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Do Psychosocial Interventions for Psychotic Disorders Improve Quality of Life in Adults with Psychotic Disorders in Forensic Settings?

-A Systematic Review and Narrative Synthesis

and

Modified Metacognitive Training for Negative Symptoms in Psychosis

- A Feasibility Study

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Thesis abstract

This thesis focuses on psychosocial interventions for psychosis. It consists of two parts: a systematic review on quality of life in forensic settings and an empirical study on negative symptoms. The systematic review follows the publication guidelines of the journal *International Journal of Forensic Mental Health* whilst the empirical study follows the publication guidelines of the journal *Clinical Psychology and Psychotherapy*. Reasonable adjustments have been made to the formatting of this thesis to enhance readability.

Purpose: The systematic literature review aimed to summarise and critically appraise studies that have evaluated the effects of psychosocial interventions for psychotic disorders in forensic settings on quality of life. The empirical study aimed to evaluate the feasibility of Metacognitive Training (MCT) for negative symptoms and to identify mechanisms of change.

Methods: The literature was systematically searched (using four databases) for research that included any quantitative measure of quality of life (i.e. self-esteem, quality of life, life satisfaction, and/or self-efficacy in relation to life-goals). In the empirical study, a new intervention was developed by modifying MCT for negative symptoms and four aspects of feasibility were evaluated: acceptability, practicality, demand and limited efficacy. The quantitative approach was supplemented with qualitative interviews on participants' views of the intervention. In addition, potential mechanisms of change were evaluated using a promising new method for analysing data from case-series: multilevel modeling.

Results: In total, 10 papers met the inclusion criteria in the systematic review. Significant improvements in quality of life were found in five studies. The modified version of MCT showed good feasibility as demonstrated by the attendance rate, the positive oral feedback from participants and the multidisciplinary team, and the improvements on negative symptoms that were found following the intervention. Multilevel modeling proved useful in explaining the variance attributable to three different predictors: depression, internalised stigma, and reflective functioning.

Conclusions: It was found that quality of life can be improved in forensic settings using psychosocial interventions. The pilot study indicated that MCT for negative symptoms has high feasibility and that changes in negative symptoms can partially be explained by depression, stigma, and reflective functioning.

Lay summary

Systematic Review

Introduction: Interventions for patients with psychosis in forensic settings tend to focus on symptom reduction and the risk of re-offending. However, it can be argued that this focus on deficits fails to take into account the value of developing and enhancing the individual's existing skills. During the last 20 years, an interest in individual potential and resilience has developed within research on mental wellbeing.

Aims: This systematic review aimed to systematically summarise the literature and critically appraise studies that have evaluated psychosocial interventions for psychotic disorders in forensic settings that included any quantitative measure of quality of life (i.e. self-esteem, quality of life, life satisfaction, and/or self-efficacy in relation to life-goals).

Main findings: Overall, five of the ten identified studies found significant improvements in quality of life following the intervention.

Conclusions: It was found that quality of life can be improved in forensic settings using psychosocial interventions. Though the results were encouraging, further research on quality of life for the forensic population is needed.

Empirical study

Introduction: The second part of this thesis is an empirical study focusing on negative symptoms. Negative symptoms typically include: emotional flattening; poverty of speech; loss of interest and motivation; inability to feel pleasure in normally pleasurable activities; and social withdrawal. Negative symptoms may develop as a coping strategy, where the shutting down of psychological systems allows the individual to cope with overwhelming situations. Disengagement might then be maintained by certain dysfunctional beliefs (e.g. low expectations of pleasure, success or acceptance) that can arise as a consequence of stigma. As depression typically co-exists with negative symptoms, it has been hypothesised that depression might by more than a co-morbid condition. In addition, it has been suggested that negative symptoms might be related to metacognitive functioning (i.e. the ability to think about oneself and others in a complex way).

Aims: Metacognitive training (MCT) is an intervention that aims to improve insight into cognitive processes. As the intervention is designed for positive symptoms in schizophrenia, the main author of this study created a modified version to address negative symptoms. The purpose of this study is to evaluate four aspects of the feasibility of the modified version of MCT for negative symptoms: acceptability, practicality, demand and limited efficacy. It also aims to investigate whether internalised stigma, depression, and metacognitive functioning have an impact on changes in negative symptoms.

Main findings: The modified version of MCT showed good feasibility as demonstrated by the attendance rate, the positive oral feedback from participants and the multidisciplinary team, and the improvements on negative symptoms that were found following the intervention. It was also found that stigma explained more of the improvement on negative symptoms than depression whilst metacognitive functioning explained more than both depression and stigma.

Conclusions: The empirical study suggests that MCT can be used for targeting negative symptoms and that the intervention has good overall feasibility. The promising results in terms of outcomes suggest the intervention should be systematically assessed in future research with a larger sample, a control group, and an independent research group.

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Do Psychosocial Interventions for Psychotic Disorders Improve Quality of Life in Adults with Psychotic Disorders in Forensic Settings?

-A Systematic Review and Narrative Synthesis

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Abstract

Quality of Life (QoL) in forensic services is an important topic given the emphasis on recovery in mental health. The aim of this review is to systematically review the literature and critically appraise studies that evaluated psychosocial interventions for psychotic disorders in forensic settings that included quantitative measures of QoL. Overall, five of the ten identified studies found significant improvements in QoL following the intervention. Whilst these findings were encouraging, the heterogeneity and the quality of the included studies prevented any firm conclusions. Further research on QoL for the forensic population is needed.

Keywords: forensic, quality of life, intervention

1. Introduction

1.1. Psychosocial interventions in forensic settings

As pointed out in the literature, "*Practitioners tasked with the rehabilitation of forensic mental health patients commonly face formidable challenges*" (Barnao & Ward, 2015, p. 77). This patient group, referred to as mentally disordered offenders (MDOs), typically presents with complex and chronic mental health difficulties (Palijan, Radeljak, Kovac, & Kovacevic, 2010), cognitive deficits (Fioravanti, Bianchi, & Cinti, 2012), and severe trauma (often involving maltreatment during childhood) (Spitzer, Chevalier, Gillner, Freyberger, & Barnow, 2006) in addition to having committed serious offenses which tend to be of a violent or sexual nature (Rutherford & Duggan, 2008). They tend to come from psychosocially deprived backgrounds which have often involved being in care or having multiple changes of caregivers, and have a history of substance abuse, poor education, unemployment and contact with psychiatric and criminal justice services (Völlm et al., 2017). This means that these individuals have a plethora of treatment needs relating to their mental health difficulties as well as their offending behavior (The Forensic Network, 2012).

In addition to the challenges posed by the patient group itself, the practitioner is faced with a lack of evidence-based interventions and theoretical rehabilitation models applicable to this patient group (Blackburn, 2004; Duncan, Nicol, Ager, and Dalgleish, 2006; Robertson, Barnao, & Ward, 2011; Barnao & Ward, 2015; Völlm et al., 2017). Though there has been increase in research on interventions developed for

the forensic services and on how interventions developed for the non-forensic population generalise to this patient group, it is not yet possible to reach any conclusions due to the fact that the majority of these studies have been small scale and of varying quality (Duncan et al., 2006).

The lack of a coherent treatment model could be explained by the fact that the forensic services have their roots in two different systems: the mental health services and the criminal justice system; these approaches have different emphases as the psychopathology paradigm focuses on the treatment of mental illness whilst the risk paradigm focuses on assessing and managing the risk of re-offending (Robertson et al., 2011). To target the treatment needs required by both these paradigms, blended treatment programs addressing both mental health difficulties and crimogenic needs are typically implemented (Vandevelde et al., 2017). However, this "hybrid" treatment approach could be problematic as these systems can have contrasting priorities and ethical values as practitioners working within mental health typically value individual wellbeing and autonomy whilst practitioners working within correctional services would typically value justice and public protection. In the absence of guidance on what issues should be targeted or what focus should be prioritised, the inconsistent care approach might mean that practitioners emphasizing mental health needs in their clinical practice may be criticized for neglecting criminogenic needs (e.g. Maden, Williams, Stephen,Wong, & Leis, 2004) whilst practitioners focusing mainly on risk management might be blamed for failing to fulfill the central role in forensic mental health services: to provide both care and treatment (e.g. Lindqvist & Skipworth, 2000) (Barnao & Ward, 2015).

1.2. Recovery and Quality of Life in forensic mental health

However, it can be argued that this focus on deficits and problems fails to take into account the value of developing and enhancing the individual's existing skills. During the last 20 years, an interest in individual potential and resilience has developed within research on mental wellbeing. This is reflected in the recovery model of mental illness, which proposes that mental health services should aim to increase an individual's potential for growth despite residual symptoms (Ferguson, Conway, Endersby, & MacLeod, 2009). One of the most cited definitions describes recovery as "*a deeply personal, unique process of changing one's attitudes, values, feelings, goals, skills and/or roles. It is a way of living a satisfying, hopeful, and contributing life, even with limitations caused by illness. Recovery involves the development of new meaning and purpose in one's life as one grows beyond the catastrophic effects of mental illness*" (Anthony, 1993, p. 527). Due to a growing consumer-led movement, the traditionally pessimistic view of schizophrenia in terms of prognosis and quality of life has been challenged; the alternative conceptualisation of the condition has been supported scientifically as long-term studies have found that as high as 50 per cent of individuals with schizophrenia have good outcomes (Bellack, 2006).

This more holistic approach in terms of mental health and recovery has created a focus on Quality of Life (QoL) (Connell, O'Cathain, & Brazier, 2014). Though this is a difficult construct to define, it is typically described "as individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns" (World

Health Organisation (WHO), 1995, p. 1405). A less formal definition of QoL has been suggested by Lehman (1996): "…patients' perspectives on what they have, how they are doing, and how they feel about their life circumstances. At a minimum, QoL covers persons' sense of well-being…" (Lehman, 1996, p. 78). Though there is no overall definition of what QoL should include, it is widely agreed within the field that QoL should cover the individual's evaluation of their life in terms of their: physical state; their psychological functioning (i.e. cognitive and affective state); and their social life (i.e. interpersonal relationships and social roles) (Basu, 2004). This conceptualisation of QoL seems to be reflected in terms of outcome measures, a review (Van Nieuwenhuizen et al., 2011) found that the most commonly assessed domains when measuring QoL for people with severe mental illness included health, employment or work, leisure, living situation, and relationships. The conceptualisation mentioned above also maps neatly onto what service users have identified as the most important aspects of QoL and recovery for them (i.e. well-being and ill-being; relationships and a sense of belonging; activity; self-perception; autonomy, hope and hopelessness; and physical health) (Connell et al., 2014). Though there is a general consensus that QoL should be based on the patients' perspective of their overall life, some researchers have argued that subjective evaluations may be compromised by other factors (e.g. medication, cognition, emotional functioning, and motivation for life improvement) (Basu, 2004).

Though a focus on recovery has also been applied in forensic services, the process is more complex as it must also include recovery in terms of offending (Barnao & Ward, 2015). Despite this, QoL might have an important role to play in forensic

mental health services through its close links with both criminal behavior and psychological functioning; indeed, it is possible that a strength-based approach might reconcile the two existing paradigms in forensic services by transcending the focus on problems and limitations. As proposed in the General Strain Theory (Agnew, 1992), crime might be understood as a consequence of how individuals who lack skills and resources are coping with conditions involving goal blockage, loss of positive stimuli, and/or the presentation of negative stimuli. The theory is similar to the concept of "Good Lives Model" (Ward, 2002), which proposes that maladaptive behaviour (including offending) diminishes when the person's underlying needs ("primary goods") are met (Bouman, Schene, & de Ruiter, 2009). These suggestions are supported empirically by research showing that certain objective indicators of QoL (e.g. adequate financial management, church attendance and work) as well as indicators of subjective QoL reduce re-offending (Bouman, de Ruiter, & Schene, 2010). Improved QoL has also been found to predict reductions in recidivism whilst a meaningful life was found to be negatively related to recidivism in a sample of forensic psychiatric outpatients (Bouman et al., 2009). In addition, unfulfilled primary goods have been found to be associated with unfavorable outcomes including mental health difficulties and offending (Barendregt, 2015). This illustrates the importance of targeting QoL in interventions for individuals in forensic services.

2. Aims of the review

This systematic review will focus on the efficacy of psychological interventions on QoL among mentally disordered offenders with psychotic disorders. The focus is

important from a scientific point of view as previous reviews have shown that there is a lack of evidence-based research (Laithwaite, 2010; Tapp, Perkins, Warren, Fife-Schaw, & Moore, 2013; Slater & Townend, 2016) and clinical guidelines (National Health Service (NHS) Education for Scotland (NES), 2015); The Forensic Network, 2012) for this patient group; this means psychosocial interventions for this patient group are routinely offered in forensic mental health settings despite the fact that little is known about necessary adaptations to this context or the treatment effects (Laithwaite et al., 2009). This is worrying considering that the majority (70%) of patients in secure forensic settings suffer from psychosis (Walker et al., 2013). Further research is also needed from a clinical point of view as NICE has recommended that psychological therapies should be offered in conjunction with medication to support recovery from psychosis (Attard & Larkin, 2016). This is important as a significant proportion of individuals with psychosis have a poor response to antipsychotic medication (Aust & Bradshaw, et al., 2017) and as outcomes are shown to improve when medication is combined with psychosocial interventions (Guo et al., 2010). As discussed above, a focus on QoL would, in addition to the value this would have for the individual, be of value for public protection due to its potential to reduce criminal behaviour. It is therefore hoped that a systematic review of the current literature will add to our current understanding of QoL among mentally disordered offenders with psychotic disorders to inform current practice and future research.

Extensive reviews of the literature found two systematic reviews of relevance to this systematic review: Ross, Quayle, Newman, & Tansey (2013) and Geddes (2015).

Ross et al. (2013) found that 8 of the 10 studies that were included in their review on psychosocial interventions for violent behaviour in forensic and clinical settings led to reduced physical aggression. In a review by Geddes (2015) that focused on the efficacy of psychosocial interventions on psychotic symptoms, it was found that four of the included eight studies led to significant improvements in psychotic symptoms. However, as pointed out by both Ross et al. (2013) and Geddes (2015), the findings were limited by the heterogeneous nature of the included studies which made it difficult to identify differences between interventions and specific populations that would be likely to benefit from these. Both the studies were of importance as they had a similar design due to the review question and participant population. This review will therefore expand on these previous reviews to address gaps in the evidence base by focusing on the impact of psychosocial interventions on QoL for individuals diagnosed with a psychotic disorder in forensic settings.

3. Method

The Population, Intervention, Comparison and Outcome (PICO) (Booth & Fry-Smith, 2003) parameters were used to formulate the research question and to facilitate the search strategy (Tapp et al., 2013). The acronym was modified to PICOCS to reflect the importance of the Context and to describe the rationale for the Study design as suggested in the Centre for Research and Dissertation's (CRD) guidelines for undertaking reviews in health care (University of York, 2008).

3.1. Population

Studies focusing on a forensic adult (over 16 years old) population with a psychotic

disorder (as defined by a stated diagnosis of schizophrenia, schizoaffective disorder, delusional disorder, bipolar affective disorder, psychotic depression or atypical psychosis) were included. Forensic patients were defined as in the Forensic Matrix: "*forensic patients are considered to include adults who are subject to compulsory measures under mental health legislation and who present a significant risk to others, such that they require care under conditions of security and/or specialist 'forensic' expertise in their management"* (The Forensic Network, 2012, p. 2).

3.2. Interventions

Studies were included if they used any form of psychological intervention that focused on improving mental wellbeing.

3.3. Comparison

All types of controlled trials and cohort studies were included. Case series (both with small numbers and single cases) were excluded due to the likelihood of bias due to limited participant numbers and issues around generalising results.

3.4. Outcome measures

Included studies had to apply psychometric self-rated outcome measures that reported on aspects of QoL. The current systematic review included studies that assessed either internal or external domains of QoL (either as a primary or a secondary outcome measure); this included self-esteem, quality of life, life satisfaction, and/or self-efficacy in relation to life-goals. Self-esteem was defined as

an individual's overall evaluation of the self (Smith & Mackie, 2007). Quality of life was conceptualised as an individual's perception of their position in life in relation to their goals and standards (WHO, 1995) whilst self-efficacy was defined as an individual's confidence in one's ability to achieve their goals (Ormrod, 2006).

3.5. Context

Studies focusing on any type of forensic setting (i.e. both in-patient hospitals and community services) were included.

3.6. Study design

A narrative synthesis was chosen rather than a meta-analysis due to the heterogeneous nature of the included studies. Interventions were grouped according to research design and outcome measures.

