# Effectiveness of third wave group interventions for psychosis
# A systematic review; A third wave group intervention for severe mental illness: Evaluating the feasibility of delivery by Protocol-Based Intervention Facilitators

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# Volume I

## Systematic Review &
## Empirical Research Project

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# Chapter 1

# Effectiveness of third wave group interventions for psychosis: A systematic review

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Supervised by

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## Abstract

**Background**: The evidence base for psychological interventions for psychosis has grown over the last decade to include approaches known as third wave therapies, which focus on processes and context. Third wave therapies include models such as Acceptance and Commitment Therapy (ACT), Dialectical Behaviour Therapy (DBT), Mindfulness-Based Cognitive Therapy (MBCT) and Compassion Focussed Therapy (CFT). Such therapies commonly include a group component. Group intervention can be more cost-effective as it enables one clinician to provide the intervention to several people at once. To date, reviews have combined individual and group interventions for psychosis and have focussed on mindfulness and ACT approaches. The aim of the current review was to specifically include only studies evaluating group interventions and to extend the scope to include both CFT and DBT interventions for psychosis.

**Method:** OvidSP (Embase, Global Health, PsychINFO, Medline), Web of Science, PubMed and the Cochrane Library were searched. The Downs and Black (1998) checklist was used to determine the quality of the included studies. A total of 3840 papers were screened.

**Results:** The review included 24 papers. Interventions consisted of similar components across studies, including mindfulness, group discussion and the use of homework. Practical aspects of the interventions such as session length, frequency and treatment duration varied greatly. Several studies were evaluating feasibility and were not adequately powered to definitively evaluate interventions. Changes in outcomes post-intervention were in the expected direction and suggest potential for

change in negative symptoms of psychosis, general psychopathology and level of functioning.

**Conclusions:** The impact of third wave groups on negative symptoms of psychosis suggests they may be helpful as an adjunct to CBTp, where the focus is on positive symptoms such as delusions and hallucinations. Evaluation of third wave interventions in the future should measure efficacy by an individual's ability to manage symptoms rather than alleviate them. Findings indicate the potential for clinical change and warrant full-scale randomised controlled evaluation in the future. Further pilot studies of standard delivery are not required and should be discouraged. There is promising support for new methods of delivery, and further pilot evaluation of these is indicated.

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# 1. Introduction

## 1.1 Background

The term psychosis is an 'umbrella' term often associated with schizophrenia, and can also include delusional disorder, brief psychotic disorder, schizoaffective disorder, psychotic disorder due to another medical condition, catatonia, and unspecified schizophrenia spectrum and psychotic disorder amongst others (Bhati, 2013). Psychosis is often a challenging experience characterised by positive symptoms such as auditory or visual hallucinations, paranoia or delusions (Garety et al., 2001), and negative symptoms such as becoming withdrawn, losing interest in enjoyable activities or low affect (Piskulic & Addington, 2011). These symptoms have a significant impact on the individual's life in a wide range of domains such as family life, social life, employment and wellbeing (Killaspy et al., 2014).

Although there is evidence supporting the effectiveness of antipsychotic medication, approximately 35% of those diagnosed with a psychosis spectrum disorder do not respond effectively to pharmacological interventions (Liu-Seifert, Adams, & Kinon, 2005). In addition, people with psychosis have high rates of depression and anxiety symptoms (Lewandowski et al., 2016). In the United Kingdom, the National Institute for Health and Care Excellence (NICE) guidance recommends Cognitive Behavioural Therapy (CBT) for a range of severe mental health conditions including psychotic, bipolar, other severe affective, and personality disorders (NICE, 2014). The combination of psychological and medical intervention has been shown to improve outcomes (Turner et al., 2014).

The evidence base for psychological interventions for psychosis has expanded over the last decade to include approaches known as third wave therapies (Wykes et al.,

2008). Third wave CBT aims to focus on a person's relationship to thought and emotion rather than on thought content, through contextual and experiential change strategies (Hayes, 2004). Though many elements of third wave concepts have played a role in "traditional" CBT for some time (Hayes & Hofmann, 2017), the focus on processes and context characterises a number of therapeutic models such as Acceptance and Commitment Therapy (ACT), Dialectical Behaviour Therapy (DBT), Mindfulness-Based Cognitive Therapy (MBCT) and Compassion Focussed Therapy (CFT). Each model has its own theoretical framework, but there is significant overlap in targeting awareness of processes and promoting strategies that increase mindfulness, acceptance, and psychological flexibility (Dimidjian et al., 2016) with the aim to reduce experiential avoidance and thought suppression (Hayes, 2004).

## 1.2 Mindfulness

The principles of mindfulness date back to Buddhist philosophy, but mindfulness has become increasingly popular in Western psychology, and the core concepts of mindfulness are part of many modular third wave interventions (Hofmann & Gómez, 2017). Whether mindfulness is the central focus of the intervention, as in MBCT, or whether it has been integrated into other third wave approaches as just one component, such as in ACT or DBT, the core principle remains the same. Mindful individuals learn to become more reflective by purposefully paying attention to the present moment in a non-judgemental way and thus become less reactive to negative internal events (Kabat-Zinn, 1982), thus changing the relationship between the self and the contents of thoughts.

The use of mindfulness has grown significantly in recent years, given the surge in information that demands attention on a daily basis, for example through increased

use of digital technology to access social and news media (Berthon & Pitt, 2019), which has been linked to increased levels of anxiety, depression, stress and addiction (Gotink et al., 2015). Due to its focus on healing, Kabat-Zinn (1982) initially trialled mindfulness based stress reduction (MBSR) with those suffering from chronic pain (Kabat-Zinn, 1982) and found that participants reported a significant reduction in their pain following the intervention. In addition to physical health benefits, research has also found mindfulness interventions to improve mental health (Creswell, 2017). Notably, mindfulness cognitive based therapy has been found particularly effective in treatment resistant depression, significantly reducing symptoms post-treatment compared with a health enhancement programme (Eisendrath et al., 2016). Increasing one's mindfulness skills will decrease experiential avoidance, that is the tendency to avoid distressing internal experiences, which has been linked to anxiety (McCluskey et al., 2020).

Mindfulness interventions for individuals on the psychosis spectrum are a more recent development, and are thought to have the potential to be well suited for this population, as those with psychosis often use avoidance strategies, such as alcohol or drug use, become fixated on their symptoms, or a mixture of both of these (Cramer et al., 2016). Chadwick and colleagues developed group interventions for people with psychosis using mindfulness techniques over six sessions, which was found to significantly improve wellbeing (Chadwick, Taylor, & Abba, 2005). Clear distinction needs to be made, however, in regard to clinical outcome where the emphasis is not on symptom reduction, but the level of distress experienced by symptoms (Chadwick, 2014).

## 1.3 Acceptance and Commitment Therapy

Acceptance and Commitment Therapy (ACT) is based on Relational Frame Theory (Barnes-Holmes & Roche, 2001), which argues that human behaviour is largely governed by networks of verbally constructed rules known as relational frames (Hayes, 2004). Whilst this is useful in the external environment for keeping us safe, it becomes problematic when we apply these rules to our internal experiences, which results in us restricting our lives to avoid distressing experiences (Dahl & Lundgren, 2006). ACT works on developing skills in six core therapeutic processes; contact with the present moment, values and knowing what matters, committed action, noticing the self, defusion from your thoughts and openness and acceptance (Harris, 2019). These six processes are collectively known as the ACT Hexaflex and therapy allows the therapist and the individual to move flexibly around each of the processes in a non-linear and fluid way.

ACT differs from traditional CBT by targeting the purpose and context of thoughts, feelings and emotions instead of trying to change the validity or occurrence of these (Hayes et al., 2011). More specifically, ACT posits that in order to achieve psychological flexibility, people should behave in line with their values, even when thoughts and feelings challenge attempts to take valued action (Levin & Hayes, 2009).

ACT appears to be particularly promising in the treatment of severe and enduring mental illness. One study evaluated the impact of an ACT group intervention for individuals with Borderline Personality Disorder and found that the intervention significantly reduced difficulties with emotion regulation and deliberate self-harm behaviours (Derakhshan, Daliri, & Gholamzade, 2020). In another study investigating the effectiveness of a manual based ACT group intervention for those with Bipolar

Disorder with co-existing anxiety, it was found to significantly improve across all outcomes including quality of life, anxiety symptoms and depressive symptoms (Pankowski et al., 2017).

Initial findings demonstrated a move towards integrating an acceptance and commitment approach into existing cognitive-behavioural interventions to reduce distress associated with psychosis. Early trials focused on providing ACT to individuals admitted to inpatient wards. Bach and Hayes (2002) found that those receiving an ACT intervention were significantly less likely to believe in positive symptoms compared to individuals receiving treatment as usual (Bach & Hayes, 2002). In addition, they also compared re-hospitalisation rate and found that those receiving treatment as usual were twice as likely to be re-admitted to an inpatient ward as those who had received the ACT intervention (Bach et al., 2013). However, results demonstrated that overall symptom reduction was less in the group that had received ACT than those receiving TAU. This is in line with ACT facilitating an increase psychological flexibility rather than reducing the frequency of symptoms. These findings were supported by Gaudiano and Herbert (2006), who also found that individuals receiving an ACT intervention showed a significant decrease in belief of hallucinations or delusions following treatment.

### 1.4 Compassion Focussed Therapy

Compassion Focussed Therapy (CFT) was developed by Paul Gilbert (Gilbert, 2005a, 2010). Throughout his literature, Gilbert frequently refers to the definition of compassion given by the Dalai Lama, which states that it is recognizing the suffering of self and others, and a drive to alleviate it (Dalai Lama, 1995). This definition highlights the importance of an individual's commitment to relieving distress,

comparable to ACT's concept of openness and commitment to change. Like mindfulness and ACT, CFT aims to reduce suffering by changing the relationship with the psychological distress. CFT aims to do so not only by paying more attention to the present moment, but also by increasing kindness towards others and the self in order to satisfy the innate human desire to alleviate suffering. The rationale for nurturing self-compassion in an individual is based on the evolutionary premise that there are three basic emotion regulation systems that interact to choreograph human behaviour: the threat system, the drive system and the soothe system (Liotti & Gilbert, 2011). As the name suggests, the threat system is designed to detect dangers in the environment and the activation of survival strategies. In psychological terms, this can materialize in the form of distressing emotions such as anger, fear, repulsion and shame (Gilbert, 2005b). Both the drive system and the soothe system are characterised by positive affects. The drive system is responsible for incentive driven behaviours based on the evolutionary concept of reward and punishment. The soothe system is more closely linked with attachment theory (Ainsworth, 1978), suggesting that compassion is rooted in the need for humans to form bonds with others. CFT therefore aims to address distress by supporting an individual to navigate the interactions between these systems to establish a sense of safety (Gilbert, 2014; Tarlow, 2012).

As with other third wave models of cognitive behavioural therapy, CFT has developed an evidence base for its effectiveness with a range of mental health diagnoses (Kirby, 2017). Higher levels of self-compassion have been associated with lower levels of depression and anxiety (MacBeth & Gumley, 2012). Further evidence has supported the notion that greater self-compassion is correlated with general psychological wellbeing (Zessin, Dickhäuser, & Garbade, 2015). CFT has also been found to be

effective in severe and enduring mental illness. A sixteen week CFT group intervention for individuals with chronic personality disorder that focussed on developing skills in self-soothing resulted in significant decrease in feelings of shame and self-hatred in comparison with others at a one year follow-up (Lucre & Corten, 2013). Judge and colleagues found group CFT to be effective for a range of conditions including depression, anxiety, OCD and deliberate self-harm (Judge et al., 2012). Collectively, early research demonstrates the potential for future developments in CFT interventions for different long term conditions.

CFT targets transdiagnostic processes that are common in psychosis, such as shame, stigma, self-criticism and social avoidance (Braehler, Harper, & Gilbert, 2013c). Gumley et al. (2010) developed a compassion focussed model of recovery after psychosis rooted in the notion that psychosis results in difficulties with emotion and drive, and the challenges this can cause may result in increased shame and stigma. Mayhew and Gilbert (2008) carried out a case series with individuals diagnosed with schizophrenia, evaluating an intervention that focussed on developing self-compassion and understanding towards safety behaviours. They found that all participants' auditory hallucinations became less persecutory and malicious.

### 1.5 Dialectical Behaviour Therapy

Dialectical Behaviour Therapy (DBT) was originally developed as an intervention to support individuals with Borderline Personality Disorder who were complex and chronically suicidal (Linehan, 1993a). This arose out of the difficulties clinicians had with trying to apply the traditional cognitive behavioural model to these particular clients (Sayrs & Linehan, 2019). Difficulties included clients feeling invalidated by being encouraged to change specific behaviours, motivation to learn different skills

was difficult alongside intent to die or deliberate self-harm, and clients were often perceived to be hostile towards the therapist until the therapist would collude with the client's avoidance of difficult topics (Dimeff & Linehan, 2001). Similar to the strategies used in ACT, the modifications involved implementing radical acceptance of what the client is currently able to achieve, but balances this with recognising the need for behaviour change. The treatment model works through a series of four stages; the first stage is the most comprehensive of the four, as it focuses on stabilisation, decreasing suicidal behaviours, reducing behaviours that hinder therapy sessions (e.g. arriving late or missing sessions entirely) and working through the impact of factors that may reduce quality of life (e.g. substance use, depression, homelessness). It also focuses on developing behavioural skills in emotion regulation, distress tolerance and interpersonal effectiveness (Robins & Chapman, 2004). The remaining stages involve establishing treatment goals in a non-traumatic way (Stage 2), to experience positive emotions and reduce the impact of problems (Stage 3) and to develop a sense of being whole in order to engage with positive experiences (Stage 4) (Linehan, 1999).

DBT has a preliminary evidence base to support its effectiveness in treating a variety of mental health disorders, predominantly for working with borderline personality disorder (BPD). Van den Bosch et al. (2005) found that DBT significantly reduced parasuicidal behaviour in women with BPD with and without substance use. Effectiveness was sustained at 6 months compared with treatment as usual with regards to reduced parasuicidal behaviour and alcohol use (van den Bosch et al., 2005). However, although research continues to predominantly evaluate DBT in the context of BPD and associated problems, evidence is also emerging to support the effectiveness of DBT in other mental health disorders. Courbasson, Nishikawa and

Dixon (2012) investigated the use of DBT among a group of individuals with co-occurring eating disorder and substance use, finding that the intervention had a significant positive impact on disordered eating, substance use, depressive symptoms and perceived ability to regulate and cope with difficult emotions compared with treatment as usual (Courbasson, Nishikawa, & Dixon, 2012). Evidence also suggests DBT is effective in reducing symptoms of PTSD in victims of single-event sexual assault (Bohus et al., 2013), obsessive-compulsive disorder (Ahovan et al., 2016) and treatment-resistant depression (Harley et al., 2008). DBT skills can also be applied to transdiagnostic emotion dysregulation, which could be effective particularly in a group intervention (Neacsiu et al., 2014b).

## 1.6 Group Interventions

Despite growing evidence for the effectiveness of psychological therapies for psychosis, barriers to care, such as lack of capacity in services, often mean that effective interventions cannot be delivered (Switzer & Harper, 2019). One way of overcoming these barriers, is to provide interventions in group format so that fewer resources are required to treat a greater number of patients (Mueser & Noordsy, 2005). Group interventions are often protocol-based, meaning that the protocol is specified in such systematic detail that they often require less experience to deliver thus can be facilitated by a greater number of staff members across a service.

Group therapy can be more cost-effective as it enables one clinician to provide an intervention to several people at once (Kahn & Kahn, 1992). McCrone et al. (2005) found group therapy to be more cost-effective than individual therapy and suggest that being more open to different formats of therapy could mean that staff resources

become more available and treatment could be offered to more patients (McCrone et al., 2005).

There are also possible social advantages to providing interventions in group format. Individuals on the psychosis spectrum often experience greater levels of social isolation and have a smaller social network than those without mental health difficulties (Macdonald, Hayes, & Baglioni Jr, 2000). Groups offer the chance to share experiences and help each other find ways to cope with the same challenges as themselves (Ridsdale et al., 2017), addressing the social isolation often felt by this population and providing the opportunity for normalizing experiences and individuals feeling validated (Lecomte, Leclerc, & Wykes, 2012). Groups also give the opportunity for individuals to engage in more emotionally meaningful interactions, providing humour and sharing insight (Sigman & Hassan, 2006), which may prove invaluable in alleviating distress related to positive symptoms. Peer support in itself can be considered a form of mental health intervention in that it can offer encouragement and hope as well as provide the opportunity for mentorship (Davidson et al., 2006b). This can be particularly helpful for those experiencing negative symptoms such as difficulties with social functioning and withdrawal. Negative symptoms are thought to be more resistant to medication (Rector & Steel, 2013), highly related to poor social functioning (Kimhy et al., 2012) and poor quality of life (Mäkinen et al., 2008).

## 1.7 Rationale

To date, reviews have combined group and individual interventions for psychosis (Cramer et al., 2016; Wood et al., 2020); however, no review has examined group interventions alone. A recent review by Jansen et al. (2020) evaluated mindfulness and acceptance-based interventions for psychosis, combining individual and group

interventions (Jansen et al., 2020). The focus of the current review is to both extend examination from previous reviews to include a range of third wave interventions and to further specify that studies included evaluate group interventions. The current review also aims to extend the scope to include studies evaluating both CFT and DBT group interventions for psychosis. The idiosyncrasy of recovery from psychosis means it is essential to offer a wide range of psychosocial interventions to individuals (Pitt et al., 2007). The findings from this review may support mental health professionals to assist individuals on the psychosis spectrum recover in a way that is meaningful to them (Byrne, Davies, & Morrison, 2010).

# 2. Methodology

## 2.1 Design

The PICOS (participants, interventions, comparators, outcomes and study design) format was used to improve the search strategy (Higgins et al., 2019). The process of this systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher et al., 2009). Details of the protocol for this systematic review were registered on PROSPERO (CRD42020181153) and can be accessed at www.crd.york.ac.uk.

## 2.2 Search Strategy

The review was evaluating studies of various designs due to the recent developments in this area and the possibility of too few papers. Studies were all published in English and the search included the following databases: OvidSP (Embase, Global Health, PsychINFO, Medline), Web of Science, PubMed and the Cochrane Library between January 2009 and July 2020. The search strategy was developed to maximise paper inclusion (Table 1), though small adjustments had to be made to meet the search strategy criteria for each of the different databases (for example the scope of including keywords in title alone versus title and abstract). After de-duplication of the papers, the strategy involved three systematic stages; title screening, abstract screening and full-text screening. At each stage of screening, papers were assessed according to inclusion and exclusion criteria (see sections 2.3 and 2.4). At full text screening, manuscripts were accessed electronically and were assessed according to the presence of each inclusion criteria. Studies that contained any exclusion criteria were eliminated from the review, and recorded separately, along with the reason for exclusion.

## 2.3 Search Terms

Search terms to identify participants with psychosis spectrum disorders were: psychosis OR psychotic OR schizo* OR hallucination* OR delusion* OR severe mental illness. The term AND group was used to identify group interventions. Search terms used to identify third wave interventions were: cognitive OR acceptance OR dialectical OR compassion OR mindfulness or third wave OR CBT OR DBT OR ACT OR CFT OR contextual. Studies were excluded if they were not available in English. For the purposes of this search, the focus was on process-focussed third wave interventions such as those listed above, meaning the review did not include metacognitive and narrative enhancement therapies.

## 2.4 Inclusion Criteria

- Studies where there was a majority sample with a diagnosis of schizophrenia or psychotic disorders.
- Studies where the majority sample were working age adults.
- Studies that involved evaluation of a psychological or psycho-educational intervention in group format.
- Studies employing a third wave approach
- Studies published since 2009

## 2.5 Exclusion Criteria

- Literature reviews, conference abstracts, study protocols or statistical plans, texts from non-peer reviewed journals, book chapters, grey literature or doctoral theses
- Qualitative studies
- Studies looking primarily at first-episode and at-risk populations

- Studies with a sample size of less than 10
- Studies including individuals under the age of 18 or adults over the age of 64
- Manuscripts not available in English
- Studies using data collected from a previous study

## 2.6 Data Extraction

Papers were managed using EndNote X9 throughout the review process to identify and remove duplicates and to review titles and abstracts. Where possible, the software was also used to locate manuscripts to aid full-text screening. Screening was carried out by the lead author, with 80% of the full-text manuscripts also being checked against inclusion and exclusion criteria by an independent researcher.

Data was recorded according to the following information;

- Lead author, year of publication and location
- Design
- Study participants (sample size, gender, age)
- Outcome measures used
- Summary of relevant findings

## 2.7 Quality Assessment

As the systematic review is covering recent developments in the area of group interventions for psychosis, a quality assessment tool was used that allows for the inclusion of both randomised and non-randomised studies. The Downs and Black (1998) quality assessment tool allows for the inclusion of different study designs and so facilitates the comparison of quality between a greater number of papers.

Deeks et al. (2003) reviewed 60 quality assessment measures and identified Downs and Black's tool as one of the most effective measures available. The Downs and Black checklist provides an overall quality index and four sub-scales of quality assessment, including reporting, external quality, internal validity bias and internal validity-confounding.

Quality assessment was carried out by the lead author and an independent rater.

## 2.8 Data Synthesis

In order to maximize the number of included studies, narrative synthesis was used in accordance with the guidance from Popay et al. (2006). There was no requirement for a minimum number of studies to be reviewed for completion as the group format of third wave interventions is a recent development in the area of interventions for psychosis.

Meta-analysis was not possible, as there was significant heterogeneity in outcome measures used by clinicians, the specific population for each study, and research design. The focus of the synthesis was to highlight similarities and differences between studies, particularly within and between third wave approaches, to explore what, if any, factors are found to be helpful for improving quality of life. Synthesis aimed to describe outcome measures in a quantitative format and to report a qualitative description of significant findings.

The review looked at a primary outcome of the proportion of participants achieving improvements in outcomes as determined by validated clinician rated or self-report measures (e.g. Positive and Negative Syndrome Scale, CORE-10).

Exact comparators for included studies were not specified other than treatment as usual (TAU). This would also include waitlist control groups. As the review did not detail the settings of the intervention (e.g., inpatient, community), treatment as usual was variable across different settings and countries but broadly consisted of anti-psychotic medication and clinical care from a multidisciplinary team. As third wave group interventions for psychosis are a recent development, comparators for included studies were not required but single-arm trials were accounted for using the quality assessment measure (Downs & Black, 1998).

The narrative synthesis involved the following steps in order to address the research question;

- Improvement in outcome measures from baseline to follow-up
- Comparative findings of effective and ineffective third wave interventions
- Exploration of any differences between specific third wave interventions
- Assessment of the robustness of findings from studies, in accordance with Popay et al. (2006).

## 2.9 Search Outcomes

Searches for this review were carried out in compliance with PICOS and PRISMA guidelines. The initial search of Web of Science returned 1175 studies, 2438 studies matched initial search terms from Ovid (Embase, Global Health, PsychINFO, Medline), 649 from Pub Med and 1153 from the Cochrane library. All study references were downloaded into EndNote X9 software before removing duplicate manuscripts. 2175 manuscripts were removed using the Auto Duplicate tool and 431 manuscripts were removed after manual review of the remaining studies. A total of 3409 studies were

left after de-duplication. Studies with clear and apparent irrelevant titles were removed (n=2347), before abstracts were screened and a further 877 papers were found to be inappropriate for review. This left a total of 185 studies for full-text screening, where 161 manuscripts were deemed unsuitable for review. A total of 24 studies were considered to match the review inclusion and exclusion criteria. The flow diagram for this process can be found in Figure 1.

# 3. Results

The results are presented in three sections: 1) a description of the included studies, 2) overall risk of bias assessment and 3) a description of the main findings of the included studies in relation to the effectiveness of third wave group interventions improving the impact of symptoms on individuals with psychosis. Due to the heterogeneity of study designs, outcome measures and interventions, meta-analyses were not feasible.

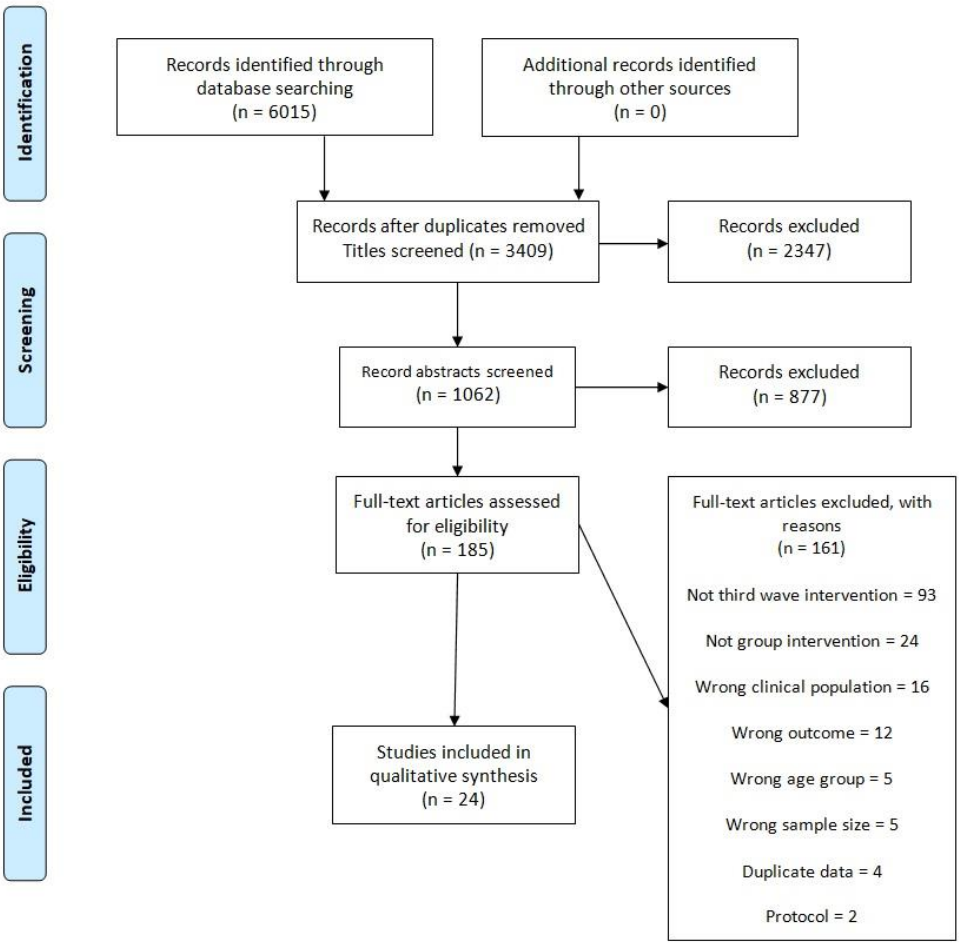


***Figure 1*** *PRISMA flow chart of study selection*

## 3.1 Descriptive Characteristics

### *3.1.1 Study characteristics*

A total of 24 studies were included in this review. A description of these studies can be seen in Table 1. Data was gathered from 1783 participants. Sample sizes ranged from 14 (Moulden et al., 2020) to 342 (Chien et al., 2017) with an average sample of 73 participants.

