequencing, relative weighting, and degree of integration between quantitative and qualitative components (Cresswell & Plano Clark, 2011). For this study, the qualitative metasynthesis and RCT components ran concurrently, and recruitment for the qualitative investigation began after several participants had experienced at least one MOL session. The reasons for running the metasynthesis and the RCT concurrently were largely pragmatic. If these components had run sequentially, it would not have been possible to complete all elements of the research within the planned timeframe of the PhD. The RCT and the qualitative study were partially sequential, with some overlap in timeframes. The reason for this is that it was necessary for the qualitative study to begin after recruitment for the RCT had commenced to ensure that sufficient participants had been exposed to the MOL intervention prior to being interviewed (see Appendix D for a study flow chart). Roughly equal weightings were given to the qualitative and quantitative components of the thesis; both were deemed equally important for the purposes of answering the research questions. The three studies were, largely, conducted independently of each other, with data being merged only in the interpretation stage rather than during the analysis stage. For this reason, the thesis is perhaps more accurately described as using a partially, rather than fully, mixed methods design. Using the typology of mixed methods designs described by Leech and Onwuegbuzie (2009), the design

falls into the category of a partially mixed concurrent equal status design, where both qualitative and quantitative components were afforded equal weight in answering the research questions of the thesis.

### **2.3 Study 1: Systematic review and qualitative metasynthesis**

The aim of study 1 (Chapter 3) was to answer the first research question:

- (1) What are the self-reported sources of distress amongst people who have experienced FEP?

#### *2.3.1 Rationale for conducting a qualitative metasynthesis*

Given that a substantial amount of qualitative literature is available which explores first-person perspectives of FEP (e.g. Childs, McCarthy-Jones, Rowse, & Turpin, 2011; Ferrari et al., 2015; Tan, Gould, Combes, & Lehmann, 2014), a qualitative metasynthesis was judged to be the most appropriate method of increasing our understanding of the sources of distress for this population. Although these studies have not specifically aimed to answer the question of what people experiencing FEP find distressing, the studies were thought to contain sufficient data on the topic of interest to justify a systematic review and qualitative meta-synthesis.

Methods that aim to synthesise qualitative research have been growing in popularity since the idea was first proposed by Noblit and Hare (1988). Similar in its aims to meta-analyses of quantitative research (Haidich, 2010), the purpose of synthesising qualitative research is to combine and analyse secondary data drawn from multiple qualitative studies to answer a specific research question (Erwin, Brotherson, & Summers, 2011). The synthesis of qualitative research is particularly relevant in the field of healthcare and to the development of evidence-based practice

because of the insights it can provide into the lived experiences of people affected by a specific health issue (Korhonen, Hakulinen-Viitanen, Jylha, & Holopainen, 2013).

To answer the question of what people who have experienced FEP say causes them distress, the decision was taken to conduct a systematic rather than narrative review of the literature. Systematic reviews have the advantage of using a predefined protocol specifying the search strategy, inclusion and exclusion criteria, and proposed method of analysis. This increases transparency and makes systematic reviews more consistent with the current trend in healthcare research towards evidence-based practice (Pae, 2015).

Booth et al. (2016) provide guidance on selecting the most appropriate synthesis method from the wide range of approaches that have been developed. They argue that the decision about which method to use should be based on the nature of the review question and the epistemological stance of the researcher. However, they also emphasise that pragmatic factors should be taken into account, such as the resources available, the timeframe of the research, and the degree of researcher expertise. These factors were all considered when evaluating the relative strengths and weaknesses of possible synthesis methods. On balance, thematic analysis (Braun & Clarke, 2006) was thought to be the most appropriate method for this study. The following section provides a rationale for this decision.

### *2.3.2 Rationale for using thematic analysis to synthesise the data*

Thematic analysis is a method of organising large amounts of qualitative data in a systematic fashion to enable themes to be identified across the whole data set (Braun & Clarke, 2006). Themes can then be described in rich detail. Thematic analysis has been used both as a method for analysing primary qualitative data and

for synthesising multiple qualitative studies (Thomas & Harden, 2008). For the purposes of this thesis, a strength of thematic analysis is that it is considered a foundational method for researchers who are relatively new to conducting qualitative research (Braun & Clarke, 2006). Additionally, it is well suited for research into health and wellbeing (Braun & Clarke, 2014) and can be applied across a range of epistemological and theoretical standpoints (Braun & Clarke, 2006). This meant it was possible to include primary studies which adopted a range of theoretical assumptions and methods. Because one aim of this study was to capture a broad range of perspectives relating to the topic of distress and FEP, this was an important consideration. Limiting primary studies on the basis of their methods or epistemology would have excluded potentially relevant data from the synthesis.

There are a wide range of methods available for synthesising qualitative data (Booth et al., 2016) – although some authors have argued that differences in terminology actually obscure some fundamental similarities between the various methods (Barnett-Page & Thomas, 2009). Two commonly used methods that were considered for this study – in addition to thematic analysis – were grounded formal theory and meta-ethnography.

Grounded formal theory is an approach to qualitative synthesis which developed from Glaser and Strauss's (1967) original grounded theory method (Barnett-Page & Thomas, 2009). Grounded theory is a systematic, inductive method of generating theory from primarily qualitative data using a constant comparative method. Grounded formal theory attempts to maintain consistency between the methods used to generate original grounded theories and the approach to their synthesis. Unlike thematic analysis, grounded formal theory is not designed to include studies with diverse methodologies or epistemological assumptions (Barnett-



Page & Thomas, 2009). Given that one aim of this study was to include as many first-person perspectives as possible, the use of grounded formal theory would have precluded a large number of potentially relevant studies. Grounded formal theory was, therefore, discounted as a possible method for this study.

Originally developed by Noblit and Hare (1988), meta-ethnography was one of the first approaches to be developed for the purpose of synthesising qualitative data. Since Noblit and Hare (1988) first described their seven-step method for synthesising a small number of ethnographic studies, it has gone on to be used widely in healthcare research (Cahill, Robinson, Pettigrew, Galvin, & Stanley, 2018). However, while thematic analysis is frequently used to integrate and aggregate the findings of qualitative studies to answer a specific research question, meta-ethnography is primarily used as a means of developing theory or conceptual models (France et al., 2014). The aim of the synthesis was to integrate findings of studies that could help answer the question of what people who have experienced FEP find distressing, as opposed to generating a new conceptual model. Thematic analysis was, therefore, thought to be the more appropriate of the two methods. Additionally, some have argued that only primary studies that use ethnographic approaches should be included in a meta-ethnography (Walsh & Downe, 2005). As was the case with grounded formal theory, this would have excluded a large number of potentially relevant studies from being included in the synthesis. The flexibility of thematic analysis, and its ability to accommodate studies with different methods and epistemological assumptions, was considered advantageous.

Although the thematic analysis was conducted in line with the principles outlined by Braun and Clarke (2006), additional elements more usually associated with meta-ethnography were included in the method to create a novel 'hybrid'

approach. Since the aim was to understand first-person experiences of the topic being studied, it was seen as essential to retain and prioritise the perspectives of people with lived experiences of FEP. To achieve this, data were coded as either first- or second-order constructs. First-order constructs captured the perspectives of participants in the primary studies included in the synthesis. Second-order constructs represented the interpretations of the original study authors. Second-order constructs were used to contextualise first-order constructs. Both first- and second-order constructs informed the development of third-order constructs, which were the interpretations of the researchers conducting the meta-synthesis. These third-order constructs were treated as candidate themes for the thematic analysis.

### *2.3.3 Defining “distress”*

During the peer review process for the journal *Qualitative Health Research*, one peer reviewer commented that the article would be improved by having a clearer definition of “distress”. Following a discussion with the supervisory team, it was agreed that it would be useful to develop a clear operational definition of distress to guide the coding of qualitative data. A definition was developed with reference to the literature relating to psychological distress (Ridner, 2004), which was also consistent with PCT (Powers, 2005). Data were then checked against the operational definition of distress to ensure consistency. This process increased the overall transparency and rigour of the analysis.

### *2.3.4 Credibility*

Qualitative researchers should take measures that aim to increase confidence in the “soundness” of the methods used (Noble & Smith, 2015). Unlike quantitative research, qualitative researchers are not aiming to achieve objectivity and

generalisability in relation to the research topic, because these concepts are believed to be unobtainable (Slevitch, 2011). Instead, it is acknowledged that the views and attitudes of the researcher influence the overall process of conducting a study. It is usually recommended, therefore, that researchers adopt a stance characterised by *reflexivity* (Spencer & Ritchie, 2012). This involves declaring the values and theoretical assumptions researchers bring to a study, and being transparent about the ways in which these influenced the research.

Over the course of conducting the metasynthesis, the PhD student met members of the supervisory team on a weekly basis. This provided an opportunity to review the progress of the study, to reflect on how the emerging findings related to existing knowledge on the topic of interest, and to consider how the PhD student's values and assumptions were shaping the study. The PhD student included a reflexivity statement in the study manuscript with the aim of increasing transparency about the theoretical orientation of the research team. Additional measures were also included in the study to increase its credibility, such as members of the supervisory team making a series of coding decisions to compare with the original decisions made by the PhD student. These additional measures are described in more detail in Chapter 3.

### *2.3.5 Roles and responsibilities for the metasynthesis*

The PhD student designed the research and wrote a first draft of the study protocol. After receiving suggestions for improvements from Dr Sara Tai, Dr Warren Mansell, and Dr Dawn Edge, the PhD student wrote the final draft of the protocol and registered the study with the PROSPERO international prospective register of systematic reviews (<https://www.crd.york.ac.uk/prospero/>). With guidance from the

supervisory team, the PhD student conducted the literature searches, coded the data, and carried out the data analysis. The PhD student wrote the first draft of the manuscript and revised this based on feedback from the other authors.

## **2.4 Study 2: Feasibility RCT of Method of Levels for first-episode psychosis**

Study 2 (Chapters 4 and 5) aims to answer research questions two to five:

- (2) Is it feasible to recruit and retain people experiencing a first-episode of psychosis in a randomised controlled trial of Method of Levels (MOL)?
- (3) Is it feasible to deliver MOL to people experiencing FEP?
- (4) Is MOL an acceptable psychological intervention for people experiencing FEP?
- (5) Are adaptations necessary to overcome problems or barriers to the implementation of MOL in EIP services?

### *2.4.1 Rationale for conducting a feasibility RCT*

The decision to conduct a feasibility RCT was informed by the Medical Research Council (MRC) guidelines on developing complex interventions (Craig et al., 2006). This guidance outlines four key stages in the development and implementation of complex interventions: (1) development; (2) feasibility/piloting; (3) evaluation; and (4) implementation. The current evidence for MOL's use with people experiencing FEP was reviewed in relation to the MRC guidelines. The intervention had previously been well described in several treatment manuals (Carey, Mansell, & Tai, 2015; Carey, 2006; Mansell, Carey, & Tai, 2013), the theoretical assumptions of the approach had been clearly articulated (Powers et al., 1960a; Powers, 2005), and the rationale for MOL's use with this population had been

provided (Tai, 2009, 2016). Ultimately, the aim is to conduct an effectiveness trial of MOL for FEP. However, because no previous trials of MOL for FEP had been conducted, a full effectiveness trial was not justified at this stage. The most appropriate next step was, therefore, judged to be a feasibility trial that aimed to establish the suitability of MOL for further testing in a larger trial.

The purpose of carrying out a feasibility trial prior to conducting an effectiveness RCT is to ask "...whether something can be done, should we proceed with it, and if so, how" (Eldridge et al., 2016, p. 1). For practical, financial, and ethical reasons it is appropriate to answer these questions prior to embarking on lengthy and costly large-scale trials of complex interventions. Feasibility trials provide valuable information about the appropriateness of the study design and can help to identify problems that might undermine the findings of any future trial (Blatch-Jones, Pek, Kirkpatrick, & Ashton-Key, 2018). In this case, it was necessary to determine the feasibility of recruiting and retaining participants in a clinical trial of MOL for FEP, to establish the acceptability of the intervention for this population, and to decide whether adjustments were required that would eventually enable MOL to be implemented into routine clinical practice.

Some potential alternatives to conducting an RCT that were considered included case studies, practice-based studies, and qualitative methods (Timulak, 2015). Given that a number of practice-based studies have already been conducted (Carey & Mullan, 2008; Carey, Carey, Mullan, Spratt, & Spratt, 2009; Carey, Tai, & Stiles, 2013), and that a substantial qualitative component was incorporated into the design of this study, an RCT was deemed to be the logical next step in the process of evaluating MOL. Another option would have been to conduct research that specifically examined MOL's proposed mechanism of change. While mechanistic

research is likely to form an important part of investigating MOL in future studies, the primary focus here was on establishing the feasibility of conducting an RCT of MOL with this population.

#### *2.4.2 Strengths and weaknesses of RCTs*

Proponents of RCTs argue that they are the most rigorous method of evaluating healthcare interventions (Sibbald & Roland, 1998), primarily because they mitigate a range of potentially confounding biases which cannot be controlled using other methodologies (Backmann, 2017). Another advantage is the strong internal validity created by the randomisation process, which aims to ensure that the only difference between groups is their exposure to the intervention being tested (Booth & Tannock, 2014). For these reasons, RCTs are often described as the “gold standard” in healthcare research, with systematic reviews of RCTs placed at the top of a hierarchy of evidence (Backmann, 2017).

The external validity of RCTs has been questioned, however, with some researchers suggesting that study samples are frequently unrepresentative of the population from which they are drawn (Kennedy-Martin, Curtis, Faries, Robinson, & Johnston, 2015). Others have expressed concern that classifying RCTs as the “gold standard” of evidence is unhelpful, arguing that this assumption has impeded progress towards the development of effective psychological treatments (Carey et al., 2017). Creating a hierarchy of evidence – where the findings produced by one research method are deemed superior to others – is also at odds with the assumptions of pragmatism, which proposes that methods should be chosen on the basis of their appropriateness for answering the research question (Cresswell & Plano Clark, 2011).

Salkovskis (2002) argues that outcome research, such as RCTs, is just one element in the development of what he describes as empirically grounded clinical interventions. Salkovskis describes a reciprocal model for advancing our knowledge of psychological interventions, where outcome research, theory development, experimental studies, and clinical practice are all interrelated. Salkovskis, however, acknowledges that RCTs are an important aspect of this model. Others researchers who have criticised the over-reliance on RCTs in advancing psychological interventions also acknowledge that there are occasions when they are the most appropriate method of answering certain research questions (Carey et al., 2017).

#### *2.4.3 Choice of clinical outcome measures*

Outcome measures were chosen on the basis that they were deemed particularly appropriate to the evaluation of MOL, or they were seen as relevant to a FEP population. The Psychological Outcome Profiles (PSYCHLOPS; Ashworth et al., 2004), the proposed primary clinical outcome measure, was selected on the grounds that it would capture change to problems specified by participants at the outset of therapy. Others measures, such as the Questionnaire about the Process of Recovery (QPR; Neil et al., 2009), were chosen because they are routinely used in EIP services, and personal recovery is judged to be an important outcome for this group (Pitt et al., 2007). The reason for not including a specific measure of psychotic symptom reduction, such as the Psychotic Symptoms Rating Scale (PSYRATS; Drake, Haddock, Tarrier, Bentall, & Lewis, 2007) or the Positive and Negative Syndrome Scale (PANSS; Kay, Fiszbein, & Opler, 1987) is that MOL is designed to reduce clinical distress, rather than lead to symptom reduction. Given the stated aims of MOL, and to avoid increasing participant burden, additional measures of psychotic symptom reduction were not included. The extent to which this could be

considered a limitation of the design is discussed in the paper outlining the rationale for conducting a RCT of MOL for FEP (Chapter 4).

#### 2.4.4 Analysis of the RCT

Consistent with CONSORT guidelines for feasibility and pilot trials, the primary outcomes of the RCT were the extent that it proved possible to recruit and retain participants in the trial (Eldridge, Chan, et al., 2016). The issue of how to analyse and report the results of the RCT were a topic of debate amongst members of the trial steering committee (TSC), the panel of clinicians, academics, and service user members established to provide trial oversight. There was some disagreement between the psychologist and statistician members of the TSC about the most appropriate approach to the analysis.

There are two common ways that randomised controlled trials with baseline and follow up data can be analysed (Vickers & Altman, 2001). The first approach is to compare the follow up scores of both groups. The second is to subtract the follow up scores from baseline scores for each group to calculate a change score. The psychologist member advocated using the change score, whereas the statistician member thought that the follow up score was more appropriate.

Vickers and Altman, (2001) argue that neither method is incorrect, providing the method used is clearly pre-specified in the trial protocol, rather than selected on the basis that it produces a more significant result. Bland and Altman (2011), however, have argued that comparisons within randomised groups can be misleading. The whole point of conducting a randomised trial, they argue, is not to find out if there is a change from baseline *within* groups, but whether there is a difference *between* groups. The trial protocol for this study stated that the intention



was to compare the effects of random allocation on outcome measures at follow up, adjusting for scores at baseline. Therefore, in line with the original plan for data analysis, comparing follow up scores on the proposed primary clinical outcome measure was deemed to be the most appropriate approach.

CONSORT guidance (Eldridge, Chan, et al., 2016) specifically advises against using feasibility trials for the purposes of efficacy testing, and there is evidence that sample sizes of less than 35 participants per group are inadequate for the accurate estimation of effect sizes (Teare et al., 2014). This led to a slight change in the analysis plan, which was originally developed prior to the publication of the new CONSORT guidance. Although the original plan had stated that one of the secondary aims was to calculate an effect size, the decision was taken to focus primarily on descriptive statistics that summarise the main feasibility outcomes. Inferential statistics were performed only on the proposed primary clinical outcome measure, the PSYCHLOPS (Ashworth et al., 2004). One-way ANCOVA were performed to compare the effects of allocation to treatment as usual (TAU) compared to TAU plus MOL on outcomes at 10 and 14 months, using baseline scores as a covariate. This is generally agreed to be the most appropriate approach to analysing clinical trials with outcomes measured at baseline and follow up (Vickers & Altman, 2001). These results are presented in Chapter 5 with the caveat that the sample size is too small to draw conclusions about the effectiveness of the intervention. This approach was supported by Professor Richard Emsley, the trial statistician.

#### *2.4.6 Maintaining fidelity to the MOL approach*

Several steps were taken to ensure that the MOL intervention delivered to participants in the trial was consistent with the approach as described in recognised

treatment manuals (e.g. Carey, 2006). Firstly, prior to starting recruitment, the PhD student attended a three-day course on MOL delivered by Professor Timothy Carey, a member of the supervisory team and the psychologist who first developed MOL as a clinical intervention. This training was in addition to previous MOL training courses that the PhD student had attended. Secondly, the PhD student received weekly clinical supervision on the approach from Dr Sara Tai and Dr Warren Mansell, clinical psychologists who have been instrumental in developing both MOL and its evidence-base. These supervision sessions were an opportunity for the PhD student to develop MOL skills and knowledge using a variety of methods, including the discussion of clinical issues, reviewing audio recordings of therapy sessions, and practising the delivery of MOL. Thirdly, the PhD student attended a weekly MOL supervision group facilitated by Dr Sara Tai and Dr Warren Mansell. This group is attended by clinicians, students, and academics who wish to develop their MOL skills and knowledge using a combination of discussion and practical exercises. Finally, Dr Sara Tai and Dr Warren Mansell rated a sample of 20% of MOL sessions delivered as part of the trial. Audio recordings were selected at random and rated using the MOL Session Evaluation Form (Carey & Tai, 2012).

#### *2.4.7 Roles and responsibilities for the RCT*

The PhD student designed the research and wrote the first draft of the trial protocol. All supervisors provided feedback on the appropriateness of the protocol. Professor Richard Emsley, a biostatistician with experience of conducting clinical trials, agreed to provide statistical input for the RCT. He also made suggestions for possible improvements to the protocol and plan for the analysis of data from the RCT. The PhD student developed the final version of the protocol based on feedback from the supervisory team and trial statistician. The RCT was prospectively

registered with the ISRCTN online trial registry by the PhD student (ISRCTN13359355).

With guidance from the supervisory team, the PhD student applied for ethical approval from the North West – Greater Manchester Central Research Ethics Committee using the Integrated Research Application System (see Appendix A). He also applied for and received approval from the University of Manchester to act as research sponsor.

As part of the recruitment strategy, the PhD student collaborated with Nicholas Young, a graphic designer, to develop a trial logo, promotional material (Appendix C), and Twitter account. These were used to raise awareness of the RCT amongst potential participants and referrers. The PhD student also developed a Participant Information Sheet (PIS; Appendix E) to help participants make an informed decision about taking part. Feedback was sought from a service user reference group by the PhD student about whether the intended audience was likely to find the PIS and promotional material acceptable.

Ongoing trial management was carried out by the PhD student. This included data management and storage, monitoring of recruitment, and ensuring that the standard operating procedures of the trial were consistent with the policies and procedures of the host National Health Service (NHS) trust. Raising awareness of the RCT amongst Early Intervention in Psychosis (EIP) Teams where recruitment took place was conducted by the PhD student in collaboration with the National Institute of Health Research's (NIHR) Clinical Research Network. This was done through a combination of posters and verbal presentations to mental health teams and

individual clinicians. To support the aim of increasing recruitment, the PhD student also offered training sessions on MOL to EIP clinicians.

Study enrolment, baseline assessments, and follow up assessments were conducted by the PhD student. Randomisation was carried out by the PhD student using the *Sealed Envelope* website (<https://www.sealedenvelope.com>). All therapy sessions were delivered by the PhD student under the clinical supervision of Dr Sara Tai and Dr Warren Mansell. The PhD student identified and booked the clinic rooms in community centres where MOL sessions took place. Using the *Simply Book* website (<https://simplybook.me/>), the PhD student also designed and managed the online appointment booking system that participants used to book MOL sessions. He liaised with the Information Governance department of the host National Health Service (NHS) mental health trust to ensure the booking website was compliant with relevant policies and procedures.

All data entry was carried out by the PhD student. Emma Izon (a research assistant and PhD student working in the NHS trust where the RCT was conducted) contributed to data cleansing by checking the accuracy of data entry. The data for a randomly selected sample of 20% of participants ( $n = 7$ ) were checked for accuracy. Analysis of the RCT data was conducted by the PhD student.

The first draft of the two articles that describe the rationale, design, and results of the RCT (Chapters 4 and 5) were written by the PhD student. These articles were revised based on the feedback of the supervisory team and trial statistician.

## **2.5 Study 3: Qualitative study of MOL**

Study 3 (Chapter 6) takes a qualitative approach to answering research questions three to five:

- (3) Is it feasible to deliver MOL to people experiencing FEP?
- (4) Is MOL an acceptable psychological intervention for people experiencing FEP?
- (5) Are adaptations necessary to overcome problems or barriers to the implementation of MOL in EIP services?

### *2.5.1 Rationale for qualitative study*

There is an increasing acceptance that mixed methods approaches are likely to lead to greater knowledge about a topic than using either quantitative or qualitative methods alone (Braun & Clarke, 2014; Johnson & Onwuegbuzie, 2004). The use of qualitative methods is particularly relevant to clinical trials (Craig et al., 2008; O’Cathain, Thomas, Drabble, Rudolph, & Hewison, 2013) and research into psychological interventions (Binder et al., 2016). To complement and enhance the quantitative data gathered as part of the RCT, therefore, the use of qualitative approaches to understand participants’ experiences of receiving MOL was believed to be an important aspect of answering the research questions of the thesis.

### *2.5.2 Rationale for conducting semi-structured interviews*

This study used semi-structured interviews to gather qualitative data about the topic of interest. This is just one of several approaches to data collection that can be used in qualitative research. Frith and Glesson (2012) identify a number of possible alternatives to semi-structured interviews, including the use of focus groups,

email interviews, solicited diaries, and recordings of naturalistic interactions. One reason for using semi-structured interviews in this study, as opposed to one of these alternatives, was that it allowed the interviewer and interviewee to build rapport during the interview process. It was hoped that participants would feel more comfortable and in control of the interview process when it was conducted by someone they had met personally. The interviewer was also able to be more responsive to participants than other methods might allow. For example, by using follow up questions to pursue potentially relevant topics that arose during interviews, or responding to any indications that the participant was experiencing psychological distress. Additionally, unlike some alternative methods, semi-structured interviews do not rely on participants' ability to write down their responses or have access to information technology. Data gathered using semi-structured interviews are also compatible with the epistemological assumptions of thematic analysis (Braun & Clarke, 2006; Frith & Glesson, 2012), the method of data analysis used in this study.

### *2.5.3 Service user researcher involvement*

To mitigate any potential bias created by the fact that the PhD student delivered the MOL sessions as part of the RCT, it was decided that a different researcher would conduct the semi-structured interviews for the qualitative study. It was thought that participants might feel less inhibited about offering their perspectives on the experience of receiving MOL if the interview was conducted by another researcher.

There were several reasons for employing a service user researcher to take on this role. Recent policy guidelines recommend that researchers and the public work together to co-produce research (National Institute for Health Research (NIHR),

2015). The use of co-production creates a context where power is shared more equally between researchers and the public, and the research process is informed by a broader range of perspectives and skills (INVOLVE, 2018). There is also evidence that the use of service user researchers can overcome perceived inequalities in the interviewer-interviewee relationship, which might otherwise inhibit participants from discussing their experiences openly (McLaughlin, 2006). Heather Peel, a service user researcher with lived experience of using mental health services, was employed in this role.

#### *2.5.4 Thematic analysis*

As discussed earlier in this chapter, thematic analysis is one of many approaches to analysing qualitative data that are available. One reason for selecting thematic analysis for this study was the fact that it is well-suited to analysing the large amounts of data that are produced when conducting semi-structured interviews (Braun & Clarke, 2006).

The level at which data were coded was another reason for using thematic analysis. Since the aim of this study was to understand participants' experiences of receiving MOL, a semantic rather than latent approach to coding was used (Braun & Clarke, 2006). Semantic codes are derived directly from a literal reading of the data, whereas latent codes are based on researchers' interpretations of what might be underpinning participants' accounts (Braun & Clarke, 2006). Although researchers using semantic coding are still required to interpret rather than simply describe their data, they are not seeking to speculate about hidden meanings or assumptions that might lie beneath what a participant has said. The use of semantic coding in this study was a means of maintaining the primacy of participants' perspectives – as

opposed to using an approach that went beyond participant accounts by adding additional layers of researcher interpretation. For this reason, thematic analysis was chosen over alternative approaches that rely on a greater degree of interpretation. Interpretative phenomenological analysis (IPA), for example, was not used because it relies on the use of a *double hermeneutic*, whereby the researcher attempts to “decode” participants’ attempts to make sense of their world (Pietkiewicz & Smith, 2014). Additionally, the intention was to gather a relatively broad cross-section of perspectives on the topic of interest, which meant that this study used a larger sample size than is typically found in IPA studies (Pietkiewicz & Smith, 2014).

Another strength of thematic analysis in the context of this study is its applicability to studies that use either inductive or deductive coding, or to studies that use some combination of both (Braun & Clarke, 2006). This study began by using inductive coding to develop a codebook, but then shifted to a deductive approach once the codebook had been developed. The flexibility of thematic analysis and its applicability to studies where both inductive and deductive coding were used was another reason for choosing the approach. A full account of the approach to coding can be found in Chapter 6.

Thematic analysis was also thought to be an appropriate method of analysis given the study’s sampling strategy. At the outset, the intention was to interview as many participants with experience of receiving MOL in the RCT as possible. This sampling strategy would have been inconsistent with qualitative approaches such as grounded theory (Glaser & Strauss, 1967) and its use of theoretical sampling (Draucker, Martsof, Ratchween, & Rusk, 2007), where researchers decide who to collect data from next based on the evolving grounded theory. For the present study, however, a pre-determined sampling strategy was used. In total, there were 14



participants who had received MOL as part of the RCT, and the intention was to interview as many of these people as possible. This approach to sampling is acceptable in thematic analysis (Braun & Clarke, 2006).

On a related point, unlike many qualitative studies, the concept of *saturation* was not used to determine when sufficient data had been collected (Saunders et al., 2018). There were a finite number of potential participants available. This meant that the decision to stop interviewing was reached when no further participants were willing to take part in the study. This approach was consistent with the study's aim of collecting a broad range of perspectives on the topic.

#### *2.5.5 Qualitative study roles and responsibilities*

This study was designed by the PhD student under the guidance of the supervisory team. Participants had previously been recruited for the RCT of MOL by the PhD student, and they had been informed at enrolment that they would also be invited to participate in a qualitative study. The PhD student made initial contact with potential participants to establish whether they would like to take part in this study. Assuming verbal consent was given at this point, the service user researcher contacted participants by telephone to arrange an interview appointment.

In collaboration with the supervisory team, the PhD student designed a training package for the service user researcher to ensure she had the knowledge and skills necessary for her role. This included specific training on qualitative methods, conducting interviews, managing participant distress, and risk management. Training took the form of taught sessions, provision of relevant literature, and use of role plays. The PhD student also arranged for the service user researcher to meet with the wider research team to discuss her role. An additional training session was arranged

with Dr Rory Byrne, an experienced service user researcher with expertise in psychosis research. The PhD student provided ongoing supervision on a weekly or fortnightly basis for the duration of the time the service user researcher was in her role. This provided an opportunity to problem solve any recruitment issues that had arisen, give feedback on audio recordings of interviews, and practice specific skills relevant to the service user researcher's role. These supervision meetings were also an opportunity to discuss possible refinements to the topic guide.

The service user researcher contributed to the development of a codebook that was used to analyse the data collected in this study. A detailed account of how the codebook was developed, and the service user researcher's role in this, is available in Chapter 6. The PhD student transcribed the majority ( $n = 10$ ) of interviews, with a minority of transcribing being carried out by the service user researcher ( $n = 2$ ). The final analysis of the interviews, which used the codebook developed for this purpose, was performed by the PhD student. The PhD student met with all members of the supervisory team over the course of the study to discuss ongoing progress, to reflect on preliminary themes identified in the data, and to promote reflexivity. The PhD student wrote the first draft of the manuscript and then revised this based on feedback from the supervisory team and the service user researcher.

## **Summary**

This chapter has provided a detailed account of key decisions taken across the course of the thesis, given a broad rationale for using a mixed methods approach to answering the research questions of the thesis, and justified the use of the chosen methods over possible alternatives. It has also outlined the relative contributions of

the PhD student, the supervisory team, and others who collaborated on the three studies that comprise the thesis.

**CHAPTER 3: Sources of distress in first-episode psychosis: A systematic review  
and qualitative metasynthesis**

## **PREFACE**

This paper was published in *Qualitative Health Research* (Griffiths, Mansell, Edge, & Tai, 2018) and has been formatted in accordance with the manuscript requirements for that journal. The authors are Robert Griffiths, Dr Warren Mansell, Dr Dawn Edge and Dr Sara J. Tai. The PhD student designed the research, developed the study protocol, conducted the literature searches, coded the data, and conducted the data analysis under the supervision of Dr Sara Tai, Dr Warren Mansell, and Dr Dawn Edge. All authors contributed to measures designed to increase the credibility of the metasynthesis. The PhD student wrote the first draft of the manuscript and all authors contributed to and approved the final manuscript.

### **3.1 Abstract**

In this study, we aim to increase our understanding of the self-reported sources of distress amongst people who have experienced first-episode psychosis. Following a systematic literature search, 33 relevant studies containing first-person accounts of first-episode psychosis were identified, which were synthesised using thematic analysis. Two interrelated superordinate themes were identified: intrapersonal distress and interpersonal distress. Participants reported multiple, diverse, and multifaceted sources of distress across both themes. These were substantially different from those routinely recognised and targeted in clinical practice. This review suggests that practitioners who maintain a stance of genuine curiosity about the potential sources of distress for this population will be perceived as more helpful. The findings also highlight the importance of being service user-led when planning and delivering mental healthcare. Additional clinical and research implications are discussed.