4. Literature search strategy

4.1. Keywords

A systematic review of peer-reviewed published literature was conducted between August and September 2017. The following online databases were included: PsycINFO (1806-present); Ovid Medline (including Ahead of Print; In-Process & Other Non-Indexed Citations and Daily) (1946-present); Embase (1974-present); and Web of Science (1900-present). In order to generate search terms, the author of this review discussed key terms from related reviews with the second and third authors of this review and used the thesaurus and 'map terms' functions within databases

drawing on the university librarian to modify and/or expand on these. The final search terms were schizophrenia OR schizophren* OR psychotic OR psychosis OR schizoaffective AND cognitive OR psychosocial OR psychological AND forensic OR security OR secure OR offender.

4.2. Results and Prisma

The search resulted in 2582 articles, which after removal of duplicates became 1984 articles (see Figure 1). A further 1819 were excluded after reading the title and/or abstract. After reading 165 full-text articles, 45 studies were assessed for eligibility and 5 were classified as relevant. A further five articles were identified as they were referred to in the full-text articles. Of the 50 relevant articles, 10 were intervention studies that included quantitative measures on QoL and were hence included (see Appendix A for a table of excluded studies reasons for exclusion).

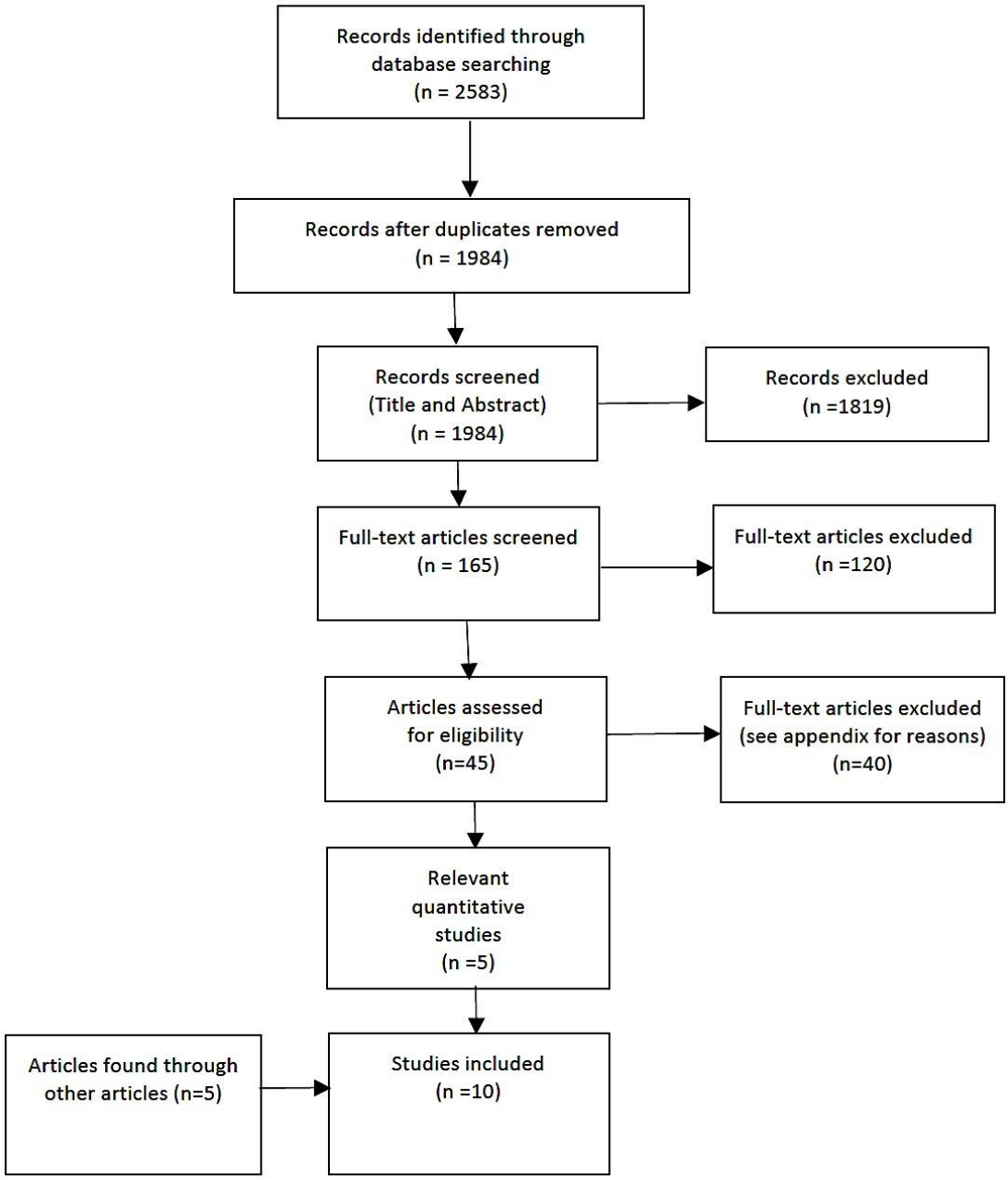

Figure 1. Literature Search Strategy Flowchart.

5. Assessment of quality of included studies

The quality criteria used in the studies by Ross et al. (2013) and Geddes (2015) was used to assess the quality criteria of the included articles as they were developed for a similar design and were hence considered more appropriate than generic guidelines (e.g. National Institute for Health and Care Excellence (NICE), 2013). The criteria were based on CRD's guidelines (University of York, 2008) which are accepted internationally for conducting systematic reviews in healthcare settings; these propose that the following aspects should be evaluated: study design; bias; study quality; outcome measures; statistical analysis; quality of reporting; quality of intervention; and generalisability.

Twelve quality criteria were used to assess the papers, with the outcomes scored as: well covered (3); adequately addressed (2); poorly addressed (1); or not addressed, reported, or applicable (0) (see Appendix B for full criteria). A strength of this approach is that it was used in previous research and developed for this specific type of research and population, whilst a limitation of the quality criteria was that equal weights were assigned to all aspects and that it treated all types of studies (i.e. RCT and cohort studies) equally. A second rater (E.E.) assessed 5 articles (50% of the sample) to measure inter-rater reliability; a Kappa co-efficient for overall agreement of 0.75 was found which indicates adequate inter-rate agreement (Randolph, 2008). Differences between markers were discussed and amended when appropriate. As the quality criteria were applied to four of the ten included studies in a previous review (Geddes, 2015), these articles were rated and then compared against the previous ratings. No differences between the ratings were found.

6. Results

6.1. Characteristics of included studies

The included studies are summarised in Table 1. Two were randomised controlled (RCT) studies (Aho-Mustonen et al., 2011; Walker et al., 2013) whilst eight were cohort (pre-post) designs (Ferguson et al., 2009; Jennings et al. 2002; Laithwaite et al., 2007; Laithwaite et al., 2009; Livingston, Nijdam-Jones, Lapsley, Calderwood, & Brink, 2013; Long, Banyard, & Dolley, 2016; McInnis, Sellwood, Jones, 2006; Vallentine, Tapp, Dudley, Wilson, & Moore, 2010). Most studies focused on male participants (N= 9) in high security settings (N=6) in England (N=5) or Scotland (N=3) with other studies taking place in Finland (N=1) and Canada (N=1). The most commonly measured construct in the studies was self-esteem (N=7), where the majority of these studies used the Rosenberg Self-esteem Scale (RSE) (Rosenberg, 1965) (N=4). Other measurements included quality of life (N=2); self-efficacy (N=2); and satisfaction with life (N=1). All interventions were delivered in a group format and based on Cognitive Behaviour Therapy (CBT) principles.

6.2. Summary of results- the impact of psychosocial intervention on increasing Quality of Life

The results are divided into sections depending on the outcome measures used: the most commonly used measure of self-esteem, RSE, or other measures.

6.2.1. Studies using Rosenberg Self-esteem Scale (RSE) (Rosenberg, 1965)

In a RCT by Aho-Mustonen et al. (2011), psychoeducation was compared to

treatment as usual (TAU) at a psychiatric hospital for forensic, difficult-to-treat and/or dangerous patients with mental disorders in Finland. The study found that the intervention led to significant improvements on self-esteem (as measured with RSE) when compared to the TAU group when administered to forensic patients post intervention (p= .03); however this effect was not maintained at follow-up three months later (p= .06). Interestingly, significant (no p-values reported) improvements on quality of life (as measured with Sintonen's (2001) 15D instrument) were found for the control group at follow-up when comparing this to the control group's baseline but not when comparing the different groups at post intervention (p= .50) or follow-up (p= 0.09) ; the authors of the articles suggested that the control group's improvements might be due to the control group receiving more attention than usual but without the potentially negative effect of increased insight on quality of life that might have taken place as a consequence of the intervention. This study was the study with highest quality of the included studies due to being a well-designed RCT. It was also the intervention that led to the largest effect size as a medium to large effect size (Cohen's d= .71) was found on RSE. The study's main limitation was that no power calculation had been reported. Also, the intervention was only described to a limited extent meaning the study did not contain enough information to be replicated. As the intervention was based on Ascher-Svanum & Krause's *Psychoeducational Groups for Patients with Schizophrenia* from 1991, it is possible that the psychoeducation would have benefited from being updated considering the improved understanding of the condition that has been established since then (e.g. in relation to causes and outcomes).

In a study by Jennings et al. 2002, the effect of a psycho-educational programme in a high security setting was evaluated. The study found that self-esteem did not improve following the intervention as the mean on RSE prior to the intervention was 23.57 compared to 23.28 following the intervention. Although this increased to 27.43 at the six-month follow-up, it was found that the intervention did not lead to any significant improvements post intervention (Cohen's *d*=.12) (no p-values reported). It was hypothesised that RSE might be a rather crude measure which may not have been sensitive enough to detect minor changes. This does not seem to be supported as other studies (e.g. Aho-Mustonen et al. 2011) included in the review found differences on this measurement.

Laithwaite et al. (2007) applied an intervention (previously evaluated in a non-forensic population) developed to improve self-esteem to offenders in a high-security setting in Scotland. Significant improvements were found on the RSE (p <.05) and the Self-image Profile for Adults (SIP-AD) (Butler & Gasson, 2004) (p <.01) following the intervention which was still significant at follow-up three months later for RSE (p <.05) but not on the SIP-AD. No differences were found on the third measure (The Robson Self-Concept Questionnaire (RSCQ) (Robson, 1989)) (p = .20). The authors thought that the lack of effect on the RSCQ might be due to the RSCQ tapping into particular aspects of self-esteem that were not targeted by the programme or due to the measure not being validated for a forensic population. As each session lasted for 2 hours 30 minutes, it is remarkable that subjects (N=15) were able to complete all 10 sessions.

In a subsequent study by Laithwaite et al., (2009) on the same study population, a compassionate mind training (CMT) group intervention was evaluated. It was argued that CMT was needed as many patients taking part in the self-esteem programme described above were able to challenge their self-critical thinking style on an intellectual level but continued to feel worthless; this suggests that processes in relation to self-compassion and self-soothing might need to be addressed to create a positive self-image on an affective level. It was found that the intervention led to significant changes on the RSE when comparing baseline and follow-up (p >.01) but not post intervention (no p-values reported) but that no changes were found on the SIP-AD (p = .566) or the RSCQ (p =.603); the reasons for the differences between the self-esteem measures were not discussed but might be the same as in the previous study (i.e. outcomes tapping into different constructs of self-esteem). The quality of the study was high as most essential parts (with the exception of power) were addressed. However, the CMT did not have a strong effect on self-esteem as effect sizes were found to be .14 (Cohen's d) on RSE which is below the threshold for a small effect.

6.2.2. Alternative measures

Ferguson et al. (2009) piloted an intervention aimed at increasing QoL among other variables by developing goal setting and planning skills in forensic settings in the London area; the intervention has been applied before to individuals with affective disorders in a non-forensic setting with promising results (MacLeod, Coates, & Hetherton, 2008). In the current study, significant improvements (p <.05) were found on satisfaction with life (as measured with the Satisfaction with Life Scale (SWLS)

(Diener, Emmons, Larsen & Griffen, 1985) at follow-up but not post intervention (p-values not reported). Though it was stated that the format of the intervention was tailored to the population (e.g. more sessions, simplified language), the study could have been improved by considering how the content of the intervention could have been adapted for the forensic population (e.g. whether the process of establishing goals was affected by the constraints posed by being cared for in a forensic setting). This was the only study where a researcher would meet with the participant to cover session material on occasions they were unable to attend a session; this was a strength of this research.

Livingston et al. (2013) conducted a naturalistic longitudinal study in Canada that looked at the effect of an intervention (that included a peer support programme, a patient advisory committee, and a patient research team) on, among other measurements, empowerment (which included self-esteem and self-efficacy) as measured by the Making Decisions Empowerment Scale (MDES) (Rogers, Chamberlin, Ellison, & Crean, 1997). It was found, when evaluated after nine months, that taking part in the overall intervention did not led to significant differences ($p > .05$) which was suggested to be due the fact that the study did not have enough power for detecting small to medium effects. A particular strength of the study was the inclusion of a power calculation, a qualitative approach being added to the quantitative measures which included patients' view of the service development, and the observations of staffs' reluctance to engage with a recovery-oriented care approach. The unusual design makes it difficult to compare it to the

other studies in terms of quality as the study was a process evaluation rather than a theoretically driven intervention.

In one of the few studies evaluating interventions for female offenders with psychotic disorders, Long et al. (2016) administered a psychoeducation programme (the Living with Mental Illness Programme) that was specifically tailored for female offenders at a Women's Service at a secure psychiatric hospital in England. The intervention was found to lead to significant improvements (p <.01) on a self-efficacy measurement (Generalized self-efficacy (GSES)) (Jerusalem & Schwarzer, 1992) for completers but not for non-completers following the intervention. Due to its focus on female offenders, this study differed from the other included studies by addressing an obvious gap in the literature which represents a strength. A significant limitation is the lack of power calculation, baseline data for this specific measure, and follow-up.

In a study by McInnis et al. (2006), it was found that a group based educational programme did not lead to any improvements (no p-values reported) on self-esteem (as measured by the Culture Free Self Esteem Inventory 2nd edition (CFSE-II) (Battle, 1992)) in a sample of male offenders. This might be explained by the fact that the measure contained a subscale relating to social self-esteem (i.e. perception of quality of relationship with peers) which is likely to be affected by being cared for in a forensic setting where the patient has not chosen his or her social network. In similarity to many of the other included studies, the study lacked means and standard deviations, power calculations, and a sufficient description of the intervention. A

strength of the intervention was how the multidisciplinary team and other contributors contributed to sessions (e.g. drama therapist in a session on assertiveness, voluntary organisation providing community work placements in a session on negative symptoms).

Finally, in a study by Vallentine (2010), psychoeducation was provided to 31 mentally disordered offenders in a high security hospital in London where indices of clinical and reliable significant change were calculated in addition to aggregated means analysis (t-tests). Self-esteem was measured with RSCQ; this was found to result in a clinical change for two subjects and a reliable change for five subjects. The alternative analysis applied in the study adds to the interpretation of the data as no significant changes were found (*p*-values not reported) when applying paired sample t-tests to pre and post intervention scores on the RSCQ. A limitation is that no information except the title of the intervention was included. As no significant change was found on the RSCQ in similarity to Laithwaite et al. (2007) and Laithwaite et al. (2009), it is possible that this measurement might not be sensitive enough for measuring changes in self-esteem over time in a forensic population.

Walker et al.'s (2013) study compared psychoeducation to TAU in a RCT across four sites of various levels of security in Scotland. In contrast to the study by Aho-Mustonen et al. (2011), this study evaluated a psychoeducational programme (Coping with Mental Illness) that was explicitly created for psychosis in a forensic setting, making it more relevant for the patient group. It was found that the intervention did not lead to significant improvements on quality of life (as measured

by the Schizophrenia Quality of Life Scale Revision 4 (SQLS-R4) (Martin & Allan, 2007) post intervention (p = .47). However, as it was found though that the measure was significantly affected by level of intelligence (as measured by the Wechsler Abbreviated Scale of Intelligence (WASI) (Wechsler, 1991)), the validity and the reliability of the measure are questioned (Nishiyama & Ozaki, 2010). The most significant limitation of the study was that it was underpowered due to issues of random allocation (i.e. all subjects had been allocated to the treatment group on instructions from the line management). It could also be suggested that the patient group was rather heterogeneous considering that they were recruited from one high security, two medium security and one low security setting and included patients with schizophrenia, schizotypal, delusional disorders, and mood disorders as well as mental and behavioural disorders due to substance abuse. As no baseline data was reported, it was not possible to calculate effect sizes. In addition, the study would have been of higher quality if the validity and reliability of the outcome measures had been reported.