Studies provided a third wave group intervention to 866 participants, 277 participants received another psychological intervention (Conventional Psychoeducation or Integrated Rehabilitation Treatment) and 619 participants received either Treatment As Usual (TAU) or acted as waitlist controls. Participants were recruited from volunteer samples, community mental health services, day centres and inpatient wards and were aged between 18 and 65 years (mean = 35.2 years, data only available for 21 studies). Studies included more men than women, with 986 male participants and 685 female participants. Two studies did not report the sex of participants in their findings and four studies reported on sex only for those who completed the intervention, leaving the sex of a total of 112 participants unknown.

Ten studies employed an RCT design (Braehler et al., 2013; Cetin & Aylaz, 2018; Chadwick et al., 2009; Chadwick et al., 2016; Chien & Lee, 2013; Dannahy et al., 2010; Lam et al., 2020; Langer et al., 2012; Lee, 2019; Lopez-Navarro et al., 2015; Spidel et al., 2018). Seven studies employed a single-arm design with no comparator (Jacobsen et al., 2019; Johns et al., 2016; Johnson et al., 2011; Laithewaite et al., 2009; MacDougall et al., 2018; Moulden et al., 2020; Randal et al., 2016) and two studies had a control arm but did not use randomization (Yilmaz & Okanli, 2017; Yilmaz & Kavak, 2018). Four studies had a third comparator that consisted of "conventional psychoeducation" with no third wave element, all of which involved randomization (Chien & Thompson, 2014; Wang et al., 2016; Chien et al., 2017; Chien et al., 2019). In addition, Lopez-Navarro et al. (2015) randomized to either a mindfulness-based intervention with Integrated Rehabilitation Treatment (IRT) or IRT alone. IRT consisted of pharmacotherapy combined with 26 weekly sessions of CBT, social skills training and conventional psychoeducation.

### *3.1.2 Clinical characteristics*

Inclusion criteria for this review required studies to have a majority sample (≥50%) of individuals with a diagnosis of schizophrenia-spectrum disorders according to diagnostic criteria in the *Diagnostic and Statistical Manual of Mental Disorders* (American Psychiatric Association (APA), 2014) or the *ICD-10* (World Health Organization (WHO), 2004). Eight studies exclusively recruited participants with a diagnosis of schizophrenia. However, 16 studies used several diagnostic terms and included individuals with diagnoses other than schizophrenia. As such, 1176 patients had a diagnosis of schizophrenia, 183 patients had a diagnosis of schizoaffective disorder, 209 participants had a diagnosis of psychosis or psychosis not otherwise specified, 115 participants had a diagnosis of schizophreniform disorder, 29 participants had a diagnosis of bipolar disorder and 22 participants had other diagnoses such as personality disorders or post-traumatic stress disorder (37 participants had unknown primary diagnoses; see Table 3).

The average length of time since diagnosis was 10.7 years (n=11 studies, 6 unknown). The remaining five studies defined duration of illness in categories, which can be seen in Table 3. Duration of illness was specified in the inclusion criteria for nine studies, with three studies requiring participants to have had the diagnosis for no more than 5 years, two studies requiring participants to be in remission (though this was not objectively defined) and two studies requiring participants to have had the diagnosis for at least 2 years. Lopez-Navarro et al. (2018) required participants to be in a stable post-acute state and to have had no hospital admissions in the month prior to taking part.

## 3.2 Interventions

Of the interventions provided across the 24 studies, 18 evaluated a mindfulness-based intervention, three evaluated a compassion-focussed intervention, two studies

evaluated ACT groups and one study investigated DBT. For the purposes of this review, other interventions that may sometimes be considered as third wave, such as meta-cognitive therapy or Narrative Enhancement Therapy, were not included.

### *3.2.1 Intervention facilitators*

Interventions were facilitated by different professionals with varying degrees of experience. Most interventions were facilitated by clinical psychologists (n=9 studies). The remaining interventions were facilitated by psychiatric nurses, or other healthcare professionals (social workers, CMHT clinicians, occupational therapists). On three occasions, the facilitator was the researcher conducting the study and this has been accounted for in the quality assessment measure. All studies stressed that their facilitators were experienced in the therapeutic model being used and highlighted that therapists had undergone specific training prior to providing the interventions (e.g., mindfulness-based stress reduction, ACT training, specific study intervention training).

### *3.2.2 Intervention Components*

The duration of interventions ranged between 4 weeks and 12 months and sessions lasted between 60 and 150 minutes, with an average of 90.4 minutes per session. Session frequency varied, with 14 studies providing weekly sessions, 6 studies offering two sessions a week, and 4 studies running sessions every two weeks (See Table 3). This equated to interventions providing an average of 21.6 hours of group therapy across the intervention in total (range = 7 hours to 130 hours). Spidel et al. (2018) designed an intervention consisting of 8 sessions after reporting that brief ACT (usually 4 to 5 weekly sessions) did not appear to be effective for a third of patients experiencing positive symptoms (Bach & Hayes, 2002). The number of sessions per intervention varied, with 22 of the studies having a minimum of 8 sessions and a maximum of 52 sessions. Two studies had fewer than 8 sessions (4 and 6 sessions respectively) and both reported

significant improvements in symptom severity and psychological recovery (Johns et al., 2016; Johnson et al., 2011; Table 3). Although both studies were feasibility trials, their results demonstrate the potential for clinical change in fewer sessions.

All studies described the importance of intervention protocol in order to standardize treatment across groups. Many of the protocols had been adapted from previous interventions such as Mindfulness-Based Stress Reduction (MBSR; Kabat-Zinn, 1990), Mindfulness-Based Cognitive Therapy (MBCT; Segal, Williams and Teasdale, 2002) or mindfulness for psychosis (Chadwick, 2006). The nature of structured, modular protocols means that the intervention can be tailored easily for different populations. For example, Moulden et al. (2020) made changes to the protocol for a forensic population and Chien et al. (2013) reported updating existing protocol to accommodate traditional Chinese cultural principles.

### *3.2.3 ACT interventions*

Two of the studies in this review investigated ACT interventions. One study was from the UK (Johns et al., 2016) and one study was conducted in Canada (Spidel et al., 2018). Johns et al. (2016) designed a group intervention based on ACT for psychosis developed by Bach and Hayes (2002) and Gaudiano and Herbert (2006). A significant component of this intervention was the use of the "passengers on the bus" metaphor (see Hayes et al., 1999), which was used to facilitate the application of the model to the participants' real-life experiences. Authors also stressed the importance of encouraging practice outside of the group setting by committing to values-based actions between sessions.

Spidel et al. (2018) also investigated an intervention that focussed on developing skills in acceptance and defusion, integrating mindfulness meditation exercises into sessions. The intervention was designed for individuals experiencing psychosis who also had a

history of trauma, though there is no mention of any trauma-related content in the intervention description. Spidel et al. (2018) described the need for caution using mindful meditation in order to decrease the risk of participants experiencing psychotic symptoms during the exercises. This intervention did not use metaphors; citing cognitive difficulties often experienced by individuals with psychosis (see Khoury et al., 2015 for detailed protocol).

Table 1 Characteristics of the studies included in the systematic review

| Author & Year (Location) | Study Design | Sample Size | Mean Age (years) | Population | Intervention | Frequency (Duration) |
|---|---|---|---|---|---|---|
| 1. **Braehler et al. (2013b)** | Randomized, open-label, blinded end point evaluation | CFT = 22<br>[13 men, 9 women]<br>TAU = 18<br>[9 men, 9 women] | 41.6 | Primary diagnosis of a schizophrenia spectrum disorder<br>or<br>bipolar disorder with psychotic features (ICD-10) | Group CFT + TAU<br>vs.<br>TAU alone | 16 x 120-min weekly sessions |
| 2. Çetin and Aylaz (2018) | True experiment pre-test & post-test design | MBPG = 55 [37 men, 18 women]<br><br>Control = 80 [55 men, 25 women] | No mean available<br><br>≥ 43 years = 45.92% | Diagnosis of Schizophrenia (DSM-5) | MBPG vs. Control group | 8 x 70-min sessions, twice weekly (4 weeks total) |
| 3. Chadwick et al. (2009)<br>(UK) | Replication & randomized feasibility trial | Tx = 11<br><br>Waitlist = 11<br><br>(no info on sex) | 41.6 | Psychotic disorder with prominent distressing voices for at least 6 months | Group Mindfulness + meta-cognitive insight<br>vs.<br>Waitlist | 10 x 60-min sessions, twice weekly (5 weeks total)<br>+<br>5 weeks home practice |
| 4. Chadwick et al. (2016)(UK) | Single-blind pragmatic RCT | PBCT = 54 [27 men, 27 women]<br>TAU = 54 [26 men, 27 women, 1 unknown] | No mean available<br><br>Median 42 | Diagnosis of Schizophrenia or schizo-affective disorder (ICD-10). | Group PBCT + TAU vs. TAU | 12 x 90-min weekly sessions |
| 5. Chien and Lee (2013)<br>(Hong Kong) | Single-blind multi-site RCT with a repeated measures design | MBPP = 48 [26 men, 22 women]<br>TAU = 48 [27 men, 21 women] | 25.8 | Diagnosis of Schizophrenia (DSM-IV) | MBPP vs.TAU | 12 x 120-min sessions, twice weekly (6 weeks total) |
| 6.Chien and Thompson (2014)<br>(Hong Kong) | Single-blind multi-site RCT with a repeated measures design | MBPP = 36 [20 men, 16 women]<br>CPEP = 36 [21 men, 15 women]<br>TAU = 35 [20 men, 15 women] | 25.63 | Diagnosis of Schizophrenia (DSM-IV) | MBPP vs CPEP vs TAU | 12 x 120-min sessions every 2 weeks (24 weeks total) |
| 7. Chien et al. (2017)(Hong Kong, China and Taiwan) | Single-blind multi-site RCT with a repeated measures design | MBPEG = 114 [72 men, 42 women]<br>CPEG = 114 [70 men, 44 women]<br>TAU = 114 [74 men, 40 women] | 25.63 | Diagnosis of Schizophrenia or other psychotic disorder (DSM-IV) | MBPEG v CPEG v. TAU | 12 x 120-min sessions every 2 weeks (24 weeks total) |
| 8. Chien et al. (2019)<br>(China & Hong Kong) | Single-blind multi-site RCT with a repeated measures design | MPGP = 60 [34 men, 26 women]<br>CPGP = 60 [32 men, 28 women]<br>TAU = 60 [34 men, 26 women] | 25.1 | Diagnosis of schizophrenia or its subtypes (DSM-IV-TR) | MPGP v CPGP v TAU | 12 x 120-min sessions every 2 weeks (24 weeks total) |
| 9. Dannahy et al. (2011)<br>(England) | Pilot feasibility RCT | 62 (22 men, 40 women)<br><br>50 completed | 41.1 | Treatment-resistant and subjectively distressing voices for at least the preceding two years | Group PBCT | 9 x 90-min weekly sessions<br>+<br>Up to 12 x 90-min weekly sessions |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10. Jacobsen et al. (2019) (UK) | Service Evaluation | 34 (15 men, 19 women) | 45 | Individuals experiencing psychotic symptoms | Mindfulness for Psychosis group | 8 x 90-min weekly sessions |
| 11. Johns et al. (2016) (UK) | Feasibility & acceptability within-subjects pre-post design | 89, 60 completers (40 men, 29 women) | 33.6 | Individuals with Psychosis | ACT group | 4 x 120-min weekly skills building workshops |
| 12. Johnson et al. (2011)(USA) | Single-arm, pilot feasibility uncontrolled trial | 18 (15 men, 3 women) | 29.4 | Schizophrenia Spectrum Disorder (DSM-5 or ICD-10) | Loving Kindness Meditation | 6 x 60-min weekly sessions<br>+<br>1 booster session 6 weeks later |
| 13. Laithwaite et al. (2009) (Scotland) | Single-arm within-subjects design | 19 (all male) | 36.9 | Primary diagnosis of schizophrenia, schizoaffective disorder or bipolar affective disorder | The Recovery After Psychosis Programme based on Compassionate Mind training (Gilbert, 2009) | 20 x 60-min sessions twice a week (10 weeks total) |
| 14. Lam et al. (2020) (Hong Kong) | Pilot feasibility RCT | MBPP = 24 [6 men, 18 women]<br>Control = 22 [5 men, 17 women] | No mean available<br><br>45-54 years = 43.5% | Diagnosis of Schizophrenia (DSM-V) | MBPP<br>vs.<br>TAU | 8 x 90-min weekly sessions |
| 15. Langer et al. (2012) (Spain) | Feasibility & replicability RCT | 23 (11 Tx, 12 TAU)<br><br>18 completed<br><br>MBCT = 7 [4 men, 3 women]<br>TAU = 11 [7 men, 4 women] | 34.3 | Schizophrenia-spectrum Disorder (DSM-IV) | Group MBCT<br>vs.<br>Waitlist | 8 x 60-min weekly sessions |
| 16. Lee (2019) (Taiwan) | Multi-centre RCT | MBI = 30<br>TAU = 30<br><br>50 completed<br>MBI = 20<br>TAU = 30 | 52.96 | Schizophrenia-spectrum Disorder (DSM-V) | Mindfulness Based Intervention vs TAU | 8 x 90-min weekly sessions |
| 17. López-Navarro et al. (2015) (Spain) | Single-centre pilot RCT | IRT + MBI = 22 [19 men, 3 women]<br>IRT alone = 22 [17 men, 5 women] | 38.75 | Schizophrenia-spectrum disorder or bipolar disorder (ICD-10) | Group IRT + MBI<br>vs.<br>IRT alone | 26 x 60-min weekly sessions |
| 18. MacDougall et al. (2019) (Canada) | Pilot single-blind randomized design | MAP = 11<br>TAU = 10<br><br>13 men,<br>4 women,<br>4 unknown | 23.71 | Primary psychotic disorder (DSM-V) | Group Early Psychosis Intervention (EPI) – Mindfulness Ambassador Programme vs Group EPI-TAU | 12 x 60-min weekly sessions |
| 19. Moulden, Mamak, and Chaimowitz (2020) (Canada) | Retrospective pre-post descriptive outcome study | 14 [9 men, 5 women] | 36.36 | Axis 1 disorder (DSM-5) | Group DBT | 150-min weekly sessions for 12 months<br>+<br>Ad-hoc Individual |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | sessions + telephone coaching |
| 20. Randal et al. (2016) (UK) | Open trial, within-subjects repeated measures design | 21 [17 men, 4 women] | 36.8 | Psychotic disorder | MBCT Group | 8 x 120-min weekly sessions |
| 21. Spidel et al. (2018) (Canada) | Multicentre RCT | ACT= 30<br>TAU = 20<br><br>[24 men, 26 women] | 40.4 | Schizophrenia-spectrum disorder or bipolar disorder (DSM-5) and history of trauma | Group ACT vs TAU | 8 x 70-75min weekly sessions |
| 22. Wang et al. (2016) (Hong Kong) | Multicentre, assessor-blind, repeated measures RCT | MPGP = 46<br>[24 men, 22 women]<br>CPGP = 46<br>[23 men, 23 women]<br>TAU = 46<br>[25 men, 21 women] | 24.3 | Schizophrenia-spectrum disorder or bipolar disorder (DSM-IV) | MBPEG<br>vs.<br>CPEG<br>vs.<br>TAU | 12 x 120-min sessions every 2 weeks (24 weeks total) |
| 23. Yilmaz and Okanli (2018) (Turkey) | Semi Experimental | MBPG = 21<br>[16 men, 5 women]<br>Control = 24 [18 men, 6 women] | 38.15 | Schizophrenia (DSM-5) | Mindfulness Based Psychosocial Group Training<br>vs.<br>Control | 16 x 40-50 min twice-weekly sessions (8 weeks total) |
| 24. Yılmaz and Kavak (2018) (Turkey) | Quasi Experimental | MBPG = 34<br>[24 men, 10 women]<br>Control = 35<br>[27 men, 8 women] | No mean reported | Schizophrenia (DSM-5) | Mindfulness Based Psychoeducation Group<br>vs.<br>Control | 12 x 60-min sessions twice-weekly (6 weeks total) |

### *3.2.4 Compassion-focussed interventions*

Three studies evaluated interventions based on compassion-focussed therapy. Laithewaite et al. (2009) developed an intervention based on compassionate mind training (Gilbert, 2001) designed to be implemented in a high-secure inpatient setting. The intervention was split into three phases; understanding psychosis and recovery, understanding compassion and developing a plan for recovery. The focus of this intervention is on building skills in compassion, particularly through the development of an "ideal friend" to encourage participants to internalize the characteristics of a compassionate other. This intervention utilized the "pebble in the water" metaphor to demonstrate that progress in one area of life also has an impact on other areas. The protocol emphasises the importance of homework between sessions in the form of a diary where participants were asked to record distressing experiences and how they responded to them.

Braehler et al. (2013) adapted the forensic group manual developed by Laithewaite et al. (2009) for use in the community. The intervention kept the same structure, consisting of three phases; phase 1 involved exploring the impact of psychosis and formulating blocks to recovery based on the CFT model, phase 2 focused on building skills in compassion for others and oneself, and during phase 3, participants engaged in expressive writing tasks to enable self-reflection and implement changes going forward. Group dynamics were a key part of the intervention in order to foster a compassionate group mind and promote a supportive and encouraging environment. Practising skills in compassion was encouraged between sessions.

Johnson et al. (2011) evaluated an intervention based on ancient Buddhism meditative practises referred to as Loving Kindness Meditation (LKM). The focus of group sessions was on developing kindness towards the self and others and to change relationships with

life experiences by broadening emotional responses. The intervention was discussion-based, with skills teaching and practice between sessions. This intervention also involved imagining a person they feel compassion for with the idea that they may then be able to apply these skills to themselves.

### *3.2.5 Dialectical Behavioural Intervention*

The intervention evaluated by Moulden et al. (2020) included TAU, which consisted of recreational and vocational activities and anti-psychotic-medication. The DBT programme adapted the traditional DBT model (Linehan, 1993a) for a forensic population. The intervention involved a combination of group sessions lasting 2.5 hours, and individual sessions, with telephone coaching from a therapist. The group sessions were skills-based and, as in conventional DBT, would involve radical acceptance of current abilities and qualities whilst acknowledging the need for behaviour change. Individuals would develop skills in emotion regulation and distress tolerance, as well as interpersonal effectiveness. Towards the end of sessions, work would centre on establishing treatment goals and reducing the impact of negative experiences, shifting the focus towards recovery and meaningful engagement in improved quality of life.

### *3.2.6 Mindfulness interventions*

It should be noted that six studies from Hong Kong in this review evaluated the same or very similar interventions (Chien & Lee, 2013; Chien & Thompson, 2014; Wang et al., 2016; Chien et al., 2017; Chien et al., 2019; Lam et al., 2020). The interventions have varying titles; mindfulness-based psychoeducation programme (MBPP), mindfulness psychoeducation group programme (MPGP) and mindfulness-based psychoeducation group (MBPEG), however all groups provided intervention outlines that covered identical or very similar content. The interventions consisted of three phases. Phase 1 involved developing skills to focus on the present moment through guided awareness exercises to recognize

difficult body sensations, thoughts and emotions. Phase 2 moved on to educational workshops to develop coping skills and enable problem solving. In one study, it also included intentionally exploring symptoms and challenging avoidance (Chien et al., 2014). Phase 3 involved planning relapse prevention, increasing awareness and willingness to engage with community resources and identifying future goals. The latest study evaluates an intervention with an additional focus on building skills in emotion regulation and includes a very detailed session outline (Lam et al., 2020).

Seven other studies (Chadwick et al., 2009; Dannahy et al., 2011; Langer et al., 2012; Lopez-Navarro et al., 2015; Chadwick et al., 2016; Randal et al., 2016; Jacobsen et al., 2019) based their protocol on mindfulness interventions for psychosis developed by Segal (2002) and Chadwick (2005), or followed the "Person-Based Cognitive Therapy" model (PBCT; Chadwick, 2006), which adapted the traditional CBT approach for psychosis (Chadwick et al., 2000) by adding components of mindfulness. In addition to formulating the group's experience using the cognitive framework, therapists also encouraged the acceptance of voices rather than avoidance and attempts to control them. Sessions involved guided meditation practice lasting approximately 10 minutes, where participants were encouraged to draw their attention to psychotic experiences and their reactions to them, as well as other bodily sensations, emotions and thoughts. The aim was to challenge the instinct to avoid distressing experiences and to support the acceptance of them as part of the self, whilst also challenging the narrative that the self is bad. Sessions avoided didactic formats and instead included group discussion and guided discovery to help participants express insights and reflections.

MacDougall et al. (2018) evaluated the "Mindfulness Ambassadors Programme" (MAP) that involved 12 weekly 1-hour sessions that each focussed on a different topic such as practising gratitude, open-mindedness and managing difficult experiences. Sessions

were accompanied by a range of mindfulness exercises including body scan and mindful breathing. As with the other interventions, MAP involved a significant homework component with the aim of reinforcing the learning that takes place in sessions. MAP specifies that it focuses on building emotional and social skills through mindfulness exercises that makes this approach particularly helpful for young people experiencing early psychosis. The S-ART (self-awareness, regulation and transcendence) intervention (Vago & Silbersweig, 2012) involves eight weekly sessions using mindfulness practises to regulate behaviours and promote awareness and maintain a positive relationship with the self and others. This intervention was used by Lee (2019). Patients were asked to engage with simple tasks in a mindful way such as playing games, eating, reading or writing. They were also asked to complete daily homework tasks that involved repeating 15 minutes of mindful meditation that they had learnt in sessions. Towards the end of the intervention, facilitators also introduced the idea of self-compassion to encourage kindness towards the self and others.

Three studies conducted in Turkey evaluated similar mindfulness interventions (Yilmaz & Okanli, 2017; Yilmaz & Kavak, 2018; Cetin & Aylaz, 2018). Cetin and Aylaz (2018) investigated an intervention based on Mindfulness-Based Stress Reduction (MBSR; Kabat-Zinn, 2003) that aimed to increase illness insight and medication adherence. The group sessions ran twice a week and had a strong psychoeducation component. Mindfulness exercises were used to enhance the impact of the didactic content and consisted of body scanning, mindful movement and a three minute respiration exercise. The aim was to assist patients in focussing their attention on the present moment, observe their thoughts, emotions and sensations, and wholly accept themselves without judgement. This would enable them to articulate the impact of symptoms on their quality of life and establish coping skills for difficult experiences. The mindfulness-based psychosocial skills training (MBPST) evaluated by Yilmaz and Okanli (2018) aimed to

improve individuals' ability to function by increasing their insight and life skills. The group programme consisted of two 50-minute sessions a week for 8 weeks and combined psychoeducation about illness, medication, communication and addiction, with learning skills in mindfulness through activities such as mindful eating, body scan, meditation practise and gratitude exercises. Participants were expected to take part in role play exercises and were given homework between sessions. The programme concluded with consolidation of skills and relapse prevention. Yilmaz and Kavak (2018) explored a Mindfulness-Based Psychoeducation programme with aim to alleviate ruminative patterns and stress associated with self-stigma by improving illness insight. It differed from the previous study by focussing more on internalized stigma and shame, whilst maintaining a strong mindfulness component throughout. This included exercises such as those mentioned in the previous study. In addition, sessions included learning about acceptance of threatening thoughts and experiences through exposure to difficult memories whilst practising self-soothing techniques. Sessions ran twice a week for a total of 6 weeks and lasted 60 minutes.

### 3.3 Quality Assessment

Quality of included studies was measured using the Downs and Black (Downs & Black, 1998) quality assessment checklist. This measure was used as it allows for the inclusion of both randomized and non-randomized trials. Studies were screened by two independent raters to ensure inter-rater reliability. The checklist consists of 26 questions, with a total possible score of 27 for randomized trials and 25 for non-randomized trials. Higher scores indicate higher quality of study. Scores were categorized as follows; poor (≤14); fair (15-19); good (20-25); excellent (26-28) as used in a study by Hooper et al. (2008).

| Study | Quality Rating | Reporting | External Bias | Internal Bias | Internal Selection Bias | Total |
|---|---|---|---|---|---|---|
| *Braehler et al.* | Good | 11 | 1 | 5 | 4 | 21 |
| *Cetin & Aylaz* | Fair | 8 | 3 | 4 | 3 | 18 |
| *Chadwick et al.(2009)* | Fair | 9 | 1 | 5 | 4 | 19 |
| *Chadwick et al. (2016)* | Good | 6 | 3 | 6 | 5 | 20 |
| *Chien et al. (2013)* | Good | 6 | 3 | 6 | 5 | 20 |
| *Chien et al. (2014)* | Good | 8 | 3 | 5 | 6 | 22 |
| *Chien et al. (2017)* | Good | 10 | 3 | 6 | 6 | 25 |
| *Chien et al. (2019)* | Good | 8 | 3 | 5 | 6 | 22 |
| *Dannahy et al. (2011)* | Fair | 9 | 1 | 4 | 1 | 15 |
| *Jacobsen et al. (2019)* | Fair | 8 | 3 | 4 | 0 | 15 |
| *Johns et al. (2016)* | Fair | 9 | 3 | 5 | 1 | 18 |
| *Johnson et al. (2011)* | Poor | 8 | 1 | 5 | 0 | 14 |
| *Laithwaite et al. (2009)* | Fair | 9 | 2 | 5 | 1 | 17 |
| *Lam (2020)* | Good | 10 | 1 | 6 | 3 | 20 |
| *Langer et al. (2012)* | Fair | 8 | 1 | 4 | 3 | 16 |
| *Lee (2019)* | Good | 10 | 3 | 5 | 5 | 23 |
| *Lopez et al. (2015)* | Good | 10 | 1 | 5 | 5 | 21 |
| *MacDougall et al. (2020)* | Good | 9 | 1 | 6 | 4 | 20 |
| *Moulden et al. (2020)* | Poor | 8 | 2 | 3 | 2 | 15 |
| *Randel et al. (2016)* | Fair | 9 | 3 | 4 | 2 | 18 |
| *Spidel et al. (2018)* | Good | 8 | 3 | 5 | 4 | 20 |
| *Wang et al. (2016)* | Good | 10 | 3 | 5 | 5 | 23 |
| *Yilmaz et al. (2018)* | Fair | 8 | 1 | 5 | 5 | 19 |
| *Yilmaz et al. (2018)* | Good | 9 | 3 | 5 | 3 | 20 |

Table 2 Quality Assessment (Downs & Black, 1996)

### 3.4 Feasibility

Due to the developments of third wave interventions for psychosis over the past 15 years, particularly in ACT, CFT and DBT, a number of the studies included in this review were considered feasibility studies. In these studies, feasibility was the primary outcome with measures of efficacy often included in ancillary analysis. Feasibility was predominantly measured through recruitment rates, retention rates and number of participants that completed the intervention. Given that mindfulness was one the first of the third wave approaches to be adapted for individuals with psychosis (Chadwick, 2005), the majority of the mindfulness studies in this review were full-scale RCTs and five studies were feasibility or pilot trials. However, with the exception of Spidel et al. (2018), all other ACT, CFT and DBT studies were considered feasibility studies.