### 3.2 Introduction

Despite significant developments in our theoretical understanding of distress specific to psychotic symptoms (e.g. Garety, Kuipers, Fowler, Freeman, & Bebbington, 2001; Morrison, 2001) less attention has been paid to other sources of distress for people who experience psychosis (Andrade et al., 2016; Vracotas et al., 2007). Increased knowledge about this subject would support the development of interventions designed to reduce psychological distress, encourage clinicians to take a wider view on service users' difficulties and promote the delivery of care tailored to meet individual needs. Because the early phase of psychosis is recognised as a distinct period (Reading & Birchwood, 2005), and specialised Early Intervention in Psychosis (EIP) services have been established to meet the needs of this population, this review will focus specifically on sources of distress in people who have experienced a first-episode of psychosis (FEP).

Although the term 'psychological distress' is frequently used within a healthcare context, the concept has been defined in a variety of ways and is often used interchangeably with other related concepts, such as 'stress' or 'strain' (Ridner, 2004). The concept of distress has also been used for diagnostic purposes as a marker of underlying mental health problems, or defined as a symptom in itself (Phillips, 2009). One of the most widely cited definitions of psychological distress comes from Ridner (2004), who argues that there are five critical attributes which distinguish it from other similar concepts: (1) perceived inability to cope effectively, (2) change in emotional status, (3) discomfort, (4) communication of discomfort, and (5) harm (either permanent or temporary). Ridner (2004) states that the presence of a number of these attributes would suggest an individual is experiencing psychological distress. From this perspective, distress is not seen as a symptom of pathology or as the

absence of well-being. Instead it is better understood as an individual's subjective response to a discomforting problem that they do not feel able to adequately resolve.

The assumption that the experience of psychosis is inherently distressing has informed approaches to research and treatment. This assumption is evident in the choice of psychotic symptom reduction as the primary outcome measure for the majority of randomized controlled trials of cognitive behavioural therapy (CBT) for psychosis (Greenwood et al., 2010). Given the increased risk of suicide, reduced social functioning and relatively poor clinical outcomes associated with experiencing psychosis (Díaz-Caneja et al., 2015), the assumption that psychosis is inherently distressing might appear reasonable. However, to date, there has been little research exploring distress for people experiencing psychosis from a first person perspective (Andrade et al., 2016; Vracotas et al., 2007), despite arguments for prioritising the development of interventions that focus less on symptom reduction and more on reducing psychological distress (Chadwick, 2006; Greenwood et al., 2010)

Findings from epidemiological studies showing that psychotic-like experiences are present in non-clinical populations (e.g. Hanssen, Bak, Bijl, Vollebergh, & van Os, 2005) represent a challenge to the conventional medical model of psychosis, where experiences such as hearing voices or holding unusual beliefs are viewed as indicators of underlying psychopathology (Read, Bentall, & Fosse, 2015). Instead, psychotic experiences are now believed to exist on a continuum with 'normal' human experiences (Van Os, Hanssen, Bijl, & Ravelli, 2000). This has led to developments in the treatment of psychosis. Rather than focusing on treating syndromes, many psychological interventions focused instead on reducing the symptoms of psychosis and, more recently, on reducing psychological distress (Chadwick, 2006). Given that reducing psychological distress



is the stated aim of many current interventions for psychosis, an exploration of what causes this population distress is justified.

Research suggests that people diagnosed with psychosis frequently experience a range of other mental health difficulties and related co-morbidities. These include anxiety (Braga, Reynolds, & Siris, 2013), substance misuse (Duke, Pantelis, McPhillips, & Barnes, 2001), and depression (Upthegrove et al., 2010). There is also evidence that individuals experiencing FEP rate other problems – such as depression, low self-esteem and anxiety – as more distressing than positive or negative symptoms of psychosis (Vracotas et al., 2007). Additionally, service users have concerns and priorities that do not necessarily fit with the primary aims of many mental health services. For example, when asked what the concept of ‘recovery’ meant to them, participants with psychosis emphasised achieving an acceptable quality of life, feeling better about themselves, and regaining control over their lives as more important than symptom reduction (Law & Morrison, 2014). Although mental health services often recognise that service users have priorities in addition to symptom reduction, these findings support the view that a greater understanding of the distress connected to wider difficulties is required.

There is now a growing body of qualitative research that explores the lived experience of FEP. These studies give an insight into topics as diverse as adjustment after FEP (Tan et al., 2014), cannabis use (Childs et al., 2011), and pathways to care (Ferrari et al., 2015). Within these qualitative studies, there exist first-hand accounts of distress from people who have experienced psychosis. In addition to details of what is distressing about psychotic symptoms, these accounts also highlight distress occurring across the broader domains of people’s lives.

To date, these qualitative accounts have not been synthesised to answer the question of what people who have experienced FEP say causes them distress. Answering this question will give clinicians, researchers and service providers a deeper understanding of what this population actually find distressing, which would help guide clinical practice and could potentially contribute to the development of interventions that directly target these factors. This knowledge could also inform future research priorities; for example, by providing a clearer understanding of the most important treatment outcomes for this group, adding to existing knowledge in this area (e.g. Byrne et al. 2010).

Previously reported studies (e.g. Firth, Carney, Jerome, et al., 2016; Hon, 2012; Yung & McGorry, 1996) do not directly investigate sources of psychological distress in FEP. This means that participants in these studies were unlikely to have been explicitly asked “What do you find distressing?” Despite this, many participants in these studies spontaneously described distressing experiences, even when this was not the primary focus of the research.

The recognition that the early phase of psychosis represents a distinct and critical period (Reading & Birchwood, 2005) has led to the development of specialist EIP services designed to reduce treatment delay and increase access to evidence-based interventions (Bird et al., 2010; Marshall & Rathbone, 2011). This review will focus exclusively on studies with participants experiencing FEP, rather than psychosis more broadly. The focus on a clearly defined population aims to make the review findings directly applicable to the care received by individuals experiencing FEP using EIP services.

Our review has been influenced by a theory of human behaviour called Perceptual Control Theory (PCT; Powers, 2005). PCT proposes that the survival of all living organisms is dependent on their ability to control important perceptual variables. Humans are able to control a wide range of perceptual variables, from relatively simple perceptions (e.g. temperature) to those that are more complex and abstract in nature (e.g. sense of identity). Control is achieved by comparing the current state of a perceptual variable to reference values specifying the desired state of that variable. Human behaviour serves the function of reducing discrepancies between the perceived and desired state of perceptual variables, while counteracting the effects of environmental disturbances that would otherwise disrupt control. From a PCT perspective, psychological distress arises from a sustained inability to maintain effective control over important perceptual variables.

### *3.2.1 Review question*

The aim of this review is to answer the following question: what are the self-reported sources of distress for people who have experienced a first-episode of psychosis?

## **3.3 Method**

To answer the review question, we completed a metasynthesis of relevant qualitative literature. The term metasynthesis refers to a range of methods for synthesising findings from qualitative studies on the same research topic (Barnett-Page & Thomas, 2009; Korhonen et al., 2013). Metasynthesis can be used with a variety of aims, including as a method of understanding health issues from the perspective of people experiencing them (Thomas & Harden, 2008).

### *3.3.1 Eligibility criteria*

Articles that met the following inclusion criteria were included: (1) qualitative research; (2) published in English language peer reviewed journal and relating to human participants; (3) contains first-person accounts of distress reported by individual who have experienced psychosis; and (4) participants are reported to have experienced FEP or are using EIP services.

Articles that met the following criteria were excluded: (1) quantitative and mixed methods research; (2) contains only theoretical or observational data; (3) research into experiences of organic psychosis (for example, dementia); and (4) case studies or single case designs.

### *3.3.2 Search strategy*

The review protocol was registered with the PROSPERO International prospective register of systematic reviews (<http://www.crd.york.ac.uk/prospero>) prior to screening studies for inclusion.

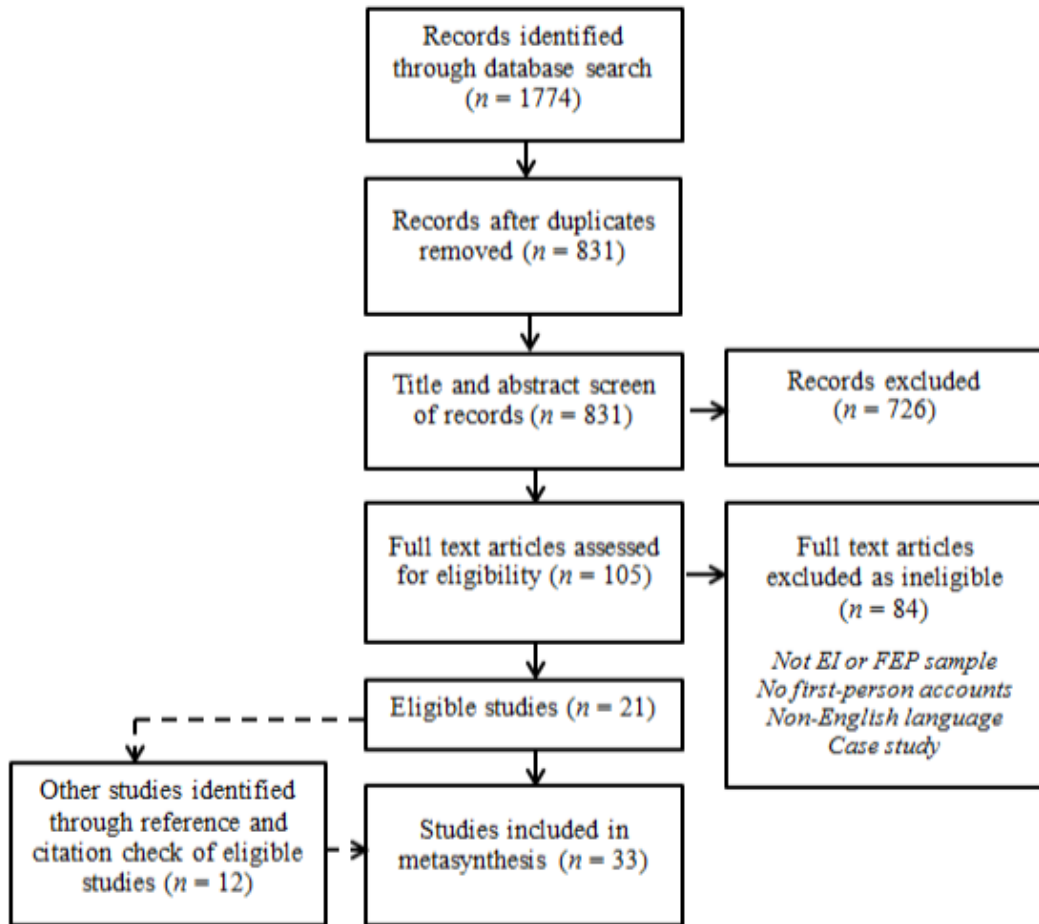
A search of peer reviewed journals was undertaken in line with PRISMA guidelines (Moher et al., 2009) using the following electronic databases:

Your Journals@OVID; PsycARTICLES Full Text; All EBM Reviews – Cochrane DSR, ACP Journal Club, DARE, CCTR, CMR, HTA, and NHSEED; AMED (Allied and Complementary Medicine); CAB Abstracts; Embase; Global Health, Health and Psychosocial Instruments; HMIC – Health and Management Consortium; Ovid MEDLINE; PsycINFO.

The SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) framework (Alison Cooke, Smith, & Booth, 2012) was used to develop an

appropriate research question and generate search terms. MeSH (Medical Subject Headings) terms were also used to help generate the list of search terms. Three categories of search terms were used: 'Psychosis', 'Service user', and 'Qualitative research'. 'Psychosis' and 'Qualitative research' search terms were limited to journal titles; 'Service user' search terms were expanded to include keywords within journals. Appendix F contains a full list of search terms. To increase the chances of capturing relevant data, journals published at any time were included in the review.

The search was conducted in four stages. Firstly, electronic databases were searched using the three categories of search terms. Secondly, after removing duplicates, titles and abstracts returned by the search were entered into Mendeley Desktop (version 1.16.1). Titles and abstracts were screened against the inclusion and exclusion criteria and clearly ineligible studies were excluded. Thirdly, the full texts of the remaining articles were screened for eligibility. Fourthly, a further search of reference and citation lists from eligible studies was conducted. Where there was uncertainty about eligibility, this was discussed by members of the research team to achieve consensus. A study identification flow chart is presented in Figure 1.



**Figure 1** Study identification flow chart

The most suitable methods for establishing reliability in qualitative research are a matter of debate (Syed & Nelson, 2015), with some authors questioning whether it is ever appropriate to apply concepts such as reliability to qualitative research (Noble & Smith, 2015). However, we took the view that some measure of reliability would help to increase the trustworthiness of the review findings. Therefore, a sample of 20% ( $n = 20$ ) of full text articles selected at random were subjected to a second screen by the second and fourth authors. Outcomes of this eligibility screen were compared to the initial screen by the first author. An interrater

reliability analysis was conducted using the Fleiss's Kappa (Fleiss, Joseph, 1971) statistic to determine consistency between raters. The interrater reliability for the raters was found to be  $Kappa = 0.86$  ( $p < 0.05$ ), 95% CI (0.599, 1). Although there is no universally accepted approach to the interpretation of Kappa, as a benchmark, scores over 0.81 are proposed to represent almost perfect agreement (Landis & Koch, 1977).

The primary research topic of the articles being screened was not psychological distress, and participants were unlikely to have been asked directly about this subject. To achieve a balance between being overly-interpretative and reviewing the articles in a superficial manner, a clear operational definition of distress was required to guide decisions about inclusion and exclusion. However, there is currently no single accepted definition of distress, and those that do exist have generally been developed to guide health professionals in clinical practice (e.g. Ridner, 2004), rather than for the purposes of identifying distress in qualitative literature. To resolve this, we developed a working definition of psychological distress based on the existing literature. Articles were included if they contained data that met the following definition: the experience appears to be deemed problematic by the participant, and it can be inferred that the participant wants to change the experience in some way.

This definition was also informed by a theory of human behaviour called Perceptual Control Theory (PCT), which proposes that distress is a consequence of sustained discrepancies between individuals' current perceptions and how they would like to experience the world (Powers, 2005).

### *3.3.3 Quality appraisal*

Whether qualitative research should be subjected to a quality appraisal and how this should be conducted is a matter of debate (Walsh & Downe, 2005). The current review aimed to include as many potential studies as possible and there was no plan to exclude studies on the basis of quality. Consequently, no systematic quality appraisal was undertaken.

### *3.3.4 Data extraction*

Eligible full text articles were uploaded to NVivo qualitative data analysis software (QSR International Pty Ltd. Version 11, 2015). The following study details were extracted using a standardised form: author(s), study title, date of study, methodological details, sample characteristics and identified themes. Appendix G contains a summary of study details.

### *3.3.5 Theoretical assumptions of included studies*

Although some authors have argued that synthesising studies that employ different qualitative approaches can be problematic (Sandelowski, Docherty, & Emden, 1997), Yardley & Bishop (2007; 2015) propose that an approach defined by pragmatism is a legitimate means of combining research produced using different methods. From this perspective, while epistemological differences need to be acknowledged when combining research, one should "...ask not whether the knowledge produced by research accurately represents 'reality' but whether it has valuable external consequences in the context of the researcher's own time and place" (Bishop, 2015, p.7). This pragmatic approach was used here to maximise the number of studies that could be included in the synthesis and avoid missing



potentially important data. Methodological differences between studies were extracted alongside other data and taken into account when conducting the synthesis.

### *3.3.6 Data analysis*

Originally developed to analyse primary qualitative data, thematic analysis has subsequently been identified as an appropriate method for synthesising qualitative data (Thomas & Harden, 2008). This analysis was based on the recommendations for thematic analysis outlined by Braun & Clarke (2006). In addition to the six steps outlined by Braun & Clarke (2006), we drew on other established methods for synthesising qualitative research to ensure that themes were sufficiently abstract to capture all of our data while, at the same time, remaining anchored in participants' first-person accounts. Specifically, drawing on meta-ethnographic approaches (Bennion, Shaw, & Gibson, 2012; Malpass et al., 2009), two additional steps were included to develop first, second, and third order constructs (see below for details). NVivo was used to organise data and conduct the analysis.

The first author began by familiarising himself with the data through repeated, 'active' reading of the full text articles, before generating initial codes for data which appeared interesting or relevant within the texts. Data were coded line-by-line. An inclusive approach to coding was taken at this stage. Some data were coded multiple times if more than one code appeared relevant. Data were coded when they met the study's operational definition of psychological distress.

The purpose of this metasynthesis was to generate new insights into distress experienced by individuals with FEP. This required the synthesist to add an additional layer of interpretation to 'go beyond' the interpretations made by the original study authors (Malpass et al., 2009; Thomas & Harden, 2008). To reflect

this, data were coded as either ‘first order constructs’ or ‘second order constructs’.

First order constructs captured participants’ views, experiences and perspectives. The review was primarily aimed at capturing these first-person perspectives. Second order constructs represented the original study authors’ interpretations of participants’ experiences. They were used to contextualise first-person accounts and inform the development of themes. Once all data were coded, first and second order constructs were analysed to develop a collection of possible ‘third order constructs’ to represent the interpretations of the authors of this review. Third order constructs were treated as candidate themes for the metasynthesis. Table 1 presents definitions of first, second and third order constructs.

**Table 1** Definitions of First, Second and Third Order Constructs

<b>Construct level</b>	<b>Definition</b>
<b>First order constructs</b>	Views, experiences, and first-person perspectives of study participants
<b>Second order constructs</b>	Interpretations of participants’ experiences made by the original authors of the articles included in this review. Used to contextualise first-person accounts and inform theme development
<b>Third order constructs</b>	Interpretations of the authors of this review. Treated as candidate themes for the metasynthesis

Once identified, candidate themes were reviewed and revised at two levels. Firstly, at the level of the individual codes to check that they made sense in relation to the candidate theme to which they belonged. Secondly, candidate themes were reviewed to check consistency with the data set as a whole. Themes were judged using Patton's (1990) dual criteria of internal homogeneity and external

heterogeneity. This process ensured that codes coalesced around a theme coherently, while ensuring that themes remained sufficiently distinct from each other.

Themes were refined further, named, and a brief description was produced to capture the essence of individual themes. Themes were then organised into superordinate- and sub-themes to provide a coherent structure. Finally, a report was produced to ‘tell the story’ of the data, making extensive use of extracts from the source texts to illustrate the narrative. Findings are reported in line with Enhancing transparency in reporting the synthesis of qualitative research (ENTREQ) guidelines (Tong, Flemming, Mcinnes, Oliver, & Craig, 2012).

### *3.3.7 Credibility of the metasynthesis*

All authors met regularly throughout the course of conducting the research to discuss the progress of the synthesis and themes emerging from the data. Using NVivo, reflective memos were kept by the first author throughout the process of completing the synthesis (Shenton, 2004). The memos helped him to reflect on the values and assumptions he brought to the synthesis and informed discussions with the other study authors.

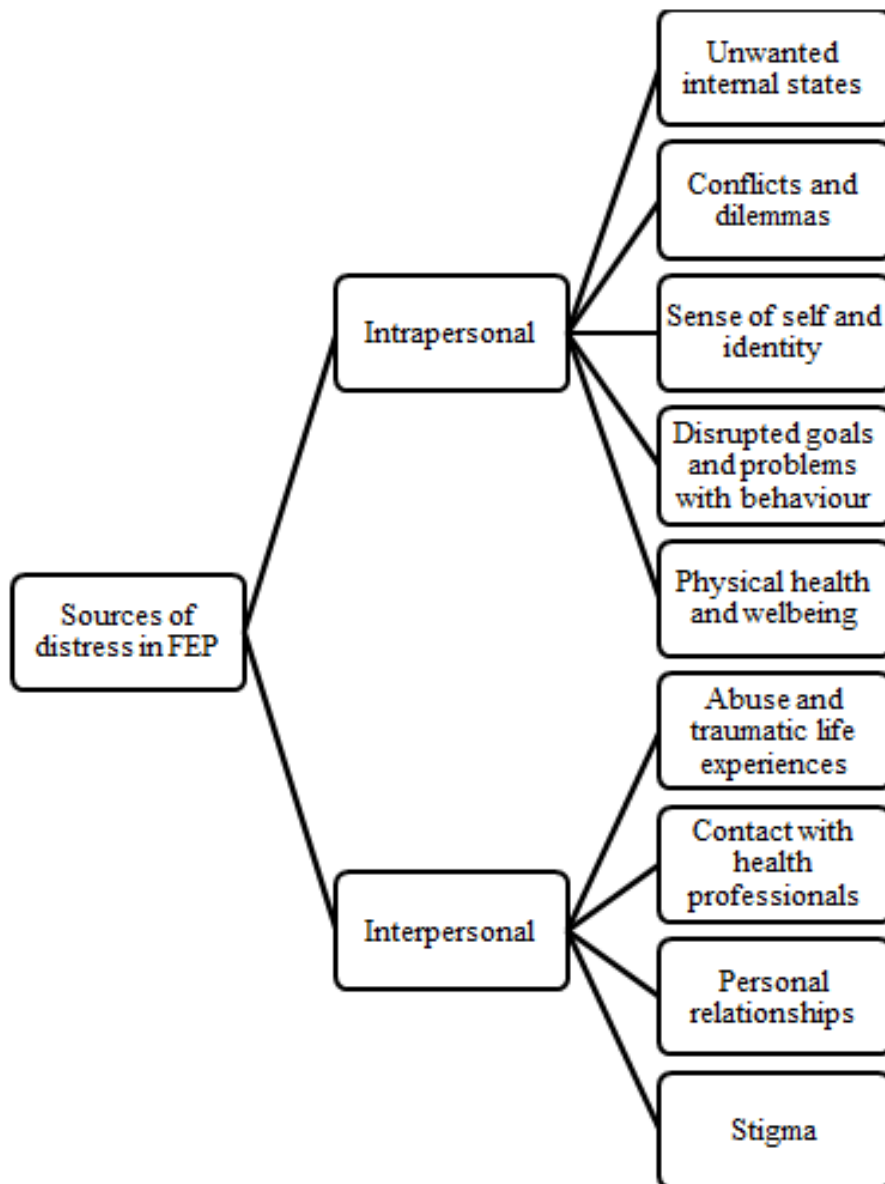
To provide a measure of the validity of the analysis, the third and fourth authors independently reviewed a sample of 22 codes. They matched each code to the sub-theme with which they thought it was most strongly associated. Their choices were checked against the original coding decisions made by the first author to see how closely these corresponded. The Fleiss’s Kappa (Fleiss 1971) statistic was used to establish interrater reliability between the three raters. This was found to be Kappa = 1 ( $p < 0.05$ ), 95% CI (0.921, 1), representing almost perfect agreement (Landis & Koch, 1977).

### 3.3.8 Reflexivity statement

The first author has a background in mental health nursing and has worked as a psychological therapist in EIP services for several years. He is currently completing a PhD in Clinical Psychology evaluating a transdiagnostic cognitive therapy called the Method of Levels (MOL) for people experiencing FEP. MOL directly applies the principles of Perceptual Control Theory (PCT; see Powers, 2005) to the practice of psychotherapy. The second and fourth authors are researchers and clinical psychologists. Their research has mainly focused on PCT and the development of MOL. The third author is a senior lecturer in psychology and mental health. Her current research focuses on the development of culturally appropriate psychological interventions for psychosis. The authors' views on the causes of psychological distress have been influenced by PCT, a central tenet of which is that all human experiences are a product of our perceptions. This does not mean that an independent 'reality' does not exist outside of our subjective experience. However, we can only know this reality through our perceptions. As such, our epistemological position is most closely aligned to a 'critical realist' perspective (Fletcher, 2017).

### 3.4 Results

After screening, 33 studies were found to meet the criteria for inclusion in the metasynthesis. Studies were conducted between 1996 and 2016, in eight different countries, using a range of qualitative methodologies. A summary of study details can be found in Appendix G. Two distinct but interrelated superordinate themes were identified: *intrapersonal distress* and *interpersonal distress*. Both superordinate themes comprised several sub-themes. A thematic map is presented in Figure 2.



**Figure 2** Map of themes and sub-themes

### 3.4.1 *Intrapersonal distress*

This theme relates to sources of distress that arise from participants' internal experiences. The theme is comprised of five sub-themes: (1) unwanted internal

states, (2) conflicts and dilemmas, (3) sense of self and identity, (4) disrupted goals and problems with behaviour, and (5) physical health and wellbeing.

*Unwanted internal states.* This sub-theme includes a wide range of internal experiences (including cognitions, affect, perceptions, memories and bodily sensations) that were reported as sources of distress for individuals. In some cases, distress was related to symptoms of psychosis, as illustrated in this quote where a participant describes a distressing incident of voice hearing:

I kept it [the voices] to myself until... Well there was an incident and I was locked up in a cell by the Police and when I was in the cells that's when the voices like... It was like an explosion in my head and then the voices just took over completely...I was in the cell for two and a half hours just listening to these voices going over and over in my head. (Milligan, McCarthy-Jones, Winthrop, & Dudley, 2013, p. 112)

Other participants identified distress primarily connected to symptoms that were non-psychotic in nature, such as problems with anxiety and depression. In response to unusual auditory and visual experiences, this participant commented:

I used to be nervous and panicky before. Now I am not looking out for this person that I used to see and I don't hear him whisper any more. I've got more confidence in myself because the voices that I heard were putting me down and making me feel down. (Hon 2012, p. 357)

Although feeling 'nervous', 'panicky', and 'down' are attributed to experiencing symptoms of psychosis, the participant appears to be describing these emotional responses as distinct sources of distress in themselves.

This sub-theme also captures participants' meta-cognitive statements indicating some dissatisfaction with their internal experiences. In this quote, a participant comments on problems with thinking clearly prior to receiving support for first-episode psychosis:

I know when I first went into it [psychosis] my thoughts were really jumbled... I couldn't see a solution to it. (Ashcroft et al. 2012, p. 332)

In addition to the internal states themselves, distress also arose out of the struggle to comprehend these states. This participant describes feeling distressed by experiencing visual hallucinations that were difficult to make sense of:

...I didn't understand what was happening to me, I didn't understand what I was seeing. (Tan et al., 2014, p. 87)

A recurrent theme of participants' accounts was distress connected to experiencing internal states perceived as uncontrollable, as this quote illustrates:

I feel like I can't control my thoughts or I can't control what thoughts enter in. (Connell, Schweitzer, & King, 2015, p. 79)

In this quote, a participant describes how his psychotic symptoms felt out of control, leading to the development of other mental health problems:

I get paranoid and the voices contribute to the paranoia and the paranoia will get out of control and that's when the depression will set in from the paranoia. (Milligan et al., 2013, p. 111)

People experiencing FEP frequently report distress connected to internal states. Often, these states could be described as 'symptoms' of psychosis (e.g.

disorganised thinking, persecutory beliefs, or hallucinations) or common mental health problems (e.g. anxiety or depression). However, sometimes it is the perceived uncontrollability or incomprehensibility of the state that leads to distress, rather than the state itself.

*Conflicts and dilemmas.* Participants described a range of conflicts and dilemmas that appeared to be a source of distress. The most frequent conflicts were related to substance use (Asmal, Mall, Emsley, Chiliza, & Swartz, 2014; Childs et al., 2011; Esterberg & Compton, 2005). This participant describes the struggle to stop using cannabis:

I got like my friends who like and I introduced them to it, and erm, bit of a vicious circle like I give up they carry on, I carry on they give up and, er, then I moved up here and then found like my experience was like the same thing and, er, it was just like smoking weed and the whole drug culture was around. (Childs et al. 2011, p. 706)

In this quote, the participant is struggling to make sense of why he continues to smoke cannabis when it causes him to feel physically unwell:

...why am I having that spliff if I'm going to be sick? (Childs et al. 2011, p. 706)

As well as using substances, dilemmas regarding personal relationships (Jansen et al., 2016), seeking support or treatment (Connell et al., 2015; Tanskanen et al., 2011), and disclosing details about mental health difficulties (Connell, Schweitzer, & King, 2014) were described. For example, in this quote, the participant's dilemma about taking medication appears to be a source of distress:



I get depressed that I'm on an antipsychotic. But without it, would I be able to control myself? (Esterberg & Compton 2005, p. 79)

Irrespective of the exact nature of participants' dilemmas, the state of being in conflict appeared to be a source of distress in itself.

*Sense of self and identity.* Distress related to participants' sense of self or personal identity was described in several studies. Participants' distress was frequently related to the fact that they saw themselves as having lost some aspect of their self or that personal experiences had altered their sense of self in an undesirable way. One participant stated:

I just wanted to be back to myself. (Connell et al. 2015, p. 82)

Another reported:

I don't even understand how I got like this. This isn't me, where's me gone?  
(Tan et al. 2014, p. 87)

Participants described a sense of frustration that they were unable to engage in the same activities as their 'old self' (Connell et al., 2014, 2015), as illustrated by this quote:

I want more than anything to get back to how I was, but I don't know that I can. I just miss, like how I was and like now, I feel like I'm completely different. (Connell et al. 2015, p. 80)

An altered or undesirable sense of self was seen as a barrier to engaging in valued social, vocational, and recreational activities. Although this sub-theme is a component of the intrapersonal distress superordinate theme, there is clearly a social

dimension to distress caused by a lost or altered sense of self. Not having a satisfactory sense of self is distressing, at least in part, because of its potential impact on participants' interpersonal relationships. The impact of experiencing FEP and its treatment was reported to be particularly problematic in adolescence and early adulthood because it was seen as a serious threat to the development of a satisfactory sense of self (Fenton et al., 2014).

Participants appeared to compare their current experience with a remembered or imagined sense of self that was seen as more desirable or acceptable. It seems likely that this sub-theme captures distress arising from disparities between participants' perceived and desired sense of self, as this quote illustrates:

I don't like to think of myself as someone with a mental illness. I don't think anybody does. Because that makes you feel vulnerable, a person who has to be cared for, and I like to be an independent kind of guy. (Judge, Estroff, Perkins, & Penn, 2008, p.98)

*Disrupted goals and problems with behaviour.* Participants described distress connected to a perceived inability to work towards valued goals and aspects of their own behaviour. The core feature of this sub-theme is a disparity between how the participant wants to act and their actual behaviour. For example, this participant describes how experiencing psychosis impaired his ability to work towards important personal goals:

...it takes over, it's like a stuck record that you keep going over and over again, you're not achieving anything, and it's just meaning that you're not just getting on with your day and being overwhelmed with your problem. (Ashcroft et al. 2012, p. 332)

Another participant described the impact of psychosis on her relationship with her family and work:

I became very withdrawn and remained indoor[s]... I was not communicating with my family much and stopped working. (Hon 2012, p. 358)

Being unable to pursue a personal goal of working was clearly a source of distress for this participant:

If you don't work, staying at home, it just drives you insane. (Perry, Taylor, & Shaw, 2007, p. 788)

Some participants were distressed by activities they were unable to engage in as much as they would like. For example, participants in this study described the impact of cannabis use on their levels of motivation:

Jed talked of "becoming part of the sofa". Zac described how it "takes away all your drive and ambition and just zaps you of all energy and focus and you just, you, you, start to not care about things and you know, put off things for another day and let it slip". (Childs et al. 2011, p. 705)

Other participants expressed dissatisfaction with behaviours they engaged in to an extent that, from their own perspective, were excessive. For example, this participant describes how their level of drug use became problematic:

...there was a lot of pressure to excel in school and succeed. I dabbled too much in, dabbled too much in drugs, that was my problem... that was really my fault. I have no one else to blame but myself... (Ferrari et al. 2015, p. 6)

The participant in the above quote also seems to hold himself accountable for the development of his problems. Although not sufficiently prevalent to constitute a sub-theme in its own right, elements of self-criticism and self-blame were present in several participants' accounts.