6.3. Summary across all studies

There were 271 participants in total across all the studies. Of the ten included studies, half of these (Aho-Mustonen et al., 2011; Ferguson et al., 2009; Laithwaite et al., 2007; Laithwaite et al., 2009; Long et al., 2016) found that psychosocial interventions lead to significant improvements on QoL either post intervention or at follow-up despite different designs, length of follow-up periods, and outcome measures whilst half did not find any significant differences (Jennings et al., 2002; Walker et al., 2013; Livingston et al., 2013; Vallentine et al., 2010).

The improvements were suggested to be due to participants developing rational (Laithwaite et al., 2007) or compassionate (Laithwaite et al., 2009) alternatives to self-critical thoughts which might lead to improvements in mood (Laithwaite et al., 2007). It was also proposed that QoL improved due to the development of goal mastery that allowed patients to work towards desired "primary goods" (e.g. intimacy, knowledge, mastery) in accordance with the Good Lives Model (Ferguson et al., 2009). A further potential explanation was that improvements were due to a sense of empowerment through subjects accessing knowledge about their illness (Vallentine et al., 2010; Long et al., 2016) or increased service involvement (Livingston et al., 2013). The effect sizes between pre and post intervention varied from non-existent (Jennings et al., 2002; Laithwaite et al., 2009; Livingston et al., 2013; Vallentine et al., 2010) to small (Ferguson et al., 2009) to medium (Aho-Mustonen et al., 2011; Laithwaite et al., 2007). As all findings were based on small sample sizes, it is difficult to generalise findings to the wider forensic population.

6.4. Quality of included studies

Table 2 provides quality ratings for each of the ten studies. It was found that the both the RCTs (Aho-Mustonen et al., 2011; Walker et al., 2013) were of highest quality which could be explained by the superiority of their design (e.g. inclusion of control group) which gave them high scores on variables (i.e. randomisation and concealment) that cohort studies would not have been given. The earliest study (Jennings et al., 2002) received the lowest quality ratings due to lack of statistical analysis. Overall, the most common quality issues were not reporting validity and

reliability of the measurements; not including power calculations; not using standard clinical guidelines for reporting; and not describing the intervention in enough detail.

Table 1. Summary of included studies.

Author, year, country	Number of participants	Gender	Design	Level of security	Interven-tion	Follow-up (Months)	Quantitative outcome measures	Main findings for quality of life, self-esteem, self-efficacy in relation to life goals, or life satisfaction	Effect size Cohen's *d,* pre vs post
Aho-Mustonen 2011 Finland	N= 39 (35 male, 4 female) Intervention: 19 TAU: 20	Mixed	RCT	High	Psycho-education	3	RSE-self-esteem Sintonen 15D – quality of life	Self-esteem was significantly improved compared to TAU post intervention (p= .03) which was not maintained at follow-up 3 months later (p= .06) whilst the intervention had no impact on quality of life post intervention (p= .50) or at follow-up (p= .09)	RSE: .71 S15D: -.14
Ferguson 2009 England	N=14 (male)	Male	Cohort (no control group)	Medium	Goal setting and planning (GAP) training	2	SWLS – satisfaction with life	Life satisfaction was significantly higher at follow-up 2 months later (p <.05) but not post intervention (p-values not reported)	SWLS: .33
Jennings 2002 England	N=7	Male	Cohort (no control group)	High	Psycho-education (Group format)	6	RSE- self-esteem	Self-esteem did not improve following the intervention as the mean on RSE prior to the intervention was 23.57 compared to 23.28 following the intervention. However, this increased to 27.43 at the six-month follow-up. No statistical analysis was applied	RSE: .12
Laithwaite 2007 Scotland	N=15 (male)	Male	Cohort (no control group)	High	Self-Esteem Progra-mme	3	RSE- self-esteem RSCQ-self-esteem SIP-AD-self-esteem	Significant improvements were found on RSE post intervention (p <.05) and at follow-up (p <.05) and on the SIP-AD post intervention (p <.01) but not at follow-up (p-value not reported). No effect over	RSE: .69 RSCQ: .51 SIP-AD: .39

Author, year, country	Number of participants	Gender	Design	Level of security	Interven-tion	Follow-up (Months)	Quantitative outcome measures	Main findings for quality of life, self-esteem, self-efficacy in relation to life goals, or life satisfaction	Effect size Cohen's *d*, pre vs post
								time were found on the RSCQ (p = .2)	
Laithwaite 2009 Scotland	N=19 (male)	Male	Cohort (no control group)	High	Compassionate Mind Training (CMT)	1,5	RSE- self-esteem RSCQ-self-esteem SIP-AD-self-esteem	Significant improvements were not found at the RSE post intervention (p-value not reported) but were found at follow-up (p <.01). No significant effects were found at RSCQ (p = .603) or the SIP-AD (p = .566) over time	RSE: .14 RSCQ: .01 SIP-AD: .02
Livingston 2013 Canada	N=25 (20 male, 5 female)	Mixed	Cohort (no control group)	High	Recovery Intervention	n/a	MDES-self-esteem and self-efficacy	No significant differences were found between patients' scores on the MDES (p >.05) following the intervention	MDES: .20
Long 2016 England	N=20 (female)	Female	Cohort with non-completers used as control	Medium	Psychoeducation (Living with Mental Illness)	n/a	GSES- self-efficacy	A significant increase at the GSES was found for completers compared to non-completers (p <.01) following the intervention	n/a as baseline data is missing
McInnis 2006 England	N= 9 (7 male, 2 female)	Mixed	Cohort (no control group)	Low	Psychoeducation (Recovery themed)	n/a	CFSE-II-self-esteem	No significant differences post intervention on self-esteem (p-values not reported)	n/a as missing means and SD
Vallentine 2010	N=42 (male)	Male	Cohort (no	High	Psychoeducation	n/a	SCQ- self-esteem	No significant differences were found pre and post intervention on	SCQ: .15

Author, year, country	Number of participants	Gender	Design	Level of security	Interven-tion	Follow-up (Months)	Quantitative outcome measures	Main findings for quality of life, self-esteem, self-efficacy in relation to life goals, or life satisfaction	Effect size Cohen's *d*, pre vs post
England			control group)		(Understanding Mental Illness)			SCQ (*p*-values not reported)	
Walker 2013 Scotland	N= 81 (79 male, 2 female) Intervention: 46 TAU: 35	Mixed	RCT	Medium and low	Psychoeducation (Coping With Mental Illness)	6	SQLS-R4- quality of life	No significant (p = .47) differences between TAU and intervention were found on quality of life as measured by the SQLS-R4 (follow-up data between groups not reported)	n/a as missing baseline data

Measures: RSE: Rosenberg Self-esteem; SWLS- Satisfaction with Life Scale; RSCQ- The Robson Self-Concept Questionnaire; SIP-AD The Self-Image Profile for Adults; MDES- Making Decisions Empowerment Scale; GSES- Generalized Self-efficacy; CFSE-II -Culture Free Self Esteem Inventory (2nd edition); CORE-OM- Clinical Outcomes in Routine Evaluation – Outcome Measure; SCQ- The Self-Concept Questionnaire; SQLS-R4- The Schizophrenia Quality of Life Scale Revision 4

Table 2. Quality ratings of studies included in the review.

	Random-isation	Conc eal-ment	Attrit ion	Outcome Measures	Measure Relevance	Power	Analysis	Reporting Quality	Interventio n Definition	Fidelity	Routin e	Follow-up	Overall Score (/36)
Aho-Mustonen et al. 2011	AA	WC	WC	AA	WC	NA	WC	WC	WC	WC	WC	AA	30
Ferguson et al 2009	NA	NA	WC	AA	WC	WC	WC	AA	AA	AA	WC	AA	25
Jennings 2002	NA	NA	WC	PA	WC	NA	NA	PA	AA	AA	WC	WC	18
Laithwaite et al 2007	NA	NA	WC	PA	WC	NA	WC	AA	WC	AA	WC	AA	22
Laithwaite et al 2009	NA	NA	WC	PA	WC	NA	WC	AA	WC	WC	WC	WC	24
Livingston et al 2013	NA	NA	NA	WC	WC	WC	WC	AA	PA	AA	WC	NA	20
Long et al 2016	NA	NA	PA	WC	WC	WC	AA	WC	WC	AA	WC	NA	22
McInnis et al 2006	NA	NA	NA	WC	WC	NA	AA	AA	AA	AA	WC	AA	19
Vallentine et al 2010	NA	NA	PA	AA	WC	NA	AA	AA	AA	WC	WC	AA	20
Walker at al 2013	WC	AA	WC	PA	WC	NA	WC	WC	AA	PA	WC	WC	27

Well Covered (WC) (3); Adequately Addressed (AA) (2); Poorly Addressed (PA) (1); or Not Addressed/Applicable (NA) or Not Reported (NR)

7. Discussion

7.1. Overall findings

This systematic review aimed to synthesise and critically appraise the available evidence base on the effectiveness of psychosocial interventions on QoL in adults with psychotic disorders in forensic settings. Quality of Life in forensic services represents an under-researched but important research topic given the emphasis on recovery in mental health (Ferguson et al., 2009). Five of the ten included studies (i.e. Aho-Mustonen et al., 2011; Ferguson et al., 2009; Laithwaite et al., 2007; Laithwaite et al., 2009; Long et al., 2016) found that psychosocial interventions led to improvements on QoL either at post-intervention or at follow-up. Whilst these findings were encouraging, the heterogeneity and the quality of the included studies prevented any firm conclusions.

7.2. Discussion of findings

In the study (McInnis et al., 2006) that did not find any improvements, the lack of effect on self-esteem was suggested to be due to in-session material which encouraged patients to reflect on difficulties with previous community placements and to problem-solve future difficulties with community living; it was hypothesised that this might have led to doubts in relation to patients' perceptions of their ability. This is similar to the suggestions made by Jennings et al. (2002) as they hypothesised that the intervention's focus on increasing individuals' awareness of their ability to exert control over their behaviour might have led to a greater sense of

responsibility for their past offences and consequently more negative self-perceptions initially. Both these suggestions seem to suggest that improvements in insight might have a negative impact on self-esteem. Paradoxically, insight has been linked with both lower self-esteem and better functioning in previous research. These contradictory findings might be due to a third confounding variable: the degree which to which an individual internalises stigma in relation to mental illness. It has been found that persons with high insight who internalised stigma had lower self-esteem and hope than those with high insight who did not internalise stigma and those with low insight who did internalise stigma (Lysaker, Roe, & Yanos, 2006). The relationship between the variables is further supported by the fact that internalised stigma was found to moderate the relationship between insight and low self-esteem/quality of life (Staring, Van der Gaag, Van den Berge, Duivenvoorden & Mulder, 2009). It has therefore been recommended that psychosocial interventions in schizophrenia should incorporate information on stigma and quality of life issues. It was encouraging to find that this recommendation was followed by all the interventions discussed in this systematic review.

As most of the interventions focused on providing psychoeducation in relation to mental health (Aho-Mustonen et al., 2011; Jennings et al., 2002; Long et al., 2016; McInnis et al., 2006; Vallentine et al., 2010; Walker et al., 2013), the results indicate that this might be a effective approach to improve QoL in forensic settings despite, as suggested by Barnao & Ward (2015), its focus on deficits. Similar findings have also been found in non-forensic settings, where psychoeducational interventions have been found to lead to improvements on QoL (e.g. Knight, Wykes, & Hayward,

2006; McCoy et al., 2006; Fung, Tsang, & Cheung, 2007; Sauvanaud et al., 2017). This might be due to the participants feeling empowered by being trusted with this information and self-care tools by the practitioners, which might make participants feel that they are not just passive recipients of treatment (Walker et al., 2013). It could also be due to the psychoeducation limiting the degree of internalised stigma, which, as discussed above, should have a positive impact on QoL. Additionally, the improvements in QoL might be due to most psychoeducational programmes for mental health difficulties currently used in forensic settings (e.g. Road to Recovery) are applying a strength-based approach. This might suggest that a shift from focusing on deficits to strengths has already been observed in forensic services (Vandevelde et al., 2017) and that implementing new ways of working (e.g. Good Lives Model) might in fact not be needed. It is interesting that Scottish Intercollegiate Guidelines Network (SIGN) advise against offering psychoeducation as a stand-alone treatment for schizophrenia (SIGN, 2013). This might be due to the focus on symptoms and behavior rather than QoL when reviewing the existing evidence base.

As all of the studies were based on principles of CBT, the review suggests that there is evidence for the effectiveness of this on self-esteem, quality of life, life satisfaction, and/or self-efficacy in forensic settings. However, it is difficult to draw firm conclusions on effective mechanisms for change due to the different forms and treatment focuses of CBT used in the studies (i.e. psychoeducation; compassionate mind training; self-esteem programme; goal setting and planning training). Further research identifying mechanisms of change is therefore required. This should ideally also address other aspects of the provision of therapeutic interventions that differ

between the studies and which could have an impact on the outcome (e.g. dosage, group or individual, level of training of the providers, supervision arrangements).

7.3. Limitations of the findings and areas for future research

It is also important to acknowledge that there was heterogeneity between the studies in terms of patients as some studies included subjects who, in addition to a primary diagnosis of a psychotic illness, also had emotionally unstable personality disorders (Long et al., 2016; MacInnes et al., 2006) or anti-social personality disorders (Laithwaite et al., 2007; Laithwaite et al., 2009). This is important as the presence of a diagnosis of emotionally unstable personality disorder was linked with poor attendance in the study by McInnis et al. (2006); it was suggested this was due to difficulties with group interactions or including women with a history of sexual abuse in settings with mainly men. (It should be noted though that the participants struggled with attending a psychoeducational group in the study by Long et al. (2016) despite being delivered in a women's only service). Differences between studies were found on inclusion and exclusion criteria for psychotic disorders too as Aho-Mustonen et al. (2011) excluded patients with delusional disorders, which most other studies did not. The variations between study populations make it difficult to identify for whom psychosocial interventions would be most suitable for. Further research would therefore be needed to disentangle this.

In addition, it is difficult to generalise findings due to the different measures used to measure QoL. This might reflect a wider confusion in the literature in relation to QoL (Camfield & Skevinton, 2008). The most commonly used measurement in this

study was found to be the Rosenberg Self-esteem Scale. Though an acceptable level of internal consistency for the scale was established in the study by Aho-Mustonen et al. (2011), the factor structure of the scale has been questioned elsewhere (see Huang & Dong, 2012 for a review). As none of the tests were validated on a forensic population, it is possible that the conclusions found in the studies may be affected by unnecessary measurement bias. This is a shame as a validated measure of QoL for the forensic population has been developed: the Forensic inpatient Quality of Life questionnaire (FQL) (Vorstenbosch, Bouman, Braun, & Bulten, 2014). It is recommended that this, or another validated measure, is used in future research.

Finally, the findings are difficult to generalise as populations at different levels of security were used. Once a stronger evidence base for psychosocial interventions has been developed a further systematic review, or a meta-analysis would be recommendable to identify what interventions are most effective in high, medium, and low security settings. Further studies could have been included in this review if grey literature had been included as previously done in a systematic review by Slater & Townend (2016) where CBT for psychotic disorders in high security settings was evaluated in the peer-reviewed and fugitive literature. However, this review only focused on material that had been peer reviewed as the quality of the material in the grey literature cannot be guaranteed which would reduce confidence in any findings.

An important issue raised in the study by Livingston et al. (2013) was the observation that forensic staff was reluctant to engage with the recovery-oriented care approach. This highlights an important aspect of implementing interventions that promote power sharing in forensic services: it may be perceived as risky

(Livingston et al., 2013). It is possible that restrictive practices are preferred at the expense of recovery-promoting practices due to the anxiety professionals feel over the consequences of underestimating an individual's actual risk and in their duty of public protection (Mann, Matias, & Allen, 2014). There might also be a psychological element to the findings in the study by Livingston et al. (2013) as summarised by Mann et al. (2014), "*staff may find it difficult to share power with people guilty of violent crimes. Slade (2009a) highlighted the importance of an equal partnership in supporting a recovery focus, but staff may struggle to accept that they are equal to their patients, as this would mean they need to acknowledge there is nothing distinctly different between them and people who have committed serious crimes, thereby forcing them to face the 'evil' in all of us. It is far easier for staff to create a divide between themselves and those that commit such crimes*" (Mann et al., 2014, p. 128). The concept of recovery must therefore, in similarity to the mental health interventions promoting it, need to be modified to fit into forensic services. Further research on the empirical implementation of recovery in forensic services would therefore be essential.

Finally, it is also possible that the conceptualisation of QoL had an impact on the results of the review as only studies that included self-reported measures of self-esteem, quality of life, life satisfaction, and/or self-efficacy in relation to life-goals were included. Future literature reviews could extend on the current review by focusing on research that also includes objective measures of QoL as the validity of self-reported measures depend on the individual's ability to reflect on his or her situation. This might be important as some research has found that self-reported QoL

is compromised by cognitive difficulties in patients with serious mental illness (Nishiyama & Ozaki, 2010) but not all research (Baumstarck et al., 2013).