The cumulative findings from these studies suggest that these interventions are feasible regardless of the third wave model the interventions are based on. For example, Braehler et al. (2013) reported an attrition rate of 18% (4 of 22) and attendance rate of 82% for 4 or more sessions and concluded that this indicated the CFT-based intervention was safe and acceptable to participants. Johnson et al. (2011) reported an attendance rate of 84% for the intention-to-treat sample, with a 91% completion rate. Participants reported finding the intervention accessible and enjoyable, with some participants specifying that they enjoyed the social support aspect of the group intervention. Johns et al. (2016) reported high satisfaction and acceptability ratings based on quantitative and qualitative feedback, with participants finding it helpful to hear from others experiencing similar difficulties and appreciated the practical nature of the intervention. All feasibility studies made recommendations for larger scale RCTs in order to better establish the potential efficacy of third wave group interventions for psychosis.

## 3.5 Effectiveness of third wave group interventions for psychosis

### *3.5.1 ACT Interventions*

The two ACT interventions showed improvements in clinical outcomes. Johns et al. (2016) measured levels of functional impairment using the Sheehan Disability Scale and levels of depression using the Hospital Anxiety and Depression Scale (HADS). They found significant improvements between baseline and follow-up after 20 weeks, with small to medium effect sizes. Mechanisms of change will be reported in section 3.6. Spidel et al. (2018) also found a positive impact of a group ACT intervention and reported that at 3-month follow-up, those in the intervention arm experienced a significant improvement in overall symptom severity and anxiety symptoms (*Cohen's d = 0.60)*, as measured by the BPRS-E and GAD-7 respectively, when compared with controls. There was no reduction in trauma symptoms (Trauma Symptom Checklist 40). They also found a significant

reduction in help-seeking, measured on the subscale of the Service Engagement Scale *(Cohen's d = 0.43)*. No significant differences were found in treatment adherence, collaboration or availability subscales.

### *3.5.2 CFT Interventions*

The Recovery After Psychosis (RAP; Laithwaite et al., 2009) programme had multiple primary outcome measures, most of which were measuring mechanisms of change that will be discussed in section 3.6. As a pilot trial, results for the RAP study should be interpreted with caution. The study found significant change for levels of depression (p=.018) and self-esteem (p=.006) as measured by the Beck Depression Inventory II, and the Rosenberg Self-Esteem Inventory. However, no significant changes were found on the other measures of self-esteem. There was also a significant reduction in general psychopathology (p=.022) as measured by the PANSS subscale. No other significant changes were found on the PANSS Positive, Negative or Depression subscales.

The Loving Kindness Meditation (LKM) study (Johnson et al., 2011) was also a pilot study and reported feasibility and acceptability as the primary outcome. They administered a number of clinical measures as their secondary outcomes. Results showed large improvements in experiences and frequency of positive emotions (mDES; modified Differential Emotions Scale; *Cohen's d=0.78*) on completion of the intervention and were maintained after 3 months. There was also a significant decrease in negative symptoms (*Cohen's d=1.68),* experiences of anhedonia (*Cohen's d=1.88)* and asociality (*Cohen's d=0.5*) as measured by the subscales of the Clinical Assessment Interview for Negative Symptoms (CAINS). However, analysis of findings from the Temporal Experience of Pleasure Scale (TEPS) anticipatory pleasure subscale revealed very little change following the intervention and a small negative effect size after 3 months, contradicting findings from the CAINS. Finally, the Scales of Psychological Wellbeing (SPWB) found

significant differences in all three domains of environmental mastery, self-acceptance and purpose in life on completion of the intervention with large effect sizes and after 3 months with medium to large effect sizes. No significant differences were found using the Trait Hope Scale or the Satisfaction with Life Scale.

The study by Braehler et al. (2013) evaluated associations between clinical outcomes and compassion and avoidance processes. They did not report on clinical change independently. Following a CFT group intervention, authors found a significant negative correlation between compassion scores and levels of depression (r=-0.78), in that as compassion improved, symptoms of depression decreased. This correlation was significantly different from the TAU group (p=0.03). However, no significant changes in psychosis symptoms were found.

### *3.5.3 DBT Intervention*

The preliminary evaluation of a DBT group intervention for psychosis in a forensic setting (Moulden et al., 2020) used a combination of clinical and forensic outcome measures. The authors found a significant improvement on the intrapersonal subscale of the BarOn EQ-i (t=2.55, p=0.3), which aims to measure emotional intelligence and social functioning. However, no significant changes were found on the remaining 3 subscales; interpersonal, adaptability and general mood. There were also improvements in levels of aggression (p=0.04) on completion of the intervention, as measured by the Aggression Questionnaire. Again, no other significant changes were found on the other three subscales; physical aggression, verbal aggression and hostility.

### *3.5.4 Mindfulness Interventions*

Studies by Chien and colleagues (Chien et al., 2017; Chien et al., 2019; Chien & Lee, 2013; Chien & Thompson, 2014; Lam et al., 2020; Wang et al., 2016) found significant

improvements for those attending the mindfulness-based psychoeducation interventions across a range of outcome measures. Authors reported reductions in overall psychotic symptoms (BPRS, PANSS), with Chien et al. (2017) and Chien et al. (2019) also specifying significant improvements in both positive and negative subscales of the PANSS. All five studies also reported significant improvements in functioning (Specific Level of Functioning Scale; SLOF) and increased insight (Insight and Treatment Attitudes Questionnaire; ITAQ) for those that attended mindfulness-based psychoeducation interventions, compared with those that attended a conventional psychoeducation programme or those that received TAU. Each study also found a significant reduction in duration of hospital admissions for those that attended the mindfulness-based intervention. Three of the five studies reported a significant reduction in the number of hospital admissions (Chien & Lee, 2013; Wang et al., 2016; Chien et al., 2017). Lam et al. (2020) and a significant reduction in symptoms of depression (Depression Anxiety Stress Scale; DASS-21) following completion of the intervention, though this reduction was also found in the control group. There were no changes in anxiety or stress. Pair-wise comparisons demonstrated a minor between-group difference in overall psychotic symptoms (C-PSYRATS) at follow-up, with those that attended the intervention reporting a greater reduction in severity of symptoms when compared with those receiving TAU.

Of the remaining 12 studies, seven reported on outcomes measuring psychosis symptoms. Those using the PSYRATS (Chadwick et al., 2009; Chadwick et al., 2016; Randal et al., 2016) reported mixed findings, with Chadwick et al. (2009) and Randal et al. (2016) reporting no significant improvements and Chadwick et al. (2016) reporting an initial improvement in voice intensity and disturbance post-treatment that was not maintained at 10 month follow-up. Chadwick et al. (2009) and Randal et al. (2016) also found no significant changes on the BAVQ-r. Studies administering the PANSS (Lopez-Navarro et

al., 2015; Lee, 2019) found no significant changes in positive symptoms; however Lee (2019) found a significant improvement in negative symptoms that was maintained at 3 months ($p=0.03$). MacDougall et al. (2018) administered the SAPS and the SANS as ancillary outcomes in their feasibility study and found no significant changes in positive or negative symptoms post-intervention. Lee et al. (2019) administered the SANS and found a significant reduction in negative symptoms following the intervention ($p=0.01$).

Dannahy et al. (2011) and Jacobsen et al. (2019) both made use of visual analogue scales as outcome measures in their studies. Dannahy et al. (2011) asked participants to rate voice control on a scale from 0 ("none at all") to 100 ("total control over me") and voice distress on a scale from 1 ("not at all distressed") to 5 ("very distressed indeed"). They found significant improvements in both voice control ($p<0.01$) and voice distress ($p<0.01$) following a mindfulness intervention. Jacobsen et al. (2019) presented participants with visual depictions of "bubbles" increasing in size representing different degrees of the scale. This study was investigating within-session effects and found that there was a decrease in general distress and symptom-related distress following each of the 8 sessions.

Four studies administered the Clinical Outcomes Routine Evaluation Outcome Measure (CORE-OM), or the short version consisting of 10 items (CORE-10). Chadwick et al. (2009; 2016) and Randal et al. (2016) found small improvements but none were significant. However, Dannahy et al. (2011) found significant reduction in CORE-OM scores ($p<0.001$) post-treatment, which was maintained at 1 month follow-up. Of the three studies that measured impact of mindfulness interventions on mood, two found significant improvement in symptoms of depression. Chadwick et al. (2016) administered the Hospital Anxiety and Depression Scale (HADS) and found that those in the intervention arm reported a significant reduction in depression subscale scores at 10 month follow-up

(p=0.037). MacDougall et al. (2018) measured depressive symptoms using the Profile of Mood States (POMS) and found significant between-group differences post-intervention, with participants who had attended the mindfulness intervention reporting lower levels of depressive symptoms.

In addition to the studies conducted by Chien and colleagues that all found a significant change in insight using the Illness and Treatment Attitudes Questionnaire (ITAQ), four other studies measured impact of group mindfulness interventions on insight. Chadwick et al. (2009) measured participants' beliefs about their voices (Beliefs About Voices Questionnaire; BAVQ) and found improvements following the intervention (p=0.509). Randal et al. (2018) also administered the BAVQ and found an increase in scores, indicating a worsening of symptoms. However, these findings were also not significant (p=0.16). Cetin and Aylaz (2018) measured insight using the Beck Cognitive Insight Scale (BCIS) and found that there was a significant between-group difference in scores post-treatment. Participants who had received group mindfulness-based psychoeducation reported significantly greater improvement than those in the control group (p<0.001). Yilmaz and Oklanli (2017) also used the BCIS and found participants in the treatment arm showed significant improvements in insight following the group intervention (p<0.01).

## 3.6 Mechanisms of change

Commonly in third wave studies, authors attempt to demonstrate that change occurs by the hypothesised and targeted psychological processes (Johansson & Høglend, 2007).

### *3.6.1 Acceptance*

Johns et al. (2016) measured acceptance using the Acceptance and Action Questionnaire (AAQ-II; Bond et al., 2011) and the Cognitive Fusion Questionnaire (CFQ; Gillanders et al., 2014) and found significant reductions in experiential avoidance (p=0.001) and cognitive

fusion (p=0.002) at 3 month follow-up. Langer et al. (2012) also administered the AAQ-II and found a between-group difference in post-intervention scores, with those in the experimental group showing lower levels of experiential avoidance than the control group. However, this finding was insignificant (p=0.353). Braehler et al. (2013) implemented the Narrative Recovery Style Scale (NRSS; Gumley et al., 2010), which includes an assessment of avoidance. Braehler et al. (2013) found that there was a significant reduction in avoidance for participants that had attended the CFT group intervention.

### *3.6.2 Compassion*

The NRSS measures compassionate narrative strategies, allowing Braehler et al. (2013) to also measure levels of compassion in participants. Findings demonstrated that participants from the experimental group showed significantly more compassion than those from the TAU group. Laithewaite et al. (2009) measured compassion using the Self Compassion Scale (Neff, 2003) and found no significant changes following the intervention. However, they did find significant improvements in self-image scores suggesting that participants saw themselves more positively following a CFT-based group intervention. They also found significant change in Social Comparison Scale scores (Allan & Gilbert, 1995), meaning that participants were able to see themselves as less inferior to others after the group.

### *3.6.3 Emotion regulation*

Spidel et al. (2018) measured emotion regulation using the Cognitive Emotion Regulation Questionnaire (CERQ; Garnefski & Kraaij, 2007). They found that participants who attended the ACT group intervention showed a significant increase in their use of acceptance as an emotion regulation strategy, compared with those in the control group ($p<0.05$). Lam et al. (2020) also employed a measure of emotion regulation by

administering the Chinese version of the Emotion Regulation Questionnaire (ERQ; Zhang et al., 2014), which looked specifically at reappraisal and suppression. They found a significant improvement in reappraisal at 3 month follow-up (p=0.033) for those that attended a mindfulness-based psychoeducation programme compared with participants that received TAU.

### *3.6.4 Mindfulness*

Ten studies investigated the impact of third wave group interventions on mindfulness. Wang et al. (2016), Randal et al. (2016), Chien et al. (2019) and Lam et al. (2020) all administered the Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2006). All found significant improvements in mindfulness following the group interventions, with the exception of Randal et al. (2018), whose findings were in the right direction but were not significant.

Chadwick et al. (2009) administered the Southampton Mindfulness Questionnaire (Chadwick et al., 2008) and the Southampton Mindfulness Voice Questionnaire (Chadwick, Barnbrook and Newman-Taylor, 2007), both of which assess the degree to which participants respond mindfully to distressing experiences. They found improvements across both measures but only the pre-post SMQ score was significant (p = 0.037) and not the SMVQ. Langer et al. (2012) also found a statistically significant difference in scores on the SMQ (p = 0.028; d = 1.306). This suggests that participants in the mindfulness-based group intervention demonstrated an increase in mindful awareness of distressing thoughts and images. Johns et al. (2016) also found a statistically significant reduction in SMQ scores after a 3 month follow-up (p=0.001) after attending an ACT-based group intervention.

**Table 3** Outcome measures used across 24 studies

| Psychosis Symptoms | Other Clinical Measures |
|---|---|
| Beliefs About Voices Questionnaire (BAVQ) | Beck Depression Inventory (BDI-II) |
| Brief Psychiatric Rating Scale (BPRS) | Depression Anxiety Stress Scale (DASS-21) |
| Brief Symptom Inventory (BSI) | Generalized Anxiety Disorder (GAD-7) |
| Clinical Assessment Interview for Negative Symptoms | Profile of Mood States (POMS) |
| Clinical Global Impression Scale – Schizophrenia | Short Ruminative Response Scale (SRRS) |
| Functional Remission of General Schizophrenia (FROGS) | Temporal Experience of Pleasure Scale (TEPs) |
| Positive And Negative Affect Schedule (PANAS) | Trauma Symptom Checklist – 40 |
| Positive And Negative Syndrome Scale (PANSS) | Anger Disorders Scale (ADS) |
| PSYRATS (inc. Chinese version) | The Aggression Questionnaire (AQ) |
| Self-Assessment of Negative Symptoms (SANS) | |
| Self-Assessment of Positive Symptoms (SAPS) | |
| **Functioning, Recovery & Wellbeing** | |
| Beck Cognitive Insight Scale (BCIS) | Questionnaire about Process of Recovery (QPR) |
| Clinical Outcomes in Routine Evaluation – Short (CORE-10) | Rosenburg Self Esteem (RSE) |
| CORE-Outcome Measure (CORE-OM) | Service Engagement Scale |
| Day Reconstruction Method (DRM) | Sheehan Disability Scale |
| EQ5D | Social Functioning Scale |
| Fear of Recurrence Scale (FORSE) | Social Support Questionnaire (SSQ) |
| Insight and Treatment Attitudes Questionnaire (ITAQ) | The Coping Inventory for Stressful Situations (CISS) |
| Internalized Stigma of Mental Illness Scale (ISMIS) | Time Budget Measure |
| Narrative Recovery Scale (NRS) | The Warwick-Edinburgh Mental Wellbeing Scale |
| Personal Beliefs about Illness Questionnaire - Revised | Self-Report Visual Analogue Scale |
| Insight and Treatment Attitudes Questionnaire (ITAQ) | |
| **Acceptance** | **Compassion** |
| AAQ-II | Self-Compassion Scale (SeCS) |
| Valuing Questionnaire (VQ8) | Self-Image Profile for Adults (SIP-AD) |
| The Goal Scale (GS) | Social Compassion Scale (SCS) |
| | The Other As Shamer Scale (OAS) |
| | Internalized Stigma of Mental Illness Scale (ISMIS) |
| **Mindfulness** | **Emotion Regulation** |
| Five Facet Mindfulness Questionnaire (FFMQ) | Cognitive Emotion Regulation Questionnaire |
| Kentucky Inventory Mindfulness Skills (KIMS) | Emotion Regulation Questionnaire (ERQ) |
| Mindfulness Attention Awareness Scale | Modified Differential Emotions Scale (mDEFS) |
| Southampton Mindfulness Questionnaire (SMQ) | The BarOn Emotional Quotient Inventory |
| **Other** | |
| Brief Core Schema Scales (self & others) | Hamilton Anatomy of Risk Management (HARM) |
| Therapeutic Factors Inventory | Paulhus Deception Scale (PDS) |

Lopez-Navarro et al. (2015) and Lee (2019) administered the Mindfulness Attention Awareness Scale (Brown & Ryan, 2013) but found no significant differences between groups in either study. MacDougall et al. (2018) used the Kentucky Inventory of Mindfulness Skills (KIMS; Baer, Smith & Allen, 2014) to evaluate levels of mindfulness in their study. However, they also found no significant improvements following participation in the group mindfulness-based intervention.

Across the 24 studies, there were over 60 outcome measures used to evaluate group interventions outlined in this review. Multiple authors acknowledged the heterogeneity of measures and the difficulty this brings when trying to synthesize findings.

Table 4 Key findings from included studies

| Author & Year (Location) | Diagnoses (%) | Duration of illness (years) | Primary Outcome(s) | Key findings | Limitations |
|---|---|---|---|---|---|
| 1. Braehler et al. (2013) | Schizophrenia = 12 (30)<br>Other non-affective disorder = 10 (25)<br>Schizoaffective disorder = 5 (12.5)<br>Depressive psychosis = 9 (22.5)<br>Other = 4 (10) | 10.35 years | Feasibility & acceptability | Group CFT was associated with greater improvement and a significant increase in self compassion when compared with TAU | Variability in TAU conditions<br>No utilization of diagnostic interview<br><br>No follow-up |
| 2. Cetin & Aylaz (2018) | Schizophrenia = 135 (100) | 1-14 years = 73 (54.1%)<br>15-29 years = 50 (37%)<br>30 and over = 12 (8.9%) | Insight (BCIS) + Medication Adherence (MARS) | Psychoeducation programme was effective in improving insight and medication adherence | Treatment arm & control arm were recruited from separate sites<br><br>No follow-up |
| 3. Chadwick et al. (2009) | Schizophrenia = 22 (100) | 17.7 years | Feasibility + Replication | No significant differences were found between waitlist and treatment. Secondary analysis showed improved mindfulness of thoughts & images, but not voices. | Sample had longstanding treatment resistant psychosis so generalization cannot be assumed |
| 4. Chadwick et al. (2016) | Schizophrenia = 108 (100) | Unknown | Psychological distress (CORE-OM) | The intervention arm showed lower levels of depression post-treatment, which was maintained at 6 months follow-up. Intensity of voices was also decreased | Recruitment target was not met<br>Lack of active control group |
| 5. Chien & Lee. (2013) | Schizophrenia = 96 (100) | 3.1 years | Symptom severity (PANSS)<br>Insight (ITAQ)<br>Psychosocial Functioning (SLOF) | The intervention arm showed significant improvements in insight, symptom severity, functioning and length of hospitalization compared with TAU | Duration of illness >5 years and findings may not generalized to chronic psychosis<br>Confounding effects (medication adherence, other psychological interventions) were not accounted for |
| 6. Chien et al. (2014) | Schizophrenia = 107 (100) | 2.6 years | Mental State (CHECK)<br>Readmission rate<br>Insight (ITAQ) | The mindfulness group demonstrated significant improvement in symptom severity, insight, functioning and duration of hospital admissions, compared with TAU. | Selective sampling<br>Participants were volunteers<br>Short duration of illness |
| 7. Chien et al. (2017) | Schizophrenia = 178 (52.05)<br>Schizophreniform disorder = 41 (11.98)<br>Schizoaffective disorder = 78 (22.8)<br>Other psychotic disorders = 45 (13.15) | 2.6 years | Symptom Severity (PANSS)<br>Number & length of hospital readmissions<br>Insight (ITAQ) | Participants receiving MBPEG showed a shorter mean duration of re-hospitalization than those in the other groups over 24 months | Selective sampling<br>Facilitators had intensive training, which may reduce applicability into TAU |

| | | | | | |
|---|---|---|---|---|---|
| 8. Chien et al. (2019) | Schizophrenia = 96 (53.3)<br>Schizophreniform disorder = 36 (20)<br>Schizoaffective disorder = 28 (15.5)<br>Other psychotic disorders = 20 (11.1) | 2 years | Psychosocial functioning (SLOF)<br>Insight (ITAQ)<br>Symptom Severity (PANSS) | The mindfulness group reported significant improvements in insight, functioning, symptom severity and duration of hospital readmissions compared with the other groups. This was maintained at 18 months. | Short duration of illness and low level of antipsychotic medication use may not be representative of the wider population |
| 9. Dannahy et al. (2010) | Schizophrenia/schizoaffective disorder = 55 (88.7)<br>Psychosis = 5 (8.06)<br>Non-specified PD = 1 (1.61)<br>PTSD = 1 (1.61) | 14 years | Feasibility<br>Psychological distress (CORE-OM)<br>Voice distress<br>Voice control<br>Relationship with voices | Participants reported significant benefits in distress, control and dependence on voices. | Non-randomized design<br>No comparison treatment<br>Small sample size<br>2:1 ratio of women to men not representative of the broader population |
| 10. Jacobsen et al. (2019) | Schizophrenia = 27 (79)<br>Bipolar Disorder = 7 (21) | 1-5 years = 5 (15)<br>6-10 years = 4 (12)<br>11-15 years = 9 (26)<br>>15 years = 16 (47) | Single-session impact<br>General stress<br>Symptom Related distress | Average ratings of stress and symptom-related distress were reduced following 8 sessions of mindfulness, though not all differences were significant | Non-experimental design<br>Use of non-standardized measures<br>Facilitators had undergone substantial training, |
| 11. Johns et al. (2016) | Psychosis = 89 (100) | Established = 36 (52)<br>Early intervention = 33 (48) | Feasibility & acceptability<br>Functioning (Sheehan Disability Scale)<br>Mood (HADS) | Participants attending a brief group ACT intervention reported improvements in functioning and mood at follow-up. | Completers only had to attend one session<br>Uncontrolled design<br>Assessments not blind<br>Receipt of other interventions unrestricted |
| 12. Johnson et al. (2011) | Schizophrenia = 8 (44)<br>Schizoaffective = 6 (33)<br>Psychosis NOS = 4 (22) | Unknown | Feasibility & acceptability | The intervention was associated with decreased negative symptoms and increased positive emotions and psychological recovery. | Uncontrolled design<br>Small sample size<br>Sample had high average education and intelligence not representative of broader population |
| 13. Laithwaite et al. (2009) | Schizophrenia = 5 (27.8)<br>Paranoid schizophrenia = 10 (55.6)<br>Bipolar affective disorder = 3 (16.6) | Average length of hospital stay = 8 years | Self-compassion (SCS, SeCS)<br>Depression (BDI-II) | Participants reported significant improvements in self-compassion, depression and general psychopathology | Small sample size<br>No control group<br>Bonferonni corrections not performed<br>Measures not validated in a forensic clinical population |
| 14. Lam et al. (2020) | Schizophrenia = 38 (84.5)<br>Paranoid schizophrenia = 2 (4.4)<br>Brief psychotic disorder = 5 (11.1) | <10 years = 3 (6.5)<br>10-19 years = 11 (23.9)<br>20-29 years = 20 (43.5)<br>30-39 years = 10 (21.7)<br>≥40 years = 2 (4.4) | Feasibility<br>Emotion regulation (ERQ)<br>Rumination (SRRS) | The intervention was associated with improvements in emotion regulation and a reduction in rumination. | Convenience sampling<br>3:1 ratio of women to men not representative of the broader population<br>Participants recruited from regions associated with high poverty rate<br>Long duration of illness |

| | | | | | |
|---|---|---|---|---|---|
| 15. Langer et al. (2012) | Schizophrenia, schizophreniform disorder, schizoaffective disorder or delusional disorder (n=unknown) | Unknown | Feasibility & Replication | Following the intervention, those in the experimental group showed significant improvements in mindfulness as measures by the SMQ. | Small sample size<br>No follow-up<br>No significant difference in clinical outcome |
| 16. Lee (2019) | Schizophrenia = 50 (100) | Unknown | Psychosis symptoms (SANS, CMV-PANSS)<br>Depression (BDI-II)<br>Mindfulness (MAAS) | Mindfulness mitigates the severity of negative symptoms and depression. | Small sample size<br>Improvements not maintained at follow-up |
| 17. Lopez-Navarro et al. (2015) | Schizophrenia = 30 (68.1)<br>Schizoaffective disorder = 9 (20.4)<br>Bipolar disorder = 3 (6.8)<br>Delusional disorder = 2 (4.7) | 14.02 years | Quality of life (WHOQOL-BREF) | Mindfulness added to IRT was associated with enhanced quality of life. | No follow-up<br>Small sample size |
| 18. MacDougall et al. (2018) | Schizophrenia = 8 (47.1)<br>Schizophreniform disorder = 1 (5.9)<br>Schizoaffective disorder = 1 (5.9)<br>Psychosis NOS = 3 (17.6)<br>Other = 4 (23.5) | ≤ 3 years | Feasibility & acceptability | The Mindfulness Ambassador Programme (MAP) has beneficial effects for depression and fatigue in individuals with early psychosis. | Small sample size<br>Descriptive analysis |
| 19. Moulden et al. (2020) | Schizophrenia = 6<br>Schizoaffective disorder = 3<br>Psychosis NOS = 2<br>Bipolar disorder = 1<br>Personality disorder = 7<br>(N=14, unable to determine) | Unknown | Mental state (GS, AQ, ADS, BarOn EQ-I, BSI, CISS) | Scores indicated a significant increase in insight and acknowledgment of problems. | Small descriptive study<br>No follow-up<br>No control group |
| 20. Randal et al. (2016) | Schizophrenia = 12 (57.14)<br>Bipolar w/psychotic features = 3 (14.28)<br>Schizoaffective disorder = 2 (9.52)<br>First episode psychosis = 1 (4.76)<br>Other = 3 (14.78) | 11.65 years | Psychological change (Repertory Grids)<br>Psychological distress (CORE-OM) | Improvements were found in ability to act with awareness as measured by the FFMQ, but in no other areas of mindfulness. Improvements were also found in self-rated recovery. | Small sample size<br>No control group<br>Underpowered |

| | | | | | |
|---|---|---|---|---|---|
| 21. Spidel et al. (2018) | Schizophrenia = 33 (66)<br>Bipolar disorder = 10 (20)<br>Psychosis NOS = 7 (14) | 21.2 years | Emotion regulation-acceptance (CERQ)<br>Psychiatric symptoms (BPRS-E)<br>Trauma symptoms (TSC-40)<br>Anxiety (GAD-7) | Following intervention, participants reported decreased overall symptoms and decreased anxiety. Participants' ability to regulate their emotional reactions increased. | Small sample size<br>No intervention fidelity checks<br>Clinician recording feedback was also clinician facilitating group |
| 22. Wang et al. (2016) | Schizophrenia = 58 (42)<br>Schizophreniform disorder = 37 (26.8)<br>Schizoaffective disorder = 29 (21)<br>Other psychotic disorders = 14 (10.14) | <1 year = 40 (28.9)<br>1-2 years = 44 (31.8)<br>2-3 years = 31 (22.5)<br>3-5 years = 23 (16.6) | Psychosocial functioning (SLOF)<br>Hospital readmission rates | MBPG participants reported a greater reduction in psychotic symptoms, greater insight into their illness and improved level of functioning at the 6 month follow-up. | Short duration of illness<br>Participants had high level of education, low use of antipsychotics and well established family support. |
| 23. Yilmaz & Okanli (2017) | Schizophrenia = 45 (100) | 18.5 years | Functional Recovery (FROGS)<br>Insight (BCIS) | The intervention group scored significantly higher in functional recovery and insight levels than the control group | Did not use randomization<br>Small sample size |
| 24. Yilmaz & Kavak (2018) | Schizophrenia = 69 (100) | Unknown | Internalized stigma (ISMIS) | Mindfulness-based psychoeducation was effective in reducing stigma in patients with schizophrenia | No follow-up<br>Did not use randomization |

# 4. Discussion

## 4.1 Key findings

The current review evaluated the evidence for third wave group interventions for psychosis and included 24 studies. Overall, findings were promising with studies reporting improvements across a range of both symptomatic and functional outcomes. Initial findings suggest that third wave group interventions are feasible and may offer an effective treatment format when compared with TAU, routine psychoeducation or waitlist controls.