*Physical health and wellbeing.* This sub-theme describes participants' distress connected to their physical health and wellbeing. Participants described problems with their general physical health, as this quote illustrates:

I told him [GP] that I was having burning feelings and something was wrong with my heart and that when that happened I was like "huh, huh", I couldn't breathe at all. I was really messed up and she thought I had asthma or something and they gave me some asthma pumps. I tried it but it didn't really help I just had to wait for it to wear off. It took a long time and I was really messed up. (Tanskanen et al. 2011, p. 7)

In addition to problems with general physical health, difficulties with sleep and appetite were reported in several studies:

I was always tired . . . I also had some problems with my digestion. I was hungry all the time. I didn't get any satisfaction from anything. I would get a stomach upset every time. [Food] would just give me some stomach aches and bloating and whatever. (Yung & McGorry 1996, p. 593)

Participants described a range of other physical health problems that were also a source of distress, such as stiffness of limbs, fatigue, and problems with coordination (Yung & McGorry, 1996). Mainly, these physical health problems were described as sources of distress because they prevented participants achieving a

desired sense of wellbeing. However, sometimes physical health problems were seen as signs that something was wrong and additional support might be required, as this quote illustrates:

In the end I got to the stage where I wasn't eating, I just made out I was eating and I just... wasn't sleeping, I just couldn't look after myself. (Tan et al., 2014, p. 89)

### 3.4.2 *Interpersonal Distress*

The second superordinate theme to emerge is comprised of four sub-themes that describe sources of distress arising from participants' perceptions of their interactions with others. These were: (1) abuse and traumatic life experiences, (2) contact with health professionals, (3) personal relationships, and (4) stigma.

*Abuse and traumatic life experiences.* Participants talked about a range of traumatic life experiences, including instances of being abused, bullied, and neglected by others. Participants often described these experiences as precipitating events for the onset of psychotic symptoms:

I was attacked when I was out with my friend by a group of... well, by a gang, and I was hit on the head with a machete, in the back of the head and I went to hospital... there was no major damage, I've got a scar and that and I went home that night and that's when I started hearing voices. (Milligan et al. 2013, p. 111)

Recalling incidents such as the one described above continued to cause participants distress long after the event. For example, some participants attributed ongoing problems with depression and suicidal thoughts to traumatic incidents, or

described engaging in substance use as a means of escaping from painful memories (Tan et al., 2014). Other participants described how they thought abusive experiences had adversely affected their development. The following participant describes how experiences of abuse led to what was perceived to be irreparable damage to their personality:

I was like abused and all that when I was younger... it's still in my mind and stuff and I know that it shattered my personality as a young kid and I've never been able to repair that. (Perry et al. 2007, p. 785)

*Contact with health professionals.* Contact with health professionals and systems were frequently cited as a source of distress for participants. Specifically, participants found it distressing when they were not treated in the way they would have liked by health professionals. The following quote gives an example where a participant's reported conversation with a health professional – a psychiatrist in this case – focused on narrow discussions about medication, limiting opportunities for the participant to discuss wider concerns:

...talking to a psychiatrist erm, it was really only talk of "are you still experiencing hallucinations, yes right we need to up your medication" and that was kind of the jist [sic] of every conversation. (Cairns et al. 2015, p. 54)

The following quote describes a situation where a general practitioner addressed questions to a family member, rather than to the participant directly. The feeling that decisions were being made without including him in the discussion created a sense of disempowerment:

He didn't even say anything, he just looked at my sister . . . and he said I'm going to send him to the clinic . . . he spoke to my sister more than he spoke to me. (Connor et al. 2016, p. 341)

This participant describes being intrusively questioned by health professionals:

Two doctors come and give you a drill and like ask you a hundred questions in five minutes. (Cadario et al. 2012, p. 99)

Participants described a range of other unhelpful responses from health professionals that increased their distress, including feeling dismissed, not having their concerns taken seriously and not being treated as an individual.

The process of receiving a psychiatric diagnosis was a source of distress for some participants. This participant describes how receiving a diagnosis elicited a range of difficult emotions and a sense of powerlessness:

Being told I had psychosis – that's been the most difficult thing. You know, to be told I was incapable of making decisions. It made me feel a bit insulted, a bit like disappointed in myself as an adult as well. (Connell et al. 2014, p. 4)

Problems with medication and associated side effects were referenced in several studies as being a source of distress for participants:

Oh it's horrible. They gave me [an anti-psychotic] first and, um, my hands, I couldn't hold anything. I'd go to pick up a cup of tea or something and I'd drop it straight away. (Cadario et al. 2012, p. 99)

Participants also described distress arising from the process of being hospitalised. One common cause of distress related to being detained involuntarily in hospital and the treatment participants received there:

I kind of felt like people might think, “oh, she’s crazy.” And not listen to me about anything because that’s how I was kind of treated at the hospital when I went to the hospital... they just ignored me and put me in restraints and stuff like that. It was a really terrible experience. I don’t like to think about it that much. (van Schalkwyk et al. 2015, p. 526)

The loss of control and restrictions experienced by participants who had been compulsorily detained were frequently described as sources of distress. In this quote, a participant describes the dehumanising effect of being detained:

I just felt like an animal, being locked up all of the time. (Perry et al., 2007, p. 786)

Being detained was particularly problematic in situations where it interfered with participants’ ability to engage in valued activities, as illustrated by the following quote:

I couldn’t even go for a walk. Do you know what I mean? People are entitled to exercise and stuff. (Perry et al. 2007, p. 786)

In some cases, participants described how the preconceived ideas they held about mental health services, prior to accessing support, were additional sources of distress that deterred them from seeking help:

I don't know if I should do this... I'm scared, I'm petrified of that place. Of going into the asylum. (Anderson et al. 2013, p. 389)



*Personal relationships.* Distress connected to personal relationships was a recurrent feature of many participant accounts. Distress was partly a consequence of feeling disconnected from family and peer networks. For this participant, their experience of FEP led to the loss of friendships:

I feel like it's [psychosis] taken my friends away from me, and I feel like I resent them in a way, because they're so happy and carefree and I'm the one with all these problems. (Connell et al. 2015, p. 80)

Participants described how fear of being negatively evaluated by others made it difficult talk about their experiences of psychosis (Lockett et al., 2012), and this increased the sense of being ostracized from their peer group (Judge et al., 2008). In addition to creating feelings of social isolation, problems communicating difficulties within personal relationships were thought to be a causal factor for delays in accessing treatment:

P5: Well I couldn't talk to her [Girlfriend].

Interviewer: You said you couldn't talk to her about it?

P5: No because you just sound... too weird. (Harris, Collinson, & Das Nair, 2012, p. 460)

This participant described disclosing experiences to their mother as the first step towards seeking help. However, from the participants' account, it seems likely that the difficulties had been present for some time beforehand:

I think I eventually told my mum what happened. I didn't want to tell anyone else, yeah, I think I eventually told them what I was feeling and stuff.

(Cadario et al. 2012, p. 86)

For some participants, symptoms of psychosis, such as persecutory beliefs, led to them withdrawing from personal relationships. This participant describes how feelings of persecution created a reluctance to socialise with others:

I was starting to get a bit more, like, enclosed, like I didn't want to like socialise with people. I felt as if everyone out there was out to get me or something like that, like I just didn't want to like, talk to anyone. I felt moody I felt as if everybody was just invading my space or I was invading theirs.  
(Tanskanen et al., 2011, p. 4)

Where participants were able to maintain personal relationships, the nature of these relationships could also be a source of distress. This participant describes how being in hospital provided some respite from a stressful family life:

Luke talked about the unit as a place of escape from "normal" life where there was "family stress" and "it was a bit manic". (Fenton et al. 2014, p. 237)

The common factor across all of these first-person accounts is that personal relationships are a source of distress when there is mismatch between how the person would like to relate to others and their actual experience. For example, being socially isolated is not a source of distress per se. It is only if this experience conflicts with other personal goals held by the individual – such as developing close relationships with others – that it becomes problematic.

*Stigma.* Accounts of distress connected to stigma were present in several studies. Distress was partly a product of participants' perceptions of societal attitudes

towards mental health problems and fears of being negatively labelled or judged as a consequence:

I was worried about what people around me might say... There is a huge stigma about mental illness; people tend to like to avoid it. (Ferrari et al. 2015, p. 5)

For some participants, the stigma connected to mental health problems was closely connected to unwanted internal experiences, such as shame, and acted as a barrier to help seeking:

Karen: People are scared to look for help, and to...

Maria: And to admit to themselves even... [Karen: Yeah!] that "I have schizophrenia"... I never told anybody.

June: I'm still ashamed of what I have.

Samantha: Me too. (Ferrari et al. 2015, p. 5)

The above quote also illustrates another feature of participants' accounts, one that has previously been described as self-stigma or internalised stigma (Corrigan, 2004; Corrigan & Watson, 2002). In other words, participants were aware of the public stigma towards people with mental health difficulties – comprising stereotypes, prejudices and patterns of discrimination – and applied this to themselves.

There was evidence that contact with mental health services was perceived as stigmatising and this acted as a further barrier to people seeking support. This participant describes his reasons for not wanting to seek help:

Yeah I didn't want word spreading . . . I just didn't want to be described as mentally ill, that's the reason why, and I said don't want to be described as mentally ill. (Connor et al., 2016. p339)

Perceived stigma also influenced participants' decisions around how much to share about their difficulties within personal relationships:

...so you're just kind of afraid of being stigmatised by other people... you just know there are prejudices about all these things; I used to be like that myself... and so in order to avoid that people were thinking badly of me, I thought I'd better put on a façade. (Jansen et al. 2015, p. 90)

In the above quote, the participant describes how awareness of the societal stigma that exists around mental health difficulties interfered with the ability to relate to other people. It also gives a sense that the person is hiding their "true" identity in order to maintain social acceptance. Taken within the context of the other sub-themes identified in this review, this gives an indication of how public stigma could impact on an individual experiencing FEP and lead to psychological distress.

### **3.5 Discussion**

This metasynthesis aimed to investigate sources of distress in individuals who have experienced FEP. To our knowledge, this is the first metasynthesis of qualitative research on this topic. The results suggest that distress arises from a wide range of factors occurring across two broad and interrelated domains of intrapersonal distress and interpersonal distress. The findings have important implications for clinicians, mental health service provision, and future research in this area.

The intrapersonal distress superordinate theme comprised five sub-themes that captured a variety of internal experiences perceived as distressing by service users. Although many service users found what are commonly described as ‘symptoms’ problematic, service users also described many other sources of intrapersonal distress. These included: problems resolving conflicts, difficulties in maintaining a satisfactory sense of identity, feeling unable to work towards valued goals, and concerns about physical health. The interpersonal distress superordinate theme comprised four sub-themes that captured distress arising out of service users’ past traumatic and abusive experiences, personal relationships, contact with health professionals, and fears of stigmatisation. The numerous and complex relationships between sub-themes suggest that sources of distress are diverse in nature. For each individual, the exact source of distress is likely to be a consequence of several factors, including the person’s history, their valued goals, and current circumstances.

The sources of distress reported in this review are consistent with much of the wider literature relating to psychosis. For example, there is existing research into topics such as psychotic symptoms (e.g. Garety et al., 2001; Morrison, 2001; Morrison & Wells, 2007), physical health (Bailey, Gerada, Lester, & Shiers, 2012; Nordentoft et al., 2013), service user concerns about medication and mental health services (Berry, Ford, Jellicoe-Jones, & Haddock, 2013, 2015), trauma (Kilcommons & Morrison, 2005; Read, Van Os, Morrison, & Ross, 2005), and stigma (Wood et al., 2014). It is striking that, in the main, there has only been indirect qualitative research into the sources of distress in FEP. Instead, research has primarily focused on psychotic symptoms, experiences of mental health services and interventions, and other specific problems encountered by people experiencing FEP. To date, these

topics appear to have been prioritised over the more fundamental question of what this population finds distressing.

We believe that Perceptual Control Theory (PCT; Powers, 2005) provides a useful explanatory framework to help us understand the results of this review. From a PCT perspective, human life depends on the ability to control perceptions in line with the reference values held for the desired state of those perceptions. This is achieved by acting on the world to counteract disturbances that would otherwise create a disparity between current and desired perceptions. Carey (2016) has proposed that control is central to defining health, arguing that “Health can be defined as the control of important biological, psychological and social variables” (p. 2).

Across both superordinate themes, it was apparent that distress occurred in situations where participants’ current perceptions did not correspond with the way they would like things to be. To take an example from the intrapersonal distress theme, the experience of hearing voices did not appear to be distressing per se. However, where voice hearing interfered with other important goals – such as being accepted by one’s peer group – people did experience distress. Similarly, in relation to the interpersonal distress theme, contact with health professionals was distressing when participants’ preferences for how they would like to be treated were not met. Examples included situations where individuals were involuntarily detained, given medication against their wishes, or excluded from discussions about treatment options. The key feature of these first-person accounts is that psychological distress is a consequence of participants having reduced or impaired control over the things that are important to them. Tai (2009; 2016) outlined how we can use a PCT

framework to understand the relationship between loss of control and distress in psychosis.

What this review adds to our understanding of individuals with FEP is evidence that sources of distress are diverse and multifaceted. No single factor alone seems to account for distress in this population. It also emphasises the role that reduced control plays in causing and maintaining distress for people experiencing FEP. This fits with the findings of other qualitative research that has identified loss of control as an important source of distress for people experiencing psychosis (e.g. Campbell & Morrison 2007; Wood et al. 2015). It is also consistent with research that suggests regaining a sense of control is an important aspect of recovery for many people who have experienced mental health problems (Ajayi et al., 2009; Leamy, Bird, Le Boutillier, Williams, & Slade, 2011). The findings of this metasynthesis suggest that more research into the relationship between psychosis, control, and distress is warranted.

Another important aspect of this review is the finding that service users describe multiple sources of distress that are often unrelated to the symptoms of psychosis or other primary disorders. In recent years, several researchers have suggested that a transdiagnostic approach to understanding psychological distress is required (Harvey, Watkins, Mansell, & Shafran, 2004; Mansell, Harvey, Watkins, & Shafran, 2008). This approach argues that there are core cognitive and behavioural processes that cause and maintain psychological distress. These processes are proposed to occur across diagnostic boundaries. The transdiagnostic approach is in contrast to the 'disorder-specific' focus that currently dominates cognitive behavioural research and practice (Harvey et al., 2004). The findings of this review

suggest an acknowledgment that distress is not limited by discrete diagnostic categories is required to understand the experience of people with FEP.

The review also indicates that service users are sensitive to signs of negative attitudes amongst clinicians. This is in keeping with existing research that shows service users perceive unhelpful staff attitudes to be a barrier to recovery (Law & Morrison, 2014). The risk of iatrogenic harm is, therefore, likely to be reduced in situations where clinicians are respectful and avoid language which could be perceived as dismissive or judgemental by service users.

Interventions are currently available to people experiencing FEP that specifically aim to target many of the sources of distress reported in this review. For example, Motivational Interviewing is designed to help people resolve ambivalence about substance use (Rollnick & Miller, 1995), family interventions aim to help improve close personal relationships (Haddock & Spaulding, 2013), and specific interventions are in development that target self-stigma (Morrison et al., 2016) and problems with physical health (Firth, Carney, Elliott, et al., 2016).

Whilst interventions that specifically target some of these sources of distress are likely to be helpful for many service users, we believe that the implications of this review are more fundamental. Our findings relate more to the basic principles underpinning mental health service delivery than they do to the issue of developing further problem-specific interventions. Essentially, we believe that service users are likely to benefit most from the support of clinicians who adopt a stance of genuine curiosity towards the exploration of problems, avoid assumptions about the nature of their difficulties, and provide opportunities to discuss a broad range of concerns. Being service user-led in terms of establishing a problem focus is also likely to be



beneficial because it allows the individual to determine what they want to work on. In addition, approaches that maximise service user control over the interventions they receive will increase the likelihood that care is personalised to meet individual needs and reduce the potential for iatrogenic harm. This is consistent with other research endorsing approaches that place service users in control of the care they receive (Carey & Spratt, 2009; Carey et al., 2013), and qualitative research suggesting that clinicians are experienced as more helpful by people with FEP when they focus on the individual's concerns (Hansen, Stige, Davidson, Moltu, & Veseth, 2018; Stewart, 2013).

This study's findings should be taken in the context of the usual limitations associated with the metasynthesis methodology. Namely, it is dependent on secondary data and combines findings from studies with different methodologies and theoretical underpinnings. Additionally, the aim of the study was to include as many relevant first-person accounts as possible and no systematic quality appraisal was undertaken. This means that some studies of low quality might have been included.

None of the source studies included in this metasynthesis directly investigated sources of distress in FEP. As a result, participants were unlikely to have been asked specifically about this subject. Also, if participants alluded to potential sources of distress, this might not have been followed up by researchers who were more focused on the phenomena under investigation. It is possible, therefore, that other sources of distress exist for this population which were not captured by this review. If this is the case, however, it does reinforce a central finding of this synthesis: that there are numerous sources of distress for people who have experienced FEP and practitioners should be mindful of this. The overall generalisability of the metasynthesis is improved by the international scope of

included studies and the fact that it draws on first person perspectives from a variety of countries. However, cultural differences and the variability of service provision for FEP between countries potentially limit the generalisability of the findings to any one country in particular.

One area of future qualitative research could be a direct investigation into sources of distress for individuals who have experienced FEP. This would resolve some of the limitations inherent in this review that were caused by the fact that it synthesised evidence from qualitative research into other topics. An area of future quantitative research arising from this could be the development of a tool that measures sources of distress and their relative impact on individuals with FEP. These findings also support the use of primary outcome measures that focus on the broadest possible sources of distress (e.g. the PSYCHLOPS; Psychological Outcome Profiles; Ashworth et al., 2004).

In conclusion, given the central role that loss of control appeared to play in causing distress, helping service users to gain more control over their lives is likely to contribute to reducing psychological distress. Further research into the development and evaluation of interventions and approaches that help service users achieve greater control over factors which are important to them is also warranted. Finally, when working with people experiencing FEP, practitioners should be mindful of overemphasising the assessment and treatment of psychotic symptoms at the expense of considering wider difficulties. Adopting a stance of genuine curiosity about potential sources of distress is likely to be experienced as more helpful by service users.

**CHAPTER 4: Method of Levels therapy for first-episode psychosis: Rationale,  
design and baseline data for the feasibility randomised controlled Next Level  
study**

## **PREFACE**

This paper was published in *BJPsych Open* (Griffiths, Mansell, Carey, et al., 2018) and has been formatted in accordance with the manuscript requirements for that journal. The authors are Robert Griffiths, Dr Warren Mansell, Professor Timothy A. Carey, Dr Dawn Edge, Professor Richard Emsley, and Dr Sara J. Tai. Under the guidance of the supervisory team, the PhD student designed the research, developed the study protocol, applied for ethical and regulatory approval, managed the trial, recruited and enrolled participants, completed baseline and follow up assessments, randomised participants, delivered the Method of Levels intervention, completed the data entry, and performed the data analysis. The PhD student wrote the first draft of the manuscript and revised the manuscript based on the suggestions of the other authors. All authors approved the final manuscript.

## **4.1 Abstract**

**Background:** Method of Levels (MOL) is an innovative transdiagnostic cognitive therapy with potential advantages over existing psychological treatments for psychosis.

**Aims:** The Next Level study is a feasibility randomised controlled trial of MOL for people experiencing first-episode psychosis. It aims to determine the suitability of MOL for further testing in a definitive trial.

**Method:** The study uses a parallel group non-blind feasibility randomised controlled trial design with two conditions: (1) treatment as usual (TAU) and (2) TAU plus MOL. Participants (N=36) were recruited from early intervention in psychosis services. Outcome measures are completed at baseline, 10 and 14 months. The primary outcomes are recruitment and retention.

**Results:** Participants' demographic and clinical characteristics are presented along with baseline data.

**Conclusions:** Next Level has recruited to target, providing evidence that it is feasible to recruit to a randomised controlled trial of MOL for first-episode psychosis.

**Trial registration:** ISRCTN13359355

## **4.2 Introduction**

### *4.2.1 Background*

People experiencing a first episode of psychosis (FEP) should have access to Early Intervention in Psychosis (EIP) services that are capable of delivering appropriate psychological interventions, including Cognitive Behavioural Therapy for psychosis (CBTp) (National Institute for Health and Care Excellence (NICE), 2014; 2016). There is relatively good evidence to support the use of CBTp, with most meta-analyses estimating effect sizes in the small to moderate range (Jauhar et al., 2014; Turner et al., 2014; Wykes et al., 2008). However, despite recommendations from NICE that everyone experiencing psychosis should be offered CBTp, levels of implementation have remained low (Berry & Haddock, 2008; Ince et al., 2015; Prytys et al., 2011). A recent audit of EIP services found that just 41% of patients had been offered CBTp and, of these, only 51% accepted the offer (Royal College of Psychiatrists et al., 2016). Additionally, evidence from qualitative studies suggests that some patients find CBTp ‘difficult to engage with’ and ‘emotionally difficult’ (Kilbride et al., 2013; Wood et al., 2015). There is also evidence that CBTp has only modest benefits over other ‘generic’ interventions for people experiencing psychosis, such as befriending and supportive counselling (Turner et al., 2014).

There are high levels of co-morbidity amongst people who experience psychosis, including problems with anxiety, depression, posttraumatic stress disorder, and substance misuse (Achim et al., 2011; Addington et al., 1998; Barrowclough et al., 2010; Braga et al., 2013; Buckley et al., 2009). This presents challenges for clinicians aiming to deliver disorder-specific interventions for

psychosis. Where patients prioritise non-psychotic difficulties, CBTp practitioners will draw on relevant, compatible approaches to inform treatment (Morrison, 2017). However, clinicians require suitable training and supervision in the application of these approaches. There is also good evidence that transdiagnostic cognitive and behavioural processes maintain psychological distress across diagnostic categories (Harvey et al., 2004; Mansell et al., 2008). Interventions that specifically target transdiagnostic processes might have advantages over disorder-specific approaches in terms of efficiency (Carey, Tai, & Stiles, 2013) and the extent to which they meet the complex needs of people who experience psychosis (Tai, 2009, 2016).

Some researchers have advocated focusing on single symptoms of psychosis (e.g. persecutory delusions) and targeting the mechanisms proposed to be maintaining them (e.g. worry, reasoning biases) (Freeman et al., 2015; Waller et al., 2013). Here we present an alternative approach to psychotherapy that targets goal conflict, a core mechanism proposed to maintain psychological distress across diagnostic categories, irrespective of the exact symptoms or problems reported by individual patients.

#### *4.2.2 Method of Levels*

The Method of Levels (MOL) is a transdiagnostic cognitive therapy that has been well described in a number of treatment manuals (Carey, Mansell, & Tai, 2015; Carey, 2006; Mansell, Carey, & Tai, 2013). MOL aims to help people shift their awareness onto the conflicted goals that are believed to be maintaining distress. Sustaining awareness on the conflict facilitates an innate learning process called reorganisation, which enables people to resolve goal conflict. An MOL therapist has two goals: (1) encourage the person to talk freely about their problems, and (2) pay

attention for ‘disruptions’ and, when they occur, ask about these. Disruptions are indications that the person’s awareness has fleetingly shifted onto potentially relevant background thoughts. Examples would include interruptions to the flow of speech, smiling or laughing, and evaluative statements (e.g. “That sounds silly”).

MOL has several potential advantages over existing psychological approaches for psychosis. These include: it is applicable to patients presenting with multiple problems simultaneously; it aims to give patients greater choice and control over the interventions they receive; treatment is tailored to meet individual patient need; it is based on clear principles derived from a robust scientific theory of human behaviour (see below for more details); it has the potential to use psychological resources more efficiently; and it aims to directly target the factor proposed to maintain psychological distress.

#### *4.2.3 Study aims*

To summarise, although CBTp is the current ‘gold standard’ psychological intervention for EIP patients, there are significant difficulties with its implementation in routine clinical practice, as well as queries about how effectively and efficiently it is meeting the psychological needs of this population. MOL is an innovative and promising psychological therapy for FEP. It has several potential advantages over existing treatments and warrants further evaluation (Tai, 2009, 2016). No previous trials of MOL for FEP have been conducted, so it is necessary to establish the feasibility of recruitment and retention before a full effectiveness trial could be justified.

This study aims to answer four research questions:



- (1) Is it feasible to recruit and retain people experiencing a first-episode of psychosis in a randomised controlled trial of Method of Levels (MOL)?
- (2) Is it feasible to deliver MOL to people experiencing FEP?
- (3) Is MOL an acceptable psychological intervention for people experiencing FEP?
- (4) Are adaptations necessary to overcome problems or barriers to the implementation of MOL in EIP services?

### **4.3 Method**

Next Level is a parallel group feasibility randomised controlled trial with two conditions: (1) treatment as usual (TAU) and (2) TAU plus MOL. As a feasibility trial, participants and their clinical team, the trial therapist, and the outcome assessor are not blinded to group allocation. If MOL appears suitable for further testing in an effectiveness trial, outcome assessors would be blind to group allocation. A trial retention rate of 80% at final follow up would be considered a successful outcome. The trial was designed with reference to the MRC guidelines on developing and evaluating complex interventions (Craig et al., 2008). The trial is sponsored by the University of Manchester and is being conducted across two EIP services within Greater Manchester Mental Health NHS Foundation Trust. Participants randomised to TAU continue to receive support from their EIP team. Participants randomised to the treatment group receive MOL in addition to their usual care. A novel feature of this design is that participants in the treatment group are able to choose the number, frequency, and duration of MOL sessions they access over the course of the treatment window. This approach is consistent with the underlying theoretical assumptions of MOL. A nested qualitative study is also included in the design.

#### *4.3.1 Trial oversight and ethical approval*

A Trial Steering Committee (TSC) comprising clinical, academic, and patient members has been convened to oversee the study. As a small feasibility study, it was not deemed necessary to establish a separate Data Monitoring and Ethics Committee (DMEC). Instead, the TSC also served some of the functions normally carried out by a DMEC. The independent members of the TSC have the option to meet independently of the research team if required. Ethical approval was received from the North West – Greater Manchester Central Research Ethics Committee prior to commencing recruitment (REC reference: 16/NW/0592; IRAS project ID: 204043).

#### *4.3.2 Trial registration*

The study was prospectively registered with the ISRCTN registry ([www.isrctn.com/ISRCTN13359355](http://www.isrctn.com/ISRCTN13359355)).

#### *4.3.3 Randomisation*

Following baseline assessments, participants were randomised by the first author to one of the two conditions in a ratio of 1:1. An online randomisation service (Sealed Envelope Ltd. 2017. Simple randomisation service. [Online] Available from: <https://www.sealedenvelope.com/simple-randomiser/v1/> [Accessed 4 Sep 2017]) was used to allocate participants in random permuted blocks. There was no stratification of the study sample. To minimise the potential for bias, participants were randomised in the order they completed baseline assessments.

#### *4.3.4 Sample size*

A formal power calculation was not performed, since the aim of the study is not to estimate between-group treatment effects. A sample size of 15 participants or

more in each group is considered adequate for a feasibility RCT (Julious, 2005). To allow for potential attrition, the recruitment target was 36 participants.

#### *4.3.5 Recruitment*

Participants were recruited from two EIP services based in a single NHS Trust in the United Kingdom. Participants were either experiencing or recovering from a recent FEP. Care coordinators within those teams were asked to raise awareness of the study amongst patients on their caseloads. Presentations, posters and leaflets were used to provide study information to care coordinators. Patients who expressed an interest in the study were contacted via telephone by the chief investigator. If verbal consent was given at this point, patients were invited to meet the chief investigator in person to receive information about the study, complete a brief eligibility screen, and provide written consent to participate in the study.

#### *4.3.6 Inclusion Criteria*

- (1) People aged 16-65 years
- (2) Current user of Greater Manchester Mental Health NHS Foundation Trust Early Intervention Services
- (3) Sufficient English language abilities (verbal and written) to complete written material (for example, outcome measures) and participate in psychological therapy
- (4) Willing and able to provide informed consent

#### *4.3.7 Exclusion Criteria*

- (1) People aged under 16 or over 65 years of age

- (2) Not currently using Greater Manchester Mental Health NHS Foundation Trust Early Intervention Services
- (3) Literacy or English language difficulties that make it difficult for the person to complete written material (for example, outcome measures) or to participate in psychological therapy
- (4) Patients currently serving custodial prison sentences

#### 4.3.8 Eligibility and outcome measures

A brief screen consisting of the inclusion and exclusion criteria was used to ensure eligibility. A summary of the assessment schedule is presented in Table 2. Assessments in both arms were completed by the chief investigator, who was not blind to group allocation.

The proposed primary clinical outcome measure for the purposes of estimating an effect size is the Psychological Outcome Profiles (PSYCHLOPS) (Ashworth et al., 2004), a participant-generated outcome measure that assesses wellbeing, functioning and distress. Cronbach’s alpha in a clinical sample was 0.81(Czachowski, Seed, Schofield, & Ashworth, 2011), demonstrating satisfactory internal reliability.

**Table 2** Assessment schedule summary

	Baseline	MOL session measures	10 months	14 months
<b>PSYCHLOPS<sup>1</sup></b>	✓		✓	✓
<b>CORE-OM<sup>2</sup></b>	✓		✓	✓
<b>ROC<sup>3</sup></b>	✓	✓	✓	✓
<b>QPR<sup>4</sup></b>	✓		✓	✓
<b>ORS<sup>5</sup></b>	✓	✓	✓	✓
<b>SRS<sup>6</sup></b>		✓		

<sup>1</sup>Psychological Outcome Profiles (PSYCHLOPS)

<sup>2</sup>CORE Outcome Measure (CORE-OM)

<sup>3</sup>Reorganisation of Conflict Scale (ROC)

<sup>4</sup>Questionnaire about the Process of recovery (QPR)

<sup>5</sup>Outcome Rating Scale (ORS)

<sup>6</sup>Session Rating Scale (SRS)

The CORE-OM (Evans et al., 2002) is a 34-item self-report instrument that assesses the four domains of subjective well-being, symptoms, functioning, and risk. It shows good sensitivity to change and has been used in a variety of practice settings. Cronbach's alpha in clinical samples was found to be 0.94, indicating satisfactory internal reliability (Evans et al., 2002).

The Reorganisation of Conflict Scale (ROC) (Higginson & Mansell, 2008) is a 22-item self-report measure. Each item is scored on a scale of 0 ("I don't believe this at all") to 100 ("I believe this completely"). The study used an 11-item sub-scale of the ROC that has previously shown satisfactory internal reliability, with a Cronbach's alpha of 0.83 (T. Bird, 2013). The sub-scale measures the components of goal conflict reorganisation, which is proposed to be the key mechanism of change in MOL.

The Questionnaire about the Process of Recovery (QPR) (Neil et al., 2009) is a 22-item self-report questionnaire developed in collaboration with patients. It is designed to measure personal recovery from psychosis on two subscales: intrapersonal functioning and interpersonal functioning. Cronbach's alpha was found to be 0.94 for the intrapersonal scale and 0.77 for the interpersonal scale, indicating good internal consistency (Neil et al., 2009).

The Outcome Rating Scale (ORS) (Miller, Duncan, Brown, Sparks, & Claud, 2003) is a visual analogue questionnaire that assesses functioning in four domains: individual, social, relational, and overall functioning. It is scored from 0 to 40, with scores at or below 25 indicating clinically severe levels of psychological distress. Cronbach's alpha was found to be 0.93, indicating good internal consistency (Miller et al., 2003).

The Session Rating Scale (SRS) (Duncan et al., 2003) is also a visual analogue scale. It assesses patients' perceptions of the therapeutic alliance, including the extent to which the participant felt respected and heard. As with the ORS, the SRS is scored from 0 to 40 with scores of 36 or below indicating cause for concern about the therapeutic alliance. Cronbach's alpha was found to be 0.88, indicating satisfactory internal consistency (Duncan et al., 2003).

#### *4.3.9 Method of Levels intervention*

MOL directly applies the principles of a robust theory of human behaviour called Perceptual Control Theory (PCT) to the practice of psychotherapy. Detailed descriptions of PCT and its application to the delivery of psychological therapy are available (Alsawy, Mansell, Carey, McEvoy, & Tai, 2014; Marken & Mansell, 2013). The proposed mechanism of change in MOL is the reorganisation of goal conflict. MOL therapists aim to guide a person's awareness onto the source of the conflict, facilitating this process. MOL is a transdiagnostic psychological intervention, which means it is applicable to patients presenting with diverse problems, irrespective of any diagnosis they might have received. Sessions typically last between 15 and 60 minutes.