7.4. Strengths and limitations of this review

This review extends findings from previous reviews in this area (Ross et al., 2013; Geddes 2015) by focusing on QoL as an outcome of psychosocial interventions in forensic settings. As such, it adds to the evidence base for implementing interventions with alternative focuses to violence reduction and psychotic symptoms in forensic settings. This is important for incorporating a recovery-focused care approach into forensic services. The systematic and extensive search strategy in this review represents a strength. Subjective bias was accounted for when assessing the quality of the papers by involving a second marker, which produced a higher degree of inter-rater reliability. The most significant limitation is the heterogeneity of the included studies, which limits the conclusions that can be drawn and does not allow a meta-analysis.

7.5. Implications for further research

Further research should explore the impact of being a forensic patient on QoL as well as how to improve QoL in the forensic population and factors affecting the outcomes. In addition, it would be desirable to use validated measures of QoL in future research. It would also be useful to include measures of QoL into standard research as the majority (>80%) of the intervention studies initially found in this systematic review did not measure this important construct.

7.6. Implications for clinical practice

Despite previously mentioned limitations, the evidence found in this review supports the delivery of psychosocial interventions in forensic settings, as they are likely to increase QoL. To overcome the heterogeneity of the studies found in this review, further clinical research is needed.

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Modified Metacognitive Training for Negative Symptoms in Psychosis- A Feasibility Study

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Abstract

Metacognitive training (MCT) is an intervention designed for positive symptoms in schizophrenia that aims to improve insight into cognitive processes. The main author of this study created a modified version to address negative symptoms. The purpose of this study is to evaluate the feasibility of the modified version of MCT for negative symptoms. The quantitative approach was supplemented with qualitative interviews to incorporate participants' views of the intervention. In addition, potential mechanisms of change were evaluated using a promising new method for analysing case-series: multilevel modeling. The intervention showed good feasibility as demonstrated by the attendance rate, the positive feedback from participants and the multidisciplinary team, and the improvements on negative symptoms that were found following the intervention. Multilevel modeling showed that depression, internalised stigma, and reflective functioning all explained the variance in negative symptoms. The pilot study indicated that the intervention has high feasibility and that improvements in negative symptoms can partially be explained by improvements on depression, stigma, and reflective functioning.

Key messages for practitioners:

- Negative symptoms can be improved with interventions targeting depression, internalised stigma, and reflective functioning
- Metacognitive Training for Negative Symptoms may be an promising intervention to improve negative symptoms

Keywords: Negative Symptoms, Metacognitive Training, depression, stigma, mentalization

1. Introduction

1.1. Negative symptoms in schizophrenia

Negative symptoms in schizophrenia typically include blunted affect, alogia, asociality, avolition and anhedonia (Lincoln, Dollfus, & Lyne, 2017). Persistent negative symptoms are thought to be present in approximately 20-40% of the population with schizophrenia (Sarkar, Hillner, & Velligan, 2015). Factor analysis shows that the symptoms can be explained by two factors: diminished expression and amotivation (Elis, Caponigro, Kring, 2013). Risk factors for developing negative symptoms include being male, family history of psychosis, longer duration untreated psychosis (DUP), and lower premorbid functioning (McLeod, Gumley, MacBeth, Schwannauer, & Lysaker, 2014).

Cognitive difficulties are unlikely to explain the development of negative symptoms as no relationship was found between PANSS negative factor (with the five-factor consensus model applied) and the MATRICS Consensus Battery (MCCB). It has been suggested that the small to moderate correlations found in earlier meta-analyses (e.g. Dibben, Rice, Laws, & McKenna, 2009; Dominguez, Viechtbauer, Simons, van Os, & Krabbendam, 2009; Ventura, Hellemann, Thames, Koellner, & Nuechterlein, 2009) might have been due to confounding variables (e.g. substance abuse) or measurement overlap (e.g. the Scale for the Assessment of Negative Symptoms (SANS) (Andreasen, 1984); the Positive and Negative Syndrome Scale (PANSS)(Kay, Fiszbein, & Opfer,1987) (Bagney et al., 2015) .

The symptoms are classified as secondary negative symptoms if they are thought to be due to medication, positive symptoms, depression, hypostimulating environments, or substance abuse; in contrast, primary negative, or *deficit,* symptoms refer to symptoms that are thought to be intrinsic to schizophrenia. There is a lack of research on secondary negative symptoms as most research on negative symptoms has focused on primary negative symptoms; this is problematic considering that secondary negative symptoms are more prevalent than primary negative symptoms as they occur in more than 50% of the population (Kirschner, Aleman, & Kaiser, 2017). However, it has been questioned whether the distinction between primary and secondary symptoms remains valid as more than 80% of patients experience a depressive episode which suggests that depression might be something more than a co-morbid condition (Upthegrove, Marwaha, & Birchwood, 2017.

Despite similarities in clinical presentation, there seems to be some differences between depression and negative symptoms as the concepts have been found orthogonal (Upthegrove et al., 2010). While both conditions seem to lead to deficits in anticipatory pleasure in terms of anhedonia, some features of anhedonia might be specific to subtype as consummatory pleasure seems preserved in negative symptoms but not in depression (Upthegrove et al., 2017). It has therefore been suggested that there might be three different pathways: depression which is intrinsic to the psychotic condition; depression as a psychological response to the diagnosis; and depression as well as psychosis as a consequence of childhood trauma, social adversity and neglect as these are established risk factors for mental health difficulties (Birchwood, Iqbal, & Upthegrove, 2005).

1.2. The cognitive model of negative symptoms in schizophrenia

Negative symptoms can be conceptualised as a coping strategy that develops early in the psychosis, where shutting down of psychological systems allows the individual to cope with overwhelming or aversive situations; this leads to a reliance on negative symptoms (e.g. apathy, social isolation, and avolition) to reduce the impact of these experiences as well as the exposure to them (Beck, Rector, Stolar, & Grant, 2009). The avoidance and disengagement might be maintained by certain dysfunctional beliefs which could arise as a consequence of repeated failures and setbacks; these cognitions are suggested to include negative beliefs about social affiliations; low expectations of pleasure, success and acceptance; defeatist beliefs about performance; and a perception of limited resources (see Figure 1). Individuals diagnosed with schizophrenia may also incorporate stigmatising views of their mental illness into their self-construals, which will have a negative effect on their perceived self-efficacy. This may lead to a perception of not meeting self-imposed goals as well as feelings of guilt for failing to meet others' expectations. It might be that these factors result in hypervigilance to perceived criticism (Rector, Beck, & Stolar, 2005).

Negative expectancy appraisals associated with DSM-IV negative symptoms				
	Appraisals			
Symptoms	Low self-efficacy (success)	Low satisfaction (pleasure)	Low acceptance	Low available resources
Affective flattening	If I show my feelings, others will see my inadequacy.	I don't feel the way I used to.	My face appears stiff and contorted to others.	I don't have the ability to express my feelings.
Alogia	I'm not going to find the right words to express myself.	I take so long to get my point across that it's boring.	I'm going to sound weird, stupid, or strange.	It takes too much effort to talk.
Avolition	Why bother, I'm just going to fail.	It's more trouble than it's worth.	It's best not to get involved.	It takes too much effort to try.

Figure 1. How negative expectancy appraisals could form negative symptoms. (Rector et al., 2005, p. 252)

Research has shown that negative symptoms are found to be associated with low expectancies of success (Couture, Blanchard, & Bennett, 2011), asocial beliefs (Grant and Beck, 2010), a reduced sense of self-efficacy (Bentall et al., 2010), low self-esteem (Lincoln, Mehl, Kesting, & Rief, 2011), defeatist performance beliefs (Campellone, Sanchez, & Kring, 2016), and self-stigma (Horsselenberg, van Busschback, Aleman, & Pijnenborg, 2016). A longitudinal study has also found that low expectancy of success predicted future negative symptoms (Luther et al., 2016) whilst self-defeatist beliefs about performance were found to mediate the relationship between cognitive impairment and negative symptoms/functioning (Grant & Beck, 2009).

Though not directly contradicting the cognitive model of negative symptoms, it is suggested that additional biological, cognitive, and psychosocial processes might be involved in the development and maintenance of negative symptoms as outlined in maintenance loop for negative symptoms (see Figure 2) (Velligan, Maples, Roberts,

& Medellin, 2014). According to this model, negative symptoms are proposed to be due to disruptions in different parts of the reward system, which might be due to a biological predisposition or secondary to treatment with dopamine antagonists. Once withdrawing behaviours are established, they are likely to be negatively reinforced due to the removal of distressing stimuli and the resulting feeling of temporary relief. Over time, the coping strategy leads to disruptions in everyday functioning and decreased quality of life due to a lack of positively reinforced experiences, resulting in atrophy of previously attained skills and the ability to plan for the future. The suggestion that the negative expectancies proposed by the cognitive model are due to deficits in the brain reward systems has been supported by the fact that subjects diagnosed with schizophrenia have been found to have lower scores on anticipatory pleasure compared to a control group whilst no differences in deriving pleasure (contrary to anhedonia) were found (Gard, Kring, Gard, Horan, & Green, 2007).

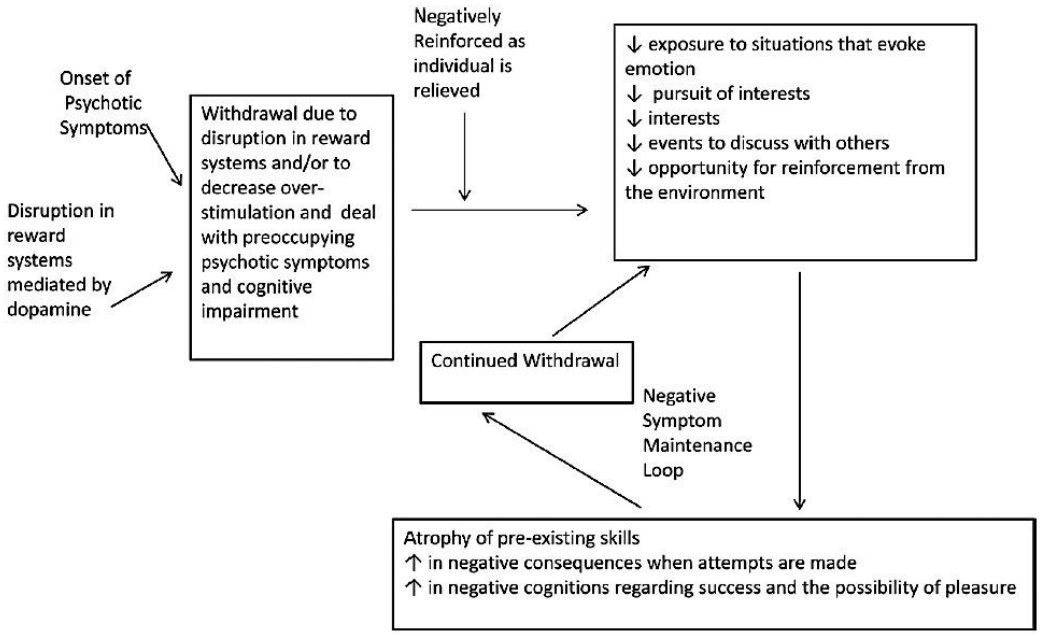

Figure 2. The negative symptom maintenance loop. (Velligan et al., 2014, p. 5)

However, there is evidence that suggests negative symptoms might also be due to complex metacognitive processes as these have been found to predict negative symptoms after controlling for the cognitions suggested by Beck and colleagues (Lysaker et al., 2015). This suggests that metacognition, which is covered in the next section, might be an important factor in the development and maintenance of negative symptoms.

1.3. The metacognitive model of negative symptoms in schizophrenia

An additional, or potentially alternative, psychological factor for the aetiology of negative symptoms may be one's metacognitive ability. Though metacognition initially referred to the capacity to think about and monitor one's mental processes (Flavell, 1979), the definition has broadened in contemporary research to cover a range of mental processes from discrete acts (e.g. identifying cognitive biases) to more complex processes (e.g. deriving meaning from significant events) (McLeod et al., 2014). The ability to reflect on one's mental states is also called mentalization or reflective functioning (Bateman & Fonagy, 2011) in the wider literature, though this does not include mastery (i.e. the ability to develop adaptive coping strategies based on one's metacognitive understanding of the world). Mentalization also differs from metacognition as it views disruptions in reflectivity as only occurring in the context of disturbed attachment (Dimaggio & Lysaker, 2015). In this paper, the mentalization concepts defined by Lysaker, Bateman & Fonagy with colleagues will be used interchangeably.

Metacognition as defined by Lysaker and colleagues is suggested to be relevant to negative symptoms as without a complex mental representation of one's and others' mental states, individuals would struggle to identify and express emotions or understand and value social interactions, making the individual less likely to experience rich emotions and volition (Lysaker et al., 2015). The suggestion that negative symptoms might be due to metacognitive deficits links in with earlier research that found schizophrenia is linked with difficulties identifying and understanding both one's own and others' mental states (Nicolo et al., 2012). The metacognitive model differs from the cognitive model as it proposes that it is the ability to engage in complex thought processes about oneself and others that will affect the richness of an individual's ability to experience life and not just the particular beliefs discussed in the section above. This is more consistent with the original ideas by Bleuler (1911, 1950) that schizophrenia is caused by disturbances in associative processes which leave the individual unable to form complex ideas in order to sustain goal-directed behaviour. The relationship between negative symptoms and metacognition could also be due to other mechanisms such as attachment style or therapeutic alliance (Lysaker et al., 2015).

Significant metacognitive deficits have been found in individuals diagnosed with schizophrenia relative to persons with bipolar disorder (Tas, Brown, Aydemir, Brüne, Lysaker, 2014); anxiety/depression (WeiMing, Yi, Lysaker, & Kai, 2015); prolonged medical conditions (Lysaker et al., 2014); PTSD (Lysaker et al., 2015); and substance abuse (Lysaker et al., 2014). A relationship between metacognition and negative symptoms is also supported empirically as severity of deficits in

metacognition has been linked to concurrent (Nicolo et al., 2012, Rabin et al., 2014), and prospective negative symptoms (Hamm et al., 2012). Metacognition was also found to predict negative symptoms in first episode psychosis (Mcleod et al., 2014). Interestingly, decentration (i.e. the ability to hold a non-egocentric perspective on others' thoughts, motives, and desires) was found to be the subscale most strongly correlated with negative symptoms. This finding was suggested to be due to an increased self-focus combined with the patient's belief that others are also focusing on them which may lead to difficulties to see events as unrelated to themselves. The results differs from the study by Nicolo et al. (2012) which found that negative symptoms were most strongly correlated to mastery; this is not surprising considering the fact that negative symptoms are argued to be a maladaptive coping strategy (Beck et al., 2009). Metacognition has also been found to predict negative symptoms in more chronic samples even after controlling for affect recognition, defeatist beliefs, and neurocognitive functioning (Lysaker et al., 2015). In a recent study (Weijers et al., 2018), mentalization was found to mediate the relationship between negative symptoms and reported childhood abuse which further supports the idea that negative symptoms may be a coping strategy of shutting down as a response to adversity.

1.4. Psychological Interventions for negative symptoms

1.4.1. Individual Studies

Few studies have focused on psychological interventions developed to primarily target negative symptoms. In the first study (Daniels, 1998) that explicitly focused

on improving negative symptoms with Cognitive Behaviour Therapy (CBT), the approach was combined with group process strategies to create a social skills training programme (Interactive-Behavioural Training (IBT)). It was found that the intervention did not lead to an overall reduction on total and subscales scores on the Modified Scale for the Assessment of Negative Symptoms (SANS) (Woerner & Robinson, 1993). Improvements were also found for social functioning on the five outcome measures used in the study, though only the Global Assessment of Functioning Scale (GAF) (American Psychiatric Association (APA), 1994) was found to be significant. Though these findings are encouraging, they must be interpreted with some caution given the issues with the GAF of concurrent and predictive validity (see Aas, 2010).