Of the 24 studies, 18 were evaluating a mindfulness-based intervention, with only 3 CFT interventions, 2 ACT interventions and 1 DBT intervention being included in the review. Mindfulness plays a key role in all third wave models (Hayes & Hofmann, 2017) as well as being an intervention in its own right, which may indicate why the majority of research to date has investigated mindfulness interventions as a useful place to start when determining the efficacy of third wave approaches for psychosis. However, given the growing interest in this area, new third wave interventions are being developed and evaluated frequently, in an attempt to build on these initial findings and branching out from mindfulness groups e.g. in DBT (Heerebrand et al., 2021; Mullen, 2021; Ryan et al., 2021), CFT (Cheli, Cavalletti, & Petrocchi, 2020; Urken & LeCroy, 2021) and ACT (Jolley et al., 2020; van Aubel et al., 2020).

Although studies had facilitators from a variety of different occupations (social workers, psychiatric nurses, CMHT clinicians, occupational therapists), the majority were clinical psychologists. Each study detailed that facilitators had all gone on specific training to deliver the intervention, regardless of their role prior to participating in the study. Although it is often the case in UK settings logical that it is

primarily clinical psychologists delivering third wave groups, it is also notable that it was found feasible for other occupations to do so. This may be an important factor in rolling out more easily accessible psychosocial interventions in both the community and inpatient care in the future. If interventions are designed in a manner that means a range of mental health clinicians can deliver them, then it reduces the likelihood of barriers to implementing the group interventions into routine care. In addition, all 24 studies also outlined the importance of protocol for ensuring fidelity and for allowing the intervention to be delivered consistently to any given population. For example, Chien et al. (2013) described adapting the protocol by Chadwick (2006) to accommodate traditional Chinese cultural beliefs, whilst still maintaining the key structure and content of the intervention. This is also likely to reduce barriers to access, as services can offer one intervention without having to develop a number of different interventions for each unique population, and learn how to offer and apply these.

Components of the interventions varied greatly, with duration ranging from 4 weeks to 12 months, and frequency of sessions variously occurring twice a week, weekly and every two weeks. There were differences in rationale for number of sessions per intervention, as Spidel et al. (2018) designed an intervention with 8 weekly sessions based on the notion that brief ACT does not appear to be effective for up to one third of patients experiencing positive symptoms (Bach & Hayes, 2002). However, the study by Bach and Hayes (2002) evaluated a brief, 4 session individual ACT intervention on an acute psychiatric inpatient ward and may not be directly comparable to group interventions. There may also be important group therapeutic factors that mean a shorter intervention in group format may be beneficial (Yalom & Leszcz, 2020). Johns et al. (2016) evaluated a 4 week intervention, with weekly 2-hour sessions and found

significant improvements in functioning and mood over time from baseline to 20 week follow-up, suggesting that ACT interventions have the potential to be effective in brief format. Although not based on ACT, Johnson et al. (2011) also evaluated an intervention lasting less than 8 weeks that was based on CFT. They found a significant reduction in negative symptoms and an increase in the experience of positive emotions. These findings highlight the potential for clinical change in fewer sessions, and suggest that the target for brief interventions may be more suited to negative symptoms and functioning, rather than reducing positive symptoms. This is in line with the basis of third wave interventions, in that the aim is not to reduce symptoms but to change the relationship with them. Brief interventions can help to increase access to care, as patients can be seen more quickly and waiting lists can reduce in size.

Another notable common component across the interventions was the use of homework between sessions. Each of the 24 studies specified that homework was set each week to enable the participants to practise the skills they were learning in session. The homework in each study consisted of a variety of formats including being given CDs to practice mindfulness exercises (MacDougall et al., 2019), written exercises such as goal setting (Johns et al., 2016) or being asked to keep a journal (Laithwaite et al., 2009). As third wave interventions are skills-based, it is consistent that homework is encouraged in order to practise and build on skills learnt in session. However, studies reported that it was difficult to determine adherence to homework tasks and to evaluate the value and contribution to effectiveness of the intervention. Future research should establish methods for investigating these factors, as they may provide useful insight into importance of specific intervention components.

Given the recency of many of these studies, particularly those that do not evaluate mindfulness, the prevalence of feasibility outcomes is not surprising. Of the 24 studies, 10 characterised themselves as feasibility or pilot studies, all of which reported findings to suggest larger scale RCT evaluation would be feasible. No study reported a high attrition rate or a low attendance rate (all were above 80%), suggesting that not only are the interventions feasible, they are also acceptable to participants. This calls for researchers to carry out larger scale RCTs in order to support any findings of efficacy outlined in this review. Although sample size ranged from 14 to 342 participants, the average sample size was 73 participants, which drops to just 21 participants if we exclude mindfulness-based studies. In addition, many of the included studies evaluating ACT, CFT or DBT (as early as Laithwaite et al., 2009) in this review highlight the need for larger studies to be conducted. Despite the growing interest in third wave interventions over the past 15 years, there is still a lack of full scale evaluations to meaningfully determine their effectiveness for individuals with psychosis. Collectively, findings from this review strongly support the feasibility and acceptability of trials investigating third wave group interventions for psychosis. It is now arguably unethical (in terms of resource use) to continue to collect more of this kind of data – full scale trials are required.

In summarizing efficacy for the included studies, targets of the interventions were greatly varied, as can be seen by the 64 outcome measures used (see Table 3). The pilot and feasibility studies included are not powered adequately to establish efficacy and, by looking at direction of outcome measures, only point to potential for clinical change. A number of the studies have a small sample size, which limits their generalisability to other populations.

Some studies targeted symptom reduction or improvement, such as Lee (2019), whether as some studies targeted improvement in quality of life or functioning, for example Chadwick et al. (2016) and Chien et al. (2019). Given that the aim of third wave interventions is to change the relationship with symptoms rather than the symptoms themselves (Hayes & Hofmann, 2017), it is surprising that so many of the studies measured symptom severity as an outcome. This notion is further illustrated when broadly examining the outcomes for symptom measures, which appear to be mixed. For example, Chien et al. (2017) and Lee (2019) found reductions in overall psychosis symptoms and negative symptoms as measured by the PANSS, but Chadwick et al. (2009) and Randal et al. (2016) found no significant improvements in psychosis symptoms using the PSYRATS. These two studies also found no significant change in beliefs about voices using the BAVQ-r. No mindfulness intervention study included in this review found a significant reduction in occurrence of positive symptoms but Dannahy et al. (2011) did find significant improvements in both voice distress and voice control as measured using visual analogue scales. As such, the findings must be interpreted with caution without support from validated measures. Nevertheless, these results highlight the difference in intervention mechanisms compared with traditional CBT, as despite no change in positive symptoms and mixed results regarding negative symptoms, participants experience less symptom-related distress. Jacobsen et al. (2019) also found less symptom-related distress. However this study has a sample size of 40 participants and was not adequately powered a priori to be a definitive evaluation of CFT. Nevertheless, the direction of scores is in the expected direction and thus warrants further investigation. Whilst previous research supports that outcomes measuring reduction in hallucinatory and delusional experiences are characteristic of more traditional CBT interventions

(Jones et al., 2018), it appears third wave approaches are still interested in determining the impact of decreasing symptom severity also.

When looking at ACT, CFT and DBT interventions, findings relating to symptom severity were also mixed. Spidel et al. (2018) found a significant improvement in overall psychosis symptom severity as measured by the BPRS-E but Laithwaite et al. (2009) found no significant change in positive or negative symptoms of psychosis and Johnson et al. (2011) only found improvement in negative symptoms. Although findings are not consistent across all studies, a pattern seems to have emerged suggesting little to no impact on positive symptoms of psychosis, with the potential for interventions to positively affect negative symptoms and overall symptom-related distress. The strongest support for these findings was found to come from the Hong Kong group (Chien et al., 2017; Chien et al., 2019; Chien & Lee, 2013; Chien & Thompson, 2014; Lam et al., 2020; Wang et al., 2016) due to their large sample sizes and randomised blind-assessor designs.

The work from the Hong Kong group (Chien et al., 2017; Chien et al., 2019; Chien & Lee, 2013; Chien & Thompson, 2014; Lam et al., 2020; Wang et al., 2016) found mindfulness-based psychoeducation in a number of formats to be significantly more effective than conventional psychoeducation or TAU in reducing positive symptoms, improving insight, improving social functioning and reducing duration of hospital admissions. With the exception of the study by Lam et al. (2020), these were all full-scale RCTs and they all achieve a quality rating of "Good" (≥20) on the Downs and Black quality assessment tool (Downs & Black, 1998). This means these results can be somewhat interpreted with confidence. The studies evaluated the same or very similar interventions across each study and used similar outcome measures, suggesting that

the findings overall are reliable. Sample sizes were also generally higher than the remaining studies in the review, with the Hong Kong sample sizes ranging from 46 to 342 participants (median 123 participants), further increasing the validity of these findings. However, as the studies take place in similar settings with similar populations (e.g. community settings) it is also possible that the findings may not be generalizable to other settings such as inpatient care or in a crisis service.

When looking at outcomes determining factors other than psychosis symptom severity, findings seem more consistent. Given the rise of transdiagnostic approaches over the past 15 years (Schaeuffele et al., 2021), it would be expected that a number of the studies in this review measured levels of other clinical symptoms such as anxiety and depression. For example, Johns et al. (2016) and Spidel et al. (2018) found that group ACT interventions had a significant impact on levels of depression and anxiety respectively as measured by the HADS and GAD-7 and Laithwaite et al. (2009) also found significant improvements in depression symptoms following the group CFT intervention, as measured by the BDI-II. These findings can also be seen in mindfulness interventions, with Chadwick et al. (2016), Lam et al. (2020) and MacDougall et al. (2019) all reporting significant reduction in depressive symptoms following a mindfulness group compared with TAU. Results seem to support the rationale for developing third wave interventions as, if the aim is to reduce symptom-related distress rather than the presence of symptoms themselves, it follows that this will have an impact on depression and anxiety. If an individual is less distressed by their symptoms, they are less likely to experience negative emotions alongside psychosis symptoms, as they develop skills in acceptance, psychological flexibility and emotion regulation. Another positive consequence of less symptom-related distress may be increased functioning in daily life. Many of the studies included

measures of functioning. Johns et al. (2016), López-Navarro et al. (2015), Yilmaz and Okanli (2018) and the Hong Kong group (Chien et al. 2013, 2014, 2017, 2019; Wang et al., 2016 ) all administered a measure of functioning, disability or quality of life and found improvements for each outcome after attending a third wave group intervention (see Table 4). There is a wider impact of third wave interventions, beyond the individual and their clinical presentation. This is in line with previous literature that has evaluated individual third wave interventions (Khoury et al., 2015; Louise et al., 2018). Previous research has found that interventions for individuals with psychosis can have a positive impact on carers' experiences (Lavis et al., 2015) and future research may want to investigate whether third wave interventions also have a similar effect on carers, in order to determine the wider impact of interventions that target functioning and quality of life for the individual rather than decreasing symptoms.

In addition to exploring the impact on parallel diagnoses, many studies also measured mechanisms of change. Again, this may seem more fitting than evaluating impact on psychosis symptom severity due to the focus of third wave interventions. Exploring mechanisms of change allows researchers to understand more about how or why an intervention is effective. The studies in this review included measures of acceptance, cognitive fusion, compassion, mindfulness, and emotion regulation. All studies that measured mechanisms of change through a variety of outcome measures found significant improvements in the specified processes (see Table 4) with the exception of Laithwaite et al. (2009), Randal et al. (2016), and Langer et al. (2012), who all found changes in the right direction but these changes were insignificant. Being able to isolate treatment-specific processes can enhance assurance in specific interventions, as it means we are able to determine that their efficacy is a consequence of the processes they target (Kangaslampi & Peltonen, 2019). This

insight can help ensure proper evaluation and development of future treatments to refine the targeting of specific processes in order to improve effectiveness and response rate even further. Thus, collating findings regarding mechanisms of change in this review can help us determine what it is that works in these interventions and for whom.

Studies in this review challenged previous caution around mindfulness exacerbating symptoms and that it may be harmful for individuals with psychosis (Böge, Thomas & Jacobsen, 2021). However, adaptations were made in many studies towards shorter practices, with more instruction. Previous research has suggested that mindfulness exercises may be harmful for individuals with psychosis (Dyga & Stupak, 2015; Walsh & Roche, 2020) but studies included in this review reported no widespread adverse effects of mindfulness exercises on participants, suggesting that with suitable adaptation mindfulness is safe and beneficial for individuals with psychosis. Further research may be required to test the most effective adaptations.

### 4.2 Comparisons with previous literature

Third wave interventions for psychosis have been a popular subject for review and meta-analysis in recent years (Aust & Bradshaw, 2017; Cramer et al., 2016; DiGiacomo et al., 2016; Jansen et al., 2020; Khoury et al., 2013; Louise et al., 2018; Wakefield, Roebuck, & Boyden, 2018), which makes sense given the rapidly growing evidence base in this area (Schaeuffele et al., 2021) and the probable need for regular updates on the expanding literature available. However, each of these reviews has evaluated both individual and group interventions and has focussed on mindfulness and acceptance approaches. Although they all carried out meta-analyses, the authors identify the vast range of measures used across included studies, as has been the

case in this current review (see Table 3). This means that meaningful comparison between studies may be difficult. This supports the rationale for conducting a narrative review, to allow for a detailed exploration of actual group intervention components (e.g. frequency and duration, homework exercises, session content), as well as focussing on group interventions only. Community mental health teams (CMHTs) in the United Kingdom (UK) are currently undergoing significant transformation with a focus on increasing accessibility, meaning that delivering interventions efficiently and to a wider range of individuals will be important. It makes sense then to explore the effectiveness and mechanisms behind group interventions as this format facilitates quicker delivery of care in the community. However, given the small number of studies evaluating third wave group interventions for psychosis that have been carried out to date, it was deemed necessary to include non-randomised and single-arm studies in order to maximise the information that could be evaluated in this review.

### 4.3 Methodological considerations and limitations

The review included a wide range of study designs; RCTs, non-randomised trials, single-arm trials, and pilot and feasibility trials. This means the quality of studies varied greatly (see Table 2). According to the Downs and Black assessment scale (Downs & Black, 1998), the studies in this review have been rated as either "Fair" (11 studies scoring between 15 and 19) or "Good" (13 studies scoring between 20 and 25), with no studies scoring higher than 26, with a rating of excellent. This may be a consequence of research into the area of third wave being a more recent development. Nevertheless, it means findings are at risk of bias and must be interpreted with caution. The pilot and feasibility studies included are not powered sufficiently to determine effectiveness and only signify potential for clinical change. A

number of the studies have a small sample size, which limits their generalisability to other populations.

Previous reviews have stated that interventions all vary significantly, but this is likely because they included both individual and group interventions. Interventions included in this review had a number of similarities. They all relied on structured protocols, most highlighted the importance of group discussion, less reliance on didactic delivery, and involved skills development and between-session homework. All interventions included mindfulness exercises and included elements of psychoeducation. Given the positive results across the included studies and the commonalities between interventions, findings suggest that these components may act as the active ingredients in the interventions that target the processes being measured (e.g. acceptance, compassion, emotion regulation). However, despite many overlapping features of the content of interventions, some of the more practical details varied greatly between trials. For example, session length, frequency and duration of the interventions differed significantly, with interventions being as brief as 4 sessions and as long-term as 12 months. Future research should investigate intervention specifications further to determine the most effective, cost-effective and feasible format in order to maximise the benefits of third wave group interventions.

However, many of the studies had no active control comparator. As mentioned previously, six studies had no comparator at all, but seven studies only compared interventions with either TAU or waitlist control groups. This means that it is difficult to determine whether the third wave element of the intervention is the reason for the improvement in symptoms and functioning, or whether it is as a result of receiving group treatment regardless of content. In contrast, only five studies compared

interventions with an active control either as well as TAU or instead of TAU or waitlist control (Chien et al., 2017; Chien et al., 2019; Chien & Thompson, 2014; López-Navarro et al., 2015; Wang et al., 2016). Each of these studies has large sample sizes and found differences between the third wave intervention and the active control, meaning findings can be interpreted with more confidence.

The differences between outcome measures means it is difficult to compare findings from studies. Even though themes emerged across the interventions, such as interventions having little to no impact on positive symptoms, alongside the potential for clinical change in negative symptoms and improvement in functioning, these were all measured differently between studies. It also means that any results that were not consistent may be explained by the use of different measures, though this cannot be determined for certain. Future research should aim to establish consistent and routine measures which can be used to capture outcome data in order to be more easily able to compare between studies.

## 4.4 Conclusions

Third wave group interventions for psychosis have the potential to provide effective care across a range of settings. Findings from this review are consistent with previous reviews of aspects of the literature, with results suggesting that third wave group interventions have the potential to improve individuals' experience of living with psychosis, either through negative symptom reduction, improvements in anxiety or depression, increase in functioning or improved insight. The impact on negative symptoms and general psychopathology may indicate usefulness as an adjunctive offer to standard CBTp, which tends to specifically target positive symptoms of delusions and hallucinations.

Studies have identified change in target processes such as experiential avoidance, compassion, emotion regulation and mindfulness and this gives important information for developing interventions and evaluations in the future. Third wave interventions are designed to help patients manage symptoms, not to alleviate symptoms. Thus, future research should aim to administer measures that reflect this shift in determining whether an intervention is effective or not. Whilst it may be of clinical and academic interest to understand the impact of third wave interventions on presence and severity of symptoms, this should not be the determining factor for effectiveness of the intervention.

Although initial results are promising, in order to build on the progress made to date, more full-scale randomised controlled trials are needed to establish a more robust evidence base. Previous reviews have found that studies investigating third wave interventions often implement less rigorous evaluation methods (Öst, 2008), emphasizing the importance for future studies to address the limitations outlined in this and other previous reviews. Despite these recommendations having been made in multiple reviews over the past 10 years, there has yet to be the increase one might expect in large scale RCTs necessary to establish the required empirical support. This should be a priority in future third wave intervention evaluation.

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## Appendix

*Checklist for measuring study quality*

*Reporting*

1. *Is the hypothesis/aim/objective of the study clearly described?*

| | |
|---|---|
| yes | 1 |
| no | 0 |

2. *Are the main outcomes to be measured clearly described in the Introduction or Methods section?*
   If the main outcomes are first mentioned in the Results section, the question should be answered no.

| | |
|---|---|
| yes | 1 |
| no | 0 |

3. *Are the characteristics of the patients included in the study clearly described ?*
   In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.

| | |
|---|---|
| yes | 1 |
| no | 0 |

4. *Are the interventions of interest clearly described?*
   Treatments and placebo (where relevant) that are to be compared should be clearly described.

| | |
|---|---|
| yes | 1 |
| no | 0 |

5. *Are the distributions of principal confounders in each group of subjects to be compared clearly described?*
   A list of principal confounders is provided.

| | |
|---|---|
| yes | 2 |
| partially | 1 |
| no | 0 |

6. *Are the main findings of the study clearly described?*
   Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).

| | |
|---|---|
| yes | 1 |
| no | 0 |

7. *Does the study provide estimates of the random variability in the data for the main outcomes?*
   In non normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

| | |
|---|---|
| yes | 1 |
| no | 0 |

8. *Have all important adverse events that may be a consequence of the intervention been reported?*
   This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

| | |
|---|---|
| yes | 1 |
| no | 0 |

9. *Have the characteristics of patients lost to follow-up been described?*
   This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.

| | |
|---|---|
| yes | 1 |
| no | 0 |

10. *Have actual probability values been reported(e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?*

| | |
|---|---|
| yes | 1 |
| no | 0 |

*External validity*

All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?*
    The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant

population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

12. *Were those subjects who were prepared to participate representative of the entire population from which they were recruited?*
The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

13. *Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?*
For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

*Internal validity - bias*

14. *Was an attempt made to blind study subjects to the intervention they have received ?*
For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

15. *Was an attempt made to blind those measuring the main outcomes of the intervention?*

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

16. *If any of the results of the study were based on "data dredging", was this made clear?*
Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

17. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls ?*
Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

18. *Were the statistical tests used to assess the main outcomes appropriate?*
The statistical techniques used must be appropriate to the data. For example non-parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

19. *Was compliance with the intervention/s reliable?*
Where there was non compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

20. *Were the main outcome measures used accurate (valid and reliable)?*

For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

*Internal validity - confounding (selection bias)*

21. *Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?*
For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

22. *Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?*
For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

23. *Were study subjects randomised to intervention groups?*
Studies which state that subjects wererandomised should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no because it is predictable.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

24. *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?*
All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

25. *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?*
This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

26. *Were losses of patients to follow-up taken into account?*
If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.

| | |
|---|---|
| yes | 1 |
| no | 0 |
| unable to determine | 0 |

*Power*

27. *Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?*
Sample sizes have been calculated to detect a difference of x% and y%.

| | Size of *smallest* intervention group | |
|---|---|---|
| A | $<n_1$ | 0 |
| B | $n_1$–$n_2$ | 1 |
| C | $n_3$–$n_4$ | 2 |
| D | $n_5$–$n_6$ | 3 |
| E | $n_7$–$n_8$ | 4 |
| F | $n_8$+ | 5 |

# Chapter 2

**A third wave group intervention for severe mental illness:**

Evaluating the feasibility of delivery by Protocol-Based Intervention Facilitators

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Supervised by

Dr Suzanne Jolley and Dr Emma O'Donoghue

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# COVID-19 Impact Statement

The national lockdown in response to COVID-19 began on 23 March 2020, after the study had been designed and all study documentation had been produced and approved by the KCL Research & Development department. The lockdown brought about changes to delivery methods of community mental health services. For instance, face-to-face services were to be delivered virtually. This had a substantial impact on the empirical research project in this thesis, which evaluated a group intervention in a community mental health setting.

Changes to the study protocol and all study-related documentation had to be made at short notice before being submitted to the Research Ethics Committee. Despite an attempt to make necessary amendments, the Research Ethics Committee granted an unfavourable opinion stating that the application dossier would need to be substantially reviewed and revised to clarify changes made as a result of the COVID-19 pandemic.

This resulted in significant disruption to recruitment as all study documentation had to be re-written including the IRAS form, the study protocol and all patient facing documents. Ethical approval could not be granted until September 2020 and by this time, there were new lockdown-related R&D procedures in place that had to be followed before commencing recruitment. As a result, recruitment did not start until November 2020 and completion of the project was under considerable time-pressure.

In addition to significant delays, the national lockdown also impacted the way in which the study could run. Liaising with the clinical team regarding recruitment had to be done via email, as visits to study sites were restricted. All communication with study participants was via telephone or email, which on occasion made it difficult for them to be contacted in a timely manner. The original protocol had intended for sessional outcome measures to be administered to both patient participants and staff participants. However, due to the increased demands on the clinical team in adapting to new ways of virtual working, the research team were asked by the clinical service not to further burden facilitators by requesting additional completions of measures. Instead, the study could only carry out assessments at baseline, 6 weeks and 10 weeks.

Adaptations made as a result of the COVID-19 pandemic are discussed throughout.

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## Abstract

**Background:** There is a growing evidence base for third wave group interventions in a variety of settings. These interventions adhere to evidence-based models, targeting specific psychological processes, and can be protocolised. They therefore lend themselves to delivery by the wider workforce after brief training. Such an approach has been recommended to increase access to psychological therapies, in line with health service guidance, and changes in which community mental health teams are undergoing significant transformation. We set out to evaluate a novel method of delivery (by junior frontline staff) of a combined third wave intervention.

**Methods:** A randomised controlled feasibility trial was used to evaluate the feasibility, acceptability and potential efficacy of a novel method of delivery of a third wave group intervention. Thirty adult patients with severe mental illness were randomised to receive the group intervention alongside their routine care (n=15) or waitlist control alongside routine care (n=15). Twelve junior frontline staff in the service were recruited as Protocol-Based Intervention Facilitators (P-BIFs). P-BIFs were trained to deliver the intervention prior to taking part in the study and had to have delivered a minimum of two group interventions prior to the study in order to be eligible for participation. Patient participants randomised to the treatment arm attended a six-week group intervention that combined components of acceptance and commitment therapy (ACT), Compassion Focussed Therapy (CFT) and Dialectical Behavioural Therapy (DBT) and was delivered by 3 P-BIFs. Participants completed outcome measures at baseline, at 6 weeks (post-intervention) and at 10 weeks (one month follow-up).

**Results:** Findings demonstrated that the intervention had 83% uptake, with 67% of participants attending 3 or more sessions. The study had a retention rate of 93% between baseline and 6 weeks and 83% after 10 weeks. P-BIFs were able to deliver the intervention competently as self-rated using the ACT Self-Competency Scale and received weekly supervision with a senior clinical psychologist in the service. Outcomes ranged from large improvements to small deteriorations for the treatment group, and small improvements to large deteriorations for the control group, and overall suggest some promise, although improvement reaching reliable and

significant levels was rare. The direction of outcome measures point to the potential for clinical change.

**Conclusions:** It is feasible for junior frontline staff to facilitate a third wave group intervention in a community mental health service for individuals with severe mental illness. Findings support the need for a larger pilot study to estimate the effects in order to power a full scale randomised controlled evaluation.