Because PCT proposes that change is nonlinear and idiosyncratic (Mansell et al., 2013), participants are expected to require a different number and frequency of sessions over the course of the 10-month treatment window. To support this, the study uses patient-led appointment scheduling, an approach that has already been used successfully with a secondary care population (Carey et al., 2013). MOL sessions will be offered at two community venues, one at each recruitment site. A total of five appointment slots will be made available each week at the site with

higher levels of recruitment. The site with lower recruitment will have three appointment slots available each week. Capacity issues will be reviewed on an ongoing basis to monitor whether additional appointment slots are required. Participants allocated to receive MOL will be able to book the sessions they require using SMS messages, telephone calls, or a dedicated on-line appointment booking website. There is no minimum or maximum number of sessions that participants are expected to attend over the 10-month treatment window where sessions are available to them. Detailed descriptions of MOL and patient-led scheduling are available in several treatment manuals (Carey et al., 2015; Carey, 2018; Carey, 2006; Mansell et al., 2013).

The MOL sessions are delivered by the study's chief investigator, a suitably trained clinician with experience of delivering psychological interventions for psychosis. The clinician receives weekly supervision from experienced MOL practitioners. The MOL intervention is delivered according to the guidelines described in published treatment manuals (Carey et al., 2015; Carey, 2006; Mansell et al., 2013). Audio recordings of MOL sessions are rated using the MOL Session Evaluation Form (Carey & Tai, 2012). To ensure fidelity to the approach, a randomly selected sample of MOL session audio recordings will be independently rated at the end of the trial. The intention is to rate 20% of audio recordings.

#### *4.3.10 Safety monitoring and reporting*

Untoward occurrences that result in death, hospitalisation, disability, are considered life threatening, or are otherwise deemed medically significant will be recorded. Incidences of threatened or actual overdose, self-harm, or harm to others will also be recorded. Potential adverse events are most likely to be identified at

MOL sessions, assessments, and qualitative interviews. In addition, participants' medical notes will be reviewed at the end of the trial to identify any other potential adverse events. In the first instance, the chief investigator, primary investigator and chair of the TSC will review potential adverse events to determine the appropriate response. All potential adverse events will be reviewed by the TSC.

#### *4.3.11 Statistical analysis*

Statistical analysis began once all follow up data had been collected in June 2018. Reporting will adhere to the CONSORT guidelines for pilot and feasibility studies (Eldridge, Chan, et al., 2016) and will include study attrition and follow-up rates.

#### *4.3.12 Primary outcomes*

Analysis will involve tabulated and graphical summaries of the primary feasibility and acceptability outcome measures. Summary statistics will include the number of patients who expressed an interest in the trial, the proportion of potentially eligible participants who consented to take part, trial drop-out, and the number of participants retained at 10 and 14 month follow up.

In line with the findings of a recent meta-analysis of attrition rates in complex interventions for schizophrenia (Szymczynska, Walsh, Greenberg, & Priebe, 2017), a retention rate of 80% within the study as a whole would be considered a successful outcome, 70% would be considered borderline and below 60% would be considered an unacceptably low retention rate.

The study's use of patient-led scheduling means it will not be possible to determine drop-out from the MOL intervention prior to the 10-month follow-up



assessment. Summary statistics will be presented showing the average number of MOL sessions attended by participants, the number of participants who attended no MOL sessions, and the number of cancelled and missed appointments. Details of any other psychological interventions received by participants in both arms of the trial will also be reported. Data from the nested qualitative study will also contribute to answering the questions regarding the feasibility and acceptability of the trial design and MOL intervention.

#### *4.3.13 Secondary outcomes*

To inform potential effect sizes for a future definitive trial, linear regression will be used to examine the effect of treatment group allocation on outcome measures at post-treatment, adjusting for outcome measures at baseline. The PSYCHLOPS will be treated as the primary clinical outcome measure for this purpose. However, because effect sizes calculated from feasibility trials with fewer than 35 participants in each arm are likely to be unreliable (Teare et al., 2014), results will be treated with caution and 95% confidence intervals for effect sizes will be considered to check if a minimal clinically important difference is within the interval. Point estimates and associated 95% confidence-intervals of effect sizes will be reported rather than statistical significance (p-values). Every effort will be made to follow up participants in both arms for assessments, and the analysis will use, where appropriate, statistical techniques for handling missing data. Statistical analysis will be conducted in accordance with the principles of intention-to-treat analysis (ITT). Data from participants in the treatment group who attend varying numbers of MOL sessions (including those who attend no sessions) will be included in the final statistical analysis.

#### 4.4 Results

Recruitment to the Next Level trial began in September 2016 and ended when the target of  $N = 36$  was met in April 2017. The randomisation procedure allocated 19 participants to TAU+MOL and 17 to TAU. Participants were recruited at an average rate of 4.5 a month from two EIP services, with combined team caseloads of 283 patients. A total of 65 patients (approximately 23% of all potentially eligible patients across the two EIP services) expressed an interest in participating in the study to their care coordinator. Relatively few patients declined to participate after expressing an interest in the study ( $n = 15$ ). The most common reasons for declining were not wanting a talking therapy ( $n = 4$ ) or feeling uncomfortable about discussing personal details ( $n = 4$ ). Just one potential participant declined due to concerns about the randomisation process. It was not possible to contact a proportion ( $n = 14$ ) of patients who were potentially eligible and had expressed an interest in the study to their care coordinators. A CONSORT (Eldridge, Chan, et al., 2016) diagram is presented in Figure 3.

Recruitment was significantly higher from one of the two EIP services, with  $n = 31$  (86.11%) of trial participants using that service. The number of potential participants identified by individual care coordinators ranged from  $n = 0$  to  $n = 15$ . It is not clear what overall proportion of eligible patients were made aware that they could participate in the study.

A summary of participant characteristics is presented in Table 3. Participants' clinical characteristics are shown in Table 4. The study has a relatively young and predominantly male sample. The majority of participants are White British, single, living in mainstream accommodation, and unemployed. Participants generally had a

relatively long duration of untreated psychosis (DUP) prior to being accepted to the EIP service supporting them. Average DUP was noticeably longer in the TAU+MOL arm of the study. On average, participants had been accepted by the EIP service just over 13 months prior to being accepted into the study. The most frequently occurring primary diagnosis across both groups was one of psychosis spectrum disorder. However, many participants had received other primary diagnoses, including common mental health problems, such as anxiety and depression. A proportion had received no diagnosis at all. Most participants were prescribed antipsychotic medication and just over half were prescribed antidepressants. A minority of participants were not prescribed any psychotropic medication. A summary of baseline statistics are presented in Table 5.

**Table 3** Participant characteristics by randomisation group

		<b>TAU+MOL</b>	<b>TAU</b>	<b>Total</b>
		<b>(n = 19)</b>	<b>(n = 17)</b>	<b>(N = 36)</b>
<b>Age (years), mean (S.D.)</b>		32.2 (13.1)	28.9 (7.3)	30.6 (10.7)
<b>Gender</b>	Male	11 (57.9%)	12 (70.6%)	23 (63.9%)
	Female	8 (42.1%)	5 (29.4%)	13 (36.1%)
<b>Ethnicity</b>	White – British	18 (94.7%)	14 (82.4%)	32 (88.9%)
	White – any other white background	0 (0.0%)	1 (5.9%)	1 (2.8%)
	Mixed – any other mixed background	1 (5.3%)	0 (0.0%)	1 (2.8%)
	Asian/Asian British	0 (0.0%)	1 (5.9%)	1 (2.8%)
	Black/Black British – African	0 (0.0%)	1 (5.9%)	1 (2.8%)
<b>Civil status</b>	Single	14 (73.7%)	10 (58.8%)	24 (66.7%)
	Married/cohabiting	5 (26.3%)	5 (29.4%)	10 (27.8%)
	Divorced/separated	0 (0.0%)	2 (11.8%)	2 (5.6%)
<b>Accommodation</b>	Mainstream housing	18 (94.7%)	15 (88.2%)	33 (91.7%)
	Homeless	1 (5.3%)	1 (5.9%)	2 (5.6%)
	Supported housing	0 (0.0%)	1 (5.9%)	1 (2.8%)
<b>Employment status</b>	Unemployed	9 (47.4%)	10 (58.8%)	19 (52.8%)
	Paid employment	5 (26.3%)	3 (17.6%)	8 (22.2%)
	Education/training	3 (15.8%)	4 (23.5%)	7 (19.4%)
	Unpaid employment	2 (10.5%)	0 (0.0%)	2 (5.6%)

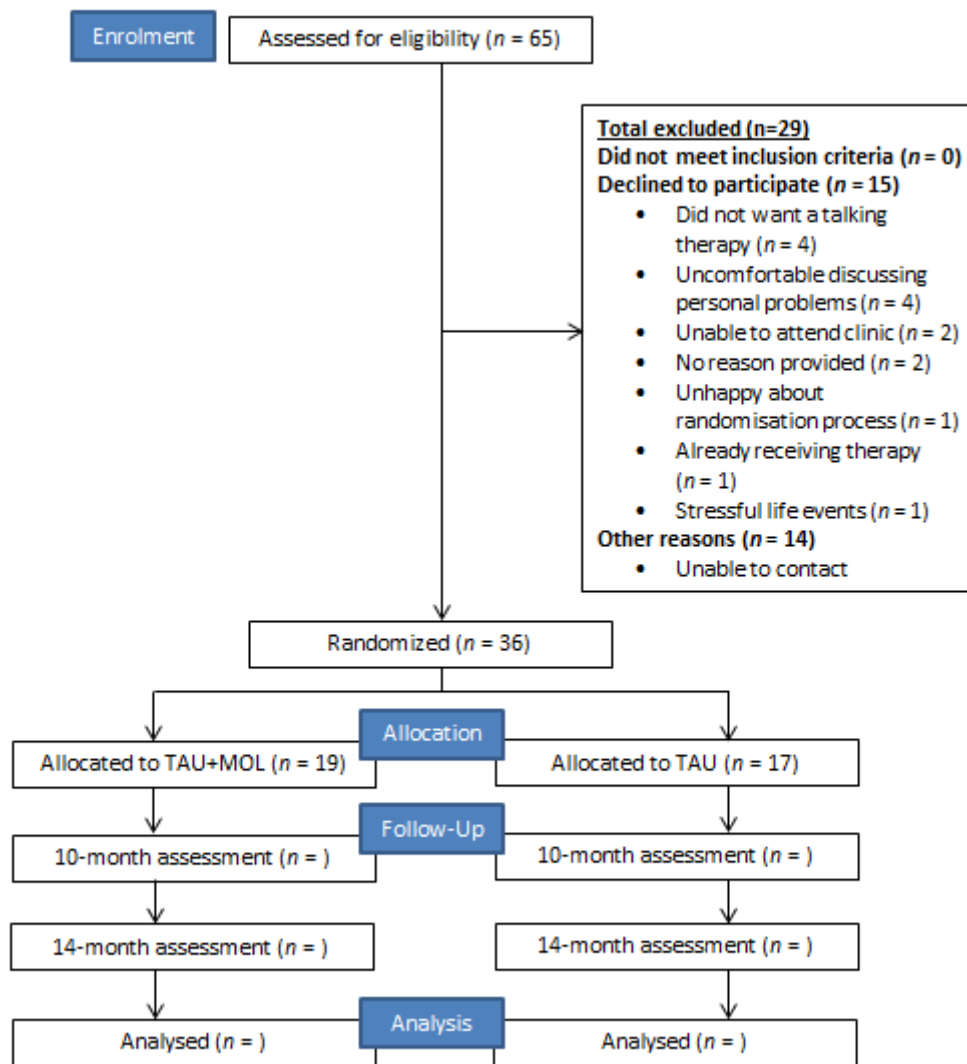
**Table 4** Clinical characteristics of participants

		<b>TAU+MOL (n = 19)</b>	<b>TAU (n = 17)</b>	<b>Total (N = 36)</b>
<b>Duration of untreated psychosis (months), mean (S.D.)</b>		46.1 (60.8)	14.6 (21.8)	30.9 (48.2)
<b>Length of EIP treatment (months), mean (S.D.)</b>		10.5 (9.5)	16.2 (11.7)	13.2 (10.8)
<b>Primary diagnosis</b>	Psychosis spectrum disorders	5 (26.3%)	6 (35.3%)	11 (30.6%)
	Depression	2 (10.5%)	4 (23.5%)	6 (16.7%)
	Bipolar disorders	1 (5.3%)	1 (5.9%)	2 (5.6%)
	Anxiety disorders	2 (10.5%)	1 (5.9%)	3 (8.3%)
	Mixed anxiety and depression	2 (10.5%)	1 (5.9%)	3 (8.3%)
	Substance misuse disorders	2 (10.5%)	1 (5.9%)	3 (8.3%)
	Eating disorder	0 (0.0%)	1 (5.9%)	1 (2.8%)
	Personality disorders	0 (0.0%)	1 (5.9%)	1 (2.8%)
	No diagnosis	5 (26.3%)	1 (5.9%)	6 (16.7%)
	<b>Medication</b>	Antipsychotics	11 (57.9%)	13 (76.5%)
Antidepressants		9 (47.4%)	10 (58.8%)	19 (52.8%)
Other psychotropic		4 (21.1%)	4 (23.5%)	8 (22.2%)
No psychotropic		7 (36.8%)	3 (17.6%)	10 (27.8%)

**Table 5** Summary of baseline statistics, mean (S.D.)

		<b>TAU+MOL (n = 19)</b>	<b>TAU (n = 17)</b>
<b>Primary outcome</b>	PSYCHLOPS <sup>1</sup>	16.3 (3.5)	14.9 (2.6)
<b>Secondary outcomes</b>	CORE-OM <sup>2</sup>	71.1 (25.7)	60.3 (24.2)
	ORS <sup>3</sup>	14.0 (10.0)	19.1 (9.2)
	QPR <sup>4</sup>	45.7 (12.9)	54.6 (13.0)
	ROC <sup>5</sup>	58.9 (20.1)	69.1 (14.6)

<sup>1</sup>Psychological Outcome Profiles (PSYCHLOPS) total<sup>2</sup>CORE Outcome Measure (CORE-OM) total<sup>3</sup>Outcome Rating Scale (ORS) total<sup>4</sup>Questionnaire about the Process of recovery (QPR) total<sup>5</sup>Reorganisation of Conflict Scale (ROC) total



**Figure 3** CONSORT diagram (enrolment and allocation details)

#### 4.5 Discussion

This is the first randomised controlled trial of MOL for people experiencing FEP. The results will be used to answer questions about the feasibility and acceptability of delivering MOL to people experiencing FEP. The issue of whether adaptations are required to deliver the intervention to people using EIP services will

also be considered. The answers to these questions will inform decision making regarding the suitability of MOL for further testing in a definitive trial.

#### *4.5.1 Main findings and interpretation*

The relatively long DUP of the sample, particularly in the TAU+MOL arm, indicates that participants had experienced symptoms of psychosis for a significant amount of time prior to acceptance by an EIP team. Longer DUP is associated with greater overall symptoms, lower functioning, and poorer quality of life (Marshall et al., 2005). The study sample's lack of ethnic diversity potentially limits the generalisability of results. The sample included participants with a diverse range of diagnoses, including some who had not received any diagnosis. This is likely to be a reflection of the fact that EIP services are commissioned to work with patients where there is 'diagnostic uncertainty' (McGorry et al., 2008).

These initial data suggest that it is possible to recruit and randomise participants to an RCT of MOL for FEP. Recruitment to target took just over 7 months at an average rate of 4.5 participants per month, which was considered a successful outcome. At least three factors are likely to account for the disparity in recruitment rates between the two EIP services. Firstly, the study was open to referrals two months earlier at the service with higher recruitment. Secondly, the site with lower recruitment is commissioned to work with significantly fewer patients (98 compared to 185). Thirdly, the chief investigator previously worked as a clinician in the EIP service with higher recruitment, so this is also likely to be a factor. This is consistent with research suggesting that clinicians are more likely to refer patients to clinical trials where they trust the investigators conducting the study (Mainous III,

Smith, Geesey, & Tilley, 2008). Future trials should consider methods of establishing trust between clinicians and researchers in order to facilitate appropriate referrals.

Another issue to consider in future trials is ensuring that all potentially eligible participants are made aware of relevant research. For ethical reasons, this study relied on care coordinators to identify potentially eligible participants. However, there was a high degree of variation in the referral rates between individual care coordinators. This suggests that care coordinators acted as ‘gatekeepers’ to the trial, potentially limiting patient choice about trial participation. Perhaps a more ethical approach in future trials would be to approach potential participants directly, with the aim of increasing equitable access.

The inclusion and exclusion criteria for this study closely matched those used by the EIP services where recruitment took place. This explains why no potential participants were deemed ineligible for the study. Relatively few participants declined to take part in the study, providing prima facie evidence that the majority of participants find the idea of randomisation acceptable.

Because the PSYCHLOPS measures within-person change related to an idiosyncratic participant-defined problem, it is not possible to interpret the baseline data in isolation. Change can only be measured meaningfully when compared to the post-therapy scores that will be collected during follow up. This also applies to the QPR and ROC measures. The mean CORE-OM scores for the TAU+MOL and TAU arms indicate ‘moderate to severe’ and ‘moderate’ levels of distress respectively. The mean ORS scores were below 25 for both study arms, indicating clinically severe levels of psychological distress.



#### *4.5.2 Limitations*

One potential limitation of this study is the lack of specific measures of psychotic symptoms. The majority of recent RCTs for psychosis include a measure of psychotic symptoms as their primary outcome (Greenwood et al., 2010). The rationale for not including a measure of psychotic symptoms is that MOL aims to reduce underlying psychological distress, rather than reduce or remove the symptoms of psychosis. Outcome measures that are consistent with the stated aims of MOL were selected. Including psychosis-specific measures, while potentially yielding some useful data, would have added to participant burden. Additionally, the approach taken here is consistent with the argument that it is more appropriate for psychological interventions for psychosis to focus on ameliorating psychological distress rather than symptom reduction (Birchwood & Trower, 2006; Chadwick, 2006).

Participants in both groups might be offered psychological interventions as part of the routine care they receive from their usual EIP service. However, participants in the TAU group were not systematically offered access to any psychological interventions as part of their involvement with this study. If there is differential access to psychological interventions between groups it could be considered a limitation of this study.

Data collection was completed as planned in June 2018. Once analysed, results will be published in peer reviewed journals and presented at relevant conferences. Results will be presented in line with the primary and secondary outcomes specified in this paper.

**Chapter 5: Method of Levels therapy for first-episode psychosis: The feasibility  
randomised controlled Next Level trial**

## PREFACE

This paper is currently under peer review with the *Journal of Clinical Psychology* and has been formatted in accordance with the manuscript requirements for that journal. The authors are Robert Griffiths, Dr Warren Mansell, Professor Timothy A. Carey, Dr Dawn Edge, Professor Richard Emsley, and Dr Sara J. Tai. Under the guidance of the supervisory team, the PhD student designed the research, developed the study protocol and statistical analysis plan, applied for ethical and regulatory approval, managed the trial, recruited and enrolled participants, completed baseline and follow up assessments, randomised participants, delivered the Method of Levels intervention, completed the data entry, and performed the data analysis. The PhD student wrote the first draft of the manuscript and revised the manuscript based on the suggestions of the other authors. All authors approved the final manuscript.

## 5.1 Abstract

**Objective:** We aimed to determine the feasibility and acceptability of Method of Levels (MOL) for people experiencing first-episode psychosis to inform decision making about the therapy's suitability for further testing in a larger clinical trial.

**Method:** A parallel group randomised controlled trial design was used. Participants ( $n = 36$ ) were allocated to receive either treatment as usual (TAU) or TAU plus MOL. Recruitment and retention in the trial and the acceptability of the MOL intervention were the primary outcomes.

**Results:** The recruitment target was met within the planned timeframe. Retention in the trial at final follow up was 97%, substantially higher than the 80% threshold pre-specified as a successful feasibility outcome. Participant feedback provided initial evidence of the acceptability of the study design and intervention for this population.

**Conclusion:** Results support progressing to a larger trial of MOL for first-episode psychosis. Recommendations for the design of future trials are provided.

**Trial registration:** ISRCTN13359355

## **5.2 Introduction**

### *5.2.1 Background*

Early intervention in psychosis (EIP) services have demonstrated improved outcomes compared to routine care for service users experiencing first-episode psychosis (FEP) (Bertelsen et al., 2008; Craig et al., 2004). Delivery of evidence-based psychological interventions is an important function of EIP teams (Bird et al., 2010). Clinical guidelines in the United Kingdom recommend that everyone using EIP services should be offered cognitive behavioural therapy for psychosis (CBTp) (National Institute for Health and Care Excellence [NICE], 2014). There is relatively good evidence to suggest that CBTp helps to reduce psychotic symptoms, with most meta-analyses reporting effect sizes in the small to moderate range (Jauhar et al., 2014; Turner et al., 2014; Wykes et al., 2008). However, there have been significant difficulties with the implementation of CBTp into routine clinical practice (Berry & Haddock, 2008; Ince et al., 2015), and access to CBTp amongst users of EIP services remains low (Royal College of Psychiatrists et al., 2016). Additionally, given the high levels of comorbidity (Achim et al., 2011; Addington et al., 1998) and diverse sources of distress (Griffiths, Mansell, Edge, et al., 2018) amongst people experiencing psychosis, questions have been raised about the extent to which disorder-specific approaches such as CBTp can fully meet the complex needs of this population (Griffiths, Mansell, Carey, et al., 2018). Transdiagnostic interventions that directly target core cognitive and behavioural processes which are proposed to maintain distress might have advantages over disorder-specific approaches (Mansell et al., 2008), particularly for people experiencing psychosis (Tai, 2009, 2016).

### *5.2.2 Method of Levels*

The Method of Levels (MOL) (Carey, 2006) is a transdiagnostic cognitive therapy based on the principles of Perceptual Control Theory (PCT) (Powers, 2005). PCT proposes that the phenomenon of control is fundamental to the survival of all living things. This is achieved through a hierarchical and parallel arrangement of negative feedback loops that control perceptual variables according to ‘reference values’ (synonymous with ‘goals’ or ‘just-right states’) that specify the desired state of the variables. The function of human behaviour, from this perspective, is to minimise any disparity between perceptual variables and reference values. People are able to control a wide variety of variables, from relatively simple perceptions lower in the hierarchy (e.g. body posture or temperature), to those higher in the hierarchy that are more complex and abstract in nature (e.g. sense of self and identity). Control is disrupted in situations where people simultaneously hold conflicting reference values for the state of the same variable. PCT proposes that we are able to resolve conflict through an innate trial-and-error system called ‘reorganisation’. Sustaining awareness on the source of the conflict is believed to facilitate the reorganisation of goals, enabling us to regain control.

MOL has been fully described in several treatment manuals (Carey, Mansell, & Tai, 2015; Carey, 2006; Mansell, Carey, & Tai, 2013). It aims to directly target goal conflict and facilitate the reorganisation process. To achieve this, therapists delivering MOL have two goals. The first is to encourage the person to talk freely about whatever their current focus of attention is. The second goal is to pay attention to ‘disruptions’ (potential signs of fleeting shifts in awareness) and ask the person to discuss these when they occur. Disruptions often indicate that the person’s awareness has momentarily shifted to potentially relevant background thoughts. Asking about

disruptions provides opportunities to 'go up levels' of the perceptual hierarchy, eventually shifting awareness onto the source of the conflict. Sustaining awareness on the conflict and then its source facilitates the reorganisation process, leading to a reduction in distress as a consequence.

Because reorganisation is assumed to be non-linear and idiosyncratic, the exact number and frequency of MOL sessions required will differ between individuals. For this reason, MOL uses a system of service user-led appointment scheduling. There is no minimum or maximum number of sessions that people are expected to attend. Instead, service users are made aware of when MOL sessions are available and have control over booking appointments as they require them. Existing research suggests that clients appreciate having greater control over appointment scheduling, and this system has the potential to use resources more efficiently than conventional approaches to appointment scheduling (Carey & Mullan, 2007; Carey, Tai, & Stiles, 2013).

Several case studies and pragmatic uncontrolled trials have found that MOL is a helpful means of reducing distress for people experiencing a diverse range of problems in a variety of practice settings (Carey & Mullan, 2008; Carey, Carey, Mullan, Spratt, & Spratt, 2009). Carey et al., (2013) conducted a practice-based study of MOL in a rural Australian secondary care mental health setting and reported an effect size of 1.45 on the Outcome Rating Scale (Miller et al., 2003). The mean number of sessions attended was 3.6 (median = 3, range = 2-11). The effectiveness of MOL, therefore, was comparable to other psychological therapies evaluated in equivalent practice-based studies, but it was significantly more efficient. Initial qualitative research also suggests that service users find attending MOL sessions to

be a useful experience (Carey et al., 2009). See Alsawy, Mansell, Carey, McEvoy, & Tai (2014) for a detailed review of current evidence supporting the use of MOL.

### *5.2.3 Rationale for Next Level*

MOL has several potential advantages over existing treatment for FEP. Firstly, MOL focuses on reducing underlying distress rather than on the treatment of specific symptoms, making it applicable to situations where service users are reporting multiple problems. Secondly, the principles underpinning the delivery of MOL remain the same, irrespective of the exact problems upon which a service user chooses to work. This has the potential to make the training and supervision of professionals delivering psychological interventions more efficient. Thirdly, the focus of MOL sessions is determined by the service user, tailoring therapy to the specific needs of the individual. Fourthly, service user-led scheduling gives people greater control over the psychological interventions they receive. Fifthly, the practice of MOL is guided by clearly defined principles derived from PCT, a robust theory of human behaviour (Marken & Mansell, 2013).

### *5.2.4 Aims of the study*

The current study, called ‘Next Level’, aimed to establish the feasibility and acceptability of MOL for FEP, and determine its suitability for further testing in a clinical trial. No previous studies had investigated the use of MOL for FEP, so a feasibility trial was required before a larger effectiveness trial could be justified. The specific research questions that this feasibility trial aimed to answer were:

1. Is it feasible to recruit and retain people experiencing FEP in a randomised controlled trial of MOL?



2. Is it feasible to deliver MOL to people experiencing FEP?
3. Is MOL an acceptable psychological intervention for people experiencing FEP?
4. Are adaptations necessary to overcome problems or barriers to the implementation of MOL in EIP services?

### **5.3 Methods**

#### *5.3.1 Trial design*

A parallel group design with random allocation to two conditions: (1) treatment as usual (TAU) or (2) TAU plus MOL. Participants were allocated to one of the two groups by the study's chief investigator in random permuted blocks using an online randomisation service (Sealed Envelope Ltd. 2017. Simple randomisation service. [Online] Available from: <https://www.sealedenvelope.com/simple-randomiser/v1/> [Accessed 30 Jul 2018]). Group allocation was in a ratio of 1:1 and future allocations were concealed until participants were randomised. The study sample was not stratified. Enrolment was completed by the study's chief investigator. To minimise bias, participants were randomised in the order of completing baseline assessments. Participants, the clinicians involved in their routine care, the research team, and the trial therapist were not blinded to group allocation. In a future effectiveness trial, the intention would be for outcome assessors to remain blind to group allocation. A nested qualitative study was also undertaken to investigate participants' experiences of trial participation, the MOL intervention, and the service user-led appointment booking system. The results of this qualitative study have been reported separately (Griffiths et al., 2019). The trial was prospectively registered with the ISRCTN registry (ISRCTN13359355).

### *5.3.2 Participants*

Participants were recruited from Greater Manchester Mental Health NHS Foundation Trust EIP services. Leaflets, posters, and training sessions were used to raise awareness with clinicians working in these services. Clinicians were invited to discuss the study with service users on their caseloads. Service users who expressed an interest in finding out more about the study were contacted by telephone by the research team. Providing verbal consent was given at this point, potential participants were invited to a face-to-face meeting where they were given more information about the study and completed a brief eligibility screen (consisting of the study's inclusion and exclusion criteria). Eligible service users were then asked to provide written consent to participate in the study. Participants received a payment for completing follow up assessments at 10 and 14 months.

### *5.3.3 Inclusion and exclusion criteria*

People meeting the following criteria were eligible to participate in the study: aged 16-65 years; current user of Greater Manchester Mental Health NHS Foundation Trust Early Intervention Services; sufficient English language abilities (verbal and written) to complete written material (for example, outcome measures) and participate in psychological therapy; and be willing and able to provide informed consent. People were not eligible to participate if they were serving a custodial prison sentence.

### *5.3.4 Interventions*

*Treatment as usual group.* Participants in the TAU group continued to receive ongoing support from their usual EIP team. This consisted of regular

meetings with a care coordinator, and less frequent reviews by the psychiatrist involved in their care. Participants had ongoing access to the full range of psychosocial and pharmacological interventions usually offered by their EIP service.

*Method of Levels group.* Participants in this group were able to choose the number and frequency of MOL sessions that they attended over a 10-month treatment window. No limits were placed on the minimum or maximum number of sessions participants could attend. MOL appointments were arranged using a dedicated booking website, by telephone, or by SMS text message, depending on participant preference. MOL sessions were delivered at two community resource centres, one based in each recruitment site. Sessions were routinely available on two days of the week during working hours. Participants were made aware that sessions could be offered on other days or in the evening if required. The availability of MOL sessions was kept under review to ensure sufficient appointment slots were available to meet participant demand. Participants in this group were also able to access any interventions that would usually be available to them from their EIP service.

MOL sessions were delivered by the first author, a mental health nurse with several years' experience of delivering psychological interventions within EIP services who has completed postgraduate training in CBT for psychosis. Clinical supervision was provided by ST, WM, and TC, who are experienced MOL trainers and practitioners. To ensure fidelity to the approach, 20% of sessions, selected at random, were rated by ST and WM using the MOL Session Evaluation Form (Carey & Tai, 2012). This eight-item measure assesses therapist adherence to the MOL approach. Each item is rated from one to ten, with higher ratings representing greater fidelity to the MOL approach.

### *5.3.5 Trial oversight*

A trial steering committee (TSC) was established to provide trial oversight. The TSC comprised clinical, academic, and service user representatives. As a small feasibility trial, a separate data monitoring and ethics committee (DMEC) was not deemed necessary. Instead, the TSC took on some of the functions normally performed by a DMEC.

### *5.3.6 Ethical approval*

All approvals were in place prior to commencing recruitment. Ethical approval was received from the North West – Greater Manchester Central Research Ethics Committee (REC reference: 16/NW/0592; IRAS project ID: 204043). The research was sponsored by The University of Manchester.

### *5.3.7 Safety monitoring and reporting*

Potential adverse events (AE) and serious adverse events (SAE) were reported to the primary investigator and chair of the TSC, who determined whether the event was likely to be related to participation in the trial (see Appendix B for the standard operating procedure for identifying and recording serious adverse events). To increase the chances of detecting potential SAEs and AEs, the chief investigator reviewed the clinical records of participants who experienced an increase of five or more in overall risk score as measured on the CORE-OM (Evans et al., 2002). Also, at the end of the trial, all participants were invited to complete a measure designed to detect potential adverse events in psychotherapy studies (Hutton, Byrne, & Morrison, 2017).

### *5.3.8 Sample size*

Since the aim of the study was not to compare the effects of treatment between groups, a formal power calculation was not performed. A sample size of 15 participants per group is considered adequate for feasibility trials (Julious, 2005). To allow for potential attrition, a recruitment target of 36 participants was set.

### *5.3.9 Primary outcomes*

Primary outcomes were consistent with CONSORT guidelines for feasibility and pilot trials (Eldridge, Chan, et al., 2016). These were successful recruitment to the trial, retention and attrition at final follow-up, and acceptability of the MOL intervention. Over 80% was deemed to be a successful retention rate, over 70% was a borderline outcome, and below 60% was considered unacceptably low. These thresholds are consistent with a recent meta-analysis of retention rates in studies investigating complex interventions for schizophrenia (Szymczynska et al., 2017). We also report on attendance, cancellation, and non-attendance rates for MOL sessions. Sessions not attended as planned or cancelled prior to the scheduled appointment time were classed as a non-attendance.

Unlike trials of psychological therapy where participants are expected to attend a predetermined number of sessions, this study's use of service user-led scheduling meant it was not possible to measure "treatment drop-out" prior to the closure of the treatment window. To better understand this, at 14-month follow up, participants in the MOL group were asked to complete a brief questionnaire that asked about their reasons for ending therapy. Participants could choose one of the following options: (i) 'I stopped attending because I got what I needed from the sessions'; (ii) 'I stopped attending because I did not get what I needed from the

sessions’; (iii) ‘I ran out of time’; or (iv) ‘I stopped attending for other reasons’. An accompanying free text box gave participants an opportunity to expand on their answer. These data will be used in conjunction with the findings of the nested qualitative study to evaluate the acceptability of MOL for this population.