Klingberg et al., (2011) conducted a randomised controlled trial where CBT was compared to Cognitive Remediation Therapy (CRT). As no difference was found between the groups post-intervention on negative symptoms, the authors suggested that the effect could be due to both interventions helping patients to experience pleasure and success leading to an impact on negative symptoms. In a study by Grant, Huh, Perivoliotis, & Stolar (2012), which compared CBT that specifically targeted the dysfunctional beliefs suggested by Rector et al., (2005) to treatment as usual, significant improvements were found on functioning, apathy and avolition but not on anhedonia, flat affect and alogia. It should be acknowledged that a high (>50) number of sessions were offered which limits the feasibility of introducing the intervention in standard clinical practice. In an uncontrolled pilot study by Staring, Ter Huurne, van der Gaag (2013) that used the same approach but only offered 20

sessions, significant improvements were found on negative symptoms; the improvements were found to be partially mediated by a change in dysfunctional beliefs. However, as the study used the original subscale of negative symptoms rather than the suggested five-factor model (Wallwork, Fortgang, Hashimoto, Weinberger, & Dickinson, 2012) as the primary outcome, it is possible that the intervention had an impact on factors that would not necessarily be conceptualised as negative symptoms.

MOtiVation and Enhancement (MOVE) Training (Velligan et al. 2014) was developed to improve initiation, success, enjoyment, and adaptive behaviours to target both the dimensions of negative symptoms (i.e. emotion expression and anhedonia/amotivation). In a randomised pilot study (Velligan et al., 2015) MOVE was compared to treatment as usual (TAU) for nine months. In contrast to other studies, the study included an impressive three measures of negative symptoms: the Negative Symptom Assessment (NSA-16) (Axelrod, Goldman, & Alphs, 1993); the Clinical Assessment Interview for Negative Symptoms (CAINS) (Forbes et al., 2010); and the Brief Negative Symptom Scale (BNSS) (Kirkpatrick et al., 2010). It was found that the intervention led to moderate effects on NSA-16 and CAINS but not BNSS; this was suggested to be due the former instruments being more sensitive to change. Though both dimensions of negative symptoms were targeted, the intervention was found to only have an impact on motivation but not emotional expression. As decreased overall cognitive performance was associated with diminished expression but not apathy by Hartmann-Riemer et al. (2015), it is possible that there is a stronger link between cognition and diminished expression

which indicates a more treatment resistant treatment target. This is supported by the cognitive resource limitation theory (Cohen, Morrison, Brown, & Minor, 2012) that suggests that fewer resources may be available for complex expression if cognitive functioning is decreased. The findings suggest a need for more nuanced treatments that are targeted specifically at either one of the two dimensions. An alternative explanation of the results could be that the proposed deficits in metacognition (as discussed in section 1.3) did not respond to the strategies on emotional processing and expression that were included in the intervention. Given the limited efficacy of medication on other psychotic symptoms and significant side-effects, it is unclear why a pharmacotherapy approach rather than an advanced therapeutical approach was suggested to improve negative symptoms.

Attempts have also been made to develop an intervention to directly improve metacognitive functioning as a way of targeting negative symptoms. The Metacognitive Reflection and Insight Therapy (MERIT), which was developed by Lysaker and colleagues (Lysaker & Klion, 2017), is currently being evaluated in a Dutch randomized controlled trial (Van Donkersgoed et al., 2014). Though the intervention has been found to lead to improvements on negative symptoms, only case studies have been published to date (Van Donkersgoed, De Jong, & Pijnenborg, 2016). A version of MERIT was also developed for early psychosis (MERIT-EP) by Vohs et al. (2017), where 20 individuals were randomised to either MERIT or TAU. Though the intervention led to improvements on PANSS total score, it is not possible to say whether the improvements were found on other subscales than negative symptoms as only the total score was reported. Another potentially

promising intervention for improving reflective functioning is mentalization based treatment (MBT) (Bateman & Fonagy, 2008) which has been applied in case studies for patients with clinical high-risk for psychosis (Debbané et al., 2016) and early psychosis (Brent, Holt, Keshavan, Seidman, & Fonagy, 2014). There is also an ongoing Dutch trial (Weijers et al., 2016).

1.4.2. Meta-analyses

Several meta-analyses have found that conventional CBT, which would mainly target positive symptoms, may have a beneficial effect on negative symptoms (Wykes, Steel, Everitt, & Tarrier, 2008; Sarin, Wallin, & Widerlov, 2011; Jauhar et al., 2014; Velthorst et al., 2015; Lutgens, Gariepy, & Malla, 2017). The earlier meta-analysis (Wykes et al., 2008) found a stronger effect (-0.44) for negative symptoms compared to the later studies; this might be due to the method employed to calculate effect sizes (Glass's method), which is known to inflate effect sizes (Jauhar et al., 2014). The differences might also be due to the lower quality of the earlier studies (Velthorst et al., 2015).

Cognitive remediation therapy (CRT) may have an effect on negative symptoms through improvements in cognitive functioning and by challenging the dysfunctional cognitions potentially underlying negative symptoms (Veerman, Schulte, & de Haan, 2017). Two meta-analyses have focused on this intervention for negative symptoms (without the distinction between primary/secondary): Cella, Preti, Edwards, Dow, & Wykes (2016) and Lutgens, Gariepy, & Malla (2017). Cella et al. (2016) found a small reduction post intervention and at follow-up compared to TAU and to an active

control group. Encouraging, this reduction was larger in studies with a more robust design. Similar results were found by Lutgens et al. (2017) though a high level of heterogeneity was found between studies.

Meta-analyses have provided further support for psychosocial interventions for negative symptoms. In an extensive meta-analysis by Fusar-Poli et al. (2015), CBT, CRT, and music therapy were all found to have a significant effect on negative symptoms. This was also found for Integrated Psychological Therapy (IPT) (Roder, Mueller, & Schmidt, 2011); mindfulness (Khoury, Lecomte, Gaudiano, & Paquin, 2013); and Social Skills Training (SST) (Turner et al., 2017). Meta-analyses have also shown that negative symptoms are improved by different types of physical exercise (Lutgens et al., 2017; Veerman et al., 2017). The findings suggest that psychological interventions are likely to be effective for treating negative symptoms but that more research is needed to understand mechanisms of change. This is especially important as Fusar-Poli et al (2015) found in their meta-analysis that whilst most treatments (e.g. antipsychotics, antidepressants, psychological interventions) have a significant effect on negative symptoms, none of these changes were found to be large enough to be clinically meaningful.

1.5. Metacognitive Training (MCT) for psychosis

Metacognitive Training (MCT) (Moritz & Woodward, 2007) is a relatively new intervention that draws on CBT, CRT, and psychoeducation. The aim of the intervention is to sow "the seed of doubt" in a neutral context with the intention that discussing various examples as well as personal experiences will lead individuals to

gain insight and practical strategies (Schneider & Andreou, 2014). The intervention is hence based on two premises: that cognitive biases play a role in the development and maintenance of psychotic symptoms and that these, as well as the associated distress, can be alleviated by targeting underlying cognitive processes (Pos et al., 2018).

The cognitive distortions covered in MCT are based on a review by Garety & Freeman (1999) and include: jumping to conclusions (JTC); impairments in social cognition/theory of mind; attributional distortions; and affective biases. Two additional cognitive biases (over-confidence in errors and a bias against disconfirmatory evidence) were added by Moritz & Woodward (2007). In addition, two modules (on self-esteem and stigma) were added in 2015 as individuals diagnosed with schizophrenia often suffer from low self-esteem (Sundag, Lincoln, Hartmann & Moritz, 2015) and are subjected to prejudices (Świtaj, Grygiel, Anczewskaa, & Wciórkaa, 2015). These modules were also added as many patients consider emotional distress a more important treatment target than psychotic symptoms (Kuhnigk, Slawik, Meyer, Naber, & Reimer, 2012); this is important as it is in line with the recovery model of mental illness which "*argues against just treating or managing symptoms but focusing on building resilience of people with mental illness and supporting those in emotional distress*" (Jacobs, 2015, p. 117).

Metacognitive training's indirect approach, where the focus is on cognitive processes leading to certain beliefs rather the content of these beliefs (which would typically be covered in CBT), is considered beneficial for clients who cannot distance themselves

from their beliefs or whose self-esteem is dependent on their positive symptoms (Schneider & Andreou, 2014). This is important as studies have shown that uncovering inconsistencies in clients' beliefs through guided discovery may negatively impact on the therapeutic alliance (Wittorf et al., 2013). The intervention further differs from CBT through its experiential format where exercises are used to make the subject experience the cognitive distortions in vivo during the session to facilitate encoding. The psychoeducational elements of the intervention, which are used to normalise and explain the unreliability of human cognition, are important as normalisation has been shown to improve treatment engagement in therapy (Lül mann & Lincoln, 2013). The intervention consists of eight modules that can be administered as a group therapy or individually (Schneider & Andreou, 2014); it has been recommended that the individual format might be more suitable for individuals with severe delusions (Moritz, Werner, Menon, Balzan, & Woodward, 2016). An Internet application that allows patients to access MCT material at home at any time is currently being tested. It is hoped that this will overcome some of the major challenges faced by all cognitive interventions: neuropsychological deficits, sedation by medication and poor motivation which, unfortunately, all limit transfer to daily life and comprehension (Moritz, Woodward, Balzan, 2016).

Despite the similarity in name, MCT differs from the transdiagnostic "Metacognitive Therapy" developed by Wells which mainly focuses on dysfunctional beliefs about thinking (Kühne et al., 2017). A further confusion is the shared name of this conceptualisation of metacognition (which is closely linked to the original model by Flavell (1979)) and Lysaker's model of metacognition (which is focused on intra-

and interpersonal functioning, see section 1.3). However, a relationship between Moritz's and Lysaker's models of metacognition has been established as jumping to conclusions (JTC) has been found to correlate with mastery. As correlation does not clarify the nature of this relationship, it might be that an inability to access psychological knowledge when solving problems makes an individual give up when faced with uncertainty, or in case of the opposite direction, that the reasoning bias in itself makes it difficult for an individual to think about their thinking (Buck, Warman, Huddy, Lysaker, 2012).

Metacognitive Training has a growing evidence-base (Moritz et al., 2016). Studies have shown that the intervention has resulted in changes in patients' delusion severity (including distress and conviction), quality of life, illness insight, memory functioning and cognitive biases (Balzan, Delfabbro, Galletly, & Woodward, 2014). In the first meta-analysis (Jiang, Zhang, Zhu, Li, & Li, 2015) on the efficacy on MCT, small but statistically significant reductions on positive symptoms were found. It is important to acknowledge though that only four studies out of 54 studies met the inclusion criteria due to the requirement for a randomised controlled trial (RCT) design and specific measurements; this limits the findings due to insufficient statistical power (Eichner & Berna, 2016).

Two subsequent meta-analyses (Van Oosterhout et al., 2016; Eichner & Berna, 2016) reached different conclusions: the former failed to find support for MCT on positive symptoms while the latter did. However, both studies were in agreement that MCT leads to small to medium effect sizes (Hedges' g = .21–.34) which are

comparable to CBT for psychosis (Moritz, Werner, Menon, Balzan & Woodward, 2016). The review by Van Oosterhout et al. (2016), which included 11 studies, reported small effect sizes of MCT on positive symptoms, delusions or data gathering with the majority of these being non-significant. The authors advised against dissemination of the intervention in routine care until more independent and rigorous research has been conducted. However, as pointed out in a reply by Moritz et al. (2016), the stringent inclusion criteria that were applied in the review led to the omission of several trials in favour of MCT (e.g. Aghotor, Pfueller, Moritz, Weisbrod, & Roesch-Ely, 2010; Erawati, Keliat, Helena & Hamid, 2014; Moritz et al., 2011).

The most recent meta-analysis (Eichner & Berna, 2016), which included the largest number of intervention studies (N=15), demonstrated that MCT leads to a small to moderate effect on positive symptoms and delusions, and a large effect size on acceptance and subjective effectiveness. Even when studies with a high risk of bias were excluded, effect sizes for positive symptoms and delusions remained in the small to moderate range. Unfortunately, the review, in similarity to most studies finding support for MCT cannot be classified as independent as it was conducted by a PhD student of Moritz (Van Oosterhout et al. 2016).

More research (preferably independent) into the efficacy of MCT is needed, as unknowns include: the mechanisms of action in terms of change (Schneider & Andreou, 2014); individual factors determining treatment effectiveness (including chronic populations and patients with low cognitive functioning) (Moritz et al.,

2016); underlying neurobiological underpinnings (Moritz et al., 2014); the sustained long term effects of MCT (Briki et al., 2014); and whether the cognitive biases addressed in MCT lead to changes in the wider conceptualisation of metacognition used elsewhere in the literature (Buck et al., 2012). Ideally the research should be in a RCT format, include standardised outcome measures that measure cognition-specific changes, and use intention to treat (ITT) analysis (Jiang et al., 2015). It is also important to identify in further research the individual contribution of each module, as the duration of a typical in-patient treatment stay is too short to cover an entire cycle of MCT (Balzan et al., 2014; Moritz et al., 2016). Most importantly, more research is needed to evaluate whether MCT has an impact on negative symptoms. Though more recent versions of MCT have incorporated some exercises that may target negative symptoms (e.g. social problems, avolition), these have not been evaluated (Moritz et al., 2014). Also, as suggested by Weijers et al. (2018), targeting mentalization may be a useful treatment approach in non-affective psychosis as it may improve negative symptoms.

1.6. Study aims and hypotheses

The purpose of this study is to adapt MCT to target negative symptoms in psychotic disorders (e.g. schizophrenia, schizoaffective or non-affective functional psychosis) as the current version focuses on positive symptoms. As negative symptoms are a stronger indicator of concurrent and future functioning than positive symptoms (Velligan et al., 2015) and as they respond poorly to medication (Veerman et al., 2017) and existing psychological interventions (Fusar-Poli et al., 2015), there is a clear rationale for developing interventions targeting negative symptoms of

schizophrenia. This is reflected in the NIMH-MATRICS consensus statement (Kirkpatrick, Fenton, Carpenter, & Marder, 2006) that emphasised that persistent negative symptoms represent an unmet therapeutic need for patients suffering from schizophrenia.

This feasibility study aims to address some of the gaps in the literature by modifying the existing MCT to explicitly target negative symptoms, addressing the relevant cognitions as discussed in section 1.2., and to improve metacognitive ability as discussed in section 1.3. Four aspects of feasibility identified by Bowen et al. (2009) will be addressed in this study:

- Acceptability: how do the individual recipients react to the intervention?
- Practicality: can the intervention be implemented and delivered in NHS settings?
- Demand: is there a clinical need for this intervention?
- Limited efficacy: does MCT for negative symptoms show promise for the intended population in terms of:
    - Reductions in negative symptoms as measured by the Brief Negative Symptom Scale (BNSS) (Kirkpatrick et al., 2010) and the Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987)?
    - Increased quality of life as measured by the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q-18) (Ritsner, Kurs, Gibel, Ratner & Endicott, 2005)? (This measure is included to reflect the recovery model of mental illness, which proposes that mental health services should aim to increase an individual's potential for growth

despite residual symptoms (Ferguson, Conway, Endersby, & MacLeod, 2009)).

- Reductions in depression as measured by the Calgary Depression Scale for Schizophrenia (CDSS) (Addington, Addington, & Schissel, 1990)?
- Improvements in reflective ability as measured by the Metacognition Assessment Scale Abbreviated (MAS-A) (Semerari et al., 2003) and the Reflective Function Questionnaire (RFQ) (Fonagy et al., 2016)?
- Reduction in internalised stigma as measured by the Personal belief about illness questionnaire (PBIQ) (Birchwood, Mason, Macmillan, & Healy, 1993)?
- Improved functioning as measured by the Global Assessment of Functioning (GAF) (APA, 1987)?

The research also aims to add to existing research by identifying and measuring potential mechanisms of change for negative symptoms (i.e. depression, reflective functioning, stigma). It will also add to the existing evidence base by measuring whether the cognitive biases addressed in MCT lead to changes in the wider conceptualisation of metacognition used elsewhere and by including patients with chronic schizophrenia. In addition, the paper will explore whether multilevel modeling (MLM) is a suitable method for analysing data from case-series.

2. Methodology

2.1. Design

A pilot study with a case series design was used to assess the feasibility of applying

MCT to target negative symptoms in non-affective functional psychosis. A case series design was chosen as it allows for a focus on the mechanisms of change within the intervention as it provides detailed data on changes over time. It was also the preferred design as it reduces variance accountable to research design whilst providing the possibility to measure individual factors that may have an impact on treatment outcomes. The quantitative design was combined with a qualitative approach as the combination allows for one design to compensate for the other; this provides more comprehensive and valid results than either method alone (Mengshoel, 2012). Similar designs have previously been applied in severe and enduring mental health conditions (Greaves, Camic, Maltby, Richardson, & Mylläri, 2012; Mairs, Lovell, Campbell, & Keeley, 2011; Heriot-Maitland, Vidal, Ball, & Irons, 2014).