# 1. Introduction

## 1.1 Background

### *1.1.1 Complex needs in the community*

Severe mental illnesses are characterized by the extent of disability and the occurrence of unusual behaviour. Formal diagnoses include psychosis, bipolar disorder, complex/difficult to treat/severe mood problems, and personality disorders (Dieterich et al., 2017). The complexities of severe mental illness can cause chronic significant distress for the individual and their network (Corrigan, Druss, & Perlick, 2014; Yesufu-Udechuku et al., 2015). Community Mental Health Teams (CMHTs) provide care for those with complex mental health needs or severe and enduring mental illness that cannot be managed in primary care (Burns, 2007). Regardless of formal diagnosis, a considerable body of research reports that psychosocial factors are key to the aetiology and intervention of any complex mental health problem typically seen in CMHTs (Kerr, Dent-Brown, & Parry, 2007). Many individuals will have most likely experienced childhood adversity (Nelson et al., 2020) and trauma (Classen & Clark, 2017), which can lead to a range of shared difficulties such as issues with social functioning (Collip et al., 2011; Liebke et al., 2017), emotion dysregulation (Cloitre et al., 2019; Martino et al., 2020), and shame (Buchman-Wildbaum et al., 2021; Hasson-Ohayon et al., 2012).

In addition to adverse experience, research also supports the high prevalence of comorbidities in individuals with severe mental illness (Buckley et al., 2008). A review by Pokos and Castle (2006) found prevalence rates of anxiety to be between 30% and 85% in psychosis spectrum disorders and that symptoms of anxiety often preceded onset of psychosis. They also found that the presence of specific anxiety disorders in psychosis, such as panic or obsessive-compulsive disorder (OCD), were associated

with higher service use and poorer psychosocial functioning (Pokos & Castle, 2006). A more recent review found that symptoms of anxiety and depression occur at a similar rate in first-episode psychosis (Wilson, Yung, & Morrison, 2020). Comorbidity of Emotionally Unstable Personality Disorder (EUPD; also known as borderline personality disorder) in individuals with a diagnosis of bipolar disorder is reported to be common, with up to 1 in every 5 bipolar patients also having a diagnosis of EUPD (Fornaro et al., 2016). This is said to result in a more difficult treatment experience, for example longer periods of illness or earlier age of onset of difficulties, increasing the developmental impact of the condition (e.g. on education, peer relationships, and individuation; (Latalova et al., 2013).

The significance of trauma, particularly in childhood, is starting to be acknowledged in the literature on severe mental illness, with prevalence rates of depression, bipolar disorder and psychosis being higher for those who have experienced childhood trauma than the general population (Xie et al., 2018). For example, research has indicated that trauma may play a causal role in the incidence and phenomenology of psychosis (Okkels et al., 2017) and a recent systematic review has shown that trauma-focussed interventions demonstrate promising effects for positive symptoms of psychosis (Brand et al., 2018). Farias et al. (2019) found that rates of childhood trauma were high in a bipolar population and that this was associated with worse outcomes than those with bipolar disorder and no history of childhood trauma.

Individuals with severe mental illness are known to have 10-25 years shorter life expectancy than the general population (John et al., 2018), poorer physical health (Bahorik et al., 2017), limited social networks (Palumbo et al., 2015) and decreased overall quality of life (Degnan et al., 2021).

### *1.1.2 Economic impact of severe mental illness*

Severe mental illness is associated with high costs to public services, including healthcare, social work and criminal justice. A report by the LSE estimated costs of psychosis and bipolar combined to amount to £3.9bn for services, with the average annual per patient cost totalling £10,605 for psychosis and £1,424 for bipolar disorder (Knapp, McDaid, & Parsonage, 2011). Treatment resistant depression is also associated with increased per patient medical costs due to more frequent mental health service use (Olchanski et al., 2013).

Similarly, personality disorders are also known to place a substantial economic impact on the healthcare system. It is a well-documented perception that people with personality disorders are more frequent users of healthcare services (Sansone, Farukhi, & Wiederman, 2011), particularly in the context of inpatient admissions (Comtois & Carmel, 2016). Many believe this to be associated with increased economic societal impact (Soeteman et al., 2008). However, Rendu et al. (2002) found that a diagnosis of personality disorder was only associated with increased higher total costs in the presence of other common mental health disorders and that personality disorder alone was not associated with higher healthcare or non-healthcare costs. More recently, Meuldijk et al. (2017) conducted a systematic review of available literature and concluded that effective treatment of individuals with borderline personality disorder led to significantly reduced costs for healthcare services.

Despite research highlighting the clear evidence of increased costs from untreated mental illness, and the existence of cost-effective treatments, it only accounts for 13% of NHS health spending (Layard et al., 2012). Implementation of cost-effective treatments remains low (Colling et al., 2017; Stefanova, Taylor, & Jacobsen, 2021)

despite the number of patients using community mental health services increasing (Oram et al., 2019).

### *1.1.3 Community mental health support*

Mental health conditions can have a significant impact on all areas of life, including work, relationships with friends and family and the ability to participate in the community (World Health Organization, 2019). Mental health support in the community has been an established component of healthcare for nearly 50 years (Department of Health & Social Security, 1975). It has shifted the focus from psychiatric inpatient care towards enabling a meaningful recovery for those with chronic mental health needs (Turner et al., 2015). The growth of community-based care for those with mental illness arose out of the decline of asylums and the reform of mental health services (Thornicroft et al., 1999). Since this time, multi-disciplinary community mental health teams (CMHTs) have been the focus of developing mental healthcare away from inpatient settings and tailoring treatment to an individual's needs (Simmonds et al., 2001). However, Thornicroft and Tansella (2004) reported that a careful balance between community and inpatient care is required in order to meet the needs of all individuals with mental health disorders and that this should be implemented by way of a stepped care model.

Research has since explored the benefits of community-based care for mental health. The use of CMHTs has been associated with significantly lower rates of hospital admission (Malone et al., 2009) and decreased death rates from suicide (Pirkola et al., 2009). Long-term studies have found that community care can improve domestic and interpersonal skills (Leff & Trieman, 2000), in addition to overall quality of life and social functioning (McInerney et al., 2018).

In 2019, NHS England and NHS Improvement published the "Community mental health framework for adults and older adults", which highlighted a number of challenges that community mental health teams often face when providing patient care. The report identified CMHTs that triage referrals as a way of improving access to appropriate care had now increased waiting times, particularly for psychological therapies from secondary care providers. Often, those with complex mental health needs can be unwittingly excluded from services as they do not meet arbitrary service criteria. Insufficient support at first contact with services can result in significant deterioration and increased demand on inpatient or emergency services. This highlights the need for meaningfully increasing access and reducing waiting times (NHS England and NHS Improvement, 2019).

## 1.2 Psychological therapies in the community

### *1.2.1 Cognitive behavioural therapy (CBT)*

Pharmacological intervention is widely used in the treatment of severe mental illness but challenges remain around individuals taking the medication sporadically or not at all; or that the medication may only be effective for some symptoms of a disorder and not the disorder as a whole (Kingdon & Price, 2009). Although initially developed for the treatment of less severe mental disorders such as anxiety and depression, the expansion of cognitive behavioural therapy (CBT) as an adjunct to medication in the treatment of severe mental illness is an ever-growing focus of research, with a promising evidence base being established over the past 40 years (Thase, Kingdon, & Turkington, 2014).

CBT addresses maladaptive cognitions that contribute to the maintenance of distressing internal and external experiences by focussing on changing the way we

interpret and rationalise these experiences (Mansell, 2008). In the UK, the National Institute for Clinical Excellence recommend CBT for psychosis (National Collaborating Centre for Mental Health (UK), 2014). Hazell et al. (2016) conducted a systematic review and found small-medium effects of low-intensity CBTp for symptoms of psychosis. This was supported by a more recent review that evaluated whether the effectiveness of CBTp was maintained across time and found that there was an increase in effectiveness across time (Sitko et al., 2020). In addition, research has found that CBT is effective in reducing the rate of transition from at-risk mental state (ARMS) to first episode psychosis and that this could reduce overall prevalence of chronic, treatment-resistant psychosis spectrum disorders (van der Gaag, van den Berg, & Ising, 2019).

Studies into the effectiveness of CBT for bipolar disorder have found the potential for reducing depressive symptoms and increasing time between episodes of relapse (Salcedo et al., 2016). This has been supported by a meta-analysis that also found CBT to reduce the relapse rate, mania severity and improve psychosocial functioning in bipolar disorder, with further analysis indicating that effectiveness of CBT increase for interventions with sessions lasting a minimum of 90 minutes (Chiang et al., 2017). Research also suggests that CBT is effective in reducing suicidal behaviour, number of emergency department attendances and duration of inpatient admissions (Davidson et al., 2006a), as well as treating comorbid PTSD in an EUPD sample, with benefits of treatment lasting up to 12 months (Kredlow et al., 2017; Zeifman et al., 2021).

However, despite strong and well-established evidence for the effectiveness of CBT across a range of disorders, the disorder-specific nature of the CBT model creates a number of limitations, in particular, lengthy training in multiple models (Schaeuffele

et al., 2021). A number of studies have argued that CBT is no more effective than other psychosocial interventions (e.g. Baardseth et al., 2013) and that the effectiveness of CBT has been overestimated (Cuijpers et al., 2013). In addition, the disorder-specific nature of CBT does not address the high comorbidity of disorders among those with severe mental illness and are likely to be an indication of overlapping mechanisms that are shared by a number of different diagnoses (Lahey et al., 2017).

### *1.2.2 Third wave CBT interventions*

In an attempt to tackle the challenge CBT faces in addressing comorbidities, research into the development of third wave CBT approaches has started to emerge. Third wave CBT aims to build on the effectiveness of the traditional first and second wave by focussing on skills-based interventions that target underlying processes behind common mental health disorders (Carvalho et al., 2017) and change the way in which an individual relates to their symptoms (Vujanovic et al., 2017).

As previously discussed in the literature review, a number of different third wave approaches have arisen out of work with various clinical populations. Acceptance and Commitment Therapy (ACT) is an early third wave CBT approach created in the 1980s (Hayes, 2004). It is based on the principle that life inevitably involves pain and suffering and living a rich and meaningful life, involves turning towards pain instead of away from it and allow your actions to be guided by your core values (Harris, 2019). The treatment revolves around the concept of psychological flexibility, which involves staying in the present moment despite distressing internal experiences (Hayes et al., 2011). ACT interventions have become increasingly popular for treating severe mental illness in recent years (Grantham & Cowtan). Numerous studies have reported on the effectiveness of ACT for a range of mental health disorders including depression and

anxiety (Bai et al., 2020; Coto-Lesmes, Fernández-Rodríguez, & González-Fernández, 2020), psychosis (Yıldız, 2020), bipolar disorder (Pankowski et al., 2017), EUPD (Morton et al., 2012) and PTSD (Boals & Murrell, 2016).

Compassion Focussed Therapy (CFT) is another third wave approach that is gaining recognition for a range of mental health disorders more recently, including severe mental illness (Beaumont & Hollins Martin, 2015). CFT promotes emotional and mental wellbeing by developing skills in self-compassion, compassion for others and compassion from others as an essential aspect of the human experience (Gilbert, 2010). It does so through specific exercises designed to build strategies for self-soothing, kindness towards the self and others, and non-judgement (Gilbert & Irons, 2005). By its nature in addressing shame and self-stigma, it is designed to support those with complex mental health problems. Promising research has found CFT to be effective for psychosis (Braehler et al., 2013a), PTSD (Beaumont, Galpin, & Jenkins, 2012), eating disorders (Gale et al., 2014), and personality disorders (Lucre & Corten, 2013). However, a recent meta-analysis found that although CFT brings about improvements in psychopathology, this is not above and beyond other psychological interventions (Wilson et al., 2019). More research is needed to evaluate the benefits of CFT-based interventions for specific disorders.

Dialectical Behavioural Therapy (DBT) was originally created to treat predominantly women that experienced chronic suicidal ideation and self-harm, most of whom had a diagnosis of EUPD (Linehan, 1993b). DBT primarily works to improve interpersonal skills, emotion regulation and distress tolerance in order to alleviate an individual's need to harm themselves (Dimeff & Linehan, 2001). Not surprisingly, the strongest evidence base for DBT comes from interventions for personality disorders,

particularly EUPD (Choi-Kain et al., 2017). However, preliminary findings suggest that DBT may also be effective in treating psychosis (Moulden et al., 2020) and Afshari, Omidi, and Ahmadvand (2019) found that DBT can be an effective therapy for bipolar disorder in reducing depressive symptoms and improving emotion regulation.

Overall, the evidence for third wave approaches is growing rapidly and even though some are in their infancy, initial findings are promising (Carvalho et al., 2017). Although third wave interventions are process-focussed and work with the underlying mechanisms that are shared between many disorders, much of the emerging randomised controlled trials (RCTs) evaluate interventions tailored to discrete clinical diagnoses rather than treating targeted process transdiagnostically, which potentially offers economies of implementation by being broadly applicable (Schaeuffele et al., 2021).

### 1.3 Barriers to care in the community

Despite the previously discussed significant cost of untreated severe mental illness and the evidence to suggest we have interventions that are known to be effective, numbers of patients receiving psychological therapies, particularly for psychosis, remains low in many areas of the UK (Ince, Haddock, & Tai, 2016). Several reasons have been put forward to explain barriers to implementing recommended psychological therapies in the community. With regards to CBTp, a narrative review by Switzer and Harper (2019) identified challenges to implementation on three separate levels; organisational barriers, staff barriers and service user barriers. The primary service user barrier is reported to be fear of disclosure following a previous negative experience (Rathod et al., 2010), which perhaps highlights the need to refine the implementation of appropriate therapies. However, on a staff level, perceived

barriers included lack of confidence in knowledge or skills (e.g. Lewis et al., 2012) or beliefs around presenting symptoms being too severe for psychological therapy (Williams, 2008). The most significant organisation barrier reported was lack of appropriately trained staff (Jolley et al., 2015; Prytys et al., 2011; Schizophrenia Commission, 2012) followed by underfunding (We still need to talk report: A report on access to talking therapies, 2013). Similar barriers have been reported when evaluating the implementation of NICE guidelines for depression (Rhodes et al., 2010), personality disorders (Pigot et al., 2019) and PTSD (Finch et al., 2020). Barriers to implementing treatment for bipolar disorder included lack of knowledge about pharmacotherapy and difficulty managing dual diagnosis of substance use disorder (Stein et al., 2015).

Lack of appropriately trained staff and low levels of staff confidence in their abilities to deliver effective therapies has arisen as a barrier to implementation across a range of disorder-specific interventions. One possible solution is to design interventions to address a number of disorders at any one time to alleviate the necessity of learning and training in numerous protocols for each disorder.

### 1.4 Transdiagnostic interventions

Transdiagnostic interventions are approaches to understanding and treating the same fundamental principles across psychiatric diagnoses without tailoring the protocol to specific disorders (McEvoy, Nathan, & Norton, 2009). They identify and target core cognitive behavioural processes that are important across a range of disorders and allow for the development of a single intervention that can be applied across a range of presentations. This means one intervention can be provided to individuals with comorbid disorders or to groups with mixed diagnoses.

### *1.4.1 Transdiagnostic processes*

When discussing third wave interventions, underlying processes were explored within the context of specific disorders, but as previously mentioned, these processes can be shared across different diagnoses. One of the most common transdiagnostic processes is experiential avoidance (Harvey, Watkins, & Mansell, 2004), which is defined as the human instinct to move away from things we don't want and towards things we do want. Its purpose originates in our interactions with the external world, for example the "fight or flight" response. However, experiential avoidance becomes problematic when this rule is applied to our internal world so that we end up moving away from negative thoughts and emotions, resulting in short-term relief. Because meaningful engagement in life necessitates pain, this results in moving away from experiences that we value and what matters most to us in life (Hayes & Gifford, 1997). Experiential avoidance is a transdiagnostic process that is shared by many disorders and is implicated in the maintenance of complex mental health difficulties (Hayes-Skelton & Eustis, 2020). Research has found experiential avoidance to play an important role in psychosis (Goldstone, Farhall, & Ong, 2011), bipolar disorder (Wenze, Kats, & Gaudiano), personality disorders (Mohi et al., 2021) and trauma (Orcutt, Reffi, & Ellis, 2020).

Another process that spans a number of different disorders is emotion dysregulation (Faustino, 2021). Emotion regulation skills are a component of many different psychological therapies, but are perhaps most prominent in DBT (Linehan, 1993b), designed to address the difficulties of EUPD, which can be defined as the development of maladaptive coping strategies for difficult and distressing emotions (Neacsiu, Bohus, & Linehan, 2014a). It may also be characterised by the inability to control impulsive behaviours, work towards goals or adapt emotional responses to different

contexts or situations (Gratz & Roemer, 2004). Emotion regulation has been implicated as an important factor in a number of severe mental illnesses. As it is the primary component in DBT, the majority of research has focussed on its role in personality disorders (Chapman, 2019). However, research has found emotion dysregulation to be an important mechanism in other severe mental illnesses such as psychosis (Wallace & Docherty, 2020), bipolar disorder (M'Bailara et al., 2009) and complex PTSD (Laddis, 2011).

Shame, stigma and self-stigma are prevalent throughout all mental health disorders (Sirey et al., 2001), particularly in severe mental illness (Ritsher & Phelan, 2004). Shame can be defined as distress arising from insight into perceived flaws, inadequacy or incompetency in one's character that frequently results in social withdrawal or safety behaviours to distract others from these perceived flaws (Lewis, 1971). This results in the maintenance of the factors that initiated feelings of shame. Gilbert (1998) argues that shame can be divided into both internal focus on self-evaluation and external fear of judgement from others. Research has identified shame as an important mechanism of change in psychopathology (Cândea & Szentagotai, 2013). A systematic review found shame to play a significant role regarding psychotic experiences in both clinical and non-clinical populations (Carden et al., 2020). A meta-analysis by Buchman-Wildbaum et al. (2021) found that individuals with a diagnosis of EUPD experienced higher levels of shame than healthy controls. They also found that levels of shame were associated with severity of PTSD symptoms in those with EUPD (Buchman-Wildbaum et al., 2021).

Other transdiagnostic processes have been a focus of research in their own right, including intolerance of uncertainty (White & Gumley, 2010), rumination (Yalvaç &

Gaynor, 2021) and meta-cognitive beliefs (Newby, Williams, & Andrews, 2014). This gain in momentum to investigate transdiagnostic processes highlights the potential shift of focus away from condition-specificity in the development of new therapeutic approaches.

### *1.4.2 Benefits and challenges of transdiagnostic approaches*

Transdiagnostic treatments address many of the existing barriers to accessing psychological therapies in the community discussed in section 1.3. The nature of transdiagnostic interventions means that there is reduced need for expensive and lengthy disorder-specific training. Transdiagnostic treatment would facilitate the treatment of a diverse group of patients with the use of one treatment manual, thus increasing access and improving cost-effectiveness. This makes it well suited for the population served by local community mental health teams who often see individuals with a broad range of different diagnoses and presenting problems (Murray, Metz, & Callaway, 2019). The transdiagnostic interventions discussed, being underpinned by mechanistic models highlighting key processes to target in therapy, also lend themselves to being protocolised and modularised, allowing choice of specific modules to adopt or exclude at any one time (Boustani et al., 2017). This also means that they can be adapted to be provided at any point of the therapeutic journey. For example, a transdiagnostic group could be offered before, alongside or after a course of individual CBT, which has the potential to enhance the effectiveness of individual CBT if used as a form of relapse-prevention (Clark, 2009). Another advantage of transdiagnostic approaches is that they are usually delivered in group format, which further improves cost-effectiveness, as not only can individuals potentially be seen more quickly, thus reducing waiting lists, but fewer members of staff are required to deliver therapy to greater number of people.

However, despite all the potential advantages of implementing transdiagnostic interventions in mental health settings, it does not come without challenges. If transdiagnostic interventions are to be delivered by frontline, potentially less clinically experienced staff, they could experience challenges in delivery of the intervention in the face of acute deterioration or difficult group dynamics. This relies on the provision of frequent and high quality supervision, which may not always be feasible. Given the concerns raised in the review by Switzer and Harper (2019) about training, confidence in competency and adequate supervision, there is a chance these problems may persist to some degree even if they are somewhat alleviated. However, protocolised interventions can play an important role in making the delivery of transdiagnostic interventions more accessible, as the protocol can outline the clear mechanisms and strategies needed for effective delivery, resulting in less need for clinical judgement.

### *1.4.3 Existing evidence for transdiagnostic group interventions*

Martin et al. (2018) argue that, even within transdiagnostic interventions, there is often a more narrow focus than the routine clinical practise they are intended to improve. Many transdiagnostic interventions focus on comorbid symptoms or processes within a specified population, for example targeting depressive symptoms in a variety of anxiety disorders (Talkovsky et al., 2017) or anxiety in a bipolar disorder sample (Perich, Mitchell, & Meade, 2020). True transdiagnostic interventions should address common underlying processes regardless of primary diagnosis. For example, Cuppage et al. (2018) evaluated a transdiagnostic CFT group, which included individuals with mood, personality, anxiety and eating disorders, in addition to individuals with psychosis or trauma-related disorders. They found that those who attended the group intervention showed significantly greater improvements in

psychopathology and self-compassion compared to the treatment-as-usual (TAU) group (Cuppage et al., 2018).

O'Brien et al. (2021) investigated a transdiagnostic group for veterans in a heterogeneous diagnostic sample. There was high level of comorbidity in the sample, with over 80% having more than one formal diagnosis and 24% having three of more formal diagnoses. Diagnoses included PTSD, depression, anxiety, EUPD, bipolar disorder and psychotic disorders. They found a decrease in symptoms of depression, anxiety and post-traumatic stress following the group.

Transdiagnostic group interventions are still a developing concept and the evidence-base is continuing to grow rapidly. More randomised controlled trials are needed to compare their efficacy with TAU or routine CBT interventions.

### 1.5 Rationale

The recent announcements regarding mental health team transformation (NHS England and NHS Improvement, 2019) highlight the expectation to increase delivery of psychological interventions for people with serious mental health conditions. Practice-based evidence in Early Intervention Psychosis services has illustrated the limitations of training expert therapists to deliver condition-specific interventions, with the best-performing services still only meeting targets of around 50% of those eligible for intervention (NHS-E, 2019, N-CAP, 2020). A paradigm shift has been mooted for some years now (Garety et al., 2018), attempting to deliver protocolised treatments. These target key processes demonstrated to play causal/maintaining roles, using effective therapy techniques, but are (usually) shorter in duration. Because of their protocolised nature, they can be delivered with less training than is

required to equip therapists to use clinical judgement to flexibly apply a range of individualised strategies. Third wave interventions lend themselves to being able to do this, as they are often designed in a modular format and can be manualised in a way that requires briefer training to implement and only requires one single protocol rather than several that are disorder-specific. In doing this, interventions can be designed in a straightforward manner that allows them to be delivered by junior frontline staff, thus increasing access and reducing costs. The transdiagnostic nature of protocol-based interventions means that patients with a variety of different diagnoses or comorbidities can benefit from attending and because of the focus on underlying mechanisms such as emotion regulation, those without formal diagnosis can also attend. Evidence is emerging to suggest that transdiagnostic groups in the community have the potential to be effective (Kristjánsdóttir et al., 2019; O'Brien et al., 2021; Roberge et al., 2020) and that frontline members of staff are able to competently facilitate third wave CBT-based disorder-specific interventions in the community (Jolley et al., 2020). This study aims to combine the progress made in these areas and evaluate the feasibility of training junior frontline staff to deliver a third wave transdiagnostic intervention in the community.

# 2. Method

## 2.1 Design

The current study used a pragmatic randomized controlled design to investigate the feasibility and acceptability of a protocol-based intervention as delivered by trained junior staff. Participants consisted of both staff delivering the intervention (Protocol-Based Intervention Facilitators, P-BIFs) and the service users to whom the intervention was delivered. Service user participants were randomized in a 1:1 ratio to either receive the group straight away or to receive the group after 10 weeks (waitlist control). Randomization was carried out using the secure online service, www.sealedenvelope.com. The intervention ran for 6 weeks from T1 to T6 and measures were completed at point of baseline (T0), after 6 weeks (T6) and after 10 weeks (one month follow-up; T10).

The study received ethical approval from the London-South East Research Ethics Committee (20/LO/1004) and received Health Research Authority (HRA) Approval to be conducted in the NHS.

## 2.2 P-BIF participants

For the purpose of this study, group facilitators are referred to as Protocol-Based Intervention Facilitators (P-BIFs), which was designated the operational term for junior staff from different areas of the service that are delivering the intervention. Junior members of the team were invited to take part if they had an undergraduate degree in psychology and/or experience of working in mental health services. They were all working in the host service, usually in either a voluntary position or on a placement as part of a qualification, and were familiar with the client group and similar group interventions that had been run in the service previously. All

participants had capacity to offer informed consent, as judged by their treating team. Participants were excluded if they could not commit in advance for the duration of the trial.

### 2.3 P-BIF training

P-BIFs attended a one day training workshop delivered by an experienced qualified clinical psychologist who currently works in the service. The workshop allowed the P-BIFs to familiarize themselves with the intervention manual, learn the structure of each session and ask questions. New P-BIFs then observed the intervention being delivered by two more experienced P-BIFs who have delivered the intervention a number of times, previously under supervision, whose delivery is considered competent.

Having observed delivery, P-BIFs then delivered a group themselves under the observation of the more experienced P-BIF. Following this, P-BIFs were considered trained, and ready to participate in the study. We recorded the number of potential P-BIFs in the service, the number agreeing to training, those completing training, and those agreeing to take part in the current study. The format for each group consisted of two newly trained and one more experienced P-BIF, with the more experienced P-BIF taking an observational role.

The same qualified psychologist that delivered the training also acted as the clinical supervisor of the P-BIFs. The P-BIFs attended a weekly supervision group. This provided them with the opportunity to discuss any issues that arose during delivery of the intervention and receive support and guidance from the clinical psychologist. The supervision group also provided the opportunity for peer supervision and was

experiential where exercises could be practised and the supervisor fed back on what went well and what needed improvement.

### 2.4 P-BIF competency and adherence

Following completion of the training, P-BIF participants were asked to complete the ACT Core Competency Self-Rating Form (Luoma, Hayes & Walser, 2007). This was to ensure facilitators felt confident in their ability to deliver the intervention according to the protocol. This also helped determine whether the training was sufficient for the P-BIFs to be able to deliver the intervention competently. The clinical supervisor also confirmed competence for each facilitator prior to taking part in the study. In order to monitor adherence to the group protocol, the clinical supervisor indirectly monitored adherence to the intervention protocol during weekly supervision sessions. The researcher attended six group sessions to determine the facilitators' ability to guide discussion effectively and follow the manual, exercises and homework tasks.