At final follow up, participants in both groups were invited to provide written comments on their experience of trial participation generally.

#### *5.3.10 Secondary outcome measures*

Psychological Outcome Profiles (PSYCHLOPS) (Ashworth et al., 2004). This is the proposed primary clinical outcome measure for future studies. It is a brief participant-generated outcome measure that assesses the domains of wellbeing, functioning, and distress. Cronbach’s alpha was found to be 0.81 in a clinical sample, demonstrating satisfactory internal reliability (Czachowski et al., 2011).

CORE-OM (Evans et al., 2002). This 34-item self-report measure is designed to measure subjective wellbeing, symptoms, functioning, and risk. It shows good sensitivity to change in a number of practice settings and has demonstrated satisfactory internal reliability in a clinical sample, with a Cronbach’s alpha of 0.94 (Evans et al., 2002).

Reorganisation of Conflict Scale (ROC) (Higginson & Mansell, 2008). An 11-item sub-scale of the ROC was used to measure goal conflict reorganisation, the proposed mechanism of change in MOL. The sub-scale has shown satisfactory internal reliability, with a Cronbach’s alpha of 0.83 (Bird, 2013)

Questionnaire about the Process of Recovery (QPR) (Neil et al., 2009). The QPR is designed to measure personal recovery from psychosis. It comprises two sub-

scales: interpersonal functioning and intrapersonal functioning. Cronbach's alpha was 0.77 for the interpersonal scale and 0.94 for the intrapersonal scale, indicating good internal consistency (Neil et al., 2009).

Outcome Rating Scale (ORS) (Miller et al., 2003). Individual, social, relational, and overall functioning were measured using this visual analogue scale, which is scored from 0 to 40. Scores below 25 indicate clinically severe levels of psychological distress. Cronbach's alpha was found to be 0.93, indicating good internal consistency (Miller et al., 2003).

Session Rating Scale (SRS) (Duncan et al., 2003). Participant's perception of the therapeutic alliance in MOL sessions was measured using this visual analogue scale, which is scored from 0-40. Scores of 36 or below indicate potential concerns about the therapeutic alliance or the suitability of the therapist's approach. Cronbach's alpha was found to be 0.88, indicating satisfactory internal consistency (Duncan et al., 2003).

The assessment schedule previously presented in Chapter 4 is shown in Table 6 below.

**Table 6** Assessment schedule summary

	Baseline	MOL session measures	10 months	14 months
<b>PSYCHLOPS<sup>1</sup></b>	✓		✓	✓
<b>CORE-OM<sup>2</sup></b>	✓		✓	✓
<b>ROC<sup>3</sup></b>	✓	✓	✓	✓
<b>QPR<sup>4</sup></b>	✓		✓	✓
<b>ORS<sup>5</sup></b>	✓	✓	✓	✓
<b>SRS<sup>6</sup></b>		✓		

<sup>1</sup>Psychological Outcome Profiles (PSYCHLOPS)

<sup>2</sup>CORE Outcome Measure (CORE-OM)

<sup>3</sup>Reorganisation of Conflict Scale (ROC)

<sup>4</sup>Questionnaire about the Process of recovery (QPR)

<sup>5</sup>Outcome Rating Scale (ORS)

<sup>6</sup>Session Rating Scale (SRS)

### 5.3.11 Statistical analysis

The statistical analysis was conducted in accordance with the principles of intention-to-treat analysis, so all participants, including those who attended no MOL sessions, were included in the analysis. Descriptive statistics were used to summarise the feasibility outcomes. The CONSORT guidance for feasibility trials (Eldridge, Chan, et al., 2016) states that efficacy testing is not recommended. Since the study was not designed to detect between-group differences, therefore, results primarily focus on tabulated summaries of means and standard deviations for both groups, on all measures, at all time points. ANCOVA were conducted using SPSS (Version 22.0, 2013) to provide an initial estimate of the effect of group allocation on PSYCHLOPS scores at 10 and 14 months, adjusting for PSYCHLOPS scores at baseline. Because effect size calculations with fewer than 35 participants in each arm are likely to be unreliable (Teare et al., 2014), we report estimated effect sizes and their associated 95% confidence intervals, rather than statistical significance (*P*-values). Prior to the main analysis, data were checked to ensure they met assumptions of normality, homogeneity of variance, and that the covariate was independent of treatment effects. Analysis was performed on all available data, and missing outcome data were assumed to be missing at random.

## 5.4 Results

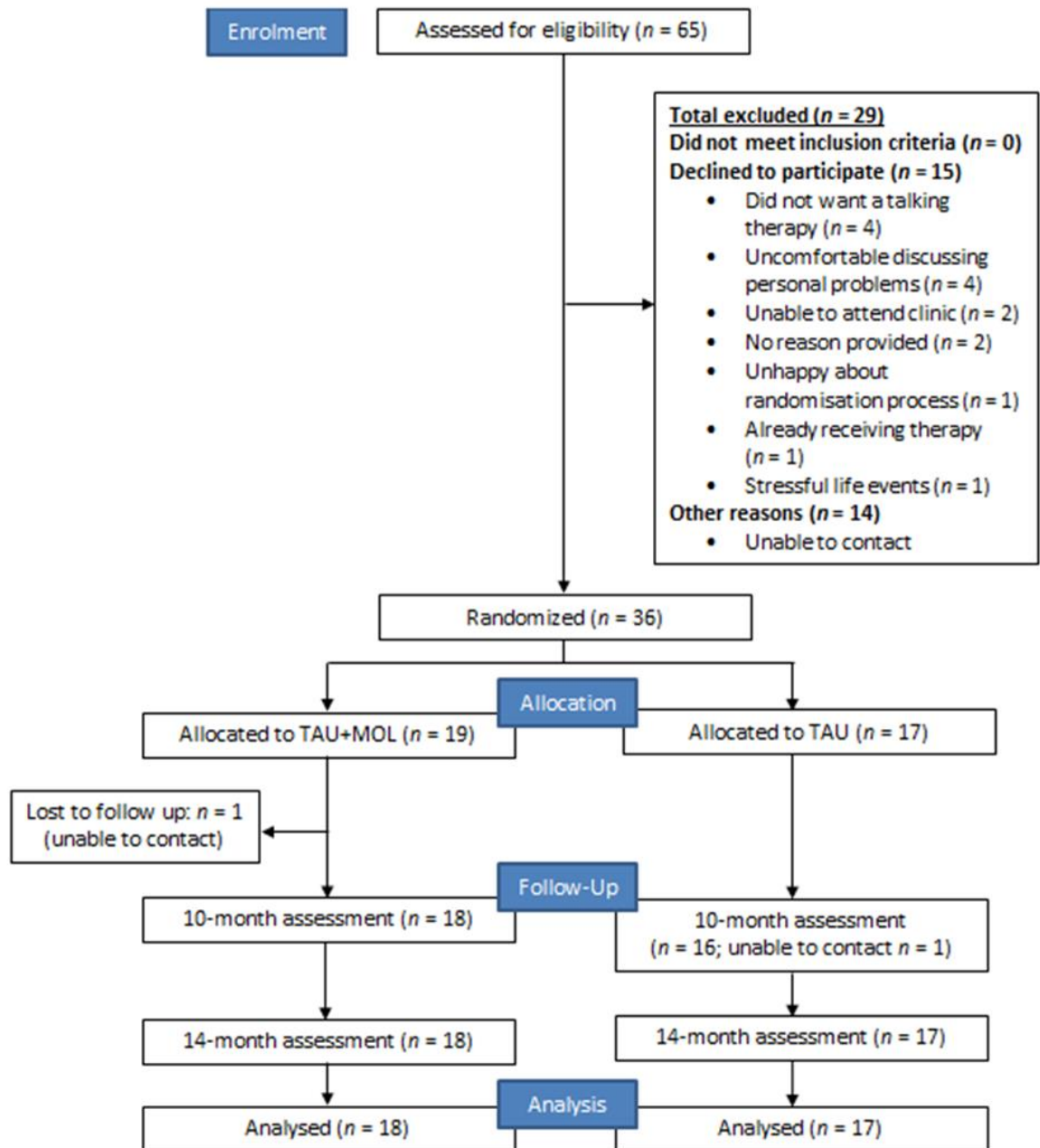
Next Level recruited to target at an average rate of 4.5 participants a month between September 2016 and April 2017. Data collection was completed in June 2018. Participant demographics and clinical characteristics are presented in Table 7. It is notable that the average duration of untreated psychosis (DUP) was longer in the MOL group. A CONSORT diagram showing the flow of participants through the



trial is available in Figure 4. One participant was lost to follow up at 14 months, giving an overall trial retention rate of 97%. This is above the 80% rate deemed to be a successful feasibility outcome. The participant lost to follow up also disengaged from all mental health services during the same period, suggesting that withdrawal was not specific to trial participation.

**Table 7** Participant demographics and clinical characteristics

		<b>TAU+MOL (n = 19)</b>	<b>TAU (n = 17)</b>	<b>Total (N = 36)</b>
<b>Age (years), mean (S.D.)</b>		32.2 (13.1)	28.9 (7.3)	30.6 (10.7)
<b>Gender</b>	Male	11 (57.9%)	12 (70.6%)	23 (63.9%)
	Female	8 (42.1%)	5 (29.4%)	13 (36.1%)
<b>Ethnicity</b>	White – British	18 (94.7%)	14 (82.4%)	32 (88.9%)
	White – any other white background	0 (0.0%)	1 (5.9%)	1 (2.8%)
	Mixed – any other mixed background	1 (5.3%)	0 (0.0%)	1 (2.8%)
	Asian/Asian British	0 (0.0%)	1 (5.9%)	1 (2.8%)
	Black/Black British – African	0 (0.0%)	1 (5.9%)	1 (2.8%)
	<b>Civil status</b>	Single	14 (73.7%)	10 (58.8%)
	Married/cohabiting	5 (26.3%)	5 (29.4%)	10 (27.8%)
	Divorced/separated	0 (0.0%)	2 (11.8%)	2 (5.6%)
<b>Accommodation</b>	Mainstream housing	18 (94.7%)	15 (88.2%)	33 (91.7%)
	Homeless	1 (5.3%)	1 (5.9%)	2 (5.6%)
	Supported housing	0 (0.0%)	1 (5.9%)	1 (2.8%)
<b>Employment status</b>	Unemployed	9 (47.4%)	10 (58.8%)	19 (52.8%)
	Paid employment	5 (26.3%)	3 (17.6%)	8 (22.2%)
	Education/training	3 (15.8%)	4 (23.5%)	7 (19.4%)
	Unpaid employment	2 (10.5%)	0 (0.0%)	2 (5.6%)
<b>Duration of untreated psychosis (months), mean (S.D.)</b>		46.1 (60.8)	14.6 (21.8)	30.9 (48.2)
<b>Length of EIP treatment (months), mean (S.D.)</b>		10.5 (9.5)	16.2 (11.7)	13.2 (10.8)
<b>Primary diagnosis</b>	Psychosis spectrum disorders	5 (26.3%)	6 (35.3%)	11 (30.6%)
	Depression	2 (10.5%)	4 (23.5%)	6 (16.7%)
	Bipolar disorders	1 (5.3%)	1 (5.9%)	2 (5.6%)
	Anxiety disorders	2 (10.5%)	1 (5.9%)	3 (8.3%)
	Mixed anxiety and depression	2 (10.5%)	1 (5.9%)	3 (8.3%)
	Substance misuse disorders	2 (10.5%)	1 (5.9%)	3 (8.3%)
	Eating disorder	0 (0.0%)	1 (5.9%)	1 (2.8%)
	Personality disorders	0 (0.0%)	1 (5.9%)	1 (2.8%)
	No diagnosis	5 (26.3%)	1 (5.9%)	6 (16.7%)
	<b>Medication</b>	Antipsychotics	11 (57.9%)	13 (76.5%)
Antidepressants		9 (47.4%)	10 (58.8%)	19 (52.8%)
Other psychotropic		4 (21.1%)	4 (23.5%)	8 (22.2%)
No psychotropic		7 (36.8%)	3 (17.6%)	10 (27.8%)



**Figure 4** CONSORT diagram (full results)

The total number of MOL sessions booked by all participants was 92. Of these, 57 (62%) were attended as planned, 27 (29.3%) were cancelled by participants, and 8 (8.7%) were not attended. Two participants accounted for 59.3% of the total number of cancelled sessions. The mean number of sessions attended by

each participant was three (SD = 3.3; median = 2; range = 0-10). The mean number of cancelled sessions was 1.4 (SD = 2.6; median = 0; range = 0-10). The mean number of sessions not attended by participants was 0.4 (SD = 0.6; median = 0; range = 0-2). Among the 14 participants who attended at least one MOL session, the mean number of sessions was 4.1 (SD = 3.2; median = 3.5; range = 1-10), and the mean length of time from the start of the treatment window to attendance of first MOL session was 6 weeks (SD = 6; median = 3.5; range = 1-23). The mean length of time from final MOL session attendance to end of treatment window was 22 weeks (SD = 14.9; median = 20.5; range = 1-42). Four participants continued to book MOL sessions in the last month of the treatment window. Participants' reasons for stopping therapy are reported in Table 8 and their general comments on trial participation are presented in Table 9. The mean length of individual therapy sessions in minutes was 48 (SD 19.3; range 7-107).

Summary statistics for both groups on all measures at all time points are presented in Table 10. Because assumptions of normality and homogeneity of variance were not met for all data, bootstrapped one-way ANCOVA were conducted to compare the effects of group allocation on PSYCHLOPS scores at 10 months and 14 months, controlling for the effects of PSYCHLOPS scores at baseline. Effects were as follows at 10 months, effect = -0.59 (standard error=2.13; 95% confidence interval -5.12 to 3.03), and 14 months, effect = -0.11 (SE=1.90; 95% CI -3.86 to 3.74).

**Table 8** Participants' reasons for stopping or not attending MOL sessions

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<b>Reason for stopping MOL sessions</b>	
I stopped attending because I got what I needed from the sessions	<i>n</i> = 3 (18.8%)
I stopped attending because I did not get what I needed from the sessions	<i>n</i> = 0 (0%)
I ran out of time	<i>n</i> = 6 (37.5%)
I stopped attending for other reasons (see below)	<i>n</i> = 7 (43.8%)

**Comments on stopping MOL sessions from participants who attended at least one session:**

“Physical health and [MOL] appointments clashed on Thursdays.”

“In college - would have had more [MOL sessions] if had more time.”

“I couldn't attend more because of work.”

“Managing [MOL] sessions with work.”

“Possibly needed one more [MOL session] towards the end, but work commitments got in the way.”

“Prefer to sort my problems out on my own.”

“It made me realise I was making too much out of my normal problems.”

**Comments from participants who did not attend any MOL sessions**

“Can't remember why I didn't attend.”

“I didn't attend because I had too much on (coincided with me having two [operations]).”

“I have [long-term physical health condition] - having lots of relapses and that was taking over - there was no time for therapy.”

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Over the course of the trial, four incidents involving participants were investigated in detail to check whether they met the criteria for classification as serious adverse events (SAE). After being reviewed by the research team and members of the TSC, none of the incidents were judged to be related to trial participation. Participant responses to the Adverse Events Measure (Hutton et al., 2017) are available in Appendix H.

**Table 9** Participants' general comments on trial participation

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<b>Comments from participants allocated to the 'Method of Levels' group</b>	
Positive comments:	<p>"I enjoyed it because it's the way I think when I was younger, and it's led me to become more caring as a human being, and use those questions on myself."</p> <p>"Everything was fine."</p> <p>"[MOL] sessions were helpful as could book whenever which made it easier to juggle recovery with work. Helpful for people who don't have lots of free time."</p> <p>"It was good."</p> <p>"I found taking part in the study incredibly useful, thank you so much! The flexibility meant I could deal with any of my issues when I felt ready to talk about them and without any pressure. "</p> <p>"It was interesting and if I could help someone out with their predicament they might benefit from it."</p> <p>"In my opinion it helped me a great deal. I'm not 100% fixed, but I'm an awful lot better. Fingers crossed more people get access to it and it's a success."</p> <p>"I found the questionnaires helpful in guiding me to think about my thought process. To step back and reconsider. Talking openly about my thoughts helped me to see my situation more clearly. It was useful to 'report' back on the impact upon me of current government policies."</p> <p>"It was a great experience to have the opportunity to speak my mind [in MOL sessions] without judgement or advice on how to control such thoughts for example in CBT."</p>
Mixed comments:	<p>"I found it helpful, I really did, but it got to the point where I was digging deeper into my thoughts, I ran out of time. But I found it helpful and I would recommend it to anyone going through the same thing."</p>
Negative comments:	<p>"I found it difficult to talk about my life."</p>
<b>Comments from participants allocated to the 'Treatment as Usual' group</b>	
Positive comments:	<p>"Hope it's helpful. Appreciate being given small bit of money for time - but the main thing is that it's valuable for others."</p> <p>"The questions don't cause me any problems if anything speaking to [researcher] helps by giving me a different point of view and a better understanding of how I am feeling."</p> <p>"It was alright and you were really nice about it, and it's an easy 20 quid."</p> <p>"Just feel that you're an understanding person - so patient - it has helped me to talk to you. Good idea to get people with mental health problems to express how they feel."</p> <p>"Very professional and helpful."</p> <p>"I'm hoping that it will help others in the future and help mental health teams understand other people's issues to help them cope."</p> <p>"It has helped me to leave the house helping in this study."</p> <p>"Thought that the study helped me look at my past week and my past. Helped me to see how much I've improved."</p>
Negative comments:	<p>"Talking to people would allow people to talk things through compared to yes/no questionnaires."</p> <p>"I found randomisation hard - at the time I was seeing another psychologist and I didn't get on with her and didn't like therapy, so I wanted to try this therapy. Because I didn't get it, that made me upset."</p>
Neutral comments:	<p>"Can't think of anything at the moment."</p> <p>"Nothing."</p>

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**Table 10** Summary statistics of outcome measures for each randomisation group at different time points

Measure	Time	TAU+MOL				TAU			
		Mean	SD	Range	N	Mean	SD	Range	N
<b>PSYCHLOPS<sup>1</sup></b>	Baseline	16.3	3.5	6.0 – 20.0	19	14.9	2.6	9.0 – 18.0	17
	10 months	9.8	6.7	0.0 – 20.0	18	10.4	4.8	3.0 – 20.0	16
	14 months	10.2	6.9	0.0 – 19.0	18	10.0	4.4	1.0 – 20.0	17
<b>CORE-OM<sup>2</sup></b>	Baseline	71.1	25.7	23.0 – 111.0	19	60.3	24.2	21.0 – 102.0	17
	10 months	47.2	35.5	2.0 – 106.0	18	44.4	22.2	9.0 – 97.0	16
	14 months	50.5	33.8	5.0 – 125.0	17	43.8	20.1	3.0 – 76.0	16
<b>QPR<sup>3</sup></b>	Baseline	45.7	12.9	23.0 – 69.0	19	54.6	13.0	28.0 – 87.0	17
	10 months	57.4	17.0	30.0 – 81.0	18	59.2	11.2	29.0 – 73.0	16
	14 months	54.6	21.4	8.0 – 81.0	17	58.8	13.1	40.0 – 87.0	16
<b>ORS<sup>4</sup></b>	Baseline	14.0	10.0	1.4 – 34.2	19	19.1	9.2	5.9 – 35.7	17
	10 months	20.4	14.5	1.1 – 39.0	18	22.6	10.6	3.3 – 36.6	16
	14 months	19.5	12.9	0.6 – 38.0	17	23.1	8.9	10.0 – 39.5	16
<b>ROC<sup>5</sup></b>	Baseline	58.9	20.1	20.0 – 90.9	19	69.1	14.6	43.6 – 95.5	17
	10 months	70.4	20.9	26.4 – 100.0	18	69.1	13.2	41.8 – 98.2	16
	14 months	68.6	27.2	6.4 – 100.0	17	73.0	13.5	45.5 – 98.2	16

The mean score on the Session Rating Scale (Duncan et al., 2003) was 37.03 (SD = 4.09, range = 24.5-40), which is above the threshold of 36 indicating that there were not apparent difficulties or problems with the therapist's approach or the therapeutic relationship.

Ten therapy sessions (20% of the total number of sessions conducted) were rated using the MOL Session Evaluation Form (Carey & Tai, 2012). The mean total score of sessions rated was 68 (SD = 6.16; range = 53-78) out of a maximum possible score of 80. This evaluation form has not yet been tested to establish its reliability and validity. The threshold for what represents an acceptable overall score, therefore, has not been established. A mean score of 68, however, was judged to be a reasonably good indication that there were not any significant difficulties in terms of the therapist's fidelity to the MOL approach.

Three participants in the TAU group reported receiving one or more sessions of CBTp as part of their routine care, and one had received sessions of supportive counselling accessed through their university. Although they were not discouraged by the research team from accessing other forms of support, none of the participants in the MOL group reported receiving any psychological interventions outside of the trial.

## **5.5 Discussion**

This is the first randomised controlled trial of MOL for people experiencing FEP. Recruitment to the trial progressed well, and the recruitment target was met within the anticipated time frame. A retention rate of 97% at final follow up was above the 80% benchmark deemed to be a successful outcome.



Feedback from participants who received MOL suggests that they generally found it to be a helpful experience. None of the participants in the MOL group reported that they stopped attending therapy because it was not meeting their needs, which suggests the intervention is acceptable to people experiencing FEP. This is supported by data collected using the Session Rating Scale (Duncan et al., 2003). Having control over therapy, being able to speak openly about problems, and having the opportunity to develop new perspectives were particularly valued by participants receiving MOL. This is consistent with research that indicates feeling in control of therapy is a good predictor of service user-perceived helpfulness (Cocklin et al., 2017). It also supports the findings of existing qualitative research that suggests having the opportunity to talk to another person about distressing problems is a helpful aspect of psychological therapy (Carey et al., 2007).

Feedback on the experience of trial participation from participants in both the MOL and TAU groups seemed to indicate that it was a predominantly positive experience. Having the opportunity to discuss problems was valued by many participants in both groups. Participants reported appreciating receiving payment for completing follow up assessments. Having a sense of helping others in a similar situation was also seen as a positive aspect of trial participation. One participant in the TAU group reported that completing questionnaires was somewhat problematic. This is consistent with research that suggests participants in clinical trials can find it hard to convey complex experiences through scoring systems used in outcome measures (Holmberg, Karner, Rappenecker, & Witt, 2014). Another TAU participant described feeling disappointed that they were not allocated to receive MOL.

The mean number of MOL sessions attended over the course of the treatment window was three (range = 0-10). This is substantially fewer than the 16 sessions of

CBTp currently recommended as a minimum course of treatment in the United Kingdom (National Institute for Health and Care Excellence (NICE), 2014). This finding is consistent with other research indicating that service users who have control over accessing psychological interventions tend to book a relatively small number of sessions compared to the amount generally recommended by practice guidelines (Carey et al., 2013). The proportion of MOL sessions that were cancelled was 29.3%, although the majority of these were accounted for by two participants. Cancellations did not have a noticeable impact on the overall efficiency of the appointment booking system because these appointment times were made available to other participants. The number of appointments not attended or cancelled was 8.7%. Because attendance figures are rarely reported in trials of psychological therapy for psychosis, it is difficult to judge how these rates compare to similar studies. Rates of non-attendance for the increasing access to psychological therapies (IAPT) programme in the United Kingdom are estimated to be between 45% and 48% (Marshall et al., 2016). Although IAPT is designed for people with common mental health problems, rather than for people experiencing FEP, these figures suggest that service user-led scheduling might have advantages in terms of efficiency over other approaches to appointment scheduling.

Some participants reported that they stopped attending MOL sessions because they had got what they needed from the sessions. However, a larger number said that they ran out of time and would have attended more sessions if the treatment window had been longer. The pressure of other commitments (e.g. work, health appointments) was frequently cited by participants as a reason for not attending as many sessions as they would have liked. Also, four participants continued to book sessions in the last month of the treatment window. A larger trial should consider

offering a longer treatment window and increase the accessibility of MOL sessions to ensure they are available at times and locations that are convenient for all participants.

No potential SAEs were deemed attributable to trial participation, providing evidence that both the research design and MOL intervention are safe for this population.

Data collected from standardised outcome measures did not appear to favour the MOL intervention over TAU. As a small feasibility trial, however, the study was not designed to detect such between-group differences, and the wide confidence intervals around the estimates of effect size should be noted.

Very few participants in the TAU group, and no participants in the MOL group, accessed any other psychological interventions over the course of the trial. This finding is consistent with research suggesting that relatively few users of EIP services currently receive psychological interventions in line with recommended treatment guidelines (Royal College of Psychiatrists et al., 2016).

#### *5.5.1 Limitations*

The number of roles the first author performed within the trial (recruitment, enrolment, conducting baseline assessments, delivery of therapy, and collection of follow up data) potentially increased the risk of bias. Additionally, the research team were not blind to group allocation, which also increases the risk of potential bias. Although treatment by an EIP service could be considered an active control, participants in TAU were not systematically offered any psychological interventions. Differential access to psychological interventions between the two groups could,

therefore, be considered a limitation of the study. Given that longer DUP is associated with poorer long term outcomes (Marshall et al., 2005), the disparity in DUP between groups could be a confounding factor and future trials should consider stratifying on this variable.

Because participants in the MOL group often had relatively long periods between their final therapy session and follow up assessments, a larger trial should consider whether the assessment schedule should be adjusted to increase the likelihood of detecting potential treatment effects.

### *5.5.2 Conclusions*

This study demonstrates that it is feasible to recruit and retain participants experiencing FEP in a randomised controlled trial of MOL. It also provides prima facie evidence of MOL's acceptability for people with FEP. These findings support the view that progressing to a larger trial of MOL for FEP is justified.

**CHAPTER 6: 'It was me answering my own questions': Experiences of Method  
of Levels therapy amongst people with first-episode psychosis**

## PREFACE

This article was published in the *International Journal of Mental Health Nursing* (Griffiths et al., 2019) and has been formatted in accordance with the manuscript requirements for that journal. The authors are Robert Griffiths, Dr Warren Mansell, Dr Dawn Edge, Professor Timothy Carey, Heather Peel and Dr Sara Tai. The PhD student designed the study, recruited participants, transcribed the majority ( $n = 10$ ) of audio recordings, analysed the data, and wrote the first draft of the manuscript under the supervision of Sara Tai, Warren Mansell, Dawn Edge and Timothy Carey. Heather Peel conducted the interviews, transcribed a minority ( $n = 2$ ) of interviews, and contributed to the data analysis under the supervision of the PhD student. All authors commented on the first draft of the manuscript written by the PhD student, made suggestions for its improvement, and approved the final version of the manuscript.

## **6.1 Abstract**

In this study, we aimed to understand how people with first-episode psychosis experienced a transdiagnostic cognitive therapy called Method of Levels (MOL). Semi-structured interviews were conducted with 12 individuals who were participants of a feasibility randomised controlled trial of MOL for first-episode psychosis. Interviews were analysed using thematic analysis. Four superordinate themes were identified: ‘The therapist’s approach’; ‘I was in control’; ‘Thinking and talking’; and ‘Looking at problems from a different perspective’. Our findings suggest that therapy was experienced as most helpful when participants perceived themselves to have control over the process of therapy, could explore and express of a wide range of difficulties, and were able to generate new perspectives on their problems. MOL and its associated system of client-led appointment scheduling were predominantly perceived to be helpful and appear suitable for further testing in a larger clinical trial.

## **6.2 Introduction**

### *6.2.1 Background*

Psychosis is a common mental health problem associated with severe negative individual, societal, and economic consequences (McCrone et al., 2008; Tsiachristas, Thomas, Leal, & Lennox, 2016). Current guidelines recommend that people experiencing psychosis should be offered cognitive behavioural therapy for psychosis (CBTp) (National Institute for Health and Care Excellence (NICE), 2014). However, ongoing difficulties exist with the implementation of CBTp in routine clinical practice (Ince et al., 2015), and less expensive ‘generic’ interventions have been shown to have benefits similar to CBTp for people experiencing psychosis (Turner et al., 2014). Additionally, given the high levels of comorbidity (Achim et al., 2011; Addington et al., 1998) and diverse sources of distress (Griffiths, Mansell, Edge, et al., 2018) amongst people experiencing psychosis, there are questions about how effectively disorder-specific approaches can meet the complex needs of this population. It has been argued that transdiagnostic interventions, which target the core processes maintaining psychological distress, could have advantages over disorder-specific approaches (Harvey et al., 2004; Mansell et al., 2008), particularly for people experiencing psychosis (Tai, 2009, 2016).

### *6.2.2 Method of Levels*

Method of Levels (MOL; Carey 2006) is a transdiagnostic cognitive therapy that directly applies the principles of Perceptual Control Theory (PCT; Powers 2005) to the practice of psychotherapy. From a PCT perspective, human health is dependent on our ability to control important biological, psychological and social variables (Carey 2016). The function of behaviour, according to PCT, is to control



our perceptions in line with ‘reference values’ (synonymous with ‘goals’, ‘values’, or ‘just rights’) specifying the desired state of relevant perceptual variables. A sustained inability to maintain control over important perceptual variables creates psychological distress. Loss of control is commonly a consequence of goal conflict, where two or more incompatible references are held for the same perceptual variable. A recent meta-analysis has provided evidence that higher levels of goal conflict are associated with greater psychological distress and lower levels of positive psychological outcomes (Gray, Ozer, & Rosenthal, 2017). Research into the relationship between goal conflict and psychosis is currently limited, but one recent study found that the content of auditory verbal hallucinations was often thematically linked to voice-hearers’ personal goals (Varese et al., 2015). The authors of the study concluded that conflict between personal goals and voice content might be implicated in the maintenance of psychological distress. The putative mechanism through which goal conflict is resolved is called ‘reorganisation’, an innate trial-and-error learning process where random changes are introduced into a system. Changes persist when they have the effect of reducing the disparity between preferred and actual perceptions (Marken & Powers, 1989; Marken & Carey, 2015).

In practice, therapists delivering MOL have two main goals. Firstly, encourage the person to talk freely about their problems. Secondly, pay attention for signs that the person’s awareness has momentarily shifted onto other background thoughts (known as “disruptions”), and then ask about these. The therapist pursues these two goals iteratively with the aim of helping the person shift their awareness onto the source of the conflict. Sustaining awareness on conflicted reference values facilitates the reorganisation process, enabling people to resolve conflicts and regain control.

### *6.2.3 Client-led scheduling*

Because the reorganisation process is believed to be non-linear and idiosyncratic, it is assumed that people will need different numbers of MOL sessions. This is a departure from other approaches that stipulate the number of therapy sessions clients should attend. A recommended course of CBTp, for example, is at least 16 sessions (National Institute for Health and Care Excellence (NICE), 2014). In contrast, MOL employs a system of client-led scheduling to enable service users to choose the number, frequency and duration of sessions. There is already some evidence that this approach to appointment scheduling is acceptable to clients, has the potential to use staff resources more efficiently, and increases client control (Carey, Tai, and Stiles 2013; Carey and Mullan 2007).

### *6.2.4 The Next Level Study*

Next Level is a feasibility randomised controlled trial of MOL for people either experiencing or recently recovering from a first-episode of psychosis (ISRCTN13359355). Primary outcomes are recruitment and retention in the trial. Additionally, the study aims to investigate the acceptability of MOL and client-led appointment scheduling. The rationale, design and baseline data for the Next Level trial have been published (Griffiths, Mansell, Carey, et al., 2018). The results of the trial are currently being prepared for publication.

### *6.2.5 Client Perspectives on Psychotherapy*

Qualitative research into what clients with psychosis find helpful about psychological interventions has produced inconsistent findings (Awenat et al., 2017; Kilbride et al., 2013; May, Strauss, Coyle, & Hayward, 2014). It is not clear whether

this variation is a product of genuinely different results between studies, or if there are actually common phenomena being described which are obscured by differences in terminology. Currently, there is limited qualitative research into the experience of receiving psychological interventions amongst people with first-episode psychosis (FEP). One study into experiences of attending a mindfulness group for FEP emphasised understanding and accepting oneself as being a helpful outcome (Ashcroft et al., 2012). To our knowledge, no qualitative studies have directly investigated how people with FEP experience individual therapy.