Small-N studies have a place in the clinical research process as while randomised controlled trials (RCT) are seen as the gold standard in research, the design is not suitable for every stage in the research process. A hierarchical model for the clinical research process has therefore been suggested, where different designs need to be implemented at different stages to develop, evaluate or create an evidence-base for an intervention (Dugard, Todman, & Todman, 2012). The chosen design for this research made an initial exploration of the feasibility and acceptability of the new intervention possible and hence provided the first stage in the evaluation of MCT for negative symptoms. The findings of small-N studies are required to decide whether interventions are appropriate for further evaluation in terms of efficacy and effectiveness (Bowen et al., 2009). In addition, though RCT:s have a high internal

validity due to their ideal conditions, it has been questioned whether the findings can be generalised to standard clinical practice due to the population selection procedures that are necessary to limit confounding factors (e.g. depression, positive symptoms, substance abuse, cognitive difficulties). Pragmatic trials like this are hence needed to inform the effectiveness of an intervention under routine circumstances with real-life populations (Saturni et al., 2014)

2.2. Participants, sample size, settings, and ethics

Eligible participants were over the age of 16 years old and diagnosed with a psychotic disorder (e.g. a diagnosis of schizophrenia, schizoaffective or non-affective functional psychosis) in the National Health Service (NHS) Lothian. Exclusion criteria consisted of: evidence of organic brain dysfunction or a learning disability that precluded them from making use of a psychological intervention; difficulty with the English language; visual and/or hearing impairment; or being unable or unwilling to provide written informed consent.

A formal power calculation was not applied as the purpose of the research was to gather information about the process of change for individuals in MCT to inform future research trials. Abu-Zidan, Abbas, & Hefny (2012) suggested that a minimum sample size of four should be used for case-series design whilst Braun & Clarke (2013) has suggested that 6 to 10 subjects are sufficient for thematic analysis. These recommendations were taken into account during the recruitment phase of this research study.

The study, which ran between March 2016 and February 2018, received approval from the South East Scotland Research Ethics Committee (REC reference: 16/SS/0046) and NHS Lothian Research and Development office in 2016 (see Appendix F). A study protocol was registered at http://www.researchregistry.com (http://www.researchregistry.com/browse-the-registry.htmlhome/registrationdetails/59be8be7307d850c14bb519e/).

2.3. Intervention

There were eight sessions in total in the modified MCT. Core metacognitions from the current MCT (see section 1.5.) were adapted to negative symptoms by incorporating psychoeducation and strategies designed to target the cognitions implicated in the development and/or maintenance of negative symptoms (see section 1.2.). The order of the sessions was randomised using an online random sequence generator. The researcher delivered MCT for negative symptoms individually as studies have found larger effect sizes for individual MCT than MCT delivered in a group format (Eischner & Berna 2016); an individual approach may also be more suitable for this patient group as group MCT is not recommended for patients with severe delusions (Moritz et al., 2016). Individual MCT also had the advantage of facilitating recruitment in the pilot study. The developer of MCT for schizophrenia (Professor Steffen Moritz) approved the modification of the intervention for negative symptoms. Every session started with a short summary of what negative symptoms are and how certain unhelpful cognitions (see section 1.2.) might maintain them. Subjects were provided with homework after each session.

Table 1. Summary of the intervention

Session 1	<u>Introduction to negative symptoms (developed for MCT for negative symptoms)</u> Psychoeducation, exercises, and discussion on what negative symptoms are and how certain unhelpful cognitions (e.g. negative beliefs towards social engagement and low expectancy of pleasure/success) might lead to and maintain negative symptoms. Also strategies for challenging unhelpful cognitions (e.g. monitor unhelpful cognitions and take mental snapshots and/or write down enjoyable and sociable experiences and successes to challenge low pleasure expectancy).
Session 2	<u>Self-esteem (taken from the additional modules from original MCT)</u> Psychoeducation, exercises, and discussion on what self-esteem is and how low self-esteem and rumination might lead to and maintain negative symptoms (e.g. not attempting activities or not engaging with others due to fear of social judgement). Also strategies for challenging low self-esteem and rumination (e.g. becoming aware of social comparison, asking others what they value the person for, writing down achievements in a "joy diary", cognitive defusion, physical distraction).
Session 3	<u>Jumping to Conclusions (JTC) (modified from original MCT)</u> Psychoeducation, exercises and discussion on JTC and how this might lead to and maintain negative symptoms (e.g. disengagement due to mind-reading and/or fortune telling). Also strategies for challenging JTC (e.g. consider alternative interpretations; check that enough information has been gathered before drawing a conclusion (especially if it is a significant decision); checking with others).
Session 4	<u>Attribution Style (modified from original MCT)</u> Psychoeducation, exercises, and discussion on how a one-sided explanation style might lead to and maintain negative symptoms (e.g. blaming oneself for failures and give others or circumstances credit for successes which might lead to social withdrawal and emotional shut down). Also strategies for challenging attribution style (e.g. consider that multiple factors (i.e. oneself, others and the situation/circumstances) might contribute to the outcome of a specific event).

Session 5	Cognitive Difficulties (modified from original MCT) Psychoeducation, exercises and discussion on how common cognitive difficulties in psychosis (i.e. verbal memory, mental flexibility, attention) may lead to and maintain negative symptoms (e.g. difficulties with planning may lead to avolition) but that the relationship might also be the opposite (e.g. brain becoming "rusty" due to long-term avoidance) or be due to other variables (e.g. low expectancy of success leading both to avolition and motivational difficulties/anxiety when engaging in cognitively demanding tasks). Also strategies to deal with cognitive difficulties (e.g. mnemonics, problem solving, learning new information in a space without distractions).
Session 6	Social Cognition (modified from original MCT) Psychoeducation, exercises and discussion on how difficulties detecting and evaluating facial expressions (which may be due to expected social rejection) might lead to and maintain negative symptoms (e.g. not gaining pleasure from social interactions as they are perceived as confusing). Also strategies for understanding what others mean or feel (e.g. gaining knowledge from environment/situation, self-observation, gut feeling).
Session 7	Mood (taken from original MCT) Psychoeducation, exercises and discussion on how depression may lead to and maintain negative symptoms through the loss of drive and motivation to engage with the world and social isolation due to fear of being rejected. Also strategies (e.g. cognitive restructuring, writing down strengths, compliments and positive things from the day in a "joy diary", cognitive defusion, do enjoyable things, remember previous enjoyable events with all senses, exercise) for overcoming certain cognitive traps (e.g. exaggerated generalisation; selective perception; catastrophic thinking).
Session 8	Stigma (taken from the additional modules from original MCT) Psychoeducation, exercises and discussion on how stigma may lead to and maintain negative symptoms (e.g. disengagement due to internalisation of the incorrect view of psychosis that is portrayed by the media (e.g. dangerous, low IQ)). Also strategies to counteract this (e.g. educate others about mental illness).

2.4. Outcome Measures

In the study a combination of interviews and self-rated questionnaires were used (see below). As consideration to participation burden was given throughout the study (Newington & Metcalfe, 2014), only instruments that measured the specific constructs of interest in a reliable and time efficient way were applied. All the outcome measures were administered and interpreted by the primary researcher who had training in the specific measurement (PANSS) or accessed resources (BNSS; MAS-A) from the developers to undertake this independently. A Kappa-coefficient of 0.70 for overall agreement between the primary researcher and a research collaborator (E.E.) on all three measures indicated adequate inter-rater reliability (Randolph, 2008). The total scores were used for all subscales with the exception of PANSS.

2.4.1. Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987)

The Positive and Negative Syndrome Scale (PANSS) is one of the most widely used tests for assessing positive and negative symptoms in schizophrenia. Though evidence of internal reliability was established for the original measure in previous studies (Cronbach's alpha < .70 for all scales), the original structure of grouping items into scales for positive, negative and general psychopathology is questioned in contemporary research; instead a five-factor model that includes positive symptoms, negative symptoms, disorganisation, depression, and excitement is suggested as it seems to better capture the symptoms present in schizophrenia (Bagney et al., 2015). The negative factor (N1, N2, N3, N4, N6, G7) of the five-factor model as proposed by NIMH researchers Wallwork et al. (2012) will therefore be used in this study.

2.4.2. The Brief Negative Symptom Scale (BNSS) (Kirkpatrick et al., 2010)

The Brief Negative Symptom Scale (BNSS) is an assessment of negative symptoms developed to address recommendations from the NIMH consensus development conference on negative symptoms in 2005 (Strauss et al., 2012). The scale has strong inter-rater, test–retest, and internal consistency with intra-class correlation coefficients of .93. Its validity is also supported by its relationship with two other commonly used scales for assessing negative symptoms (i.e. SANS and PANSS)

2.4.3. The Metacognition Assessment Scale Abbreviated (MAS-A) (Semerari et al., 2003)

The abbreviated version of the Metacognition Assessment Scale (MAS-A) was used to assess metacognitive ability. The MAS-A is scored on transcripts generated with the Indiana Psychiatric Illness Interview (IPII) (Lysaker, Clements, Plascak-Hallberg, Knipscheer & Wright, 2002); the interview consists of five open questions to elicit the patient's life story and illness history (Van Donkersgoed et al., 2014). By analysing the narratives with the MAS-A, three components of metacognition are assessed: understanding one's own mind, understanding the mind of others, and mastery in the ability to think purposefully regarding a particular problem or source of distress. The MAS-A has shown good inter-rater reliability with intra-class correlations of .89 (Lysaker et al., 2005).

2.4.4. The Calgary Depression Scale for Schizophrenia (CDSS) (Addington et al., 1990)

Measuring depression in schizophrenia represents a challenge as many widely used scales (e.g. the Hamilton Depression Scale (Hamilton, 1960)) are influenced by negative symptoms. The Calgary Depression Scale for Schizophrenia (CDSS) was developed to overcome this problem. The scale, which consists of a structured

interview with nine questions, has good reliability and validity (Schennach et al., 2012).

2.4.5. The Personal belief about illness questionnaire (PBIQ) (Birchwood et al., 1993)

The Personal belief about illness questionnaire (PBIQ) was used to measure clients' view of their condition and the impact this has on their future, social status, and social marginalisation. The self-administered assessment has five subscales: control over illness, self as illness, expectations in relation to independence, stigma, and social containment. The measure has been widely used to study how individuals adapt to psychosis and has extensive psychometric validation (Acosta, Aguilar, Cejas, & Gracia, 2013).

2.4.6. The Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q-18) (Ritsner et al., 2005)

The Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q-18) is a short, self-administered questionnaire based on the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) (Endicott, Nee, Harrison, & Blumenthal, 1993). The Q-LES-Q-18 has shown high reliability, validity, and stability of test-retest ratings in patients with severe mental illness (schizophrenia, schizoaffective disorder and mood disorder) (Ritsner et al., 2005).

2.4.7. The Global Assessment of Functioning (GAF) (APA, 1987)

The Global Assessment of Functioning (GAF) is a rating scale for assessing a person's psychological, social and occupational functioning. The scale has been found to have good reliability even with limited practitioner training (Jones, Thornicroft, Coffey, and Dunn, 1995). Although there are validity and reliability

issues with the scale (Aas, 2010), it will be used in this study due to the fact that it is the most commonly used scale for assessing impact of mental illnesses in clinical practice and research.

2.4.8. The Reflective Function Questionnaire (RFQ) (Fonagy et al., 2016)

The Reflective Function Questionnaire (RFQ) is a 46-item self-reported questionnaire that was developed by Fonagy & Ghinai (unpublished manuscript) to assess mentalising capacity in adults (Ha, Sharp, Ensink, Fonagy, & Cirino, 2013). The scale consists of statements where the subject rates (1-6) the extent to which they agree. The measure has been found to have good internal consistency and re-test reliability (Fonagy et al., 2016).

2.5. Procedure

The researcher provided information about the project to mental health teams who referred participants. Subjects were provided with written information about the research and referred to the researcher if they chose to take part. The researcher met with the subjects prior to participation to obtain written consent, to gather relevant demographic information, and to complete the baseline measures which included PANSS; BNSS; MAS-A; CDSS; PBIQ; Q-LES-Q-18; GAF; and RFQ. Participants then began the MCT intervention.

Table 2. Timing of measurement.

Time points	BNSS/CDSS/GAF/ Q-LES-Q-18	MAS-A/PANSS	RFQ	PBIQ
Baseline	X	X	X	X (+3X)*
Session 1	X			
Session 2	X			
Session 3	X			
Session 4	X		X	
Session 5	X			
Session 6	X			
Session 7	X			
Session 8 (Post)	X	X	X	X
Follow-up	X	X	X	X

* PBIQ was administered after the sessions (3 in total) that focused on self-stigma, depression, or low self-esteem

Subjects completed three session-by-session measures: BNSS to assess negative symptoms, Q-LES-Q-18 to assess quality of life, and CDSS to assess whether the outcome on the other measures could be due to depression; only these brief measures were completed at each individual session to decrease participation burden. In addition, the PBIQ was administered after sessions (3 in total) that focused on self-stigma, or psychological processes (i.e. depression and low self-esteem) that are known to be associated with the "Why Try" phenomenon (i.e. when individuals perceive themselves as incapable of achieving personal goals due to internalisation of stereotypes of mental illness) (Corrigan, Larson, & Ruesch, 2009; Corrigan, Bink, Schmidt, Jones, & Rüsch, 2016). The RFQ was administered after the subjects had completed half the intervention to monitor metacognition over time. All measures were administered at a follow-up 12 weeks after to see if the intervention had a long-term effect. Subjects were asked to attend an individual exit interview between one

and two weeks after finishing the intervention. The interview was recorded with a digital audio recorder.

2.6. Analysis

Descriptive statistics on recruitment and attendance rates were combined with the participants' perspectives of the intervention to explore the feasibility and acceptability of the intervention. Wilcoxon Signed Rank tests were used to evaluate whether the intervention led to improvements on negative symptoms, quality of life, depression, reflective ability, stigma; and global functioning whilst multilevel modeling methods (MLM) were used to identify mechanisms of change.

2.6.1. Quantative Data Analysis

SPSS (version 23), R (version 3.4.3) and Excel (Excel for Mac 2011) were used for the statistical analysis. Missing data on questionnaires was replaced with case-mean substitution if less than 20% of the items were missing as this has been found to be a robust way of handling data missing on an item level (Fox-Wasylyshyn & El-Masri, 2005). For measures that were not administered each session (i.e. RFQ and PBIQ), the score of the last measurement was used for the session-by-session analysis during the active treatment phase unless the measure was missing or excluded. Wilcoxon Signed Rank tests were chosen for the pre, post and follow-up analysis as it is a non-parametric equivalent to the dependent t-test; this was deemed as appropriate due to the limited sample size and the repeated-measure nature of the data (Field, 2009).

Multilevel modeling (MLM) was used to explore change over time. The analysis has increasingly been used for analysing case series data (Collins & Sayer, 2001; Singer & Willet, 2003; Twisk, 2010). The method is considered an appropriate statistical analysis for case series if the aim of the study is to assess change over time and across cases as MLM can manage missing data as well as varying time points across individuals (Baek et al., 2011). In addition, MLM does not, unlike most other statistical analyses, assume that observations are independent which is unlikely when analysing data over time for the same individuals where time points may be correlated. Recent studies have provided evidence of the efficacy of MLM when applied in case series (e.g. Moeyaert, Ferron, Beretvas, & Van den Noortgate, 2014; Rindskopf & Ferron, 2014; Shadish, Kyse, & Rindskopf, 2013). The visual slope was used to explore trends (i.e. the average slope, direction of the dependent variables and individual variance across time).

2.6.2. Qualitative Data Analysis

Thematic analysis (Braun & Clark, 2006) was used in conjunction with the quantitative analysis to evaluate the feasibility and acceptability of Metacognitive Training for negative symptoms in psychotic disorders. The qualitative exit interviews were audio recorded and ranged in length from 8 minutes 36 seconds to 2 minutes 9 seconds (Mean = 3 minutes 42 seconds). A standardised interview schedule (with open-ended questions) was applied to minimise variations in questions asked in different interviews whilst still retaining enough flexibility to assess individual experiences (Patton, 1987). The interviews were transcribed by the primary researcher and transcripts were read multiple times to become familiar with

the material and to generate an overall view of the responses (Mairs, Lovell, Campbell, & Keeley, 2011). The recordings were then analysed with thematic analysis conducted according to a standard format (i.e. exploring the feasibility of the intervention and potential mechanisms of change). Themes were developed, labelled, and reviewed to assure that they were representative of the overall dataset. This analysis was undertaken by the primary researcher, and then discussed with a research collaborator (E.E.).

3. Results

3.1. Sample characteristics

A total of 45 patients were referred to the research study, which was conducted over 16 months. Of these, 18 subjects (40%) agreed to take part in the study. The most common reason for declining to take part was that patients did not want to be recorded (despite it being explained to patients that recording was not necessary). Three patients were excluded as they were unable to give informed consent due to paranoid delusions and/or severe cognitive difficulties. The patients were recruited from two mental health services at the Royal Edinburgh Hospital: the Psychiatric Rehabilitation Service (N=10) and the Acute Psychiatric Services (N=5), though three of the participants from the Acute Services transferred to the Rehabilitation Service during the study.