## 2.5 Service user participants

Participants were recruited from recovery services in the South London and Maudsley NHS Foundation Trust. The sample consisted of patients who clinicians felt would benefit from attending a third-wave group intervention being provided at the recovery service. Inclusion criteria included the following; the capacity to give informed consent, agree to communication with others involved in their care (e.g. care co-ordinators, general practitioners), as judged by their care team and sufficient English language ability to be able to complete assessment measures and participate in a group intervention without the support of an interpreter. Unfortunately, due to the nature of the intervention, it was not possible to provide simultaneous translation as having an interpreter or translator may have impacted the dynamic to allow

participation. Due to the COVID-19 pandemic, participants also required access to appropriate technology that would enable them to attend the group virtually. Exclusion criteria were as follows; known to have an organic disorder, unable to attend the group intervention for the duration of the trial virtually, unable to attend a group for 90 minutes, lacked capacity to consent or deemed otherwise inappropriate for the group by their clinical team. Participants were not excluded based on individual therapy they had received prior to the group intervention.

## 2.6 Measures

Baseline measures (Appendix G) were repeated after the intervention period (6 weeks) and at a 1 month follow-up (10 weeks).

### *2.6.1 Demographic information*

Medical records were screened by the researcher with participants' consent, to collect routine demographic information such as age, gender, ethnicity and diagnosis where available. Diagnoses were recorded according to the clinical team.

### *2.6.2 Acceptability and Feasibility*

Rates of recruitment, retention and adherence were used as a measure of feasibility. Pre-specified criteria required recruitment to reach the target sample of 15 participants per arm (30 participants in total), retention of 80% of participants by the 1 month follow-up and for at least 80% of participants to attend at least one session to be considered as having had a therapeutic dose of the intervention. Feasibility also required a recruitment rate of approximately 4 to 5 participants per month. With regards to P-BIF feasibility, the study required recruitment to the target sample of nine participants and for P-BIF participants to demonstrate adherence to the

therapeutic model, as self-rated by the P-BIFs on the ACT Core Competency Scale (Luoma, Hayes, & Walser, 2007).

### *2.6.3 P-BIF Competency and adherence*

Facilitator participants were asked to complete the ACT Core Competency Self-Rating Form (Luoma et al., 2007). The measure is divided into seven sub-categories; core competencies, developing acceptance, undermining cognitive fusion, getting in contact with the present moment, distinguishing the conceptualized self from self-as-context, defining valued directions and building patterns of committed action. Each item is scored on a scale of 1 (never true) to 7 (always true), with a maximum possible score of 210. The measure does not provide any threshold for which a therapist is deemed "competent". ACT-consistent therapists display all the behaviours. For the purposes of this study, a score of "never true" for more than one item in any sub-category was taken to indicate non-competent delivery.

### *2.6.4 Secondary Outcomes*

*The Clinical Outcomes In Routine Evaluation (CORE-10; Barkham et al., 2008)* is a brief outcome measure comprising 10 items drawn from the CORE-OM which is a 34-item assessment and outcome measure. The CORE-OM has been widely adopted in the evaluation of counselling and psychological therapies in the UK (Connell & Barkham, 2007). The 10 items measure anxiety, depression, trauma, physical problems, functioning and risk to self. The CORE-10 score ranges from 0 (low distress) to 40 (high distress). This was completed at T0, T6 and T10.

*Manchester Short Assessment Quality of Life (MANSA; Priebe, Huxley, Knight & Evans, 1999)* is a 12-item tool for measuring quality of life by exploring satisfaction

with life overall and with different domains of life. It is made up of three sections; consistent personal details, personal details that change over time and satisfaction with quality of life. Satisfaction is measured using a 7-point Likert scale from 1: could not be worse to 7: could not be better. Higher scores indicate greater satisfaction, with a minimum score of 12 and maximum score of 84. This was completed at T0, T6 and T10.

The intention was to also complete these measures after each group session but this was not possible due to limited resources as a result of the COVID-19 pandemic. The research team were asked by the clinical service not to further burden facilitators by requiring them to complete measures with participants virtually after each session. It is likely that this would be feasible in face-to-face delivery.

*Potential mechanisms of change* – Participants' relationship with their symptoms was assessed using three measures (completed at T0, T6 and T10).

- The Acceptance and Action Questionnaire (AAQ-II, Bond et al., 2011) is a 10-item questionnaire designed to measure psychological flexibility. Respondents rate the degree to which each statement applies to them from 1 (never true) to 7 (always true). Lower scores suggest greater acceptance of mental experiences and persistence with life goals in the face of these experiences. The maximum score is 70.
- The Self-Compassion Scale (SCS, Raes et al., 2011) is a 12-item questionnaire designed to measure compassion towards the self. Respondents rate the degree to which they behave in a manner described in the 12 items from 1 (almost never) to 5 (almost always). Lower scores indicate greater self-compassion. The total self-compassion score, the mean of each of the 12 items

is calculated, thus the maximum score is 5. Higher scores indicate greater self-compassion.

- The Difficulties with Emotional Regulation Scale – 16 (DERS-16; Bjureberg et al., 2016) is a brief version of the 36-item DERS that consists of 16 items that assess the following dimensions of emotion regulation difficulties: non-acceptance of negative emotions, inability to engage in goal-directed behaviours when distressed, difficulties controlling impulsive behaviours when distressed, limited access to effective emotion regulation strategies, and lack of emotional clarity. Scores can range from 16 to 80, with higher scores reflecting greater levels of emotion dysregulation.

Initially, the plan was to ask those who did not wish to be randomised for consent to include their anonymous routine clinical measures. This was with the intention of evaluating differences in characteristics and outcomes between agreeing to randomization and those receiving the intervention as part of their routine care. However, uptake for the study was high, with only two participants not consenting to be randomized but consenting to the use of their routine clinical measures, making meaningful analysis between the two samples impossible. Nevertheless, the apparent acceptability of participation in the study is an important feasibility outcome and will inform a larger scale RCT.

## 2.7 Group Intervention

The group intervention followed a standardized manual-based protocol consisting of 6, 2-hour sessions, delivered via video call using Microsoft Teams over 6 weeks by the PBIFs. The group content combined Acceptance & Commitment Therapy (ACT),

Compassion Focused Therapy (CFT) and Dialectical Behaviour Therapy (DBT) interventions.

**Table 1** Intervention Protocol Session Outline

| | |
|---|---|
| **Week 1** Introduction, ACT and Values | What is Acceptance and Commitment Therapy (ACT)? How can ACT help in response to distressing experiences? Identifying values. Identifying obstacles to moving towards values. Introducing Passengers on the bus metaphor. Mindfulness Exercise. Introducing committed actions. |
| **Week 2** DBT, Emotional Literacy and Difficult emotions | Review committed actions and obstacles to these. Mindfulness exercise. Noticing emotions and expanding ways to respond to them. Naming emotions as passengers. Distress tolerance exercises. Setting committed actions. |
| **Week 3** ACT and Willingness | Review committed actions and obstacles check-in. Mindfulness exercise. Introduce concept of Willingness. Acting out the passengers on the bus exercise. Setting committed actions. |
| **Week 4** CFT | Review committed actions and obstacles check-in. Mindfulness exercise. Introduce in three systems (CFT). Compassion for voices video. Compassion to others exercise. Setting committed actions. |
| **Week 5** Compassion to self and others | Review committed actions and obstacles check-in. Mindfulness exercise. Compassion to self and others exercise. Compassion to negative passengers. Setting committed actions. |
| **Week 6** Moving forward | Review committed actions and obstacles check-in. Mindfulness exercise. Moving forward. Troubleshooting diffusion from difficulties. Consolidating skills. Safe place exercise. Setting Committed actions. |

The nature of the manualized, protocol-based intervention means that it can be delivered in a variety of formats whilst retaining the structure and content of sessions. For the purposes of the study, the research team followed the operation of the clinical team within the service, who were offering a mixture of face to face, telephone and video call sessions, based on individual risk assessments for each service user. In the event, video call delivery was in accordance with service guidelines for all participating service users, and therefore the intervention was offered via Microsoft Teams only.

## 2.8 Procedure

Eligible participants were initially approached by a member of their clinical care team during their standard care. The care team provided the patient with a Patient

Information Sheet and acquired consent to pass their details on to the researcher, for those potentially interested in participating. The researcher contacted the potential participant via telephone to discuss the study in more detail and gain initial verbal consent before emailing participants a copy of the informed consent form for them to return.

### *2.8.1 Randomization Procedure*

Once service user participants gave informed consent, they were asked to complete the baseline assessment, either online or over the telephone with the researcher, depending on participant preference. They were then randomized by an independent randomisation service, sealedenvelope.com, which is a well-established secure online service provided for small sample randomization procedures (see Appendix H for allocations). Participants were randomized into either the group intervention arm or the waitlist control arm with a randomization ratio of 1:1. The aim was for randomisation to take place immediately after the baseline assessment in order to inform participants which arm they had been assigned to as soon as possible. This was to minimize drop-out and maximize group attendance. Patients that were randomised to the waitlist control arm received the group intervention after a minimum 10 weeks. There was no randomisation for P-BIF participants.

### *2.8.2 Service User Procedure*

If the participant had been randomized to the treatment arm, they would be contacted by their clinical team and arrangements would be made for them to attend the 6 week virtual group intervention using Microsoft Teams over an electronic device. They would attend 6 sessions, each 90 minutes long, and would have brief check-ins with one of the facilitators. Participants would be sent session packs with slides and

exercise sheets before each session. At the end of each session, participants would be asked to set committed actions that they would complete throughout the week. These actions would be reviewed at the start of the next session.

Group sessions followed a detailed protocol and were to be run by three P-BIFs, the most experienced of whom would act as the lead facilitator. Patients would be sent resources for each session via email before the session was due to start. If they were unable to attend one of the sessions, they would be offered a catch-up session with one of the facilitators before the next session. P-BIFs would have a 30 minute debrief after each session to discuss any issues that may have arisen during the session. If a participant did not attend, a member of the clinical team contacted them and they were sent reminders prior to the next session.

Service user participants needed to attend at least one group session in order to be considered as having received a therapeutic dose of the treatment. However, Did Not Attends (DNAs) were followed up by the P-BIFs in order to encourage attendance and maximize adherence to the intervention. Patients who missed a session were contacted by the clinical team and offered a booster session to catch up with missed intervention content.

After the final session, participants were asked to complete the measures again. The researcher would then contact the participants after one month to complete the final follow-up measures. For those randomized to the waitlist control arm, participants were asked to complete measures at baseline, after 6 weeks and after 10 weeks. They were then offered the group intervention once their participation was complete.

### *2.8.3 Protocol-Based Intervention Facilitator Procedure*

All P-BIFs were recruited from staff that were currently working in the service and were familiar with the service's operating procedures and a severe mental illness patient group. They thus had previous experience of working in mental health services and many were familiar with similar group interventions that had been run in the service previously.

P-BIFs attended a one day training workshop delivered by an experienced qualified clinical psychologist who currently works in the service. The workshop allowed the P-BIFs to familiarize themselves with the intervention protocol, learn the structure of each session and provided the opportunity to ask questions. Following the training, P-BIFs assisted the intervention being delivered by an experienced facilitator who had delivered the intervention a number of times and whose delivery was deemed competent by a senior member of the clinical team.

### *2.8.4 Sample Size*

The target sample size for patient participants was 12 per arm as this is sufficient to estimate parameters such as standard deviation for use in sample size calculations in a full-scale RCT (Julious, 2005). In order to account for a 20% drop-out rate, a sample size of 15 per arm was decided.

The target sample size for P-BIFs was 9 in total. This was decided on the basis of logistics of running a study of this size, as well as the number of facilitators that will be available in the service and the number required to run each group.

## 2.9 Data Analysis

All analysis was carried out using IBM SPSS Statistics Version 22.

### *2.9.1 Feasibility and acceptability*

Feasibility was assessed by pre-specified criteria details below;

a) Recruitment to the target sample of 15 participants per arm, with a total of 30 service user participants.
b) A minimum recruitment rate of approximately 4-5 per month.
c) A target retention rate between T0 and T6 of ≥80%.
d) ≥80% of participants should attend at least 1 session of the group intervention, meaning 1 session is the minimum therapy dose to be considered having received the intervention.
e) Recruitment to a target sample of nine P-BIFs.
f) P-BIFs must clinical competency and adherence to the therapeutic model, as self-rated following each session (ACT Core Competency Self-Rating Form; Luoma, Hayes & Walser, 2007).

### *2.9.2 Variability in treatment effects*

Pre-post effect sizes for all outcome measures were calculated with 95% Confidence Intervals from baseline to T6 and baseline to T10.

### *2.9.3 Reliable and clinically significant change*

Reliable and clinically significant change (Jacobsen & Truax, 1992) was calculated using the CORE-10 scores between T0 and T10. To achieve reliable improvement, scores must improve by 6.0 or more points from pre- to post-intervention (Connell & Barkham, 2007). To achieve clinically significant change, they must differ from a pre-

intervention score of 11 or above to a post-intervention score of 10 or below. To achieve reliable and clinically significant change both criteria must be met (Connell & Barkham, 2007).

# 3. Results

## 3.1 Demographic information

Demographic information can be seen in Table 2, along with information regarding clinical presentation, according to the treating team.

**Table 2** Demographics and clinical presentations

| | | |
|---|---|---|
| **Age (mean)** | 36.07 (11.641 SD) | 18-60 (range) |
| | | |
| **Sex** | | |
| Male | 10 (66.7%) | |
| Female | 20 (33.3%) | |
| | | |
| **Ethnicity** | | |
| White British | 12 | |
| Black British | 7 | |
| White - Other | 4 | |
| Mixed Race | 2 | |
| Black African | 1 | |
| British Chinese | 1 | |
| Unknown | 3 | |
| | | |
| **Diagnosis** | | |
| EUPD | 5 (16.67) | |
| Psychosis Spectrum | 5 (16.67) | |
| Bipolar Disorder | 5 (16.67) | |
| Complex affective disorders | 9 (30) | |
| Complex Trauma | 2 (6.67) | |
| Obsessive Compulsive Disorder | 2 (6.67) | |
| Antisocial Personality Disorder | 1 (3.33) | |
| Adjustment Disorder | 1 (3.33) | |
| | | |
| **No. of sessions** | **n (%)** | |
| 1 | 1 (6.7) | |
| 2 | 4 (26.7) | |
| 3 | 3 (20) | |
| 5 | 2 (13.3) | |
| 6 | 5 (33.3) | |
| Total | 15 (100) | |

## 3.2 Feasibility and acceptability

### *3.2.1 Recruitment to the target sample of 15 participants per arm, with a total of 30 service user participants*

Service user participants were recruited between November 2020 and March 2021. In this time, the service assessed 39 patients that were potentially suitable to attend the

group intervention. Of this total, 2 patients were deemed unsuitable for randomisation by the clinical team and 6 declined any participation in randomisation in principle as they wanted to receive the group intervention immediately. Two of these participants agreed to the use of their routine data only. Excluding the two that were not suitable for randomisation, this left a total of 36 eligible participants and 30 participants consenting to randomisation, resulting in an 83% uptake. One participant agreed to randomisation but had to withdraw interest prior to formal consent after not having the right technology available to attend the group virtually. One participant consented to being in the study but then withdrew consent for further use of their data on being randomised to waitlist, which they did not want.

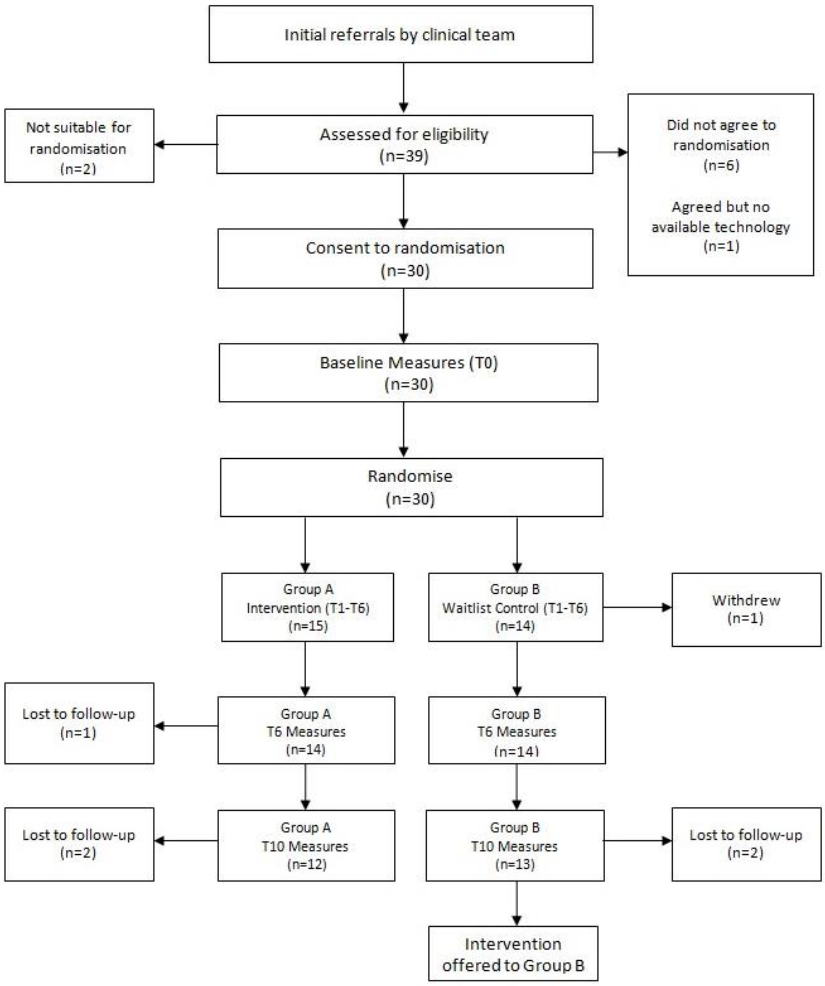


**Figure 2** CONSORT flowchart of participants through the study

### *3.2.2 A minimum recruitment rate of approximately 4-5 per month*

Recruitment rates/month varied greatly across the five months of the study. Reasons for this were diverse. In November, the clinical team were familiarizing themselves with the recruitment process, which meant that four patients were not offered the opportunity to take in the research at this time and instead attended the group immediately. There was also some understandable delay whilst the team worked out the practicalities of running the group virtually during the COVID-19 pandemic. Fluctuation in recruitment rates were also impacted by significant staff changes. However, once the service established consistency across the team, the recruitment rate increased significantly to reach a total of 12 participants in March 2021 (See Table 3). This means the feasibility criterion was partially met but that once the resources within the team had stabilized, the recruitment rate far exceeded the desired target that had been set prior to the COVID-19 pandemic. Thus, it is reasonable to suggest that with usual staffing, and without a major shift in service delivery, a recruitment rate target of 4-5 per month is feasible going forward.

Following randomisation of the first 4 participants, which proceeded according to protocol, variation in participant flow impacted on planned group start dates (as groups could not run with too few participants), and in order to avoid variability in the time elapsed from baseline assessment to group start, assessments were completed post-randomisation, deviating from protocol. This is an important feasibility indicator that has been reported in other group intervention trials, suggesting that for a future trial, mechanisms to address variability in participant flow, and the impact of this on intervention scheduling and delivery, will need to be specified in the protocol.

**Table 3** Rate of recruitment between November 2020 and March 2021

| Month | November | December | January | February | March |
|---|---|---|---|---|---|
| Recruitment Rate | 6 | 3 | 6 | 3 | 12 |

### *3.2.3 At least 80% of participants should attend at least 1 session of the group intervention*

The participants that were randomised to the intervention arm of the trial attended one of 6 groups that were facilitated between November 2020 and March 2021. The groups were attended by a combination of patients who had been randomised to waitlist and who were now receiving the intervention, those who had been randomised to receive the intervention straightaway, and those who had chosen not to take part in the research study, but nevertheless accepted the intervention. Of the 15 participants randomised to the intervention arm, all attended at least one session of the group therapy (100%). Attendance over the course of the intervention was mixed, with 1 of 15 participants (6.7%) attending for only one week before discontinuing. All participants who stopped attending the group had said that they would prefer individual therapy sessions instead of attending the remainder of the group. Where participants missed sessions, they were offered "catch-up" sessions during the week. As the group had to be delivered virtually, a number of participants had technical difficulties on occasion, which resulted in them missing a session. Despite these challenges, 5 participants (33.3%) were able to attend every week; with 10 participants (66.6%) attending 3 or more sessions (see Table 2).

### *3.2.4 A retention rate of at least 80% between T0 and T6*

The retention rate between baseline measures and after 6 weeks of either the intervention or waitlist was 93.3%, with only one participant from the waitlist arm withdrawing from the study and one participant from the treatment arm being lost to

follow-up between baseline and T6. The participant that was lost to follow-up completed the routine clinical measure (CORE-10) and this is reflected in the different sample sizes between Tables 6 and 7. After 4 weeks following the intervention period (T10), a further 3 participants were lost to follow-up (10%). One participant was unable to continue the group due to technical difficulties with their device and they became unreachable for the purposes of follow-up. One participant expressed an interest in receiving individual therapy instead of the group and disengaged from the intervention and one participant disengaged from the service entirely. However, both participants continued to take part in the research up until T6 and then became unreachable by T10. This left a remaining 25 of 30 participants who fully completed the study (83.3%).

### *3.2.5 Recruitment to a target sample of nine Protocol-Based Intervention Facilitators*

Junior psychological therapy staff in the service who met eligibility criteria and were due to facilitate a group that was running in the service routinely were approached to participate in the study. Job roles for facilitators can be seen in Table 4. All participants had facilitated at least one group prior to being approached for participation. During the same period of time where service users were recruited, 12 P-BIFs agreed to take part in the study. The P-BIF sample consisted of participants from a variety of job roles with four assistant psychologists, two first year trainee clinical psychologists and six trainee clinical associate practitioners (see Table 4). All are considered "pre-qualification". However, during this time, there was staff turnover and significant changes in roles within the team. This meant that there was a delay whilst new members of the team underwent the appropriate training and

facilitated a group prior to participating in the study, thus participant flow was variable.

Table 4 P-BIF Job Roles

| Job role | n |
|---|---|
| Assistant Psychologist | 4 |
| 1st Year Trainee Clinical Psychologist | 2 |
| Trainee Clinical Associate Practitioner | 6 |

### *3.2.6 P-BIFs adherence to the therapeutic model*

Facilitators had previously facilitated an average of between 3 and 4 similar third wave groups prior to taking part in this study (mean=3.67, SD=2.43) and all had facilitated this specific intervention at least once. In order for the intervention to be deemed feasible, all facilitators must have demonstrated competency and adherence to the therapeutic model by self-rating their competency in delivering the intervention using the ACT Core Competency Self-Rating Form (Luoma, Hayes & Walser, 2007). The intention was for the facilitators to complete this measure after each session. However, due to the COVID-19 pandemic and the increased strain on the team to engage clients remotely, this proved unfeasible. All participants completed the measure prior to facilitating their first group as part of the study. The research team were asked by the clinical service not to further burden facilitators by requesting additional completions.

The highest rated of the 7 domains of the ACT competency rating was "getting in contact with the present moment", with P-BIFs scoring themselves a mean average of 91.67% (SD=8.52) competent in this area of the ACT model. The lowest rated domain was "undermining cognitive fusion", where the mean average competency rating was 63.3% (SD=19.75). However, this was the only domain of the competency scale

averaging under 75%, with all remaining 6 domains scoring a mean average of 79% or higher. P-BIFs scored an average of 171.83 (SD=20.604) out of a possible 210 (81.83%).No P-BIF self-ratings met the non-adherence criterion.

During weekly clinical supervision, no issues were flagged by the lead clinical supervisor to suggest facilitators were not meeting clinical competence in delivery of the intervention or were not adhering to the group intervention protocol.

### 3.3 Clinical outcomes

Reliable and clinically significant change was calculated based on the CORE-10 criteria set by Connell & Barkham (2007). Table 5 reports the number of cases for which reliable and clinically significant change was achieved. From the 15 participants that attended the group intervention, 2 cases showed reliable and clinically significant improvement after 6 weeks. However, 3 participants who were on the waitlist for the intervention also showed reliable and clinically significant improvement. After the one month follow-up, the same 2 participants from the treatment arm maintained reliable and clinically significant improvement, compared with no participants from the waitlist. There were no participants that showed reliable and clinically significant improvements between 6 weeks and 10 weeks from either arm of the study. However, there were 4 cases of reliable and clinically significant deterioration between 6 weeks and 10 weeks (1 treatment participant, 3 waitlist participants).

For the waitlist group, the mean change in CORE-10 scores from 6-weeks post-treatment to baseline was -1.86 (SD 7.88; 95% CI -5.98 to 2.26). The 95% CI for the SD generated for the 6-weeks post-treatment to baseline change score was 5.71 to 12.69. The mean change score from 6 weeks to baseline in the waitlist group is in a positive

direction, exhibiting a small effect size (T6 *d*= -0.195, 95% CI -0.938 to 0.547, see Table 6). This was maintained at one month follow (T10 *d*=-0.162; 95% CI -0.93 to 0.61).

**Table 5** Summary of reliable and clinically significant change on CORE-10 (Connell & Barkham, 2007)

| | T6 | | T10 | |
|---|---|---|---|---|
| | Treatment n = 15 (%) | Waitlist n = 14 (%) | Treatment n = 12 (%) | Waitlist n = 13 (%) |
| Reliable Improvement | 5 (33.3) | 3 (21.42) | 4 (33.3) | 1 (7.69) |
| Reliable Deterioration | 1 (6.6) | 2 (14.28) | 1 (8.3) | 1 (7.69) |
| Clinically significant improvement | 2 (13.4) | 4 (28.57) | 2 (16.7) | 2 (15.38) |
| Clinically significant deterioration | 0 | 0 | 1 (8.3) | 0 |
| Reliable and clinically significant improvement | 2 (13.4) | 3 (10%) | 2 (16.7) | 0 |

- Reliable change - Scores must differ by 6 or more points from pre- to post- intervention
- Clinically significant improvement: Scores must differ from a pre-intervention score of 11 or above to a post-intervention score of 10 or below
- Clinically significant deterioration: Scores must deteriorate from a pre-intervention score of 10 or below to a post-intervention score of 11 or above

A total of 28 participants completed the MANSA at 6-weeks post-treatment (14 in the intervention group and 14 in the waitlist group). For those that attended the group, the mean change in MANSA scores from 6-weeks post-treatment to baseline was 2.93 (SD 7.12; 95% CI -0.8 to 6.66), indicating an improvement on average. The 95% CI for the SD generated for the 6-weeks post-treatment to baseline change score was 5.16 to 11.47. MANSA scores from baseline to T6 exhibited a small effect size (T6 *d*=.241, 95% CI -0.478 to 0.96). This increased to a medium size at one month follow-up (T10 *d*=0.418; 95% CI -0.35 to 1.19).

For the waitlist group, the mean change in MANSA scores from 6-weeks post-treatment to baseline was 2.857 (SD 10.64; 95% CI -2.72 to 8.43). The 95% CI for the SD generated for the 6-weeks post-treatment to baseline change score was 7.71 to 17.14. This mean change was in a positive direction, with scores from baseline to T6 showing

a small effect size (T6 *d*=0.206, 95% CI -0.537 to 0.949, see Table 6). This was maintained at one month follow-up (T10 *d*=0.234; 95% CI -0.524 to 0.991).