An initial qualitative study looking at the experience of receiving MOL suggests that clients judged it to be a generally useful experience (Carey, Carey, Mullan, Spratt, & Spratt, 2009). So far, however, there has not been any in-depth qualitative research that explores clients' experiences of receiving MOL, either for psychosis-related difficulties or more generally. Also, qualitative research into how clients' access psychological interventions is currently sparse. One of the few qualitative studies conducted so far looked at experiences of open access clinics amongst people using eating disorder services (Clinton, Almlöf, Lindström, Manneberg, & Vestin, 2014). Participants in this study appreciated the freedom and flexibility of the open access system. To date, however, there has not been any in-depth qualitative research into experiences of using client-led appointment scheduling systems for any population or psychotherapeutic modality.

#### *6.2.6 Study Aims*

The aim of the current study is to understand participants' experiences of attending MOL sessions and using the service-user led appointment scheduling

system. It also aims to explore MOL's proposed mechanism of change from a first-person perspective.

### **6.3 Method**

Qualitative methods are an important source of knowledge in psychotherapy research (Binder et al., 2016) with considerable potential to enhance the evidence generated by clinical trials (O'Cathain et al., 2013). They are particularly well suited to understanding the feasibility and acceptability of healthcare interventions (Cooper et al., 2014).

#### *6.3.1 Participants*

A total of 36 participants were recruited to the Next Level trial from specialist Early Intervention in Psychosis (EIP) services delivered by a National Health Service (NHS) mental health trust in North West England. Care coordinators working in EIP services were encouraged to raise awareness of the study amongst clients on their caseloads. Clients who expressed an interest in the study to their care coordinators were contacted by the research team and invited to participate in the trial. Participants were randomised to receive either treatment as usual (TAU), which consisted of ongoing support from their usual care team, or MOL in addition to TAU. After randomisation, 19 participants were allocated to receive the MOL intervention.

Participants randomised to receive MOL were able to book as many sessions as they required over a 10-month period. Appointment bookings were made through a dedicated website, by telephone, or by SMS 'text' message. A total of 14 participants attended at least one session of MOL over the course of the 10-month

treatment window. All MOL sessions were delivered by RG under the clinical supervision of ST, WM, and TC.

All participants randomised to the MOL arm of the trial were invited to attend an interview about their experience of therapy and trial participation. Participants were contacted by telephone by either RG or HP. In total, a purposive sample of 12 participants agreed to be interviewed, all of whom had attended at least one session of MOL during the trial. Two participants who attended one or more MOL session were not contactable at the time of conducting the interviews, although they were retained in the trial. None of the five participants who were randomised to receive MOL but attended no sessions were interviewed. Of these five participants, one dropped out of the trial altogether, two remained in the trial but were not contactable when interviews were being conducted, one declined to be interviewed, and one agreed to take part but did not attend the appointment arranged to complete the interview. Participant's demographic information and MOL session attendance rates are presented in Table 11.

### *6.3.2 Ethical approval*

All ethical approvals were in place prior to recruitment (REC reference: 16/NW/0592; IRAS project ID: 204043). Participants provided written consent to be interviewed at the point of entry to the trial. Additional verbal consent was sought prior to commencing interviews. Participants were made aware of their right to withdraw from the interview at any point. Information that could lead to the identification of specific participants has not been included in this article.

**Table 11** Participant demographic information and session attendance rates

<b>Participant ID</b>	<b>Sex</b>	<b>Age</b>	<b>Primary diagnosis</b>	<b>Civil status</b>	<b>Employment status</b>	<b>Number of MOL sessions attended</b>
<b>P01</b>	M	47	Moderate depressive episode	Single	Unemployed	1
<b>P03</b>	M	27	Mixed anxiety and depressive disorder	Single	Unemployed	10
<b>P07</b>	F	19	Post-traumatic stress disorder	Single	Education/training	1
<b>P08</b>	F	20	Acute polymorphic disorder without symptoms of schizophrenia	Single	Education/training	4
<b>P19</b>	F	26	Moderate depressive episode	Single	Paid employment	10
<b>P20</b>	M	32	No diagnosis	Single	Unemployed	5
<b>P24</b>	M	30	Unspecified non-organic psychosis	Married/co-habiting	Paid employment	4
<b>P28</b>	M	20	No diagnosis	Single	Unpaid employment	8
<b>P29</b>	F	32	Social phobia	Married/co-habiting	Unpaid employment	2
<b>P30</b>	M	54	Other nonorganic psychotic disorders	Married/co-habiting	Paid employment	1
<b>P34</b>	F	62	Person with feared complaint in whom no diagnosis is made	Single	Unemployed	5
<b>P36</b>	M	30	Mental and behavioural disorders due to multiple drug use	Single	Unemployed	3

NB. All demographic data collected at trial baseline. Details of primary diagnoses were taken from participants' clinical records.

### 6.3.3 Interviews

A topic guide was developed and piloted by the research team in consultation with a service user reference group and an experienced service user researcher who

was not part of the research team. It was designed to be used flexibly by the interviewer. Questions focused on participants' experiences of client-led scheduling and the Method of Levels intervention. The topic guide is presented in Table 12. Interviews were conducted by a service user researcher. She was provided with training and ongoing supervision appropriate to her role. This included training on conducting semi-structured interviews, responding to participant distress, and risk management procedures. Interviews lasted less than one hour and were conducted in participants' homes or community venues, depending on participant preference. All interviews were digitally audio recorded. The interviewer made field notes during and after interviews.

**Table 12** Topic guide

Experiences of receiving Method of Levels
<ul style="list-style-type: none"> <li>• Can you tell me about your experience of having Method of Levels therapy? <ul style="list-style-type: none"> <li>○ Prompt: What was this like for you? Was there anything you found helpful about Method of Levels? Anything unhelpful?</li> </ul> </li> <li>• Was there anything that would have made the therapy more helpful for you? <ul style="list-style-type: none"> <li>○ Prompt: Was there anything that changed for you during therapy? Was there anything that you hoped would change that didn't?</li> </ul> </li> <li>• Do you have any other comments about the therapy you received?</li> </ul>
Experiences of client-led scheduling
<ul style="list-style-type: none"> <li>• Can you tell me about your experience of booking therapy appointments in this study? <ul style="list-style-type: none"> <li>○ Prompt: How did you find booking your own appointments? Were there any problems with this? Anything you liked about booking appointments? Anything you disliked?</li> </ul> </li> <li>• Is there anything else you would like to say about booking appointments?</li> </ul>

#### 6.3.4 Data Analysis

Data analysis was informed by Braun and Clarke's (2006) guidance on conducting thematic analysis. Drawing on Campbell et al.'s (2013) recommendations for researchers who plan to code the majority of data alone, additional steps were included to improve the credibility of the analysis.

Data analysis was conducted according to the following steps:

- RG first familiarised himself with the data by listening to audio recordings of the semi-structured interviews, before transcribing the interviews verbatim. Transcripts were read repeatedly and initial thoughts were discussed with all members of the research team and recorded in a reflective journal (Ortlipp, 2008).
- Transcripts were uploaded to NVivo qualitative data analysis software (QSR International Pty Ltd. Version 11, 2015). The first eight interview transcripts were coded using an inductive, data-driven approach.
- Apparently related initial codes were grouped into 'code families'. A brief description was written for each code family and they were collected together to form an initial coding schedule.
- A 'gold standard/master coder' approach to coding the dataset was used, where a second rater's codes (HP) were used to increase the credibility of the coding schedule, but only [first author's] codes contributed to the final analysis (Syed & Nelson, 2015). RG coded a randomly selected transcript using the initial coding schedule. Codes were added to portions of text using Microsoft Word 2010's "comment" function.



- A copy of the annotated text with codes removed was then given to HP, who used the initial coding schedule to add codes to the empty comment boxes. Transcripts were compared to establish the degree of inter-coder agreement. The level of percentage agreement ( $P^A$ ) was calculated by comparing the number of coder agreements ( $N^A$ ) and disagreements ( $N^D$ ) using this formula:

$$P^A = \frac{N^A}{N^A + N^D} \times 100$$

- The initial coding schedule was refined based on discussions about coding disagreements. This process was repeated iteratively until inter-coder agreement was above 80%, which was deemed an acceptable level of agreement. After repeating this process three times, an 84% level of agreement was reached. Detailed descriptions of individual codes were then produced.
- RG then applied the coding schedule to all 12 interview transcripts. If potential new codes were identified that were not already included in the coding schedule, these were captured under an “other” code, recorded as reflective notes, and discussed with the wider research team to decide whether a new category of code was required.
- Once all data were coded, the analysis was refocused from the level of individual codes to identify initial themes across the dataset.
- Candidate themes were refined to ensure internal homogeneity within themes and external heterogeneity between themes (Patton, 1990). Themes were separated and collapsed as appropriate to achieve this. A thematic map of the

data (presented in Figure 1) was developed to illustrate relationships between themes and sub-themes (Braun, Clarke, & Rance, 2014).

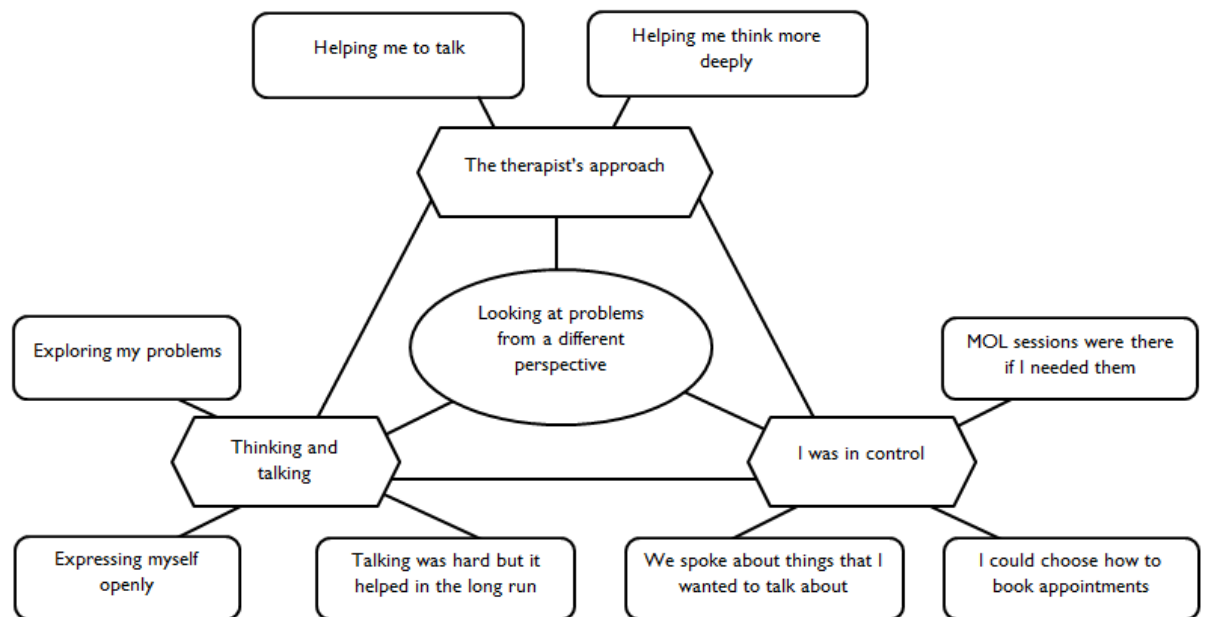
- Final themes and sub-themes were named and described in detail.

#### *6.3.5 Reflexivity Statement*

RG is a mental health nurse who has worked as a psychological therapist in EIP services for several years. ST, WM, and TC are researchers and practicing clinical psychologists. Their research has mainly focused on PCT and developing MOL. DE is a senior lecturer in psychology and mental health, and specialist in qualitative research. Her research is concerned with developing culturally appropriate psychological interventions for psychosis. HP is a service user researcher who has lived experience of using mental health services. This research has been informed by the principles of PCT (Powers, 2005). One of the assumptions of PCT is that although an objective reality is assumed to exist, we are only able to experience our own perceptions of that reality. Our epistemological position, therefore, is most closely aligned to a critical realist perspective (Fletcher, 2017).

### **6.4 Findings**

Four superordinate themes were identified: ‘The therapist’s approach’; ‘I was in control’; ‘Thinking and talking’; and ‘Looking at problems from a different perspective’. A thematic map is presented in Figure 5.



**Figure 5** Thematic map

#### 6.4.1 *The therapist's approach*

This theme captures participants' perceptions of the therapist during MOL sessions. It comprises two sub-themes: 'Helping me to talk' and 'Helping me think more deeply'.

*Helping me to talk.* Participants reported that the therapeutic process was facilitated by working with a therapist whose manner and responses they perceived to be helpful. Participants partly attributed their ability to discuss emotionally difficult material to the approach taken by the therapist. This participant describes how the therapist's approach made it easier to discuss difficult subjects:

It was not uncomfy cos of the person who was, like, talking to me, he made me feel comfortable [P03]

Several participants perceived the therapist to be non-judgemental, which enabled them to be more open when discussing their difficulties:

Like I say, whether it's just the way he is, but it, I don't know, I just feel like I'm not being judged. I can, I can, kind of, just calm down and just say things slow. [P30]

One participant – who reported that his thinking often felt disorganised – said that the therapist's responses helped him to focus his attention on a subject for a sufficient amount of time for him to be able to explore it in more detail, which was something he appreciated:

...he basically was good to keep me in one place for like, [I] tend to drift a little bit and I kind of went all over the place. [P28]

Where the therapist's responses were not perceived to be helpful, this seemed to interfere with the overall process of therapy. This participant describes how, from her perspective, the therapist's approach did not help her talk because he seemed too interested in her experiences:

The thing is I just didn't like him. Like, I like him as a person, obviously, cos he's nice, but I just mean his style of doing the therapy I just didn't like, because he just was too, he was almost too interested in what, in everything. [P08]

This highlights how perceptions of helpful therapist responses varied considerably between participants. The extent to which participants found the therapist's approach helpful appeared to impact on the overall process of therapy.

*Helping me think more deeply.* Participants described how the therapist's questioning style enabled them to explore problems, thoughts and feelings in greater depth. Participants reported that the therapist's questions often focused on present moment experiences:

[The therapist] will say "how does it feel to, you know, to hear yourself, erm, saying that, you know, saying, saying, those words?" [P34]

The following participant describes how the therapist's questions allowed them to explore problems in greater depth compared to conversations with other mental health professionals involved in their care:

...it was kind of like, erm, he'd ask me the question, "Why, why, why?", or trying to probe a little bit deeper than necessarily than, er, say somebody who I ordinarily saw from [the Early Intervention Team]. [P24]

This participant describes how the therapist would not offer advice on resolving problems. Instead, he used questions to help the participant explore their problems in more detail:

[The therapist] would just kind of probe a little bit more, he'd never actually, you know, explain "Oh, this is your answer, this is why", he'd go "Oh, why do you think that?" and "What makes you think that way?" [P19]

One participant described receiving MOL as a predominantly unhelpful experience. This was partly attributed to finding the therapist's use of questions difficult:

Like, it felt really one-sided and like I couldn't, like... it just felt too one-sided. Like, it was just all me talking. [P08]

However, where participants were willing and able to explore their problems in depth, and the therapist's questioning style supported them in this process, they were more able to use the MOL sessions to develop new insights.

#### *6.4.2 I was in control*

This theme comprises three sub-themes capturing participants' discussion of how having control over the process of therapy contributed to being able to make effective use of MOL sessions: 'MOL sessions were there if I needed them'; 'I could choose how to book appointments'; and 'We spoke about things that I wanted to talk about'.

*MOL sessions were there if I needed them.* Participants appreciated the control that client-led appointment scheduling provided, as this quote illustrates:

And, I think what was nice about this was, it was very open. You had lots of, you had all these months and you could come and go as you pleased, and that flexibility was really good. [P19]

Being expected to attend a pre-determined number of sessions was perceived to be unhelpful by participants:

...for me, I think it would be, if I was going every week and you was feeling okay, I think it would be a negative impact on me. Because I feel it would be like me saying, "Well, I'm not right, that's why I'm coming", whereas I know that I'm feeling okay. [P30]

Participants reported booking MOL sessions when they thought it would be useful for them to discuss a problem:

Yeah, so if a problem had come up, rather than getting upset and panicking about it, that I'm upset, "How am I going to deal with this?" I'd think, "Well, I don't have to wait longer than a week and I'll go and see [the therapist], and I'll be able to talk about it, and I'll deal with it." [P19]

Even during periods where participants were not attending sessions regularly, the ongoing availability of MOL sessions was regarded as helpful:

...it was a bit like a safety net almost then knowing it's there if I need it.

[P19]

For some participants, practical issues got in the way of attending as many MOL sessions as they would have liked. Others described the travelling distance as a barrier to attending more sessions.

Overall, participants described using the appointment booking system flexibly, balancing the need to discuss problems in MOL sessions against other factors, such as work, education, and family commitments.

*I could choose how to book appointments.* Having control over the method of booking appointments – SMS text message, telephone, or booking website – was appreciated by participants. Some expressed a strong preference for one method. This participant, for example, favoured the appointment booking website because of concerns about disturbing the therapist outside of office hours.

Yeah, because the text was easy, but I'd worry and think, "Oh, it's 9 o'clock at night so I can't text him now", and then I might forget to do it the next day. I'd worry about disturbing him and being out of hours, whereas on the website I could just do it and it was really straightforward. [P19]

Other participants, however, used a variety of approaches depending on how they felt at different times.

Text if you're not in the mood for talking, or, you know, if you want to ring, you just say, "Right, [therapist], can I make an appointment?" [P30]

The key factor for participants was that they were able to find a method of booking appointments that worked well for them at the point they decided to attend an MOL session.

*We spoke about things that I wanted to talk about.* In addition to having control over when and how they booked MOL sessions, participants also valued the control they perceived themselves to have over the content and process of MOL sessions:

...we spoke about things, I suppose, that *I* wanted to talk about. [P24]

For this participant, being in control of what was discussed within sessions meant that he felt able to discuss his experiences more openly than in previous experiences of psychotherapy:

I was in control. I was in control of it... Er, not as in control as in nasty control. More say, like, if there was something I was thinking about at the same time, I knew there was no obligation for me to even bring it out or mention it at that time. A lot of the time I did, a lot of the time. That's what was helpful about a lot of the time. Whereas, in the past, I would have been with counsellors or psychotherapists, or whatever, and I'll go, "Ooh, maybe I'll not mention that", but with [the therapist] there's a few times when I've thought, "Maybe not mention that", but actually, you know what, fuck it,



mentioned it anyway, which was probably a good idea, wasn't it, really?

[P36]

#### 6.4.3 *Thinking and talking*

This theme comprises three sub-themes that capture participants' experiences of taking part in MOL sessions: 'Exploring my problems'; 'Expressing myself openly'; and 'Talking was hard but it helped in the long run'.

*Exploring my problems.* Participants described MOL sessions as opportunities to explore and reflect on difficult internal experiences (e.g. thoughts, feelings, memories, or mental imagery) in greater depth than was possible in other contexts.

The process of exploring thoughts and feelings in depth was described as a means of considering aspects of experience that would have not been considered otherwise, as this quote illustrates:

Having to think in so much depth, when you're, like, in a really deep conversation. Do you know when you're going all... something, like, that you probably wouldn't, like, speak about or never thought about before.

[P29]

This participant describes how reflecting on experiences in depth enabled them to generate answers to questions he had about his experience of psychosis:

I suppose it was me answering my own questions in some ways, so I probably already knew but I didn't know, if that makes any sense? So, it just got me to think about why I felt that way or, er, possible reasons why I may have behaved that way. [P24]

*Expressing myself openly.* Being able to openly express thoughts and feelings to another person was an aspect of therapy that was particularly valued by participants. It also appeared to be integral to the process of using MOL sessions to develop new insights and perspectives on problems.

This participant describes how talking through her fears of experiencing further problems with distressing mood swings enabled her to develop a new perspective on the issue:

...it was the therapy and talking through it that made me think, 'It's okay, people get upset and it doesn't mean I'm going to be ill'. That was something we talked about. [P19]

Expressing a problem and hearing herself say it aloud was something that this participant found particularly helpful:

Erm, by me being able to talk about it in the way that I'm talking about it now, and it helps. That's important, that's the point that I'm trying to make, is that, er, I'm able to say things and hear myself say things. [P34]

This participant highlighted the fact that talking to the therapist helped them to consider other problems he had not been aware of previously:

...but it's amazing what opens up, see, when you start talking about your problems. [P20]

Being able to talk openly to somebody who was not a family member or friend was also seen as an important aspect of therapy:

...talking to [the therapist] as somebody I don't know – I mean, I do know now, but I didn't know – I find it a lot easier than talking to your family or your friends. [P30]

The one participant who reported that engaging in MOL was generally unhelpful also found talking about difficult experiences somewhat useful:

...like, it gave me an opportunity to talk about some stuff... [P08]

*Talking was hard but it helped in the long run.* Several participants described exploring and talking about emotionally difficult material in MOL sessions as a challenging but, ultimately, worthwhile process:

I was a bit apprehensive thinking I'll have to delve into some stuff here that might be upsetting and might be hard to deal with, which it was, but it needed to be done and it helped in the long run. [P19]

The same participant went on to use the analogy of physical exercise to describe what this experience was like from her perspective:

So, a bit like, here's a fitness analogy because I know all my sports, so if you do a really, really hard work out and then afterwards your muscles are really sore, and your legs are really hurting, and you feel like rubbish, but then later on, because you've done that work out and they've built back up, they're stronger, so you can do it better next time you do it. [P19]

Several participants described how they found it harder to discuss problems in earlier sessions, but said that this became easier as their familiarity with the therapist and the MOL approach increased. This participant describes how, initially,

he did not want to discuss his problems in sessions. However, he was eventually able to make use of MOL sessions to develop new perspectives:

Yeah, erm, well, obviously when I come in with, obviously, the amount of problems I did, erm, I was stubborn and things and didn't want to discuss owt [anything], but, obviously, I see [the therapist] a few times, got used to him, you know what I mean, and just, like, discussing things and it's actually give me a better outlook on life. [P20]

#### *6.4.4 Looking at problems from a different perspective*

Amongst participants who described MOL as a helpful experience, discussion of how engaging in therapy had helped them develop new perspectives on problems was a significant theme. The exact terminology used to describe this process varied between participants. For example, some participants described looking at things differently, putting problems into perspective, working out problems, finding answers, or understanding things differently. Developing a new perspective on what his life could be like was seen as a helpful outcome of MOL for this participant:

Well, it's just made me realise a lot of things I didn't care about previously. Like, I didn't care if I ended up, um, you know what I mean, if I was dead or what-not, or alcoholic on the street, or whatever, it's just put it into more perspective how life is being, you know, how different life could actually be, that I wasn't looking at previously, and it has helped, I reckon [P20]

This participant went on to describe how discussing problems in MOL sessions had helped him to develop a sense of hopefulness about his life:

...obviously, with this therapy and all that I've had, it's made me realise, you know what I mean, there is more to life, and life is worth living. [P20]

This participant describes how attending MOL sessions helped him develop a new understanding of himself. He saw this process as enabling him to solve other problems he encountered in his life. He contrasted this with the experience of being given advice from others; something he experienced as unhelpful:

And this is the psychological process, it's what helps with the understanding yourself, so you can deal with things yourself, instead of going to the next, going to your fucking friends and asking for fucking bullshit advice that doesn't fucking work. [P03]

Some participants reported that certain problems which had concerned them when they began therapy had not changed at the end of the treatment window. This included problems with specific symptoms and aspects of their social circumstances. However, even in situations where the problem itself had not changed, participants often reported that their perspective on the problem had shifted, making the problem less distressing or more understandable. For example, this participant described feeling less distressed by his dissociative experiences because he had developed a new understanding of them through the process of discussing them in MOL sessions:

Well I still have me problems and that but, you know, I've got a vast kind of understanding of it. [P28]

The nature of the problems that participants described developing new perspectives on varied considerably. For example, participants described shifts in perspective relating to voice hearing, dissociative experiences, distressing mood

swings, social anxiety, relationship difficulties, substance use, and a range of other problems. The common feature, however, were descriptions of how MOL had helped with the process of developing new insights. This was the outcome most valued amongst participants who found MOL sessions helpful.

## **6.5 Discussion**

This is the first qualitative study of MOL for FEP. It aimed to help us understand more about the acceptability of MOL and client-led scheduling for people experiencing FEP, to establish whether refinements are needed to increase acceptability, and to explore MOL's proposed mechanism of change from a first-person perspective. Participants found MOL to be a generally helpful experience. This was captured under the superordinate theme: 'Looking at problems from a different perspective'. The extent to which participants were able to effectively make use of MOL sessions to achieve shifts in perspective depended on several other factors, captured in three additional superordinate themes: 'The therapist's approach'; 'I was in control'; and 'Thinking and talking'.

Research has consistently highlighted the quality of the relationship between therapist and client as an important factor in determining psychotherapeutic outcomes (Lambert & Barley, 2001; Stamoulos et al., 2016; Wampold, 2015). In this study, participants reported that the interactions they had with the therapist were an important factor in determining the usefulness of therapy. However, it did not appear that the relationship with the therapist was seen as therapeutic in itself. While participants generally described the therapist's approach as helpful, they did not seem to be seeking a mutual bond or relationship with the therapist. Instead, it was

the activities that the therapist's approach enabled participants to engage in which seemed to be the important factor.

Using a PCT framework, Carey, Kelly, Mansell, & Tai, (2012) have outlined how the therapeutic relationship might contribute to successful outcomes in psychotherapy. They argue that effective psychotherapy is contingent on the client being able to freely consider and express whatever is on their mind, without filtering or evaluating this material prior to its expression. The findings of this study are consistent with this view. Whether clients were able to make effective use of therapy sessions was partially dependent on the extent to which they perceived the therapist's approach to impede or facilitate the exploration and discussion of problems. The majority of clients found the therapists' approach and the MOL questioning style helpful. One client reported that therapy was a predominantly unhelpful experience. Largely, this seemed to be a product of a mismatch between the client's goals (seek advice on how to resolve problems) and the therapist's goals (ask curious questions to enable the client to generate their own solutions to problems). The degree of convergence between therapist and client goals appears to be an important factor in determining whether MOL sessions are experienced as helpful or not. This is consistent with research showing that the same therapist activities can be experienced as either helping or hindering the process of change, depending on the preferences of the individual (Swift, Tompkins, & Parkin, 2017). Because MOL explicitly focuses on present moment experiences, it is anticipated that therapists using the approach will generally be well placed to detect whether therapy is being experienced as unhelpful, although clearly this is not always possible.

A novel feature of the Next Level study design was the use of client-led appointment scheduling. This allowed participants to control the number and

frequency of MOL sessions they attended over the course of the 10-month treatment window. In line with other research in this area (Carey & Mullan, 2007), participants in this study appreciated the control that the client-led scheduling approach gave them over accessing MOL sessions.

Participants also appeared to value the degree of control MOL gave them over what was discussed in therapy sessions. Consistent with related research (Griffiths, Mansell, Edge, et al., 2018), participants' experienced a wide range of problems in addition to symptoms of psychosis. Taking a flexible approach in terms of session content enabled participants to focus on the problems that most bothered them. This finding supports research showing that control over what is happening in therapy is one of the most robust predictors of client-perceived helpfulness (Cocklin et al., 2017).

Participants reported that MOL sessions were helpful because they provided opportunities to explore difficulties in depth and express problems to another person. This finding supports existing qualitative research suggesting that talking about experiences and emotions is the most helpful activity in psychological therapy (Watson, Cooper, McArthur, & McLeod, 2012) and that talking about problems to another person, as opposed to simply thinking about problems, is associated with experiencing a sense of relief (Carey et al., 2007).

The process of exploring and expressing problems was described by several participants as hard work because it involved focusing on subjects that would normally be avoided or suppressed. However, longer term, this was generally reported to be a worthwhile and beneficial process. This supports the view that the essential ingredient of successful psychotherapy is a client's ability to freely explore and



express whatever is on their mind (Carey et al., 2012; Cocklin et al., 2017). The sense that therapy can be emotionally challenging is consistent with other research into psychological interventions for psychosis (Kilbride et al., 2013; Wood et al., 2015).

More broadly, these findings support the view that goal conflict is implicated in causing and maintaining psychological distress (Powers, 2005). PCT proposes that opportunities for reorganisation to occur are limited when awareness does not move to the source of the conflict. Participants in this study described both wanting to explore problems in depth, while, at the same time, wanting to avoid thinking about their problems. MOL sessions appeared to be a context where the majority of participants felt able to maintain their awareness on problems for a sufficient length of time for reorganisation to take place.

The willingness of clients to face difficulties and actively participate in the process of therapy has been identified as an important factor in determining outcomes in psychotherapy (Carey, 2011; Higginson, Mansell, & Wood, 2011). In this study, those participants willing and able to engage in the process of therapy appeared more likely to use MOL sessions to develop new perspectives on their problems. Perspective shifts are recognised to be an important outcome of psychotherapy (Binder et al., 2010; Kilbride et al., 2013; Timulak, 2007), even if the terminology used to describe the phenomenon has varied between studies. From a PCT perspective, it seems likely that the various terms used by participants to describe shifts in perspective are referring to the process of reorganisation, the innate trial-and-error mechanism through which goal conflict is believed to be resolved. This finding supports MOL's proposed mechanism of change.

### *6.5.1 Strengths and Limitations*

Because we were able to interview 12 of the 14 participants who attended at least one session of MOL it was possible to capture a range of perspectives on the topic being investigated. We were unable to interview any of the five participants who were allocated to receive MOL but did not attend any therapy sessions. Therefore, it is not possible to say with certainty why these participants did not attend any MOL sessions. During trial follow up assessments, however, four of these participants said that they had not attended any therapy sessions because of limited time due to other commitments, rather than any specific issue with the acceptability of MOL or the client-led appointment booking system. One participant who attended no sessions was not contactable at follow up. However, this participant had also disengaged with all mental health services, suggesting that difficulties in maintaining contact with the participant were not specific to the trial.

Participants were aware that audio recordings of their interviews would be transcribed and analysed by the chief investigator, who was also the therapist for the trial. Although there were no indications that participants felt inhibited by this, it is possible that they might have withheld certain information about their experience of taking part in the study.

It is hoped that employing an independent service user researcher to conduct the interviews, and the additional steps to increase the credibility of the coding, would mitigate any bias created by the fact that chief investigator was familiar with participants from his role as trial therapist.

### *6.5.2 Clinical Implications*

All but one of the participants found participating in MOL sessions to be a predominantly helpful experience. They particularly valued the opportunity to resolve problems for themselves and develop new perspectives on their lives. This suggests that clients find it helpful to generate their own unique solutions to problems, as opposed to receiving advice or guidance from health professionals. Given that participants discussed a wide range of problems in addition to those related to psychotic symptoms, professionals that provide opportunities for clients to determine the focus of therapy are likely to be experienced as more helpful.

Participants appreciated the flexibility that client-led appointment scheduling provided. Indeed, many participants indicated that they would have preferred the treatment window to be longer. The limited timeframe of the Next Level trial meant this was not possible here. However, future commissioning guidelines for mental health services could reflect this preference by supporting client-led approaches to accessing psychological interventions. Participants in this study did not overuse the appointment booking system and attended sessions only when they had a problem to discuss, suggesting that healthcare systems do not need to restrict access to therapy appointments for this population.

Participants described idiosyncratic patterns of appointment booking, often with long periods between MOL sessions. The ongoing availability of MOL sessions, even during periods of non-attendance, was perceived as helpful. Had these clients been using routine mental health services, it is likely that they would be characterised as having 'disengaged' from therapy. This study suggests that when given control

over booking appointments, clients attend sessions in ways that are attuned to their current needs.

MOL was experienced as unhelpful when client and therapist goals for therapy were not aligned. This emphasises the importance of providing clients with sufficient information about the approach prior to commencing therapy, enabling them to make an informed choice about MOL's suitability for them. It also highlights the importance of tracking clients' present moment experience during therapy sessions to quickly detect any problems in the therapeutic relationship.