In total, 13 (87%) of the 15 subjects that were included had schizophrenia as a main diagnosis while two (13%) had schizoaffective disorder. 13 subjects (87%) were

receiving Clozapine, one (6.5%) was receiving Risperidone, and one (6.5%) was receiving Amisulpride. Of the 15 subjects, 8 (54%) had not completed secondary education. The subjects were receiving either in-patient care (N= 10, 67%) or being seen in the community (N=5, 33%). In total, 10 (67%) of the patients were currently seen or had been seen by the Psychology Department previously. The mean age for the overall sample was 42.6 years (sd=11.53). Of these 15 individuals, thirteen were male (mean age of 40.31 years, sd= 9.87) and two (13%) were female (mean age of 57.5 years, sd= 13.43). The participants were either referred by their Psychiatrist (N=5), Key Worker (N=4), Psychologist (N=4), or self-referred (N=2). The average number of sessions attended was 6.33 (sd= 2.67). In total, 10 of the 15 subjects completed all 8 sessions, 1 subject 6 sessions, 1 subject 5 sessions, 2 subjects 2 sessions, and 1 subject only completed baseline measures. The reasons for discontinuing the intervention were chaotic lifestyle due to substance abuse, difficulties with concentration as a side-effect of medication changes, significant bereavement, and severe depression.

3.2. Quantitative Analysis: Symptom change over time for completers

Multiple of Wilcoxon Signed Rank tests were applied to compare the differences in scores pre, post, and at follow-up (see Table 3 and Figure 4). A statistically significant decrease in symptom severity was found on negative symptoms on BNSS with medium effect sizes post intervention (*Mdn*= 16), z = -2.39, p = .017, r = -.75 and large effect sizes at follow-up (*Mdn*= 9.5), z = -2.52, p =.012, r = -.89. It was also found that the intervention led significant improvements on reflective

functioning post intervention (*Mdn*=192), z = -1.99, p= .046, r = -.75 which increased at follow-up (*Mdn*= 203) though this was not found significant, z = -1.07, p = .28, r = -.04. The intervention did not lead to any significant differences post intervention on negative symptoms as measured by PANSS; quality of life as measured by Q-LES-18; depression as measured by CDSS; metacognitive functioning as measured by MAS-A; or improved functioning as measured by GAF. The analysis indicated that internalised stigma as measured by PBIQ decreased to a significant level at follow-up (*Mdn*= 36), z = -2.05, p = .04, r = -.77.

Table 3. Wilcoxon sign test for completers pre and post

Variable	*Median* Pre	*Median* Post	*Z*	*P*	*r*	*Median* Follow-up	*Z*	*P*	*R*
Brief Negative Symptom Scale (BNSS)	22	16 (N=10)	-2.39a	.017*	-.75	9.5 (N=8)	-2.52a	.012*	-.89
Positive and Negative Syndrome Scale (PANSS) Negative symptoms	13	13 (N=9)	-1.34a	.182	-.45	13 (N=5)	-1.83b	.068	-.81
Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-18)	58	57 (N=9)	-.06a	.953	-.02	54.5 (N=8)	-.31b	.75	-.11
Calgary Depression Scale for Schizophrenia (CDSS)	5	4.50 (N=10)	-.83b	.40	-.26	3.50 (N=8)	-1.27b	.20	-.45
Metacognition Assessment Scale Abbreviated (MAS-A)	12	12 (N=3)	.00c	1.00	.00	n/a	n/a	n/a	n/a
Reflective Function Questionnaire (RFQ)	157	192 (N=7)	-1.99b	.046*	-.75	203 (N=3)	-1.07b	.28	-.62
Personal beliefs about illness questionnaire (PBIQ)	34	37 (N=8)	-.52a	.60	-.18	36 (N=7)	-2.05a	.04*	-.77
Global Assessment of Functioning (GAF)	40	40 (N=10)	-.58b	.56	-.18	40 (N=8)	-1.00b	.32	-.35

a= based on positive ranks
b= based on negative ranks
c= no difference
***p<.001, **p<.01, *p<.0

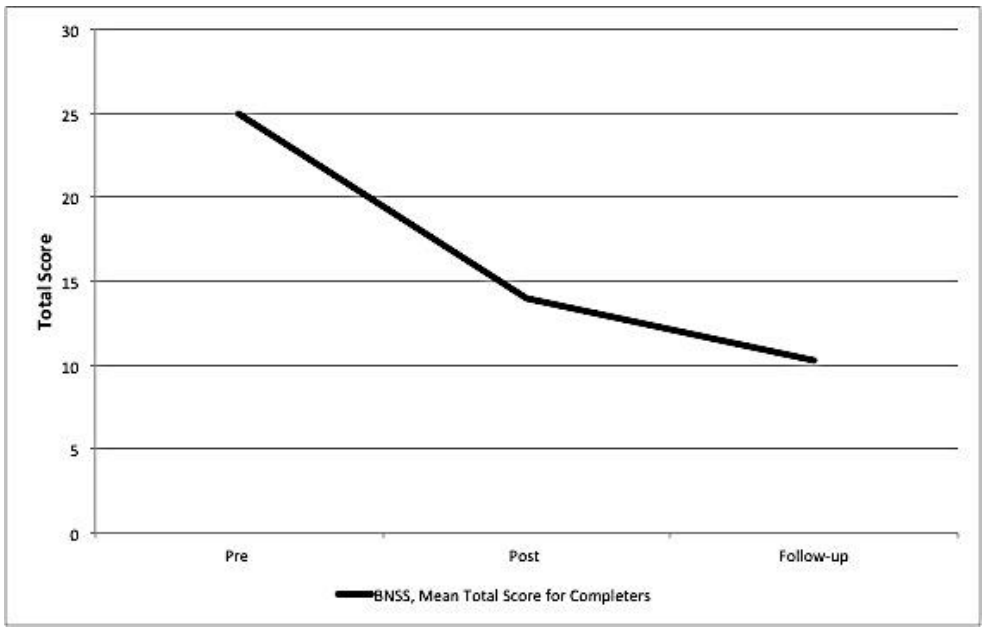

Figure 3. Pre-post mean symptom change for completers.

3.3. Quantitative Analysis: Modeling symptom change using multilevel modeling

Several models were applied to the data to assess potential mechanisms of change over time. Model 1 (which subsequent models were built on) evaluated whether there was enough variance (i.e. differences in negative symptoms) between subjects to apply subsequent models. Model 2 evaluated whether time had an effect (i.e. whether negative symptoms changed over time). Predictor variables were then added to the model to establish the effect of certain predictors (Model 3 (depression), Model 4 (stigma), and model 5 (reflective functioning)). Due to the limited sample size, the predictors were analysed individually meaning the effects were not cumulative. Parameters for the models can be found in Table 4 for the whole sample and Table 5 for the participants who completed the intervention.

The initial variance was analysed in **Model 1** (see Table 4). The intra-class correlation coefficient (ICC) was calculated to be 0.75, meaning approximately 75% of the variance in negative symptoms was attributable to between-subject variance; this indicated that there was enough variance to apply subsequent models. When time was added in **Model 2**, it was found to be significant and improved the fit of the model as the unexplained variance decreased from 809.75 to 773.80. This indicates that negative symptoms significantly decreased over the course of the therapy. Analyses were then applied to the ten completers and similar results were found. The impact of depression on negative symptoms was explored in **Model 3** which found a strong relationship between depression and negative symptoms as measured by BNSS. This suggests changes in negative symptoms over time were partially due to improvements on depression. Changes in negative symptoms were also found to relate to stigma **(Model 4)** as this improved the model fit even further. Reflective functioning **(Model 5)** was found to improve the model fit most of the three predictors. Similar patterns were found for the completers (see Table 5) where, in addition, depression was found significantly associated with negative symptoms. The MLM hence indicates that though depression and stigma are important predictors of negative symptoms, reflective functioning explains most of the changes over time on negative symptoms. As can be seen from graphs of the slopes (see Figure 4), all subjects who completed the intervention improved on negative symptoms as the scores decreased over time as seen through the slope's direction. In addition, when looking at changes over time on quality of life (see Figure 5) and not just pre and post measure, it was also found that the participant's quality of life improved over time due to the direction of the slope.

Table 4. Summary parameters with Brief Negative Symptom Scale (BNSS) as dependent variable (whole sample)

	Model 1 (Variance between subjects)	Model 2 (Effect of time)	Model 3 (Depression)	Model 4 (Stigma)	Model 5 (Reflective functioning)
Intercept	24.65(3.51) ***	29.65(3.36) ***	28.55(3.61) ***	20.54(10.78)	35.93(18.26)
Time		-1.49(.22) ***	-2.07(.34) ***	-2.67(1.28)	-2.29(2.40)
Calgary Depression Scale for Schizophrenia (CDSS)			.19(.23)		
CDSS*time			.07(.04)		
Personal beliefs about illness questionnaire (PBIQ)				.25(.28)	
PBIQ*time				.03(.03)	
Reflective Function Questionnaire (RFQ)					-.03(.12)
RFQ*time					.00(.01)
-2LL (Unexplained variance)	809.75	773.80	741.32	674.52	586.96

Parentheses values = standard errors; ***p<.001, **p<.01, *p<.05

Table 5. Summary parameters with Brief Negative Symptom Scale (BNSS) as dependent variable (completers)

	Model 1 (Variance between subjects)	Model 2 (Effect of time)	Model 3 (Depression)	Model 4 (Stigma)	Model 5 (Reflective functioning)
Intercept	19.42(1.95) ***	25.83(2.23) ***	27.65(3.08) ***	22.74(12.46)	23.80(22.00)
Time		-1.47(.24) ***	-2.27(.37) ***	-3.05(1.46)	-2.42(2.99)
Calgary Depression Scale for Schizophrenia (CDSS)			-.34(.31)		
CDSS*time			.14(.05) **		
Personal beliefs about illness questionnaire (PBIQ)				.08(.35)	
PBIQ*time				.05(.04)	
Reflective Function Questionnaire (RFQ)					.02(.13)
RFQ*time					.00(.02)
-2LL (Unexplained variance)	688.27	657.22	627.81	574.73	479.41

Parentheses values = standard errors; ***p<.001, **p<.01, *p<.05

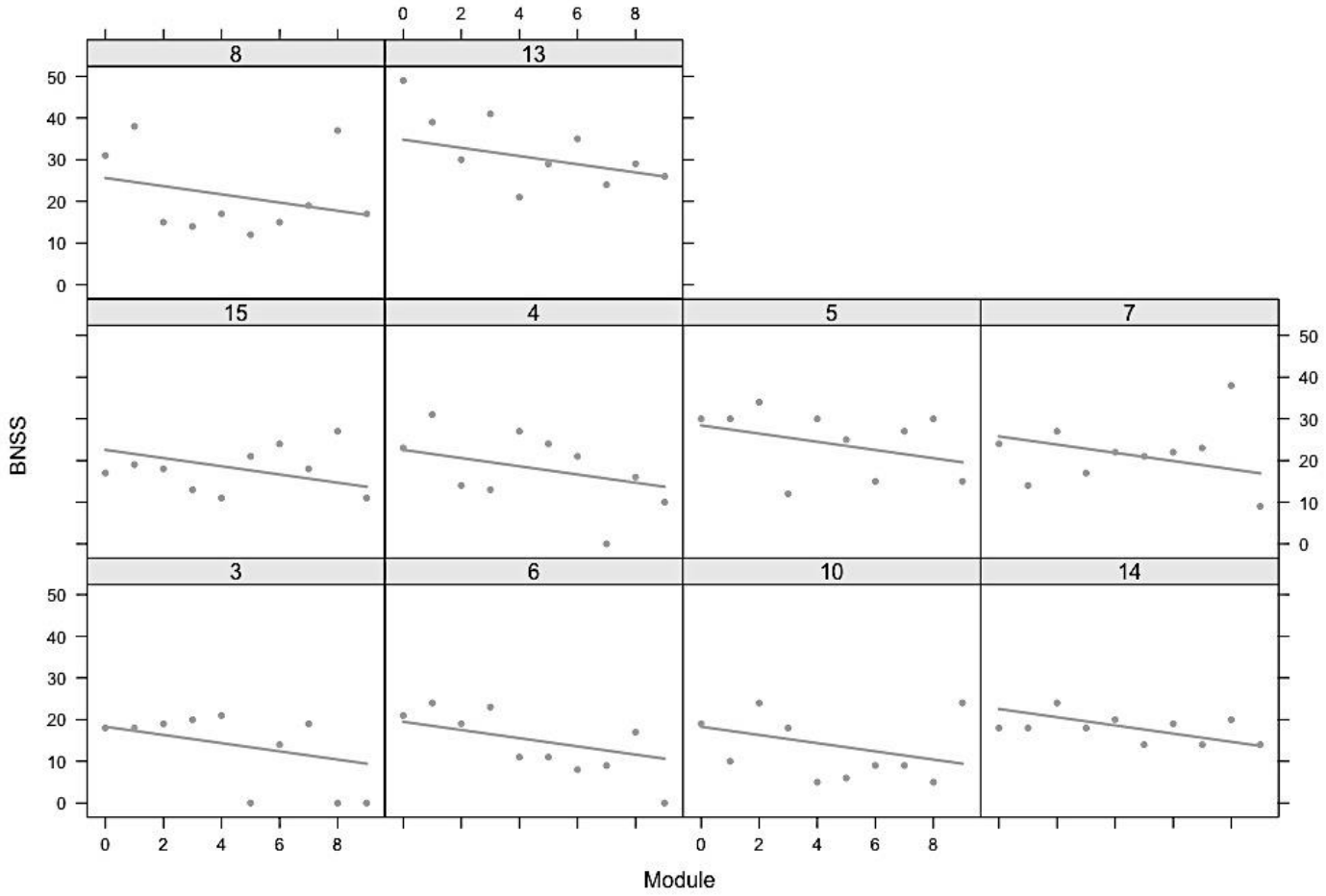

Figure 4. Improvements on negative symptoms as measured by Brief Negative Symptom Scale (BNSS) over time for completers.

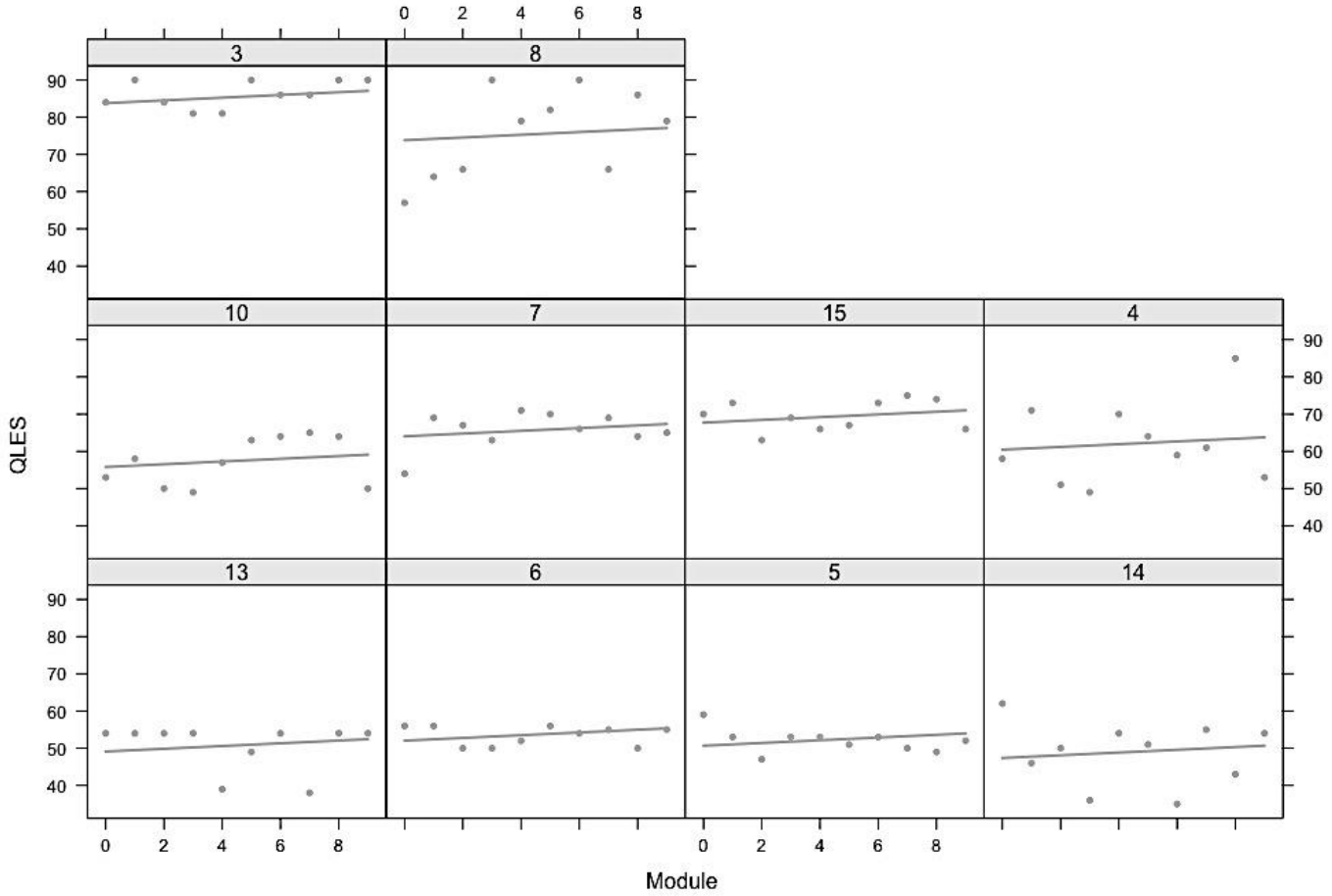

Figure 5. Improvements on quality of life as measured by the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q-18) over time for completers.