Whilst a trend suggesting improvement across secondary outcome measures in the treatment group is promising, results should be interpreted with caution as the study is not powered to detect differences and by looking at direction of outcome measures, findings only point to potential for clinical change.

### 3.4 Change in processes

Table 7 displays means and standard deviations for each of the measures of psychological flexibility, self-compassion and emotion regulation (AAQ-II, SCS, DERS-16) before treatment, after 6 weeks and after a one-month follow-up.

A total of 28 participants completed the AAQ-II, SCS and DERS at 6-weeks post-treatment (14 in the intervention group and 14 in the waitlist group). For the experimental group, the mean change in AAQ-II scores from 6-weeks post-treatment to baseline was -3.79 (SD 7.58; 95% CI -7.76 to 0.18), suggesting an increase in psychological flexibility on average. The 95% CI for the SD generated for the 6-weeks post-treatment to baseline change score was 5.5 to 12.2. Scores from baseline to 6 weeks exhibited a small effect size (T6 *d*=0.374; 95% CI -1.121 to 0.324), which increased to a large effect size at one month follow-up (T10 *d*=-0.85; 95% CI -1.655 to -0.45).

For the waitlist group, the mean change in AAQ-II scores from 6-weeks post-treatment to baseline was -3 (SD 9.098; 95% CI -7.77 to 1.77), suggesting an increase in psychological flexibility. The 95% CI for the SD generated for the 6-weeks post-treatment to baseline change score was 6.59 to 14.66. Scores from baseline to 6-

weeks exhibited small effect size (T6 *d*=-0.23; 95% CI -0.973 to 0.513), which was maintained at one month follow-up (T10 *d*=-0.25; 95% CI -1.008 to 0.508).

The mean change in experimental group SCS scores from 6-weeks post-treatment to baseline was 1.29 (SD 6.53; 95% CI -2.13 to 4.71), suggesting an increase in self-compassion. The 95% CI for the SD generated for the 6-weeks post-treatment to baseline change score was 4.73 to 10.52. Scores from baseline to 6-weeks post intervention exhibited a small effect size (T6 *d*=0.112; 95% CI -0.629 to 0.853), which increased to a medium effect size at one month follow-up (T10 *d*=0.428; 95% CI -0.351 to 1.208).

For the waitlist group, the mean change in SCS scores from 6-weeks post-treatment to baseline was 3.14 (SD 9.64; 95% CI -1.91 to 8.19), suggesting an increase in self-compassion. The 95% CI for the SD generated for the 6-weeks post-treatment to baseline change score was 6.98 to 15.53. Score from baseline to 6-weeks exhibited a medium effect size (T6 *d*=0.363 95% CI-0.384 to 1.109), which increased to a large effect size at one month follow-up (T10 *d*=0.842; 95% CI 0.055 to 1.63).

The mean change in DERS-16 scores for the experimental group from 6-weeks post-treatment to baseline was -5 (SD 10.26; 95% CI -10.37 to 0.37) indicating lower levels of emotion dysregulation. The 95% CI for the SD generated for the 6-weeks post-treatment to baseline change score was 7.44 to 16.53. The scores from baseline to 6-weeks post-treatment exhibited a medium effect size (T6 *d*=-0.363, 95% CI -1.11 to 0.384), which increased at one month follow-up (T10 *d*=-0.526; 95% CI -1.31 to 0.258).

For the waitlist group, the mean change in DERS-16 scores from 6-weeks post-treatment to baseline was -.64 (SD 14.627; 95% CI -8.302 to 7.02). The 95% CI for the SD generated for the 6-weeks post-treatment to baseline change score was 10.6 to 23.56. Scores from baseline to 6-weeks exhibited an effect size of $d$=0.045 (95% CI -0.786 to 0.696), which increased to a medium effect size at one month follow-up (T10 $d$=-0.396; 95% CI -1.159 to 0.366).

**Table 6 Clinical Outcomes –** Mean (SD) scores at baseline, 6 weeks and 10 weeks and effect size

| | T0 | | T6 | | T0-T6 *d* (95% CI) | | T10 | | T0-T10 *d* (95% CI) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | T (n=15) | W (n=14) | T (n=15) | W (n=14) | T | W | T (n=12) | W (n=13) | T | W |
| CORE-10 | 20.6 (7.42) | 21.43 (7.89) | 16.53 (8.03) | 19.57 (10.90) | -0.526 (-1.25 to 0.2) | -0.195 (-0.938 to 0.547) | 17.33 (7.64) | 20.08 (8.85) | -0.434 (-1.203 to 0.33) | -0.162 (-0.934 to 0.611) |
| MANSA | 46.57 (11.78) | 40.36 (12.84) | 49.50 (12.55) | 43.21 (14.77) | 0.241 (-0.478 to 0.959) | 0.206 (-0.537 to 0.949) | 51.92 (14.02) | 43.46 (13.73) | 0.418 (-0.35 to 1.185) | 0.234 (-.524 to 0.991) |

T = Treatment arm, W = Waitlist arm
*d = Cohen's d*

**Table 7 Change processes –** Mean (SD) scores at baseline, 6 weeks and 10 weeks and effect size

| | T0 | | T6 | | T0-T6 *d* (95% CI) | | T10 | | T0-T10 *d* (95% CI) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | T (n=14) | W (n=14) | T (n=14) | W (n=14) | T | W | T (n=12) | W (n=13) | T | W |
| AAQ-II | 51.64 (8.46) | 51.43 (12.51) | 47.86 (11.54) | 48.43 (13.55) | 0.374 (-1.121 to 0.324) | -0.23 (-0.973 to 0.513) | 43.25 (11.32) | 48.31 (12.43) | -0.85 (-1.655 to -0.45) | -0.25 (-1.008 to 0.508) |
| SCS | 2.38 (.82) | 1.98 (.61) | 2.48 (.96) | 2.24 (.81) | 0.112 (-0.629 to 0.853) | 0.363 (-0.384 to 1.109) | 2.7 (.65) | 2.567 (.78) | 0.428 (-0.351 to 1.208) | 0.842 (0.055 to 1.63) |
| DERS-16 | 59.93 (13.06) | 60.86 (14.01) | 54.93 (14.44) | 60.21 (15.11) | -0.363 (-1.11 to 0.384) | 0.045 (-0.786 to 0.696) | 52.67 (14.64) | 55.23 (14.42) | -0.526 (-1.31 to 0.258) | -0.396 (-1.159 to 0.366) |

T = Treatment arm, W = Waitlist arm
*d = Cohen's d*

# 4. Discussion

The primary aims of this study were to ascertain preliminary estimates of the feasibility, acceptability and potential for efficacy of P-BIFs delivering a six week third wave group intervention to individuals under the care of a community mental health team and the feasibility and acceptability of the randomisation process in this setting with the possibility of a large scale RCT in the future.

## 4.1 Key findings

This study hypothesised that delivery by P-BIFs of the group intervention would be feasible in a community mental health setting. Findings support this hypothesis. Pre-defined criteria were specified before commencing the project. These criteria were targeted towards each stage of the study from recruitment through to retention at follow-up and included facilitator competency to deliver the intervention and adhere to the protocol.

The study was able to recruit the target number of participants over a period of five months. Throughout the trial, the lead researcher maintained close contact with the clinical team in order to frequently check for appropriate referrals, assist with any recruitment queries, provide reminders about the recruitment process and update the team about targets and progress. Previous research has found that the development of a close working relationship with the clinical team is crucial for effective recruitment (Institute of Medicine, 2012; Liu et al., 2018). Due to the remote nature of recruitment following national lockdown requirements, communication was mostly via email. Nevertheless, the researcher and members of the clinical team would communicate daily to ensure no potential participants were missed, despite

visits to the study site not being possible. Uptake to the study was high, at 83%, meaning that the majority of people that were invited to take part gave consent, with only six participants declining. These findings are in line with previous pilot studies (Chadwick et al., 2009; Dannahy et al., 2011). Notably, this study achieved an 83% uptake rate having asked everyone on the group intervention pathway. The study also specified a recruitment rate of four to five participants per month. This criterion was only partially met. Recruitment started in the midst of the COVID-19 pandemic, meaning that the clinical team was having to become accustomed to frequent new ways of working, as recommendations to the NHS changes during the early recruitment stages. This had an impact on the rate of recruitment as the team at the time were adapting the group intervention procedures for delivery virtually, engaging temporary staff, and assisting patients with accessing relevant software. The monthly rate of recruitment ranged from 3 per month to 12 per month.

Another factor that contributed to the fluctuation in recruitment is staff turnover. Recruitment of participants was on hold whilst new members of the team were trained in the intervention, were able to deliver the intervention once and became familiar with the screening procedure for participants to be passed on to the researcher. Once the team stabilised, the recruitment rate far exceeded the target of four per month and it is reasonable to suggest that without pandemic restrictions and the addition of new roles to the team, 4-5 participants per month is easily manageable with the likely possibility of many more. This demonstrates the challenges of running a research study in clinical setting and has been reported as a barrier to efficient recruitment in an NHS setting in previous research (Kaur, Smyth, & Williamson, 2012) but also highlights possible solutions to barriers that limit recruitment at different stages of a study.

Feasibility criteria also required at least 80% of participants to attend at least one session of the group intervention. All participants randomised to the intervention arm attended at least one group session (100%). Strosahl, Robinson, and Gustavsson (2012) reported that it is possible to benefit from one session of ACT, arguing that it is a common misconception that brief therapy is a superficial intervention with minimal long-lasting benefits. Bryan, Morrow, and Appolonio (2009) found that statistically significant change can occur at all stages of a psychological intervention and that the effectiveness in the early stages often relies on the clinicians' beliefs about meaningful change over the course of the intervention i.e. if a clinician gives the impression that recovery involves long-term therapy, a client may be susceptible to colluding with that belief. Thus research suggests it is possible to benefit from a single session of an intervention and this means that all participants in the intervention arm of this trial were considered to have received a sufficient dose of the intervention.

Retention at six weeks was 93.3%. This figure is comparable with similar previous feasibility studies of single components of the current combined intervention (e.g. Johns et al., 2016) and suggests that the randomisation process and the intervention are acceptable to participants. Although participants were reminded about the next session and received session materials by email each week, this was part of routine care and was carried out by the clinical team. This suggests that the clinical teams' role in retaining participants in the study was no more labour intensive than standard treatment and it may be possible to replicate these retention rates in a larger scale RCT. Recent studies of interventions for bipolar disorder and psychosis found drop-out rates as low as 5% (Faurholt-Jepsen et al., 2020) and 9% (Ryan et al., 2021) respectively, reporting that minimising burden to participants ensured low drop-out at the endpoint of the study. As the present study mostly involved standard care

without any extra in-person appointments, it could be argued that burden was low. Those in the waitlist arm continued to receive standard care, which at times included individual therapy, meaning they may not have been as inconvenienced as they might have been had the waitlist control required not being seen at all. However, a recent meta-analysis of attrition from RCTs involving interventions for EUPD found an average drop-out rate of 22.3% (Iliakis, Ilagan, & Choi-Kain, 2021), Therefore, retention rates across severe mental illness studies are variable and whilst this study has shown potential for high retention, care should be taken in any future evaluation of this intervention to maintain these high rates, through liaising with the clinical team. Liu et al. (2018) conducted a systematic review of retention in mental health research and highlighted a number of strategies for researchers to ensure both recruitment and high retention at follow-up, including appropriate financial incentives, pre-notification of follow-up and shortened outcome measures, all of which this study incorporated into protocol.

Recruitment of P-BIFs exceeded the target of 9 participants, with 12 facilitators agreeing to take part. While 9 P-BIFs had been judged sufficient, the number required to run the groups taking place during the study lifetime exceeded this, and in order to avoid the researcher selecting participating P-BIFs, recruitment was extended to include all those willing to participate. Once the service had established a stable clinical team with fewer staff changes, there were more junior team members to be trained in the intervention thus more facilitators available to take part in the study. These findings support the feasibility of a possible larger RCT in the future.

The recruitment rate also highlights the availability and willingness of junior staff to train in third wave group interventions, thus supporting the feasibility of

implementing these interventions to be facilitated by junior staff in a community setting. The training was sufficient for the P-BIFs to rate themselves as competent in delivery of the intervention. Self-ratings were consistent with the clinical oversight of the senior supervising clinicians, and thus, while objective ratings are more desirable, appear to have some validity. High self-ratings of competence may also indicate that the manualised format of the intervention allows for adequate delivery. This supports previous studies that have found manualised interventions can be competently delivered (Conklin et al., 2020; Jolley et al., 2020; Ryan et al., 2021). This has important implications for increasing access to psychological therapies in a community mental health setting.

High ACT competency self-ratings may give insight into which components of ACT the intervention utilises the most, as P-BIFs feel more familiar with some aspects than others. For example, the highest rated component was "getting in contact with the present moment" (91.6%, SD = 8.52%), perhaps reflecting the strong element of mindfulness exercises throughout the intervention, as they were part of the content for all six sessions. It would seem logical that the frequency of each component throughout the six sessions would impact the P-BIFs' confidence in delivering that component as they build up more experience the more frequent it is during the intervention. The modular nature of the intervention combining ACT, CFT and DBT may mean that whilst there are lower rated components of ACT, this may be reflected in CFT and DBT competency. Future research into the competent delivery of a modular intervention may include a tailored competency measure, a more stringent measure of fidelity or a competency measure for each individual therapeutic model.

At six weeks post-intervention, 11 participants from the intervention arm scored lower on the CORE-10 (change score range -1 to -19; 95% CI -6.45 ± 3.39), indicating the possibility of improvement. However, only 5 participants (33%) showed reliable improvement and 2 (13%) showed reliable and clinically significant improvement. However, only a third of all participants attended all six weeks of the intervention and the two participants that demonstrated reliable and clinically significant improvement both attended all six sessions. While a dose-response relationship may explain this, this would contradict previously mentioned assertions by Strosahl et al. (2012), stating that one session is sufficient enough for improvement. It may also be that other participant characteristics explain both improvement and attendance, and this may be a useful focus for future larger scale work. One could argue that 11 participants scoring lower could reflect that they may have benefitted from fewer sessions even if not enough to detect reliable and clinically significant change.

The preliminary changes in the expected direction on the process measures are an early indicator that clinical changes may in part be credited to the group. Process measures will be an important part of any future full scale RCT in order to better determine this. Given previous findings regarding the inconsistency around measures used in third wave evaluations (Jansen et al., 2020), choice of measures should be informed by previous literature.

In line with third wave approaches, the study did not administer any measures of symptom severity (e.g. PANSS, HADS) as the target of third wave interventions is to change the relationship with symptoms by developing skills manage them rather than to alleviate symptoms. Future studies should aim to administer measures of general

distress, quality of life or level of functioning to define efficacy in third wave group interventions in order to evolve with the third wave approaches.

## 4.2 Limitations

The study has several important limitations when considering findings. Although findings are promising, as a feasibility study, they cannot be taken as any of evidence of effects and further larger scale studies must be undertaken to properly estimate these before conducting a full trial.

Psychiatric diagnosis was determined from screening patients' clinical notes and not from a clinician-administered diagnostic interview. Whilst working with a heterogeneous sample is a strength of transdiagnostic approaches, it may be particularly important when investigating the effectiveness of a transdiagnostic group to fully determine formal diagnoses for the purposes of evaluation, even if this is not a priority in clinical practise. This would allow researchers to establish if the transdiagnostic nature of the group really does benefit participants equally regardless of diagnosis or whether disorder-specific symptoms interfere. As the intervention is modular, it would also help to establish what components work best for whom. Nevertheless, this study included a diverse sample of participants with psychosis, bipolar, personality disorder, obsessive compulsive disorder, complex trauma and complex affective disorders, perhaps representing the clinically diverse population usually seen in a community mental health team. The range of diagnoses seen in individuals taking part in the trial speaks to the acceptability of the intervention and the randomisation process to those seen routinely in a CMHT.

As the intervention is in the feasibility stage, it is possible that this study would have benefitted from a parallel qualitative evaluation in order to determine participants' views on acceptability of the intervention more clearly. Although 66% of participants attended more than half of the intervention, it would be useful to know what factors obstructed others from completing. The completion rate for the study was higher than the completion rate for the intervention and participant interviews or feedback forms would provide valuable insight in being able to determine the disparity in these completion rates.

The study had a process for measuring facilitator fidelity as the researcher attended six sessions that did not have any study participants present. The researcher rated them using the same competency rating scale that the facilitators used to rate themselves but due to time constraints this was only possible for two facilitators. It was difficult to measure fidelity in practice, as group members have previously not consented to audio recording. The method was rating fidelity and competence was sufficient but was not feasible to execute in this context. Minor adjustments and lack of pandemic restrictions may improve feasibility of measuring fidelity in the future. However, all facilitators did rate themselves as competent and this was deemed sufficient for the purposes of feasibility. It would be beneficial for future research to formally assess adherence and competence.

The study was only able to recruit those that were on the group intervention pathway. This means that they had already agreed to attend the group as part of their routine care. Although uptake to the study was high, it is not possible to estimate what the uptake to the study might have been had it been offered to the wider service. There is a possibility that individuals from other pathways in the service may either decline the

group, the randomisation process or both, meaning recruitment rates in this feasibility study may not reflect true interest from the wider CMHT population. Service variability also meant it is difficult to estimate recruitment rates. The study achieved a recruitment rate of 12 participants in one month but this was after 4 months of staff and service changes, which may accurately reflect the unpredictability of a CMHT in the NHS.

A notable limitation of the study was that the researcher was not blind at the point of baseline or follow-up assessments. Variation in participant flow impacted the dates that groups could commence as groups could not run with too few participants. In order to avoid inconsistency in the time elapsed from baseline to the group commencing, assessments were completed post-randomisation. This was a deviation from protocol and is a limitation that has been found in previous group intervention studies (Jolley et al., 2020). Future trials evaluating group interventions will need to identify mechanisms to address variability in participant flow, and the impact of this on intervention scheduling and delivery, in their protocol. This may be achieved by the involvement of a second assessor who is not involved in randomisation or intervention delivery.

Previous research has cautioned that the evidence base to date is taken from group therapies delivered by highly experienced clinicians, usually clinical psychologists, who have undergone substantial additional training in the approach the intervention requires and are usually in receipt of specialist supervision (Jacobsen et al., 2019). However, findings from this study suggest that, with a strict protocolised intervention, it is feasible for junior frontline staff (e.g. assistant psychologists, clinical associate practitioners, trainee clinical psychologists) to deliver a third wave group intervention

competently without additional substantial training. The facilitators in this study received expert supervision by a senior clinical psychologist working in the service. It is possible that the combination of a protocol-based intervention, with a clear and concise manual, and expert supervision offer a potential solution to the issue of wider dissemination in the NHS, allowing staff from a more varied pool of job roles to be trained the intervention protocol, thus challenging the notion that facilitators need to be highly experienced with additional training.

### 4.3 Implications for clinical practice

Findings from this study suggest that further randomised controlled evaluation is feasible and necessary in order to determine the efficacy of this group intervention. Implementation science research highlights six important criteria for the effective implementation of a new intervention; a robust evidence base, simplicity of usability of the model, service need, organisational fit, capacity to put into practice (qualifications, resources and time) and support to implement (Metz & Louison, 2018).

Arguably, although findings are preliminary, this feasibility study has demonstrated the potential for ease of usability of the model, by manualising a protocol that can be competently delivered by junior staff. Findings also highlight the potential service need and organisational fit, in that the group intervention ran in the context of frontline clinical services in South East London and was offered as part of routine care. The study was able to recruit to target and in the final month 12 participants were recruited, suggesting that the service had identified a need for their patients that justified the running of the group. The service had the capacity to put the group intervention into practise as the P-BIFs did not require any formal qualifications and could be trained by a senior clinical psychologist who was already in the service. Once

the team had stabilised following staff changes, there were up to 12 members of staff available for training and facilitating groups, suggesting that the service has resources and time to build the implementation of groups into existing routine care. Although this study cannot speak to the "support to implement" criteria, it is notable that a robust evidence base has not yet been established for third wave group interventions in the community. This highlights the need for full-scale RCTs further, in order to facilitate the implementation of new, effective interventions into services and increase access to psychological therapies.

## 4.4 Conclusions

This study found that it is feasible for Protocol-Based Intervention Facilitators to deliver a third wave group intervention for individuals with severe mental illness in a community mental health setting. Findings indicate that participants can successfully be recruited to the study and that it is also possible to recruit a waitlist control. Facilitators were able to provide the intervention competently and made use of weekly clinical supervision. The group intervention had a high retention rate, suggesting that the sessions were acceptable to individuals with severe mental illness. A third wave group intervention combining components of ACT, CFT and DBT appears safe and acceptable and requires further evaluation to determine efficacy and cost-effectiveness.

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29 September 2020

Dear Dr Jolley

**HRA and Health and Care Research Wales (HCRW) Approval Letter**

| | |
|---|---|
| **Study title:** | **Evaluating delivery by trained Protocol-Based Intervention Facilitators (P-BIFs) of a third wave group intervention in community mental health services** |
| **IRAS project ID:** | **270595** |
| **Protocol number:** | **NA** |
| **REC reference:** | **20/LO/1004** |
| **Sponsor** | **King's College London** |

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

**How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?**
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

**How should I work with participating non-NHS organisations?**
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

**What are my notification responsibilities during the study?**

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

**Who should I contact for further information?**
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **270595**. Please quote this on all correspondence.

Yours sincerely,

Kathryn Murray
Approvals Specialist

Email: approvals@hra.nhs.uk

*Copy to:* *Professor Reza Razavi, King's College London*

**Appendix A** – Ethical Approval

## List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

| *Document* | *Version* | *Date* |
|---|---|---|
| Covering letter on headed paper [Cover Letter to Research Ethics Committee] | 1 | 27 July 2020 |
| GP/consultant information sheets or letters [Letter to inform GPs of patient participation] | 4.1 | 20 September 2020 |
| IRAS Application Form [IRAS_Form_28072020] | | 28 July 2020 |
| IRAS Application Form XML file [IRAS_Form_28072020] | | 28 July 2020 |
| IRAS Checklist XML [Checklist_31072020] | | 31 July 2020 |
| IRAS Checklist XML [Checklist_11082020] | | 11 August 2020 |
| IRAS Checklist XML [Checklist_28072020] | | 28 July 2020 |
| Letter from funder [Research budget letter from education provider] | | 05 May 2020 |
| Letter from sponsor [Letter from sponsor] | | 27 July 2020 |
| Other [Previous unfavourable opinion ] | | 18 June 2020 |
| Other [Service User Eligibility and Registration Form] | 1 | 20 July 2020 |
| Other [P-BIF Eligibility & Registration Form] | 1 | 20 July 2020 |
| Other [Demographic Form] | 1 | 20 July 2020 |
| Participant consent form [Consent form for Service Users] | 4.1 | 20 September 2020 |
| Participant consent form [Consent Form for PBIFs (Staff)] | 4 | 23 July 2020 |
| Participant information sheet (PIS) [PIS for Service Users] | 5.1 | 20 September 2020 |
| Participant information sheet (PIS) [PIS for PBIFs (Staff)] | 4.1 | 20 September 2020 |
| Research protocol or project proposal [Protocol v5] | 5 | 23 July 2020 |
| Summary CV for Chief Investigator (CI) [CV for CI Suzanne Jolley] | | 13 May 2020 |
| Summary CV for student [CV for Sarah Feehan (Student)] | 2 | 27 July 2020 |
| Summary CV for supervisor (student research) [CV for Emma O'Donoghue] | | |
| Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only) [KCL Insurance] | NA | 14 September 2020 |
| Summary, synopsis or diagram (flowchart) of protocol in non technical language [Non-technical summary] | 2 | 20 July 2020 |
| Validated questionnaire [CORE-10] | | |
| Validated questionnaire [MANSA] | | |
| Validated questionnaire [SCS] | | |
| Validated questionnaire [AAQ II] | | |
| Validated questionnaire [ACT Self Rating Form] | | |
| Validated questionnaire [DERS-16] | | |

# Participant Information Sheet

**Study title:** New ways to deliver group community mental health interventions

We would like to invite you to take part in a research study. Before you decide whether you want to participate, it is important for you to understand why the research is being done and what it would involve for you. Please read the following information carefully and talk to others about the study if you wish.

You can ask us if there is anything that is not clear or if you would like any more information. You may take the time you want to decide whether you would like to part.

**What is the research about?**
The purpose of this study is to start to find out whether it is possible to train junior frontline staff to successfully deliver therapy groups for people receiving treatment from a community mental health team. The aim is to provide more efficient therapy to a greater number of people. We hope the therapy groups will help individuals to be less affected by their symptoms and provide support to live a meaningful life.

**What type of study is it?**
The type of study we are running is called a randomised feasibility trial. A feasibility trial is a small trial to see whether it would be possible and practical to run a larger study. At the moment, we do not know if the therapy groups are any more helpful than just the normal medical care people already receive under the NHS. This means a future larger randomised trial is the most exact and fair way to test how helpful the therapy group is. Before we can do this, we need to find out things like how many people want to take part, whether people complete the group and assessments, and whether they stay involved and like the study.

Randomised means that people taking part in the trial will be put into one of two groups at random by a process a bit like tossing a coin, but completed by computer. One group will be offered the therapy group straight away whilst also receiving their normal treatment under their current care team. The other group will continue to receive their normal treatment under their current care team and will only be offered the therapy group after 10-15 weeks. The wellbeing of the individuals in the two groups is compared using a questionnaire pack, so we can see the range of how different the two groups might be in a larger study (this tells us how many people we should have in the larger study).

**Why have I been invited?**
You have been invited to take part in this research as you are currently receiving care from one of the community mental health teams in the South London and Maudsley NHS Foundation Trust.

**Do I have to take part?**
It is up to you to decide whether you want to join the study. If you agree to take part, you will be asked to sign a consent form. You are free to withdraw at any point during the study

and you will not be asked to give a reason. Whether you take part or not, or decide to withdraw, will not affect any of your usual care with your team or anywhere else.

**What will happen to me if I take part?**
If you decide to take part, let your team know, and they will arrange for a researcher to call you by telephone or video-link using Microsoft Teams at a time that is convenient for you. During this appointment, the researcher will explain the study to you in more detail and there will be the chance to ask any questions you may have. You will be given this information sheet to keep by email or by post. You will be asked to formally record your consent, via email where possible. Where this is not possible, you will be sent two copies of the consent form by post, both signed by the researcher. You will be asked to sign and return one copy via post. You will be provided with a pre-paid envelope.

You will then be asked to complete six questionnaires that the researcher will take you through over the phone and will be able to assist you with should you have any questions. The appointment should last approximately 40 minutes.