Although this study specifically investigated experiences of receiving MOL, we believe that many of the clinical implications discussed here are likely to be relevant to the delivery of psychological interventions more generally.

### *6.5.3 Research Implications*

The results of this study suggest that participants experiencing FEP find MOL and client-led scheduling acceptable. In some respects, participants described their experience of receiving MOL in the Next Level trial as preferable to approaches to psychotherapy currently taken in routine clinical practice. This suggests that a larger clinical trial of MOL for FEP is justified.

Another potential area of future research would be an economic evaluation of MOL. Given that participants booked MOL sessions only when required, the approach might have economic advantages over existing therapies and approaches to appointment scheduling.

Several participants expressed a preference for a longer treatment window, increased appointment availability, and more accessible venues for MOL sessions. The design of future trials should address these issues.

#### *6.5.4 Conclusions and relevance for clinical practice*

We believe that the most important conclusions from this study are as follows. Firstly, participants generally found MOL to be an acceptable and helpful experience, adding weight to the view that it is suitable for further testing in a larger clinical trial. Secondly, clinicians delivering psychological therapy will be experienced as most helpful when they maximise client control over the process of therapy and maintain a sense of curiosity about the nature of clients' difficulties. Thirdly, when clients are given the opportunity to simultaneously explore problems in depth and express themselves freely, they are able to generate novel solutions and insights into their difficulties.

## **CHAPTER 7: DISCUSSION**

### **7.1 Introduction and overview**

This thesis aimed to increase our general understanding of the sources of distress in first-episode psychosis (FEP), establish the feasibility of recruiting and retaining participants with FEP in a randomised controlled trial (RCT) of Method of Levels (MOL), evaluate the feasibility and acceptability of MOL for people experiencing FEP, and determine whether adaptations are required to implement MOL in EIP services. This chapter aims to bring together the key findings of the three studies and outline the novel contributions to the literature made by the thesis. To achieve this, the findings of the three studies that comprise the thesis are discussed in relation to the main research questions outlined in Chapter 1. The strengths and limitations of the thesis are then described. The chapter concludes by outlining the main clinical implications of the thesis along with proposals for future research directions.

### **7.2 Novel contributions to the literature**

#### *7.2.1 Sources of distress in FEP*

The first research question of the thesis was:

- (1) What are the self-reported sources of distress amongst people who have experienced FEP?

The qualitative metasynthesis presented in Chapter 3 (Griffiths, Mansell, Edge, et al., 2018) aimed to increase our understanding of the sources of distress reported by people who have experienced FEP. This study is an important component of the thesis because – distinct from many current psychological

interventions which aim to reduce psychotic symptoms – MOL is specifically designed to ameliorate psychological distress. Understanding the causes of distress in this population, therefore, contributes to the development of MOL as a clinical intervention for people experiencing FEP. It also enhances our general understanding of the experience of FEP from a first-person perspective. In addition to the findings of the metasynthesis, the results of the RCT presented in Chapters 4 and 5, and the qualitative study presented in Chapter 6 also add to our knowledge of what people experiencing FEP find distressing.

A key finding of the metasynthesis was that sources of distress amongst people who have experienced FEP are diverse and multifaceted (Griffiths, Mansell, Edge, et al., 2018). Sources of distress differed significantly between individuals, and distress was rarely limited to a single source. In relation to this issue, people experiencing FEP do not appear to be a homogenous group. This finding was supported by the results of the qualitative study (Griffiths et al., 2019), where participants described using MOL sessions to develop new perspectives on a wide range of problems that had been a source of distress. Problems were not limited to psychosis-related difficulties.

This is also consistent with data gathered using the proposed primary clinical outcome measure of the RCT, the PSYCHLOPS (Ashworth et al., 2004), which measures change in relation to a participant-defined problem over the course of therapy. Participants completing the PSYCHLOPS were asked to describe the two problems that most bothered them. As with the metasynthesis and the qualitative study, the types of difficulty reported varied considerably, and included problems with employment, housing, personal relationships, and symptoms of mental health

difficulties. A full list of the problems reported by participants is presented in Appendix I.

Prior to this research, relatively little was known about subjective distress in FEP (Vracotas et al., 2007), and the review presented in Chapter 3 is the first to focus specifically on the issue. The findings of the thesis on this topic have a number of important implications.

Firstly, psychological interventions that primarily focus on reducing psychotic symptoms are unlikely to adequately address the diverse sources of distress experienced by people with FEP. Interventions that can be applied flexibly across diagnostic categories, and which provide opportunities to consider wider sources of distress are likely to have advantages over disorder-specific approaches. This finding supports the use of transdiagnostic interventions, such as MOL (Carey, 2006), where clinicians aim to keep an open mind about potential sources of distress and service users are encouraged to choose which problems they focus on in therapy.

Secondly, given that psychotic symptoms are not the only source of distress for this population, the issue of appropriate outcome measures for trials of psychological interventions for FEP needs some consideration. The large majority of clinical trials conducted to date have used psychotic symptom reduction as their primary outcome (Greenwood et al., 2010). Measures that capture distress occurring across the broad domains of peoples' lives, however, might be seen as more meaningful by service users and have greater clinical relevance. A move away from focusing on symptom reduction as a primary outcome for trials would be consistent with Birchwood and Trower's (2006) assertion that psychological interventions for psychosis should not be considered a "quasi-neuroleptic".



Thirdly, the results of the thesis support the Perceptual Control Theory (PCT) (Powers, 2005) view that loss of control and conflict are implicated in the creation and maintenance of distress for people experiencing FEP. The design of the qualitative metasynthesis used an inductive approach to data analysis, and the intention was not to establish whether the literature supports the use of PCT as an explanatory framework of distress in FEP. Nevertheless, across the studies included in the metasynthesis, participants consistently described distress arising from a disparity between their desired and actual perceptions. From a PCT perspective, this would be understood as distress arising from being in a state of conflict. Similarly, during the qualitative study, participants described conflicted goals around discussing personal problems in therapy sessions. Participants wanted to talk about their problems because this was seen as helpful. At the same time, however, they wanted to avoid discussing their difficulties because this was experienced as distressing or “hard work”. PCT would predict that conflicts like these persist because they prevent people from sustaining their awareness on the conflicts for a sufficient amount of time for reorganisation to take place (Marken & Carey, 2015).

### *7.2.2 Recruitment and retention in the RCT of MOL for FEP*

The second research question of thesis was:

- (2) Is it feasible to recruit and retain people experiencing a first-episode of psychosis in a randomised controlled trial of Method of Levels (MOL)?

The feasibility RCT presented in Chapters 4 and 5 aimed to answer this question. The RCT recruited to target within the planned timeframe (Griffiths, Mansell, Carey, et al., 2018), and the large majority (97%) of participants were retained for the duration of the trial. This is the first study of its kind and provides

evidence that it is feasible to recruit and retain participants in an RCT of MOL for FEP, supporting the case for progressing to a larger trial. Additionally, comments from participants in both arms of the trial generally indicated that taking part in the study had been a positive experience. This suggests that the RCT design was acceptable to participants.

### *7.2.3 Feasibility and acceptability of MOL for people experiencing FEP*

The third and fourth research questions of the thesis were:

- (3) Is it feasible to deliver MOL to people experiencing FEP?
- (4) Is MOL an acceptable psychological intervention for people experiencing FEP?

The majority of participants allocated to the treatment arm of the RCT ( $n = 14$ ; 74%) attended at least one MOL session during the course of the 10-month treatment window. Amongst those participants who attended at least one session of MOL, the mean number of sessions attended was 4.1. These findings are broadly in line with other studies of MOL conducted in primary (Carey et al., 2009) and secondary care (Carey et al., 2013). The results of this study suggest that it is feasible to deliver MOL to people experiencing FEP.

Questions about the acceptability of the MOL intervention were primarily addressed by the qualitative study (Griffiths et al., 2019), although the RCT also provided useful information on the issue. To consider the results of the qualitative study first, all but one of the participants reported that the experience of receiving MOL had been a helpful experience. They generally found the therapist's approach helpful, appreciated the control they had over the content and process of therapy, and

valued the opportunity to reflect on problems and articulate them to another person. The therapeutic outcome most appreciated by participants was having the opportunity to develop new perspectives on their problems. One previous study of MOL included a qualitative component (Carey et al., 2009). The study presented in this thesis, however, is the first in-depth qualitative study using semi-structured interviews into the experience of receiving MOL for any population. The findings provide evidence that MOL is perceived to be acceptable by people experiencing FEP.

The results of the RCT also support this view. At the end of the study, none of the participants reported that they stopped attending therapy because they did not get what they needed from the MOL sessions. Participants' reasons for stopping were either that they had either got what they needed from the sessions or they had run out of time. This suggests that participants had either achieved the outcomes they wanted prior to the end of the 10 month treatment window, or they would have continued to book further sessions had time allowed. This is supported by the fact that a proportion of participants ( $n = 4$ ) continued to book sessions during the final month of the treatment window. Participants also gave generally positive feedback on the experience of receiving MOL. Comments from RCT participants about the helpful aspects of MOL were closely aligned with themes reported in the qualitative study. Specifically, participants appreciated the control they had over MOL sessions, valued being able to speak openly to the therapist, and were able to develop new perspectives on their problems.

#### *7.2.4 Potential adaptations required to implement MOL in EIP services*

The fifth research question of the thesis was:

(5) Are adaptations necessary to overcome problems or barriers to the implementation of MOL in EIP services?

The findings of the RCT and qualitative study contribute to our knowledge about the extent to which MOL requires adaptation in order to facilitate its implementation into routine clinical practice for people experiencing FEP. One participant reported that she found attending MOL sessions to be a predominantly unhelpful experience. This was primarily because of a mismatch between the participant's expectations of therapy (being provided with advice and guidance) and the goals of the therapist delivering MOL (use questions to help the participant develop their own insights into difficulties). This was not a concern raised by other participants. In fact, it was MOL's emphasis on *not* providing advice and guidance that most participants appreciated because this enabled them to develop their own perspectives on problems. This suggests that the MOL intervention itself does not require modification from its current form in order for people experiencing FEP to find it helpful. It might be useful, however, to provide service users with clearer information about the aims and style of MOL sessions prior to starting therapy.

The results of this thesis suggest that adaptations might be needed to the organisational structures which enable people to access MOL sessions. Although the use of service user led scheduling in this thesis was appreciated by participants, the findings suggest that additional flexibility around the delivery of therapy sessions might be required in order for service users to be able to access them in a way that meets their individual needs. Several participants reported that they stopped attending sessions because they ran out of time. The treatment window was limited to 10 months to enable the study to be completed within the planned timeframe of the PhD. Future studies, however, should consider extending the treatment window

beyond 10 months to give participants sufficient time to access the number of MOL sessions they require.

Other potential barriers to implementation highlighted by this thesis included the issue of where MOL sessions are held and the range of available appointment times. Some participants, including those that attended no MOL sessions, reported that other factors (for example, work, family, or educational commitments) prevented them from accessing the amount of sessions they would have liked. According to these participants, they might have attended more MOL sessions if the travelling distance to the clinic where the therapist was based had been shorter. Greater availability of appointments was also cited by participants as another factor that would have enabled them to attend a larger number of sessions. These factors should be addressed when considering the implementation of MOL into EIP services.

It is notable that demand for MOL sessions never exceeded the therapist's capacity to provide them. This is important because it provides evidence that access to psychological therapies does not need to be restricted or rationed by mental health services. When service users are given control over session attendance, the number and frequency of sessions that they attend is substantially fewer than the amount recommended in treatment guidelines (National Institute for Health and Care Excellence (NICE), 2014). This suggests that the principles of service user-led scheduling do not require adaptation to support the implementation of MOL into EIP services. This view is supported by the qualitative study (Griffiths et al., 2019), where participants gave universally positive feedback on the service user-led system of appointment scheduling.

### **7.3 Strengths and limitations**

This section will begin by outlining the strengths and limitations of each of the three studies that comprise the thesis. The overall strengths and limitations of the thesis as a whole will then be discussed.

One aim of the qualitative metasynthesis was to include as many potentially relevant studies as possible. A strength of the metasynthesis, therefore, was that it included a relatively large number of studies relating to the topic of interest. Included studies were conducted in several different countries and used a variety of methodologies. The measures included to increase the trustworthiness of the study's findings were another strength of the study.

Adopting an inclusive approach to the collection of secondary data, however, did lead to some possible limitations of the study. No systematic quality appraisal was undertaken, which potentially led to the inclusion of low quality studies. The international scope of studies included in the metasynthesis might limit the extent to which findings can be generalised to any one country in particular. For example, some of the sources of distress reported by participants were potentially related to cultural factors or healthcare practices specific to the context in which the study was conducted. Finally, the metasynthesis was subject to the usual limitations inherent to the approach. Namely, it was reliant on secondary data and combines studies that have different epistemological assumptions.

The RCT had a number of methodological strengths. Future allocations were concealed and participants were randomised in the order of enrolment in the study, reducing the risk of selection bias (Kunz, Vist, & Oxman, 2007). The fact that no service users who expressed an interest in the study were excluded suggests that the

inclusion and exclusion criteria closely match the entry criteria for EIP services and were, therefore, appropriate for recruiting a sample of participants with experience of FEP. Finally, the self-report data collected as part of the RCT were consistent with the findings of the qualitative study, which makes it possible to have greater confidence in the conclusion that MOL is acceptable for this population.

The PhD student performed a number of roles when conducting the RCT (including trial management, recruitment, enrolment, randomisation, trial therapist, and baseline and follow up assessments). It was necessary for the PhD student to perform these various roles due to the nature of the PhD programme and the requirements of the research funder. Because of the potential for introducing bias, however, this could be considered a limitation of the RCT. In addition, the research team were not blind to group allocation, creating another potential source of bias.

Although recruitment to the RCT was completed within the planned timeframe, rates of recruitment varied considerably between the two EIP teams where recruitment took place. The majority (n = 31; 86%) of participants were recruited from one team. Possible reasons for the variation in recruitment rate are discussed in Chapter 4, including the fact that the PhD student previously worked in the team with the higher rate. This disparity makes it difficult to predict how many recruitment sites would be required in a larger trial of MOL for FEP. This will need further consideration when planning future trials.

The RCT study sample was diagnostically heterogeneous and many participants had not received a diagnosis of psychosis-spectrum disorders. This heterogeneity is typical for EIP services, which have a specific remit around working with service users where there are issues of diagnostic uncertainty (McGorry et al.,

2008). This does, however, make it difficult to generalise the results of the RCT beyond users of EIP services. The lack of ethnic diversity (89% of the RCT study sample identified themselves as White British) might also limit the generalisability of the RCT findings to other ethnicities.

Duration of untreated psychosis (DUP) refers to the time from first onset of psychotic symptoms to the point of reaching appropriate treatment. This is measured routinely by EIP services. Mean DUP was substantially higher in the MOL group compared to the treatment as usual (TAU) group (46.1 and 14.6 months, respectively). The impact of this imbalance between groups on participant outcomes was not clear. There is evidence, however, that a longer DUP is associated with poorer longer outcomes in terms of social functioning, symptoms, and quality of life (Marshall et al., 2005).

The issue of whether participants in the TAU group received an “active control” during the RCT was a matter of some debate. One of the peer reviewers of the RCT protocol paper (Griffiths, Mansell, Carey, et al., 2018) thought that receiving a service from an EIP team and having access to the full range of psychosocial and pharmacological interventions provided should be considered an active control. A psychologist member of the trial steering committee, however, thought that this did not represent a true active control. Participants in TAU were not systematically offered access to psychological interventions as a result of taking part in the RCT. In actual fact, very few participants in either group received any psychological interventions as part of their routine care. Differential access between groups to some form of psychological intervention, however, could be considered a limitation of the study.



The fact that the reliability and validity of the MOL Session Evaluation Form (Carey & Tai, 2012) has not been established is a limitation of the RCT. Although no apparent problems were detected, a clear threshold or cut-off score defining an acceptable level of fidelity would increase confidence that therapy had been delivered in line with MOL treatment manuals (e.g. Mansell et al., 2013).

A strength of the qualitative study was that it included the majority ( $n = 12$ ; 86%) of participants who attended one or more session of MOL as part of the RCT. It was possible, therefore, to gather a range of first-person perspectives on the experience of receiving MOL. The study also paid attention to so-called “negative cases”: discrepant findings or cases that do not fit with the predominant patterns being identified in the data during the analysis. Noticing and giving sufficient prominence to negative cases is thought to be an indicator of quality in qualitative studies (Mays & Pope, 2000). The use of a service user researcher was another strength of this study (see Chapter 2 for more details on this topic).

A limitation of the qualitative study was that it was not possible to interview any participants who did not attend any sessions of MOL. The findings of the RCT suggest that participants did not attend any MOL sessions because they had other commitments, rather than because of a specific issue around the acceptability of MOL or patient-led scheduling. Because none of these participants were interviewed in detail about this topic, however, their reasons for non-attendance remain unclear.

Another potential limitation was that participants were aware that their audio recordings would be listened to and analysed by the PhD student, who had also acted as trial therapist. Although there is no evidence that participants felt inhibited by this

arrangement, it is possible that some might have been cautious about expressing critical views during interviews.

The use of mixed methods was considered an overall strength of the thesis. Drawing on both qualitative and quantitative methods made it possible to answer the research questions from multiple perspectives (Johnson & Onwuegbuzie, 2004; Johnson et al., 2007). As noted in Chapter 2, the use of mixed methods research has been criticised because it requires a combination of research methods with apparently incompatible epistemologies, a problem described as the “incommensurability thesis” (Symonds & Gorard, 2010). Adopting a pragmatic approach, however, enabled the PhD student to move beyond traditional quantitative versus qualitative dichotomies and draw on the relative strengths of both approaches when answering the thesis research questions (Johnson & Onwuegbuzie, 2004). The findings of all three studies were broadly consistent with each other, and there were no obvious examples of contradictory findings between studies, making it possible to have greater confidence in the conclusions of the thesis.

#### **7.4 Clinical implications**

This section outlines what are believed to be the most significant clinical implications of the thesis.

Firstly, the findings of all three studies suggest that sources of distress amongst people experiencing FEP are diverse and extend beyond distress connected to symptoms of psychosis alone. Consequently, approaches that prioritise the assessment and treatment of psychotic symptoms at the expense of considering broader sources of distress will be unable to fully address the needs of this population. People experiencing FEP are likely to experience mental health

practitioners who keep an open mind and remain curious about potential sources of distress as more helpful compared to those with a narrow focus on symptoms of psychosis.

Secondly, the thesis supports the view that psychological interventions that target the underlying causes of distress have advantages over disorder-specific approaches for this population. MOL aims to help people resolve goal conflict, a core process believed to maintain distress across diagnostic categories and irrespective of the exact problems being reported (Carey, 2006). Participants in the RCT and qualitative studies reported that MOL was helpful for a wide range of problems (e.g. symptoms, relationship difficulties, substance misuse). In both studies, the degree to which MOL was experienced as helpful was not dependent on the nature of the problems reported by participants. This adds to existing evidence that MOL is a helpful means of reducing distress for people experiencing a diverse range of problems (e.g. Carey et al., 2009, 2013; Carey & Mullan, 2008).

Thirdly, it was notable that participants in the qualitative study appreciated the fact that they were able to generate their own novel solutions to problems. Only one participant reported that she would have preferred to have received advice or information. The majority of participants described MOL sessions as a means of developing new perspectives on problems. This finding contrasts with research advocating the use of didactic psychotherapeutic interventions for psychosis, such as psychoeducation (Bäumel, Froböse, Kraemer, Rentrop, & Pitschel-Walz, 2006). While it might be the case that there are situations when providing people with advice or information about the nature of their problems is seen as helpful, the findings of this thesis emphasise the importance of providing a context where people can develop their own perspectives and solutions to difficulties.

Fourthly, the thesis provides evidence that when service users are given control over booking appointments for psychological interventions, they utilise sessions in accordance with their individual needs. Additionally, as stated previously, participants attended far fewer sessions of psychological therapy than recommended in current treatment guidelines for psychosis (National Institute for Health and Care Excellence (NICE), 2014). Using a system of service user-led scheduling, informed by the principles of PCT, meant that the provision of a modest number of therapy session slots per week was sufficient to meet the needs of a relatively large number of eligible participants ( $n = 19$ ). This provides support for Carey's (2018) view that PCT provides a useful basis for a theoretically informed approach to configuring mental health services. The approach appears to use limited healthcare resources efficiently and enables service users to tailor the support they access to meet their individual needs.

## **7.5 Future research**

This thesis provides evidence that MOL has the potential to be helpful for people experiencing FEP and, therefore, further research into its use with this population is justified. This section outlines possible future research directions.

A future area of quantitative research would be to conduct a larger RCT of MOL for people experiencing FEP psychosis. The sample size used in the current RCT was not sufficient to provide an accurate estimate of effect size (Teare et al., 2014). One possibility, therefore, would be to conduct a larger feasibility trial with the aim of estimating an effect size more precisely. This could be used to inform a sample size calculation for an adequately powered effectiveness trial. Given the discrepancy in DUP between groups in the current RCT, future trials should consider

stratifying on this variable. A study of this kind would be consistent with the Medical Research Council (MRC) guidelines for developing and evaluating complex interventions (Craig et al., 2006), and would represent an important stage between the current research and an effectiveness trial. The design of a larger trial could also include some form of process evaluation. This is a means of investigating exactly how a complex intervention is implemented, the proposed mechanism of change, and how the context or setting affects implementation and outcomes (Moore et al., 2015).

The health economics of the service user-led approach to appointment scheduling is another area of potentially worthwhile research. Current practice guidelines recommend that people experiencing FEP should be offered at least 16 sessions of cognitive behaviour therapy for psychosis (CBTp) (National Institute for Health and Care Excellence (NICE), 2014). In the current study, the mean number of therapy sessions attended by participants was three. This finding is consistent with research that suggests that where people are able to control their access to therapy sessions, they attend substantially fewer than the number recommended in practice guidelines (Carey et al., 2013). In addition to enabling participants to access therapy in a way that is attuned to meet their current needs, the patient-led system of appointment scheduling has the potential to be significantly more efficient compared to current approaches. Health economic research comparing patient-led scheduling to current approaches to appointment scheduling might lead to the more efficient use of limited healthcare resources.

In addition to continuing to evaluate the use of MOL with people experiencing FEP, a possible parallel stream of research could investigate its use in a more general secondary mental healthcare population. The RCT sample was diagnostically heterogeneous. In addition to those with psychosis spectrum disorders,

the sample included people with diagnoses of anxiety, affective disorders, substance misuse, and personality disorders. Given that the participants generally found MOL to be a helpful experience, evaluating its use with populations beyond EIP services might also be worthwhile. This has the potential to address the significant problems in accessing psychological interventions experienced by users of secondary care services, (Mind, 2013; Royal College of Psychiatrists, 2014), which have not received the same degree of investment in this area as EIP services (NHS England, the National Collaborating Centre for Mental Health, & National Institute for Health and Care Excellence, 2016).

MOL and service-user led scheduling represent a significant departure from current approaches to the delivery of psychological therapy. Practitioner-attitudes have a significant impact on the implementation of psychological interventions for psychosis into routine clinical practice (Haddock et al., 2014; Ince et al., 2015). At present, the attitudes of practitioners working in EIP services towards MOL and service user-led scheduling are not known. Given the emphasis placed on “assertive engagement” within EIP operational guidelines (NHS England et al., 2016) – along with the predominance of disorder-specific approaches in treatment guidelines for FEP (National Institute for Health and Care Excellence (NICE), 2014) – it would be unsurprising if the principles of MOL and its associated system of service user-led scheduling met with some resistance. This could have a significant impact on the eventual integration of MOL into routine practice. A qualitative study that aimed to understand more about this issue could help to anticipate and overcome future obstacles to implementation.

The MOL Session Evaluation Form (Carey & Tai, 2012), which is used to assess fidelity to the MOL approach, has not yet been validated. A study that aimed

to establish the scale's reliability and validity for assessing therapist adherence would increase confidence in its use in future MOL trials.

## **7.6 Summary and conclusions**

The thesis has made a substantial and novel contribution to the literature on understanding the experiences of people with FEP and improving outcomes for this population. The programme of research described in the thesis has answered the main research questions outlined in Chapter 1. The qualitative metasynthesis described in Chapter 3 was the first to synthesise evidence from a wide range of qualitative studies in order to answer the question: what do people experiencing FEP find distressing? Answering this question by drawing on first-person perspectives highlighted the diverse sources of distress amongst this population and contributed to our understanding of how practitioners might best support people experiencing FEP. Additionally, the qualitative metasynthesis provided evidence that transdiagnostic psychological interventions might have advantages over disorder-specific approaches for this population, supporting the case for MOL's further development. The RCT described in Chapters 4 and 5 was the first of its kind. The study demonstrated that it is feasible to recruit and retain participants in a trial of MOL for FEP. It also provided preliminary evidence of MOL's acceptability and safety for this population. The study described in Chapter 6 was the first in-depth qualitative investigation of MOL from a first-person perspective for any population. As with the RCT, the findings of this study support the view that MOL is acceptable to people experiencing FEP. It also provides support for MOL's putative mechanism of change: the reorganisation of goal conflict.

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## APPENDICES

## APPENDIX A: Ethical Approval



**Health Research Authority**

**North West - Greater Manchester Central Research Ethics Committee**

3rd Floor  
Barlow House  
4 Minshull Street  
Manchester  
M1 3DZ

Telephone: 02071 048022  
Fax:

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

17 August 2016

Mr Robert Griffiths  
NIHR Clinical Doctoral Research Fellow/Psychological Therapist  
Greater Manchester West Mental Health NHS Foundation Trust  
Psychosis Research Unit  
Rico House  
George Street  
Salford  
M25 9WS

Dear Mr Griffiths

<b>Study title:</b>	<b>Next Level: Evaluating the feasibility and acceptability of Method of Levels therapy for people experiencing a first episode of psychosis</b>
<b>REC reference:</b>	<b>16/NW/0592</b>
<b>Protocol number:</b>	<b>n/a</b>
<b>IRAS project ID:</b>	<b>204043</b>

We are in receipt of your correspondence responding to the Committee's request for further information on the above research and submitting revised documentation.

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

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the

A Research Ethics Committee established by the Health Research Authority

## **APPENDIX B: Standard Operating Procedure (SOP) for Potential Serious Adverse Events (SAE)**

### **Purpose of this standard operating procedure**

This standard operating procedure should be followed to ensure that serious adverse events (SAE) that occur as part of the Next Level trial are recorded and reported in accordance with the guidance provided by the Health Research Authority.

### **Definition of serious adverse events**

In research other than CTIMPs, a SAE is defined by the Health Research Authority as an untoward occurrence that:

- (a) results in death;
- (b) is life-threatening;
- (c) requires hospitalisation or prolongation of existing hospitalisation;
- (d) results in persistent or significant disability or incapacity;
- (e) consists of a congenital anomaly or birth defect; or
- (f) is otherwise considered medically significant by the investigator.

In addition to the categories of SAE defined by the HRA, the Next Level trial will also record and report cases of participant self-harm or harm to others.

An SAE occurring to a research participant should be reported to the main REC where in the opinion of the Chief Investigator (CI) the event was:

- (1) Related – that is, it resulted from administration of any of the research procedures,
- and**

- (2) Unexpected – that is, the type of event is not listed in the protocol as an expected occurrence

#### Guidance for reporting serious adverse events

Robert Griffiths (PhD student/Chief Investigator) should discuss with either Dr Sara Tai (PhD supervisor/Primary Investigator) or Dr Warren Mansell (PhD supervisor) ***within 24 hours***.

- (a) Robert Griffiths will complete the “serious adverse event form” (on NRES website) and send to his PhD supervisors ***within 48 hours***.
- (b) The PhD supervisors will review the event within 7 days of receiving the notice of a SAE and provide an opinion on whether the event is related to trial proceedings.
- (c) The chair of the independent Trial Steering Committee (TSC) to be sent details of the event and review within 7 days of the Chief Investigator providing an opinion on the event.
- (d) If the event is deemed by one or both of the reviewing parties (PhD supervisors and chair of the independent TSC) to be related to trial proceedings then the Chief Investigator will complete a National Research Ethics Committee report of a serious adverse event form and send this to the REC. This will be done **immediately** to ensure notification has been sent to the REC within **15 days** of the Chief Investigator first being made aware of the event.
- (e) A copy of the report of a serious adverse event should be sent to the Research and Development lead for Greater Manchester Mental Health NHS Foundation Trust.

NB. The REC will acknowledge receipt of the SAE form *within 30 days*. If you do not receive this acknowledgement the trial manager/Chief Investigator must follow up with the REC ASAP.

## APPENDIX C: Study Promotional Material



Greater Manchester West   
Mental Health NHS Foundation Trust



**NEXT LEVEL**  
METHOD OF LEVELS for Psychosis

Are you interested in a new  
talking therapy for psychosis?

We are evaluating a new therapy called  
**Method of Levels**

We are looking for volunteers aged 16 and older who currently use  
Early Intervention Services in Bolton, Salford and Trafford. The study involves:

- Completing questionnaires about your current problems and how you are feeling about yourself
- Repeating the questionnaires at 10 and 14 months so we can find out how things have changed
- An interview about your experience of taking part in the study.
- Not everyone will receive Method of Levels. There is a 50% chance you will receive this talking therapy in addition to your usual treatment
- If you receive Method of Levels, you will have a chance to talk about your difficulties.

This study has been reviewed by the Greater Manchester Central Ethics Committee (16/NW/0592)

Would you like to know more?

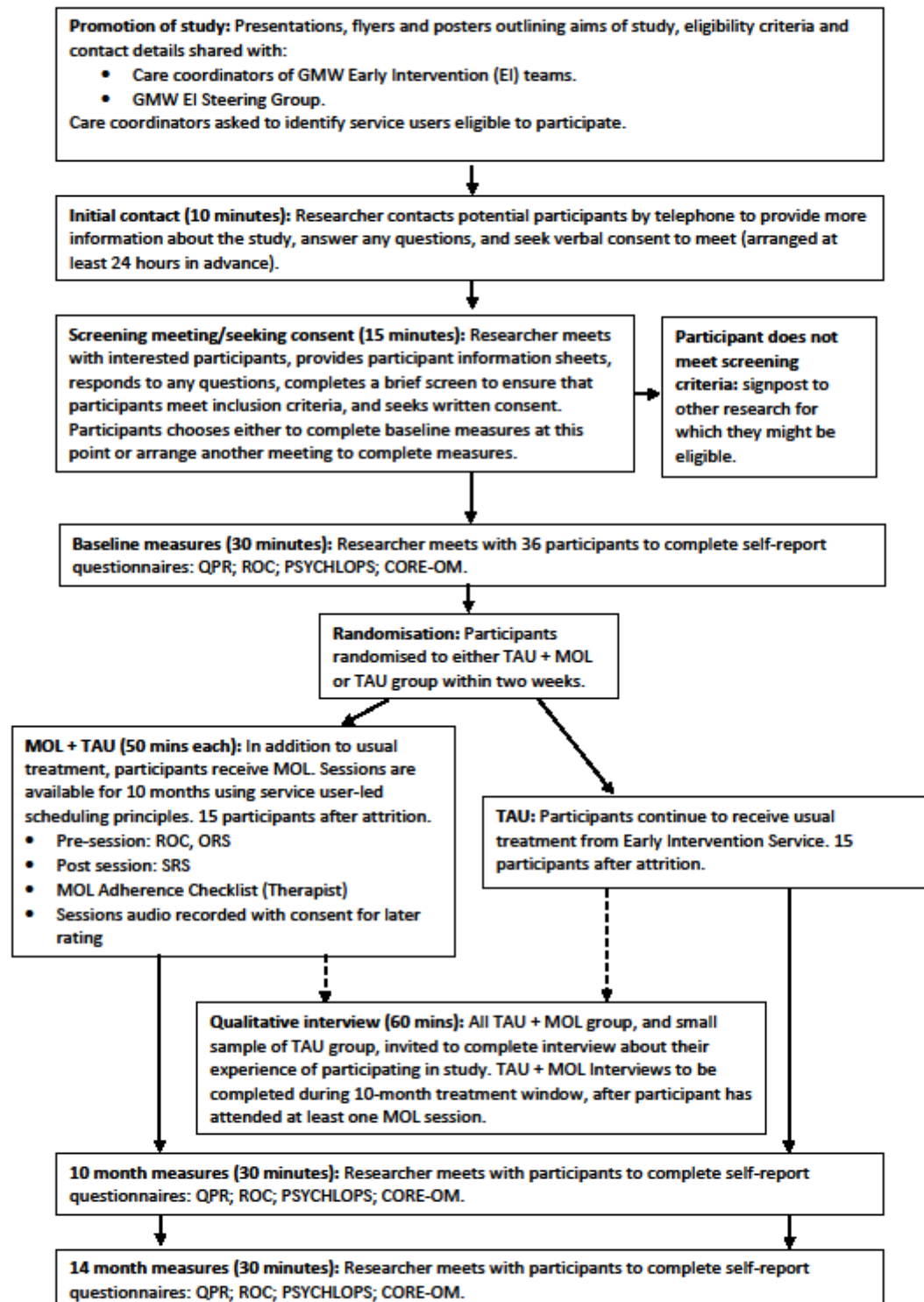
If you or someone you know would like more information about this study,  
please contact Robert Griffiths (Psychological Therapist) at:

**Psychosis Research Unit**

Rico House, George Street, Prestwich, Manchester, M25 9WS  
Telephone: 0161 358 1395 | Email: [robert.griffiths@gmw.nhs.uk](mailto:robert.griffiths@gmw.nhs.uk)

Next Level: MOL for Psychosis / IRAS Project ID: 204043 / Study poster / v.2.1 / 20<sup>th</sup> May 2016

## APPENDIX D: Study Flow Chart



Next Level: MOL for Psychosis / IRAS Project ID: 204043 / Study Activity Flowchart / v. 1.1 / 12<sup>th</sup> May 2016



## **APPENDIX E: Participant Information Sheet**



## **INFORMATION SHEET**

### **Next Level: Evaluating the Feasibility and Acceptability of Method of Levels Therapy for People Experiencing a First Episode of Psychosis.**

We would like to invite you to take part in a research study. Before you decide whether or not to take part, please read why the research is being done and what it would involve for you. Please take time to read the following information carefully. You can also speak to others about the study if that is helpful. The aim of the study is to find out whether a talking therapy called Method of Levels might be helpful for people experiencing psychosis.

#### **Why take part in this study?**

Method of Levels is a therapy that puts people in control of the support they receive. The approach involves asking people questions about their experiences, helping people to explore their problems and gain more control over their lives.

Research has already been done that suggests Methods of Levels therapy is helpful for people with a variety of different problems. However, we want to know if it is possible to recruit people using Early Intervention Teams to a study of this sort. If we are able to do this, we will plan a larger study to compare Method of Levels to other treatments available for people experiencing psychosis.

### **Who is carrying out this research?**

This research is being carried out by Robert Griffiths, a Psychological Therapist with experience of working in Early Intervention Teams. The study is part of a PhD funded by the National Institute of Health Research. The research is supervised by Dr Warren Mansell and Dr Sara Tai, Clinical Psychologists at the University of Manchester

### **What happens if I take part?**

If you decide to take part, you will be invited to a brief assessment appointment to discuss if this is the right study for you. You will have the opportunity to ask more questions about the research to help you decide whether to take part or not. If this is not the right study for you, we will help you find more suitable sources of support or other research trials that might be more helpful. Once the assessment is complete, you will be asked to sign a consent form.

### **What does the study involve?**

If you take part in this study, you will have a 50% chance of receiving Method of Levels. People will be randomly allocated to one of two groups. The first group will continue to receive their normal care from the Early Intervention Team. This is known as 'Treatment as Usual' (TAU). The second group will receive Method of Levels in addition to TAU. Method of Levels therapy will be available to the treatment group for the duration of the study only.

Everyone who takes part will be asked to complete questionnaires on three occasions over the course of the study: at the start of the study, at 10 months and 14 months. People receiving Method of Levels will be asked to complete some additional questionnaires at each session. The questionnaires ask about how you are feeling about yourself and how much your problems are bothering you. We use the questionnaires to help us understand whether these things change. If you prefer, these questionnaires can be completed over the telephone.

We will invite everyone who has received Method of Levels to take part in an interview so we can understand more about your personal experience of taking part in the study. We will

also interview some participants who received TAU to find out what this experience was like. This interview will be conducted by a research assistant who is appropriately trained and supervised. If you would prefer not to take part in the interview, you can still receive Method of Levels.

### **Participation in the study is entirely voluntary**

You are free to withdraw from the study at any point without giving a reason. If you do not take part in this study it will not affect your right to receive psychological therapy or the treatment you receive from the Early Intervention Team (or any other NHS service).

### **Will my information be kept confidential?**

Personal information from participants will be kept in a locked cabinet at a secure NHS building. For the purposes of the study, participants will be allocated a code, so they cannot be identified. Questionnaires will be recorded using this code only, unless you choose for other information to be added to your clinical records. The results of this study will be written up in a report and may be published in a scientific journal. However, participants will be referred to only by their anonymised codes and so you will not be identifiable. We will send you a summary of the findings from this study when it is completed. There is a possibility that the information gathered from participants in this study may be used in future research studies, however this information will remain confidential and anonymous.

With your agreement, we would like to audio record therapy sessions to be used by the therapist for their own training and supervision. If you do not consent to audio recording of sessions, you can still receive Method of Levels. If you agree to take part in the interview about your experience of the study, this will be recorded. The therapist's own supervision sessions will also be recorded. However, this material will be kept confidential and will not be accessible by anyone other than the researcher and their supervisors. Tapes of your therapy sessions and your interview will be typed into a transcript and then they will be destroyed at the end of the study.

Information you discuss during your treatment sessions will be available to the researcher (therapist conducting the therapy) and their supervisors. However, the therapist is required to inform your GP and/or care coordinator and other health professionals working with you that you are receiving psychological therapy as part of a research project. The therapist will have to record the times and dates of their meetings with you in the clinical notes used by your Early Intervention Team (which may include both paper notes and the electronic system used by your NHS Trust). The therapist will ask your permission to also provide an overview of the work that you do together in the clinical notes used by your team or GP. However, the content of what will be put into the notes will only include information that you agree to. If you do not want any detail about what you talk about to be shared, then we will keep this absolutely confidential. There is one exception to this: if you tell us anything that makes us think that you or anyone else is at risk of harm we will have to share this information (e.g. with your GP and your care coordinator). However, we would always discuss this with you before we spoke to anyone else.

**How long will my information be kept for?**

Your personal information will be destroyed as soon as it is no longer needed by the study. The only exception to this is your signed consent form, which will be stored securely in an NHS building.

Information gathered during the study will be kept for at least five years after the publication of the study. This information will not contain your personal details and will also be securely stored.

**Will anyone else have access to my information?**

Individuals from the University of Manchester, NHS Trust or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data but all individuals involved in

auditing and monitoring the study, will have a strict duty of confidentiality to you as a research participant.

**Are there potential benefits?**

It is hoped that this study will give you a chance to reflect on your experiences. There is also a 50% chance that you will receive access to a talking therapy called Method of Levels, which aims to help people feel less distressed and have more control over their lives.

**Are there potential risks?**

All talking therapies require people to talk about a problem that they are currently experiencing and this can feel uncomfortable or upsetting. There is no evidence that people receiving Method of Levels are more likely to feel distress compared to people receiving psychological interventions used in routine clinical practice. The researcher will routinely ask you about your experience of taking part in the study and about any distress you might be experiencing.

**Will I be able to claim expenses?**

We are able to cover the costs of participants' expenses for attending the 10 month and 14 month follow up appointments We are also able to cover expenses for attending the interview. Participants will not be paid for attending Method of Levels sessions.

**What happens if I cannot provide consent during the study?**

During the course of the study, if you lose the capacity to give consent to participate, you will be withdrawn from the study. Having capacity means you are able to weigh up the costs and benefits of taking part in the study, and can make an informed choice about participating. Before the study starts, we will ask you what you would like to happen to your information if you lose the capacity to consent.

### **Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion. The study has also been approved by the University of Manchester.

### **Harm**

In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester or Greater Manchester West NHS Mental Health Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

### **Who do I contact to find out more?**

To find out more about the study please contact Robert Griffiths (Chief Investigator).

Telephone: 0161 358 1395

E-mail: [robert.griffiths@gmw.nhs.uk](mailto:robert.griffiths@gmw.nhs.uk).

### **What if there is a problem?**

#### *Minor complaints*

If you have a minor complaint, then please contact the research supervisors in the first instance using these contact details.

Dr Sara Tai  
Telephone: 0161 275 2595  
E-mail: [sara.tai@manchester.ac.uk](mailto:sara.tai@manchester.ac.uk)

Dr Warren Mansell  
Telephone: 0161 275 8589  
E-mail: [warren.mansell@manchester.ac.uk](mailto:warren.mansell@manchester.ac.uk)

Alternatively, you can write to Dr Sara Tai or Dr Warren Mansell at:

School of Psychological Sciences

Zochonis Building

University of Manchester

Oxford Road

Manchester

M13 9PL

### *Formal Complaints*

If you wish to make a formal complaint, or if you are not satisfied with the response you have gained from the research supervisors in the first instance, then please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing:

[research.complaints@manchester.ac.uk](mailto:research.complaints@manchester.ac.uk) or by telephoning 0161 275 2674 or 275 2046.

This study has been reviewed and given a favourable opinion by North West – Greater Manchester Central Ethics Committee (16/NW/0592). The study has also been approved by the University of Manchester (research governance sponsor).



## APPENDIX F: Systematic Review Search Terms

Category of search term	Specific search terms
Psychosis terms (N = 11)	<i>Psychosis OR Psychoses OR Psychotic OR Schizophren* OR Voice* OR Hallucination* OR Delusion* OR Voice hearing OR Paranoi* OR Negative symptom* OR Positive symptom*</i>
<i>AND</i>	
Qualitative research terms (N=9)	<i>Qualitative OR Interpretative* OR Phenomen* OR Grounded theory OR Interview* OR Focus group OR Narrative OR Lived experience* OR Ethnograph*</i>
<i>AND</i>	
Service user terms (N=6)	<i>Service user* OR client* OR patient* OR consumer* OR outpatient* OR inpatient*</i>

## **APPENDIX G: Summary of Studies Included in the Systematic Review**

<b>Study</b>	<b>Design/theory</b>	<b>Country</b>	<b>Sample</b>	<b>Themes from original studies</b>
<b>Anderson, Fuhrer, &amp; Malla (2013)</b>	Interviews/ Content analysis	Canada	N = 16 4 females, 12 males Ethnicity not noted Age: median (range) = 22.5 (20-24)	(1) Lack of knowledge regarding the symptoms of psychosis and availability of services (2) Self-stigma as a barrier to help seeking (3) The importance of significant others for initiating service contact (4) Feelings of misunderstanding and loss of control throughout the help-seeking process (5) Unexpected benefits of the experience.
<b>Aref-Adib et al. (2016)</b>	Interviews/ Thematic analysis	UK	N = 22 12 females, 10 males 7 White UK, 2 White Other, 4 Black British, 3 African/Caribbean, 1 Asian, 5 Other Age: range = 21-57	(1) How and why the majority of participants sought mental health information online (2) Participants' experiences in navigating, accessing, and processing this information (3) Impact of online information on the participants' emotions and behaviour and how this was influenced by their relationship with clinicians (4) Respondents' views on self-management apps for psychosis
<b>Ashcroft, Barrow, Lee, &amp; MacKinnon (2012)</b>	Interviews/ Grounded theory	UK	N = 9 2 female, 7 male 9 White British Age: mean = 25.5	(1) Using mindfulness (2) Making sense of mindfulness and coping (3) Relating to people differently (4) Understanding and accepting myself
<b>Asmal, Mall, Emsley, Chiliza, &amp; Swartz (2014)</b>	Interviews/ Thematic analysis	South Africa	N = 40 n = 20 participants with FEP n = 20 family members Ethnicity and not noted	(1) Effect of stigma and vulnerability to abuse (2) Psychological impact of multiple stressors on caregivers (3) Impact of substance abuse dual diagnosis
<b>Cadario et al. (2012)</b>	Interviews/ General inductive approach	New Zealand	N = 24 n = 12 FEP participants n = 12 caregivers  FEP participants: 7 NZ European, 4 NZ Māori, 1 NZ Māori/Cook Island Māori Age: range = 15-18	(1) Difficulties noticed (2) Lack of awareness of mental illness (3) How help was sought, and which service was appropriate (4) Thoughts about illness precipitants (5) Experience of services and suggestions (6) Beliefs and knowledge of mental illness

<b>Cairns, Reid, Murray, &amp; Weatherhead (2015)</b>	Interviews/ IPA	UK	N = 9 2 female, 7 male 2 White, 1 White British, 5 White English, 1 White/Black African Age: mean (range) = 25.7 (19-36)	(1) A joined-up 'package' of support (2) Formulation makes a distinctive contribution (3) Shaping the experience
<b>Childs, McCarthy-Jones, Rowse, &amp; Turpin (2011)</b>	Interviews/ IPA	UK	N = 7 1 female, 6 male 6 White British, 1 White British-Irish Age not noted	(1) The journey through cannabis (2) Social and cultural world (3) The struggle to make sense (4) The depths and beyond
<b>Connell, Schweitzer, &amp; King (2014)</b>	Interviews/ IPA	Australia	N = 26 6 females, 20 males Ethnicity not noted Age: mean (range) = 21 (18-25)	(1) Experience of self-estrangement (2) Experience of self-consolidation
<b>Connell, Schweitzer, &amp; King (2015)</b>	Interviews/ IPA	Australia	N = 12 4 female, 8 male Ethnicity not noted Age: mean (median) = 21.2 (21), range 19-24	(1) Loss of self (2) Strengthening of self
<b>Connor et al. (2016)</b>	Interviews/ Framework analysis	UK	N = 28 n = 14 FEP participants n = 14 carers  FEP participants: 4 females, 10 males 2 Black African, 7 Asian Pakistani, 4 White British, 1 Black Caribbean Age: mean = 25.6	(1) Family response to illness (2) Lack of knowledge

<b>de Wet, Swartz, &amp; Chiliza (2014)</b>	Interviews/ IPA	South Africa	N = 7 3 females, 4 males 6 Black South African, 1 White South African Age: mean (range) = 35.3 (28-48)	(1) Factors associated with participants' experience of recovery (2) The meaning of recovery
<b>Esterberg &amp; Compton (2005)</b>	Interviews/ Thematic methodology	USA	N = 12 2 females, 10 males 1 Caucasian, 10 African American Age: median (range) = 25.5 (19-43)	(1) Pros and cons of smoking (2) Personal beliefs about smoking cessation (3) External influences on smoking and quitting (4) Negative attitudes toward NRT
<b>Fenton et al. (2014)</b>	Interviews/ IPA	UK	N = 6 1 female, 5 males 4 White British, 1 White European, 1 White African-Caribbean Age: mean (median) = 24.5 (24.5), range 18-33	(1) Confusion and uncertainty (2) Feeling safe (3) Feeling chaotic and unsafe (4) Maintaining identity
<b>Ferrari et al. (2015)</b>	Focus groups & interviews/ Thematic analysis	Canada	N = 34 n = 25 FEP participants FEP n = 9 family members  FEP participants: 12 females, 13 males 16 European, 5 African, 4 Caribbean Age not noted	(1) Understanding help seeking (2) Understanding delay in entering FEP programs

<b>Firth et al. (2016)</b>	Interviews/ Thematic analysis	UK	N = 13 1 female, 12 males Ethnicity not noted Age: mean = 26.5	(1) Exercise alleviating psychiatric symptoms (2) Improved self-perceptions from exercise (3) Factors determining participation
<b>Harris, Collinson, &amp; Das Nair (2012)</b>	Interviews/ IPA	UK	N = 8 3 females, 8 males 5 White British, 1 White & Black Caribbean, 2 White and Asian Age: mean (range) = 29.2 (21-37)	(1) Stigma (2) Relationships (3) Understanding the experiences (4) Sense of agency (5) Impact on sense of self
<b>Hon (2012)</b>	Interviews/ Grounded theory	UK	N = 12 5 females, 7 males Ethnicity not noted Age: mean (range): 25.2 (21-33)	(1) Support from significant others (2) The use of Internet as a source of information about psychosis and treatment (3) Lack of knowledge of symptoms or normalisation of psychotic symptoms (4) Fear of stigmatisation and embarrassment following symptom disclosure
<b>Jansen, Wøldike, Haahr, &amp; Simonsen (2015)</b>	Interviews/ Thematic analysis	Denmark	N = 11 5 females, 6 males Ethnic Danish Background Age: median (range) = 20 (18-27)	(1) Support from significant others (2) The use of Internet as a source of information about psychosis and treatment (3) Lack of knowledge of symptoms or normalisation of psychotic symptoms (4) Fear of stigmatisation and embarrassment following symptom disclosure
<b>Jansen, Pedersen, et al. (2015)</b>	Interviews/ Thematic analysis	Denmark	N = 10 5 females, 5 males Ethnic Danish Background Age: median (range) = 21 (18-27)	(1) Stigma and fear of the psychiatric system (2) The impact of traumatic experiences (3) The importance of significant others in finding the right treatment and supporting help seeking (4) The experience of safety and trust within the early detection team (5) The relief at receiving a diagnosis

<b>Jansen et al. (2016)</b>	Interviews/ Thematic analysis	Denmark	N = 15 4 females, 11 males Ethnic Danish Background Age: median (range) = 23.7 (18-32)	(1) Family support and dependency in the face of childhood traumas (2) Being in control and able to cope despite traumas (3) The relationship between trauma, diagnosis, and hope for the future
<b>Judge, Estroff, Perkins, &amp; Penn (2008)</b>	Interviews/ Inductive principles	USA	N = 15 7 females, 8 males 12 Caucasian, 2 African American, 1 Asian Age: mean = 24.4	(1) Recognising changes (2) Responding to changes
<b>Larsen (2007)</b>	Participant observation & interviews/ Ethnography	Denmark	N = 15 Gender, ethnicity and age not noted	(1) Psychosis as existential crisis (2) Early intervention offered therapeutic engagement, support and systems of explanation for psychosis
<b>Lockett et al. (2012)</b>	Interviews/ Qualitative template analysis	UK	N = 7 4 females, 3 males Ethnicity not noted Age: range = 18-33	(1) Fear of negative evaluation from others and loss of social status (2) Experiencing an impression or image that is negatively distorted (3) Fear of physical threat (4) Image/impression that everyone is staring at them, knows them or is talking about them (5) Image of what might happen in the immediate future (6) Threat perceived as being most strong from certain types of people
<b>Milligan, McCarthy-Jones, Winthrop, &amp; Dudley (2013)</b>	Interviews/ IPA	UK	N = 6 1 female, 5 males Ethnicity not noted Age: range = 17-30	(1) Negative trigger (2) Voice-affect interactions (3) The rejection phase (4) Crisis-induced change (5) Discovering, adjusting, and trying to cope (6) New understandings.

<b>Nilsen, Frich, Friis, &amp; Røssberg (2014)</b>	Interviews/ Systematic text condensation	Norway	N = 26 n = 12 participants with FEP n = 14 relatives  FEP participants: 7 females, 5 males Ethnicity not noted Age: mean (range) = 26.8 (19-38)	(1) Alliance (2) Support (3) Anxiety and Tension (4) Knowledge and Learning (5) Time (6) Structure
<b>O'Toole et al. (2004)</b>	Focus groups/ IPA	UK	N = 12 4 females, 8 males 1 Mixed (Asian/White), 2 African Caribbean, 1 Mixed (African/Caribbean/White), 2 Asian, 6 White Age: mean (median) = 29 (27), range 17-53	(1) A very different experience (2) The impact of the human touch on getting better (3) The gym as a symbol of recovery
<b>Perry, Taylor, &amp; Shaw (2007)</b>	Interviews/ IPA	UK	N = 5 5 males 5 White British Age: mean (range) = 21.8 (19-25)	(1) What's it all about? (2) Banged up (3) Belonging versus alone
<b>Tan, Gould, Combes, &amp; Lehmann (2014)</b>	Interviews/ Grounded theory	UK	N = 8 2 females, 6 males 8 White British Age: mean (median) = 24.2 (24), range 22-26	(1) The effect of past experiences (2) Not knowing/understanding (3) A challenged identity (4) Being in a psychiatric service (5) The reaction of others (6) Social disadvantage



<b>Tanskanen et al. (2011)</b>	Interviews/ Thematic analysis	UK	N = 30 n = 21 FEP participants n = 9 carers  Participants with FEP: 6 females, 15 males 3 White British, 4 White Other, 3 Black African, 5 Black Caribbean, 4 Asian Bangladeshi , 2 Mixed Race Age: mean = 26.5	(1) Understandings of symptoms and experiences (2) Help-seeking processes (3) Beliefs and knowledge about mental health services (4) Responses of social networks to illness onset and help seeking (5) Health professionals' responses
<b>van Schalkwyk, Davidson, &amp; Srihari (2015)</b>	Interviews/ Thematic analysis	USA	N = 11 1 female, 10 males Ethnicity not noted Age: range = 20-35	(1) Before entering STEP programme (2) After entering STEP programme
<b>Vodušek, Parnas, Tomori, &amp; Škodlar (2014)</b>	Interviews/ Phenomenological hermeneutics	Denmark	N = 20 8 females, 12 males Ethnicity not noted Age: mean = 22.1	(1) Emotional emptiness and the sense of loss and of being lost in the post-psychotic self (2) Emotional buffer, lack of flow and mourning for authenticity in the pre-psychotic self (3) Full contact, emotional overwhelming and fear of annihilation in the psychotic self
<b>Windell, Norman, Lal, &amp; Malla (2015)</b>	Interviews/ IPA	Canada	N = 30 7 females, 23 males 27 Caucasian, 1 Asian, 1 African-Canadian, 1 First Nations Age: mean (median) = 23.1 (23), range 16-30	(1) Symptom recover (2) Reconciling meaning and acceptance (3) Regaining control (4) Negotiating and accepting treatment
<b>Yung &amp; McGorry (1996)</b>	Interviews/ Thematic analysis	Australia	N = 21 7 females, 14 males Ethnicity not noted Age: mean (median) = 23.1 (23), 16-30	(1) Estimation of duration of prodrome (2) Symptoms and behavioural changes occurring during the prodrome (3) Pattern and sequence of changes during the prodromal phase (4) Presence of precipitating events

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## **APPENDIX H: Results of the Adverse Events Measure**



Participants' responses to the adverse events measure by randomisation group (TAU *n* = 16; MOL *n* = 17)

	Not at all		Very little		A little		Quite a lot		Very much	
	<i>TAU</i>	<i>MOL</i>	<i>TAU</i>	<i>MOL</i>	<i>TAU</i>	<i>MOL</i>	<i>TAU</i>	<i>MOL</i>	<i>TAU</i>	<i>MOL</i>
<b>Taking part hasn't helped me with my problems</b>	3 (18.8%)	6 (35.3%)	4 (25%)	5 (29.4%)	6 (37.5%)	5 (29.4%)	0 (0%)	0 (0%)	3 (18.8%)	1 (5.9%)
<b>Taking part made my problems worse</b>	16 (100%)	12 (70.6%)	0 (0%)	3 (17.6%)	0 (0%)	1 (5.9%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)
<b>Taking part made me feel more anxious</b>	9 (56.3%)	12 (70.6%)	4 (25%)	3 (17.6)	3 (18.8%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	1 (5.9%)
<b>Taking part took up too much time</b>	16 (100%)	15 (88.2%)	0 (0%)	2 (11.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Taking part led to my mood becoming very low</b>	12 (75%)	14 (82.4%)	4 (25%)	0 (0%)	0 (0%)	2 (11.8%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)
<b>Taking part made me feel more angry and irritable</b>	14 (87.5%)	12 (70.6%)	2 (12.5%)	3 (17.6%)	0 (0%)	1 (5.9%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)
<b>I didn't feel ready to talk about my problems</b>	14 (87.5%)	10 (58.8%)	0 (0%)	2 (11.8%)	1 (6.3%)	2 (11.8%)	1 (6.3%)	2 (11.8%)	0 (0%)	1 (5.9%)
<b>Taking part made me think too much about bad things that have happened in the past</b>	12 (75%)	8 (47.1%)	3 (18.8%)	2 (11.8%)	1 (6.3%)	5 (29.4%)	0 (0%)	1 (5.9%)	0 (0%)	1 (5.9%)
<b>Taking part meant I stopped looking after myself properly</b>	16 (100%)	15 (88.2%)	0 (0%)	1 (5.9%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Taking part made me feel more suspicious</b>	16 (100%)	11 (64.7%)	0 (0%)	2 (11.8%)	0 (0%)	1 (5.9%)	0 (0%)	2 (11.8%)	0 (0%)	1 (5.9%)
<b>Taking part required too much energy or motivation</b>	12 (75%)	14 (82.4%)	2 (12.5%)	1 (5.9%)	1 (6.3%)	2 (11.8%)	1 (6.3%)	0 (0%)	0 (0%)	0 (0%)
<b>Taking part increased my thoughts of killing myself</b>	16 (100%)	15 (88.2%)	0 (0%)	2 (11.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>I didn't feel listened to or believed by Next Level staff</b>	15 (93.8%)	17 (100%)	1 (6.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

	Not at all		Very little		A little		Quite a lot		Very much	
	<i>TAU</i>	<i>MOL</i>	<i>TAU</i>	<i>MOL</i>	<i>TAU</i>	<i>MOL</i>	<i>TAU</i>	<i>MOL</i>	<i>TAU</i>	<i>MOL</i>
<b>Taking part made my voices or visions worse</b>	15 (93.8%)	14 (82.4%)	1 (6.3%)	2 (11.8%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Taking part was making me fall out with my family or friends</b>	16 (100%)	16 (94.1%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Taking part was having a bad effect on my self-esteem</b>	15 (93.8%)	15 (88.2%)	0 (0%)	1 (5.9%)	6.3%	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Taking part was making me want to harm myself</b>	16 (100%)	15 (88.2%)	0 (0%)	2 (11.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>I didn't like or feel I could trust the Next Level team members</b>	16 (100%)	16 (94.1%)	0 (0%)	0 (0%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>I felt embarrassed talking about my problems with people I had not met before</b>	13 (81.3%)	9 (52.9%)	1 (6.3%)	2 (11.8%)	2 (12.5%)	4 (23.5%)	0 (0%)	0 (0%)	0 (0%)	2 (11.8%)
<b>Taking part made me have thoughts of harming other people</b>	16 (100%)	15 (88.2%)	0 (0%)	1 (5.9%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Taking part was making me feel hopeless about the future</b>	13 (81.3%)	14 (82.4%)	3 (18.8%)	2 (11.8%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Taking part meant I had to increase my medication in order to cope</b>	16 (100%)	16 (94.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)
<b>Taking part involved too much hard work</b>	16 (100%)	14 (82.4%)	0 (0%)	2 (11.8%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Taking part made me worry that people would think badly of me because of my diagnosis</b>	14 (87.5%)	15 (88.2%)	0 (0%)	1 (5.9%)	2 (12.5%)	0 (0%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)
<b>Taking part made me fall out with my doctor or care team</b>	16 (100%)	16 (94.1%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Taking part made me worry about losing control of my mind</b>	15 (93.8%)	14 (82.4%)	0 (0%)	2 (11.8%)	1 (6.3%)	0 (0%)	0 (0%)	1 (5.9%)	0 (0%)	0 (0%)
<b>My problems have improved to the point whereby I no longer feel I need help</b>	7 (43.8%)	7 (41.2%)	1 (6.3%)	2 (11.8%)	3 (18.8%)	5 (29.4%)	4 (25%)	3 (17.6%)	1 (6.3%)	0 (0%)

## **APPENDIX I: Problems Reported by Participants**

**Problems reported by RCT participants in response to question 1 of the PSYCHLOPS: “Choose the problem that troubles you most”**

<b>Interpersonal relationships</b>	<b>Psychosis-related difficulties</b>	<b>Affective problems</b>	<b>Social problems</b>	<b>Physical health</b>	<b>Miscellaneous psychological</b>	<b>Past experiences</b>	<b>Other</b>
Feeling isolated and lonely [P5/P1]	Who am I? Why can I do things that are impossible for other people? [P3/P1]	Lack of energy or motivation [P2/P1]	Living in my house - nuisance neighbours [P1/P1]		Managing link between my thoughts and behaviour - what I plan to do and my actions are different [P10/P1]	Year 4 [P25/P1]	Trying to make sense of problems [P35/P1]
Worried about the impression other people have of me [P8/P1]	Hearing an unknown voice in my head [P4/P1]	Feeling anxious [P18/P1]	Would like to move house [P6/P1]		Can't consistently stay well [P19/P1]	The way I've acted in the past [P28/P1]	
Socially awkward [P9/P1]	Telling the difference between PTSD and psychosis [P7/P1]	Depression [P20/P1]	Finding a job [P17/P1]		My sleep is not good [P22/P1]		
Trust with partner [P11/P1]	The voices [P12/P1]	A feeling of worthlessness [P21/P1]	Housing situation [P32/P1]				
Arrangements over agreeing holiday plans and transport with [my daughters] [P14/P1]	Hearing the voices and hurting myself because of them [P13/P1]	Depression [P31/P1]					

<b>Interpersonal relationships</b>	<b>Psychosis-related difficulties</b>	<b>Affective problems</b>	<b>Social problems</b>	<b>Physical health</b>	<b>Miscellaneous psychological</b>	<b>Past experiences</b>	<b>Other</b>
How my situation affects other people [P23/P1]	Paranoia [P15/P1]	Depression [P33/P1]					
Jumping to wrong conclusions [P24/P1]	Voices [P16/P1]						
Not having my family [P26/P1]	My voices [P27/P1]						
Niece moved in [P29/P1]							
Relationship with my family [P30/P1] Feeling of isolation and not fitting in [P34/P1]							
Not seeing my daughter [P36/P1]							

**Problems reported by RCT participants in response to question 2 of the PSYCHLOPS: “Choose another problem that troubles you”**

<b>Interpersonal relationships</b>	<b>Psychosis-related difficulties</b>	<b>Affective problems</b>	<b>Social problems</b>	<b>Physical health</b>	<b>Miscellaneous psychological</b>	<b>Past experiences</b>	<b>Other</b>
I'm quite solitary - don't get out and meet people much [P2/P2]	Voices in my head [P21/P2]	Lack of get up and go [P4/P2]	Getting a job - economic status [P1/P2]	Spine/bone structure [P12/P2]	Nightmares [P15/P2]	Not letting past decisions and experience affect my daily life [P10/P2]	My future - don't know where I'm going [P23/P2]
Partner's mum, brother and sister - she destroyed my family [P3/P2]	Seeing visions that aren't there [P27/P2]	Mood swings too quickly (very depressed to very happy all the time) [P5/P2]	Looking for another job - out of work for five months. [P6/P2]	Physical health (op) [P29/P2]	Blanking out [P28/P2]	Messing up life's chances [P36/P2]	
Me and my mum don't really understand each other [P8/P2]	Mental state (voices) [P32/P2]	My depression [P7/P2]	Future employment [P14/P2]		Trying to cope with a sense of loss [P34/P2]		
Being irritated with people [P9/P2]		Anxiety and depression [P13/P2]	Getting back to normality (e.g. uni, work) [P35/P2]				
Anger towards other people over way I speak to them [P11/P2]		Depression [P16/P2]					

<b>Interpersonal relationships</b>	<b>Psychosis-related difficulties</b>	<b>Affective problems</b>	<b>Social problems</b>	<b>Physical health</b>	<b>Miscellaneous psychological</b>	<b>Past experiences</b>	<b>Other</b>
Not seeing my family as much as I would like [P17/P2]		Depression [P18/P2]					
Worries that my boyfriend will leave me [P22/P2]		Emotionally unstable [P19/P2]					
Social services team won't listen to me [P26/P2]		Anxiety [P20/P2]					
Loneliness [P30/P2]		Anxiety [P24/P2]					
		My anxiety [P25/P2]					
		Anxiety [P31/P2]					
		Anxiety [P33/P2]					