After the appointment, the researcher will let you know when you will be offered the therapy group (straight away, or after 10-15 weeks). This decision is made by computer: the researcher will not know in advance, you will not be able to choose which group you are in and we will not make the decision ourselves.

**What will happen to me if I am put into the group offered the therapy straight away?**
You will be invited to attend the therapy group between one and four weeks later. This will involve attending one group session every week that will last 2 hours, during which you will learn about different ways to improve your wellbeing. The group will usually be on a video link using Microsoft Teams, but you may be able to join by telephone or attend in person depending on your current care with the team. If you are attending the group via telephone, you will be sent information about the group via email or post, in weekly instalments or all at once, depending on your preference. During the group, you will not have to talk about things if you do not want to. After each of the six sessions, you will be asked to complete a short questionnaire pack that should take no longer than 10 minutes. Depending on how you are attending the group, this will be done in person where you will be given a questionnaire to complete or via Microsoft Teams or over the telephone, where one of the group facilitators will take you through the questionnaire.

At the end of the last group session, you will be asked to complete the questionnaire pack from the first appointment again. This will take approximately 40 minutes. After another month, we will ask you to complete the same questionnaires again in another 40 minute appointment. As in the first appointment, a member of the research team will contact you via telephone to arrange a time that is convenient for you. They will then take you through the questionnaire pack via telephone and provide you with any assistance.

**What will happen to me if I am put into the group offered therapy after 10-15 weeks?**
You will continue to receive your normal care for the next 10 weeks. During this time, you will be asked to complete the questionnaire pack from the first appointment a further two times; after six weeks and after 10 weeks. Each time, a researcher will contact you by telephone and each appointment will take approximately 40 minutes. Once you have

completed the questionnaires, you will be given the opportunity to attend the therapy groups, providing we have not found any difficulties with them so far in the study. The research team will let you know when the groups are running once everyone in the study has completed their final questionnaire pack. If there were any problems with the therapy groups, that meant we were not offering them anymore, we would try to find a similar local group that you could join. In this case, you may need to wait a little longer to join a group.

**Where and how will the therapy group sessions be run?**
The group sessions will usually take place by video-link using Microsoft Teams, but you may be able to join by telephone or in person depending on your care with your clinical team at the time the group sessions are due to take place. You can discuss this with the researcher. Group sessions will be once a week for 6 weeks. The sessions will last 2 hours every week. If you are attending the group via telephone, you will be sent out information for the sessions via post or email in weekly instalments or all at once, depending on your preference. You will attend the group with approximately five other people, and it will be led by four facilitators. During the group sessions, the facilitators will talk about things such as what is important to you, setting goals, noticing emotions and overcoming obstacles. Throughout the sessions, you can ask questions. If you want to, you can also share your own experiences with the other people attending the group, but you do not have to do this if you prefer not to.

**Who are the group facilitators?**
We are trying to find out if junior staff can facilitate the therapy groups. The junior staff will have studied psychology and/or have some experience of working in mental health services, but they will not be qualified psychological therapists. They will all have been trained to deliver the therapy group, and will be managed and supervised by a qualified psychological therapist. In each group, there will usually be three newly trained junior staff, and one more experienced junior staff member. We will ask how you found them as facilitators when you complete the questionnaires at the end of the course of groups.

**Expenses and payments**
If you decide to take part in the course, you will receive £5 for the initial assessment appointment you complete with the researcher and then £10 on completion of the study as a sign of appreciation of your time and to account for any travel expenses you may incur. This will amount to £15 in total that will be given as cash.

**What are the possible disadvantages and risks of taking part?**
There are no intended disadvantages or risks of taking part. The therapy groups have been offered before within mental health services. However, the group sessions and some of the questionnaires can involve thinking about your difficulties and feelings. For some people, this can be upsetting. If you feel upset and would like support, tell your group facilitator or the researcher and they will support you. They may inform your care co-ordinator to ensure you get any further support you might need. You can stop taking part in the course or completing the questionnaires at any time and this will not impact your usual treatment.

**What are the possible benefits of taking part?**
We hope that you will get helpful information on managing your distress and feelings as a way of improving your wellbeing and help you progress towards your own personal goals.

Though this cannot be guaranteed, the information we get from this study may help us support people in mental health services in the future.

**What will happen if I don't want to carry on with the study?**
If you wish to withdraw from the study you may do so, and we will ask you what you would prefer we do with any information you provided up to that point and whether it may still be used in the study. We will also ask if you are happy to complete an exit interview when leaving the study. This will allow us to get a sense of your experience of attending the group. However, you are welcome to refuse to take part in this exit interview.

**What if something goes wrong?**
If you have a concern about any aspect of this study, you can contact your care co-ordinator who will be able to pass on this complaint to the research team in order for them to be able to call you and discuss your concerns. If you remain unhappy, you may contact the chief investigator, Dr. Suzanne Jolley by email at Suzanne.jolley@slam.nhs.uk.

If your concern has still not been addressed, you can contact the ***Patient Advice and Liaison Service (PALS)***. Their contact information is below.

- By phone on 0800 731 2864 (freephone),
  Monday to Friday 9am to 5pm
- By email to pals@slam.nhs.uk

Should you wish to escalate your concern further, you may contact the Director of Research Quality, Dr Gill Dale at gill.dale@kcl.ac.uk. In the unlikely event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). King's College London has obtained insurance which provides no-fault compensation i.e. for non-negligent harm; you may be entitled to make a claim for this.

**How will my personal data be used in compliance with General Data Protection Regulation (GDPR)?**
If you agree to participate in the study, the research team will let your care team know. This may include writing to your GP to inform them that you are taking part.

King's College London (KCL) is the lead sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. KCL will keep identifiable information about you for 12 months after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you wish to withdraw from the study you may do so, and we will ask you what you would prefer we do with any information you provided up to that point and whether it may still be used in the study. To safeguard your rights, we will use the minimum personally-identifiable information possible.



You can find out more about how we use your information by contacting the Chief Investigator, Dr. Suzanne Jolley (Suzanne.jolley@slam.nhs.uk) or by visiting the KCL website: https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research.aspx.

South London and Maudsley NHS Foundation Trust (SLaM) will collect information from you for this research study in accordance with our instructions. SLaM will use your name, and your contact details (phone number, home address and email address), to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from KCL and regulatory organisations may look at your research records to check the accuracy of the research study. SLaM will pass these details to KCL along with the information collected from you. The only people in KCL who will have access to information that identifies either of you will be people who need to contact you regarding your participation or audit the data collection process.

The research team are always obliged to pass on information if they have concerns about your safety or the safety of someone else, and this could include contacting other agencies who are there to help keep people safe, like the Police or social services. We would usually discuss this with you first.

**What will happen to the information I provide to the study?**
Following completion of the project, in line with data retention regulation stipulated by King's College London, all pseudo-anonymized data will be kept on King's College London premises in a secure location for 12 months after the research project has been passed by the Board of Examiners, at which time they will be destroyed. The Chief Investigator will act as custodian of the data and will keep a fully anonymised data in a secure location indefinitely.

**What will happen to the results of the research study?**
When you are recruited to the study, you will be given the option to be informed of the results. This will involve consenting for the researchers to contact you once the study is completed. If you wish to be informed of the results, you will receive a "results newsletter".

The results of this study will be published in a thesis for a doctorate in clinical psychology. They may also be published in a peer reviewed journal. All results will be anonymised so that it will not be possible for readers to identify you in any published documents.

**Who is organising and funding the research?**
This research is being organised and funded by the Doctorate in Clinical Psychology training programme and is co-sponsored by King's College London and South London and Maudsley NHS Foundation Trust.

**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 interests. This study has been reviewed and given favourable opinion by London South East Research Ethics Committee

**Where can I get further information about the study?**
If you would like to speak to a member of the research team to find out more about the study or have questions about it answered, you can call us on 07929858494. Alternatively, you can email me on sarah.j.feehan@kcl.ac.uk.

You will receive a copy of this information sheet and your consent form for you to keep.

**Thank you!**

# Participant Information Sheet
## (Protocol-Based Intervention Facilitators [P-BIFS])

**Study title:** New ways to deliver group community mental health interventions

I would like to invite you to take part in a research study. Before you decide whether to take part, it is important that you understand why the research is being done and what it would involve for you.

Talk to others about the study if you wish. (Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study).

**What is the purpose of the study?**
The purpose of this study is to determine the feasibility of training individuals with an undergraduate degree in Psychology and/or experience of working in a mental health setting to deliver a third wave group therapy for people with severe mental illness. The therapy is delivered to a manualised protocol, so those delivering it are referred to as 'protocol-based intervention facilitators' or PBIFs. The intervention is designed to help individuals to be less affected by their symptoms and provide support to live a meaningful life.

**What type of study is it?**
The type of study we are running is called a randomised feasibility trial. A feasibility trial is a small trial to see whether it would be possible and practical to run a larger study. At the moment, we do not know if the therapy groups are any more helpful than just the normal medical care people already receive under the NHS. This means a future larger randomised trial is the most exact and fair way to test how helpful the therapy group is. Before we can do this, we need to find out things like how many people want to take part, whether people complete the group and assessments, and whether they stay involved and like the study.

Randomised means that people taking part in the trial will be put into one of two groups at random by a process a bit like tossing a coin, but completed by computer. One group will be offered the therapy group straight away whilst also receiving their normal treatment under their current care team. The other group will continue to receive their normal treatment under their current care team and will only be offered the therapy group after 10-15 weeks. The wellbeing of the individuals in the two groups is compared using a questionnaire pack, so we can see the range of how different the two groups might be in a larger study (this tells us how many people we should have in the larger study).

**Why have I been invited?**
You have been invited to take part in this research as you are currently working or are on a placement within South London and Maudsley Foundation NHS Trust, have an undergraduate degree in Psychology and/or two years of experience working with mental health, and your supervisor has told us that you may be interested in taking part in this research. You will have attended training to deliver a third wave group for severe mental illness. For the purposes of this study, staff participants will be referred to as Protocol-Based Intervention Facilitators (P-BIFs). Approximately nine P-BIFs will be recruited to participate in this research.

**Do I have to take part?**
It is up to you to decide whether you want to join the study. If you agree to take part, you will be asked to sign a consent form. You are free to withdraw at any point during the study and you will not be asked to give a reason.

**What will happen to me if I take part?**

If you decide to take part in this study, a researcher will arrange to speak to you over the telephone or by Microsoft Teams at a time that is convenient for you. During this conversation, the researcher will explain the study in more detail and there will be the chance to ask any questions you may have. The researcher will take you through this information sheet and you will be sent a copy via email to keep. You will be sent two copies of a consent form signed by the researcher via email and will be asked to sign a copy of the form to return via email.

You will then be asked to deliver the protocol-based third wave group intervention for individuals with severe mental illness that you have been trained to facilitate. You will work with two other junior facilitators and a more experienced P-BIF. After each session, the service users will be asked to complete a short questionnaire pack, which you will be expected to help facilitate as well.

**Adjustments to intervention delivery required by the current pandemic**

In keeping with the team's current practice, group attendance will be offered flexibly: service user participants will be able to join electronically using the trust's secure platform, Microsoft Teams, to join by telephone, or, subject to the team's risk assessment for both the person and the P-BIF, attend in person using social distancing of 2 metres and appropriate protective equipment. There are rooms available that permit suitable spacing. Usual clinical practice at present is to use face to face contact only for the most important aspects of care that cannot be delivered remotely: however, where participation is viewed by the team as a scheduled activity which may assist the service user with their routine and have a wellbeing enhancing impact, such a contact may fall into this category, and as it is important to services currently not to exclude people from potential opportunities because of technological disadvantage, we will include this attendance option. If delivering the intervention in person, this will involve wearing appropriate PPE and ensuring the group remains socially distant. If delivering the intervention via Microsoft Teams, you will be able to share the PowerPoint slides on screen with the participants, which will allow you to facilitate discussion as outlined in the protocol. For participants joining via telephone, they will be sent a copy of the PowerPoint slides either in weekly instalments or all at once depending on their preference.

As the intervention is protocol-based, the study will involve you being asked to complete self-rating forms after each session that will ask you to rate how well you think you managed to adhere to the protocol when delivering each session. You will be able to return the completed forms to the research team via the trust's secure email system. You will receive group supervision remotely via Microsoft Teams from a trained clinician in order to support your delivery of the intervention.

Once the trial is complete, you may be asked to deliver the intervention to Group B who acted as waitlist controls throughout and who show an interest in participating in the intervention after completion of participation in the study.

**What are the possible disadvantages and risks of taking part?**

There are no intended disadvantages or risks of taking part. The group therapy is routinely given to individuals within the trust. However, the group sessions involve the service users thinking about their condition and feelings, and you may find this difficult. You may also be exposed to participants' distress or unusual behaviour, which could perturb you. You will be provided with regular supervision sessions by a qualified clinical psychologist while delivering this group. We do not anticipate that you will experience significant distress during the trial, but we would encourage you to use the supervision sessions as a place to share any difficulties you do encounter. Should any member of the research team have concerns about your wellbeing or the wellbeing of service users, they may need to discuss this with your supervisor, but this would always be communicated to you in the first instance.

You may wish to ask members of the research team who supervises you for a reference in the future. What supervise observe of your clinical skills during your participation will necessarily inform

any references, alongside any other experience they have of you. However, the research team will only have access to any questionnaires you complete or other data you provide for the research in an anonymised form and this would not form part of any reference or be shared beyond the research team except for anonymised dissemination of study findings.

**What are the possible benefits of taking part?**
We hope participating will give you the opportunity to learn from reflecting on your experience of delivering third wave psychological interventions. We would also hope that the training you receive will equip you with transferable skills that you will be able to build on in your future professional career. Though we cannot guarantee these benefits, the information we get from this study will help inform the treatment of people in community mental health services.

**What will happen if I don't want to carry on with the study?**
If you wish to withdraw from the study you may do so, and we will ask you what you would prefer we do with any information you provided up to that point and whether it may still be used in the study. We will also ask if you are happy to complete an exit interview when leaving the study. This will allow us to get a sense of your experience of taking part in the training and delivering the group. However, you are welcome to refuse to take part in this exit interview.

**What if something goes wrong?**
If you have a concern about any aspect of this study, you can contact Dr. Suzanne Jolley, who is the Chief Investigator of the study at King's College London. Suzanne can be contacted by email at suzanne.jolley@kcl.ac.uk.

Should you wish to escalate your concern further, you may contact the Director of Research Quality, Dr Gill Dale at gill.dale@kcl.ac.uk

In the unlikely event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). King's College London has obtained insurance which provides no-fault compensation i.e. for non-negligent harm; you may be entitled to make a claim for this.

**How will my personal data be used in compliance with General Data Protection Regulation (GDPR)?**
King's College London (KCL) is the lead sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. KCL will keep identifiable information about you for 12 months after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you wish to withdraw from the study you may do so, and we will ask you what you would prefer we do with any information you provided up to that point and whether it may still be used in the study. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the Chief Investigator, Dr. Suzanne Jolley (see details at the end of this sheet) or by visiting the KCL website: https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research.aspx.

South London and Maudsley NHS Foundation Trust (SLaM) will collect information from you for this research study in accordance with our instructions. SLaM will use your name, and your contact

details (phone number and email address), to contact you about the research study, and make sure that relevant information about the study is recorded for your wellbeing, and to oversee the quality of the study. Individuals from KCL and regulatory organisations may look at your research records to check the accuracy of the research study. SLaM will pass these details to KCL along with the information collected from you. The only people in KCL who will have access to information that identifies either of you will be people who need to contact you regarding your participation or audit the data collection process.

**What will happen to the results of the research study?**
The results of this study will be published in a thesis for a doctorate in clinical psychology. They may also be published in a peer reviewed journal. All results will be anonymised so that it will not be possible for readers to identify you in any published documents.

**Who is organising and funding the research?**
This research is being funded by the Doctorate in Clinical Psychology programme and co-sponsored by King's College London and South London and Maudsley NHS Foundation Trust.

**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 interests. This study has been reviewed and given favourable opinion by London South East Research Ethics Committee

**Where can I get further information about the study?**

If you would like to speak to a member of the research team to find out more about the study or have questions about it answered, you can call us on 07929858494. Alternatively, you can email me on sarah.j.feehan@kcl.ac.uk.

You will receive a copy of this information sheet and your consent form for you to keep.

# Thank you!

## Consent Form (Service User)

**Study title:** New ways to deliver group community mental health interventions

**Please initial each box and sign the bottom of the sheet**

| | | |
|---|---|---|
| 1. | I confirm that I have read and understand the information sheet dated (version……..) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | |
| 2. | I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason. | |
| 3. | I agree for my anonymous data to be used in further research studies. | |
| 4. | I acknowledge that any data published in a peer reviewed journal will be anonymised so that it will not be possible for readers to identify me in published documents. | |
| 5. | I understand that the research team will have access to my medical record for the purposes of the study. | |
| 6. | I understand that the research team will contact my GP/healthcare professionals to inform them I am participating in the research. | |
| 7. | I agree to take part in the above study. | |
| 8. | **OPTIONAL:** I agree to be contacted about the results of the study | |

An original copy of the participant information sheet and completed consent form is to be given to the participant, in addition to the original copy that is filed in the investigator file.

**Name of Participant:** _____ **Date:** _____

**Signature:** _____

**Name of researcher:** _____ **Date:** _____

**Signature:** _____

## CONSENT FORM (Protocol-Based Intervention Facilitators)

Study title: New ways to deliver group community mental health interventions

**Please initial each box and sign the bottom of the sheet**

| | |
|---|---|
| 1. I confirm that I have read and understand the information sheet dated (version…….) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | |
| 2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason. | |
| 3. I agree for my anonymous data to be used in further research studies. | |
| 4. I acknowledge that any data published in a peer reviewed journal will be anonymised so that it will not be possible for readers to identify me in published documents. | |
| 5. I agree to take part in the above study. | |

An original copy of the participant information sheet and completed consent form is to be given to the participant, in addition to the original copy that is filed in the investigator file.

**Name of Participant:** _____ **Date:** _____

**Signature:** _____

**Name of researcher:** _____ **Date:** _____

**Signature:** _____

<<Insert date>>
Institute of Psychiatry, Psychology & Neuroscience
Department of Psychosis
Box PO63
London
SE5 8AF

Dear Dr <<insert GP name>>,

**Re:** New ways to deliver group community mental health interventions

Your patient **<<insert patient name and NHS identifier>>**is a participant in the above research study, a randomised controlled feasibility trial that aims to investigate the feasibility and acceptability of training junior frontline staff to deliver a third wave intervention in a group format to people with severe mental illness to inform a potential larger randomised controlled trial.

Patients randomised to the active treatment arm will receive a weekly 2-hour group session with the hope that it would help individuals to be less affected by their symptoms and provide support to live a meaningful life. Those in the non-active arm will be offered the intervention following completion of the trial. Throughout participation in the study, all patients will continue to receive their usual care.

The study is approved by the <<insert REC details>> and there are no significant anticipated risks associated with participation in the group.

Should you require any further information please do not hesitate to contact the local research team on <<study or researcher telephone>>, or email <<study or researcher email>>.

Yours Sincerely,

<<Lead Researcher>>

**Appendix G** – Questionnaire Pack

**Acceptance and Action Questionnaire (AAQ-II)** - *Below you will find a list of 10 statements. Please rate how true each statement is for you by marking an **X** after each item.*

| Statement | Never true | Very seldom true | Seldom true | Sometimes true | Frequently true | Almost always true | Always true |
|---|---|---|---|---|---|---|---|
| 1. It's OK if I remember something unpleasant | | | | | | | |
| | 7 | 6 | 5 | 4 | 3 | 2 | 1 |
| 2. My painful experiences and memories make it difficult for me to live a life that I would value | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 3. I'm afraid of my feelings | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 4. I worry about not being able to control my worries and feelings | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 5. My painful memories prevent me from having a fulfilling life | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 6. I am in control of my life | | | | | | | |
| | 7 | 6 | 5 | 4 | 3 | 2 | 1 |
| 7. Emotions cause problems in my life | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 8. It seems like most people are handling their lives better than I am. | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 9. Worries get in the way of my success | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 10. My thoughts and feelings do not get in the way of how I want to live my life | | | | | | | |
| | 7 | 6 | 5 | 4 | 3 | 2 | 1 |

# CLINICAL OUTCOMES IN ROUTINE EVALUATION
# CORE-10

Please rate each statement by marking an **X** in the relevant box

| Over the last week… | Not at all | Only Occasionally | Sometimes | Often | Most or all of the time |
|---|---|---|---|---|---|
| 1. I have felt tense, anxious or nervous | 0 | 1 | 2 | 3 | 4 |
| 2. I have felt I have someone to turn to for support when needed | *4* | *3* | *2* | *1* | *0* |
| 3. I have felt able to cope when things go wrong | *4* | *3* | *2* | *1* | *0* |
| 4. Talking to people has felt too much for me | 0 | 1 | 2 | 3 | 4 |
| 5. I have felt panic or terror | 0 | 1 | 2 | 3 | 4 |
| 6. I made plans to end my life | 0 | 1 | 2 | 3 | 4 |
| 7. I have had difficulty getting to sleep or staying asleep | 0 | 1 | 2 | 3 | 4 |
| 8. I have felt despairing or hopeless | 0 | 1 | 2 | 3 | 4 |
| 9. I have felt unhappy | 0 | 1 | 2 | 3 | 4 |
| 10. Unwanted images or memories have been distressing me | 0 | 1 | 2 | 3 | 4 |

**Appendix G** – Questionnaire Pack

**MANSA**

**This page asks you how satisfied you are with several aspects of your life**

Please answer each question by entering an **X** for each question below. If there is a question you do not want to answer, leave that question blank.

1. How satisfied are you with your life as a whole today?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

2. How satisfied are you with your job as your main occupation? (Or sheltered employment or training/education)

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

*OR…if unemployed or retired…*

How satisfied are you with being unemployed / retired?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

3. How satisfied are you with your financial situation?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

4. How satisfied are you with the number and quality of your friendships?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

| 5. How satisfied are you with your leisure activities? | | | | | | |
|---|---|---|---|---|---|---|
| **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

| 6. How satisfied are you with your accommodation? | | | | | | |
|---|---|---|---|---|---|---|
| **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

| 7. How satisfied are you with your personal safety? | | | | | | |
|---|---|---|---|---|---|---|
| **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

| 8. How satisfied are you with the people that you live with? | | | | | | |
|---|---|---|---|---|---|---|
| **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

*OR…if you live alone…*

| How satisfied are you with living alone? | | | | | | |
|---|---|---|---|---|---|---|
| **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

| 9. How satisfied are you with your sex life? | | | | | | |
|---|---|---|---|---|---|---|
| **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

| 10. How satisfied are you with your relationship with your family | | | | | | |
|---|---|---|---|---|---|---|
| **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

| 11. How satisfied are you with your physical health? | | | | | | |
|---|---|---|---|---|---|---|
| **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

| 12. How satisfied are you with your mental health? | | | | | | |
|---|---|---|---|---|---|---|
| **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| **Couldn't be worse** | **Displeased** | **Mostly Dissatisfied** | **Mixed** | **Mostly Satisfied** | **Pleased** | **Couldn't Be better** |
| | | | | | | |

**Appendix G** – Questionnaire Pack

## SELF-COMPASSION SCALE (SHORT FORM)

*How I typically act towards myself in difficult times….*

Please read each statement carefully before answering. On a scale of 1 to 5, where 1 is almost never and 5 is almost always, please rate each statement:

| ***Almost never*** | | | | ***Almost always*** |
|---|---|---|---|---|
| **1** | **2** | **3** | **4** | **5** |

| | | |
|---|---|---|
| 1 | When I fail at something important to me I become consumed by feelings of inadequacy | |
| 2 | I try to be understanding and patient towards those aspects of my personality I don't like. | |
| 3 | When something painful happens I try to take a balanced view of the situation. | |
| 4 | When I'm feeling down, I tend to feel like most other people are probably happier than I am. | |
| 5 | I try to see my failings as part of the human condition. | |
| 6 | When I'm going through a very hard time, I give myself the caring and tenderness I need. | |
| 7 | When something upsets me I try to keep my emotions in balance. | |
| 8 | When I fail at something that's important to me, I tend to feel alone in my failure | |
| 9 | When I'm feeling down I tend to obsess and fixate on everything that's wrong. | |
| 10 | When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people. | |
| 11 | I'm disapproving and judgmental about my own flaws and inadequacies. | |
| 12 | I'm intolerant and impatient towards those aspects of my personality I don't like. | |

**Appendix G** – Questionnaire Pack

**Difficulties with Emotion Regulation Scale -16 (DERS-16)**

Please indicate how often the following statements apply to you by marking an **X** after each item

| | **Almost never** (0-10% of the time) | **Sometimes** (11-35% of the time) | **About half the time** (36-65% of the time) | **Most of the time** (66-90% of the time) | **Almost always** (91-100% of the time) |
|---|---|---|---|---|---|
| I have difficulty making sense out of my feelings | | | | | |
| I am confused about how I feel | | | | | |
| When I am upset, I have difficulty getting work done | | | | | |
| When I am upset, I become out of control | | | | | |
| When I am upset, I believe that I will remain that way for a long time | | | | | |
| When I am upset, I believe that I'll end up feeling very depressed | | | | | |
| When I am upset, I have difficulty focussing on other things | | | | | |
| When I am upset, I feel out of control | | | | | |
| When I am upset, I feel ashamed of myself for feeling that way | | | | | |
| When I am upset, I feel like I am weak | | | | | |
| When I am upset, I have difficulty controlling my behaviours | | | | | |
| When I am upset, I believe there is nothing I can do to make myself feel better | | | | | |
| When I am upset, I become irritated with myself for feeling that way | | | | | |
| When I am upset, I start to feel very bad about myself | | | | | |
| When I am upset, I have difficulty thinking about anything else | | | | | |
| When I am upset, my emotions feel overwhelming | | | | | |

**Appendix H** – Randomisation Allocations

| | |
|---|---|
| **P01** | B - Waitlist |
| **P02** | A – Treatment |
| **P03** | A – Treatment |
| **P04** | B – Waitlist |
| **P05** | A – Treatment |
| **P06** | A – Treatment |
| **P07** | B – Waitlist |
| **P08** | B – Waitlist |
| **P09** | A – Treatment |
| **P10** | A – Treatment |
| **P11** | B - Waitlist |
| **P12** | A – Treatment |
| **P13** | A – Treatment |
| **P14** | B – Waitlist |
| **P15** | B – Waitlist |
| **P16** | B – Waitlist |
| **P17** | B – Waitlist |
| **P18** | A – Treatment |
| **P19** | A – Treatment |
| **P20** | A – Treatment |
| **P21** | A – Treatment |
| **P22** | B – Waitlist |
| **P23** | A – Treatment |
| **P24** | A – Treatment |
| **P25** | B – Waitlist |
| **P26** | B – Waitlist |
| **P27** | B – Waitlist |
| **P28** | A – Treatment |
| **P29** | B – Waitlist |
| **P30** | B - Waitlist |