3.4. Qualitative Data analysis

All 10 completers agreed to take part in the interview about their views on the intervention. They were asked six questions in total (see Appendix F). 15 categories were identified in the thematic analysis; these were grouped into three themes: acceptability changes post intervention, and the therapeutic alliance. As four subjects (p7, p8, p9, p10) did not want to be recorded, their answers were written down by the researcher.

3.4.1. Acceptability of the intervention

3.4.1.1. Positive:

All participants were able to identify some positive aspects of the intervention. These mainly included the psychoeducational aspects, skills development, and the therapeutic relationship. Though not explicitly relevant to the intervention, several participants reported that they enjoyed contributing to the research as it would potentially help others with psychosis.

"I would recommend it to other people". P1

"I enjoyed it. I learned a lot about myself. It was also giving me coping mechanisms for when I am in trouble mentally. It has helped me a lot". P4

"Hard work sometimes but I got a lot from it. I think I have learnt from it, so it's been good". P5

"It was all relevant because of my negative symptoms". P7

3.4.1.2. Negative:

Most subjects said that the single most negative aspect of taking part in the research was completing questionnaires. In terms of what was less useful, one participant felt that the intervention was not relevant to her as she did not agree with her diagnosis of schizophrenia but felt that she had symptoms of trauma. Another patient said that the computer made him feel "paranoid" at times. It was possible some patients had false expectations of the outcome of taking part as one patient expressed disappointment that taking part in the research had not resulted in him being discharged.

"Helpful but paperwork and computer said psychosis where I have trauma and no psychosis". P8

"The computer made me feel paranoid at times". P9

"It is not going to speed up discharge…" P2

3.4.2. Changes after taking part in the intervention

Most participants said that they had reflected more on their own thinking after taking part in the intervention. This mirrors the quantitative results in the previous section which found that negative symptoms seemed to improve as a result of improved metacognitive functioning.

"I learned a lot about myself"…. "It made me think about myself in a different way". P4

"It made me think about things about myself that I hadn't noticed before"..."I am more aware of the things that affect me, and how much it affects". P6

Several participants stated that they had noticed how certain unhelpful thinking patterns (conceptualised by most subjects as "negativity" but seemed to include a high degree of expected social rejection, devaluation of relationships, or expected failure) had a direct impact on their everyday functioning. Participants also mentioned that they felt that they had developed skills during the intervention which helped them to modify these cognitions.

"I learned that I can actually do things together with other people, it is all in my head, that I need to do things just on my own"… "I am less self-critical and kinder to myself now". P6

"I am not thinking as negatively now as before". P7

"I am a bit paranoid for the moment but I got no reason to be, but I am. So I said to myself when I am walking into a shop and everyone is looking at me that is to do with the fact that I only got one arm, and that it is not anything personal". P4

"I thought about my negative ways in the past, and how I have changed them". P1

It was also reflected in the transcripts how awareness of these unhelpful thinking patterns (i.e. metacognition) had lead to the development of adaptive coping strategies.

"It was giving me coping mechanisms for when I am in trouble mentally. It has helped me a lot"…."I would never have gone on a bus but what you taught me, about getting on the bus and people are just exactly as you, so I learned from that that I can get on a bus"…"I can get out outside. You probably wouldn't understand it, I don't know if you have been through it yourself but you are getting cabin fever by only being inside. And when I go outside, I might be a bit paranoid, and a bit

scared, but yeah when I come back I feel a lot better. So it has helped that way"…

*"If you went back just a few weeks ago, and I was in the state that I am now (*referring to the distress that he felt when ending therapy)*, I think it might have been a different outcome. I might have self-harmed. I would definitely have self-harmed". P4*

"I am trying a bit harder to socialise. I went out with XXX yesterday and I was making jokes and laughed. I went to the barber shop Wednesday and had a great laugh so it's helping with my social confidence. That makes me feel good"… P5

"*I learned that I can do things to make me think and feel differently"… "That if I work purposefully and hard, things can be done which wouldn't happen if I just think". P6*

"I am more objective in my ability to motivate myself to do things which means that I am more active now". P7

It was also mentioned in several of the transcripts that the psychoeducational elements around psychotic symptoms had helped subjects to address internalised stigma.

"I understood how different aspects of negative symptoms leads to a psychotic illness". P2

"It was alright, it was insightful because I didn't really understand what psychosis was". P3

"I understand my illness more now and I know that it is just my mind playing tricks which makes the psychosis feel less real". P10

3.4.3. The therapeutic alliance

Most participants commented on how they had enjoyed taking part in the intervention due to the therapeutic alliance. This seemed to centre around two categories: the "cathartic" value of seeing the researcher and the therapeutic space as a way to reflect and problem-solve.

"It helped me. I got my feelings out" P1

"It didn't help me surviving everyday life in the ward but talking and thinking about my family did"... "That was the best bit, talking about my family... Taking it off your chest, that's useful". P2

"If you talk about it, you can solve it. Talking solves. Sitting talking, and the best ideas will come out. Just you being there Linda, it's partly you. Me and you, 1:1". P1

"It helped me to express myself, that Linda listened to me and knows where I am coming from". P9

4. Discussion

The primary aim of the research study was to evaluate the feasibility of MCT modified for negative symptoms in terms of acceptability, practicality, demand and limited efficacy. A secondary aim was to evaluate whether MCT could be used to improve reflective ability and to identify mechanisms of change in negative symptoms. The study also explored the use of MLM as a statistical approach for the analysis of case-series.

4.1. Feasibility of the intervention

4.1.1. Acceptability

In terms of acceptability, 40% of the patients who were asked to participate agreed to take part. This means that the intervention had a slightly higher success rate in recruitment than other studies for negative symptoms (e.g. 25% in Staring et al. (2013)). It is possible that this might have been the design of MCT in comparison to CBT as the participants were not required to share sensitive information to the same degree (sharing personal information can be threatening to those applying a coping strategy of disengaging with others to avoid perceived judgement).

The dropout rate during the active phase of therapy was found to be 33% (5 of 15 subjects) which is similar to other studies (e.g. 43% for CR and 25% for CBT in the study by Klingberg et al (2011) and 23% in the study by Velligan et al (2015)). However, it is higher than the studies undertaken by Beck and colleagues (i.e. 15% in Grant et al. (2012) and 14% in Staring et al. (2013)), which might be explained by the fact the study recruited from a chronic and treatment resistant patient population. A recent meta-analysis (Fernandez, Salem, Swift, & Ramtahal, 2015) of the dropout rate for CBT for various mental health disorders which covered more than 20,000 participants found that the weighted average during treatment was 26% which is similar to this study. Following completion, all subjects were able to identify aspects of the intervention that they valued; this included receiving psychoeducation on psychosis, skill development (including metacognitive ability), and the therapeutic relationship.

4.1.2. Practicality

As the intervention was manualised, it is a practical treatment option that could be delivered with ease and implemented into standard care in an NHS setting. It required minimal preparation before sessions as the only task prior to seeing a patient was to print off the homework sheets. The practical aspect of MCT might be the reason, as pointed out by Van Oosterhout et al. (2016), it has been disseminated all over the world and been translated in 33 languages.

4.1.3. Demand

The researcher received feedback from the clinical team indicating, as expected, that there was a clear demand for the intervention. This included positive feedback from several psychiatrists who welcomed the development of an intervention to target negative symptoms given the lack of evidence-based interventions available. It also included feedback from other clinicians who expressed an interest in using it. Overall, this indicates that the intervention had good feasibility in terms of acceptability, practicality, and demand. However, it should be acknowledged that the trial methodology might have led to more favourable outcomes than would have been found if the intervention had been delivered and implemented by professionals in a standard NHS care setting.

4.1.4. Limited efficacy

As this was a case-series design, limited conclusions in regards to efficacy can be made. However, based on this small sample, it was found that the intervention led to significant improvements on negative symptoms as measured with BNSS. This

supports the findings of other studies (Klingberg et al., 2011; Grant et al., 2012; Staring et al. 2013, Velligan et al., 2015) that show negative symptoms respond to psychological interventions. As Velligan et al. (2015) found that other measures of negative symptoms (i.e. the NSA-16 and the CAINS) were more sensitive to change than BNSS, it is possible that a larger effect would have been found in this study if alternative measures had been used. Contrary to Klingberg et al. (2011), this study did not find any significant improvements when using the five-factor model on the negative subscale of PANSS. This might be due to sampling difference as Klingberg et al. (2011) had a highly selective sample where patients with a significant degree of depression, positive symptoms, cognitive difficulties or substance abuse were excluded. It might also be because patients received more sessions (N=20) over a longer period of time (9 months), or because patients were seen on an outpatient basis indicating they had a higher level of social functioning. The lack of significant findings on the PANSS might be due to the fact that the measurement, in contrast to BNSS, does not assess expectations or experiences in relation to pleasure (i.e. anhedonia) (Daniel, 2013) which would have been targeted and potentially improved by the intervention.

This study also found that subjective quality of life did not significantly improve over time which is similar to previous research targeting negative symptoms in schizophrenia (Daniels, 1998). As no recent studies on negative symptoms include measures of quality of life (Klingberg et al., 2011; Grant et al., 2012; Staring et al., 2013; Velligan et al., 2015), it is difficult to conclude how this relates to more recent studies. The result might be due to the sample mainly consisting of unmarried adult

men with depression and negative symptoms in an in-patient setting who have suffered from psychosis for many years as quality of life in schizophrenia has been found to be negatively affected by older age, being male, length of illness, negative symptoms, depression and being institutionalised (Bobes, Garcia-Portilla, Bascaran, Saiz, & Bouzoño, 2007); it is hence possible that the sample represent a subgroup that are particularly difficult to treat. The results might also be due to methodological issues as research has indicated that reported subjective quality of life in schizophrenia may be affected by depressive and psychotic symptoms, metacognitive and cognitive deficits, and poor insight which may then threaten the validity and reliability of measures (Hayhurst, Massie, Dunn, Lewis, & Drake, 2014; Nishiyama & Ozaki, 2010; Boyer et al., 2012). Alternatively, it is possible that a significant effect would have been found if the sample size had been larger as the slopes in the visual inspection demonstrated positive results for all subjects on quality of life. The lack of significant differences at CDSS might be due to the fact that intervention did not explicitly target depression.

In addition, the study found no improvements on GAF. This measure might have been too crude to detect psychosocial changes in this population as suggested by previous research (Robertson et al., 2013). Contrary to the case study by Van Donkersgoed et al. (2016) that used the MAS-A to assess change following MERIT, no changes pre and post intervention were found on the MAS-A in this study; this might be due to the chronicity of the patients in this study. However, it seemed like the feasibility for the MAS-A was low as only five participants completed it at baseline and three post intervention. The main reason for not wanting to be

interviewed was a reluctance to be recorded. The oral feedback from the patients who completed the interview at two time-points was that they felt that they had already shared their life story with the researcher once and were reluctant to repeat this. It is possible that reluctance to re-tell their life story had an impact on their overall score as significant differences were found pre and post intervention on the other measurement of mentalization, the RFQ. Self-perceived improvements were also seen in the qualitative feedback from the participants. Finally, the study found that the intervention led to significant improvements on internalised stigma which is in line with previous research on the relationship between negative symptoms and stigma (Hill & Startup, 2013) as well as the qualitative results of this study. It should be acknowledged though that the intervention overall only led to modest effect sizes which, as previously discussed, is similar to other intervention studies on negative symptoms.

4.2. Mechanisms of change

This study adds to the research on mechanisms of change involved in treating negative symptoms by showing that reflective ability improved the fit of the model more than depression and internalised stigma. A link between negative symptoms and reflective functioning is also suggested as reflective ability and negative symptoms were the only measured constructs that significantly improved post intervention. This provides support for the metacognitive model of negative symptoms suggested by Lysaker and colleagues and is hence in agreement with previous research (Mitchley, Barber, Gray, Brooks, & Livingston, 1998; Doody, Götz, Johnstone, Frith, & Owens, 1998; Garety & Freeman, 1999; Greig, Bryson, &

Bell, 2004; Sergi et al., 2007). In addition, as depression was found to be significantly predictor for changes on negative symptoms over time and improved the model fit considerably, the research was in line with previous suggestions of a relationship between depression and negative symptoms (Upthegrove et al., 2017). It was also found that internalised stigma seemed to contribute to negative symptoms which parallels previous research (Hill & Startup 2013; Lysaker, Vohs, & Tsai, 2009; Staring et al., 2013) and supports the cognitive model of negative symptoms. It is hence likely that interventions addressing depression, internalised stigma, and reflective functioning would have a positive impact on negative symptoms.

4.3. Evaluation of MLM

The statistical analysis applied in the study illustrated the benefits of using MLM for case series as it accounted for the nested and auto-regressive nature of the data. MLM also had the advantage that it was able to manage data collected at various time points and with missing data.

As with all small N designs, the risk of Type I and Type II error should be acknowledged due to the small sample size. Power in this study could have been increased by having more time points, or as recommended by Shadish et al (2013), or by recruiting more subjects. As the MLM in the current study included data from 15 participants, it was larger than any of the case series included in the survey by Shadish & Sullivan (2011), where the maximum observed cases were 13 and the median was three. However, as described by the Shadish et al., (2013), more research is needed to clarify the issue of power when using MLM for small N. This

would differ from previous research as the aim would be to gain enough power to detect a within-person treatment effect rather than a between-groups effect. Due to the uncertainty in relation to power in MLM, the current study focused on improvements in model fit in addition to the findings that reached statistical significance. This provided important information about the mechanisms of change in relation to improvements in negative symptoms and quality of life.

4.4. Strengths and limitations

The current study developed Metacognitive Training for Negative Symptoms and evaluated the intervention. The triangulation of quantitative and qualitative results supports the feasibility of the intervention. The study has clinical implications as it shows that negative symptoms are affected by psychological factors which can be improved in therapy. The promising results in terms of outcomes suggest the intervention should be systematically assessed in future research.

In addition, the pilot study is also the first of its kind to identify mechanisms of change by including multiple models and factors (i.e. internalised stigma, reflective functioning, depression). This is important as previous studies evaluating psychosocial interventions for negative symptoms have targeted one specific area in isolation for intervention and outcome measures which is unlikely to fully explain the complexity of negative symptoms. The study also adds to the growing evidence base indicating the suitability of applying multilevel modeling for case series.
A strength of the study is that it is a real life study and hence shows how effective the intervention is in routine circumstances. Furthermore, the patient group used in

this study had positive symptoms, depression, substance abuse, and extrapyramidal symptoms; this is a representative sample of a chronic treatment resistant group in standard care. This means that the findings of this study have high generalisability compared to an RCT which would have a highly selected group. For example, 65% of the population did not fulfil the inclusion criteria in the study by Klingberg et al., (2012) whilst a screen failure rate of 44% was found in the study by Velligan et al., (2015) after a month.

The study has some obvious limitations due to its sample size limiting the ability to perform more sophisticated analyses (e.g. interactions between predictors). The absence of multiple baseline measurements also mean it is not possible to assess whether changes in symptoms were a result of treatment or chance. In addition, it would have been preferable if an independent researcher had administered the outcome measurements as this would have controlled for potential biases. As all participants received treatment as usual whilst taking part in the intervention, it is possible that improvements were due to care that they received from other sources (e.g. medication, psychological intervention, and nursing care) which may have influenced the outcome measures. It was encouraging that the qualitative data indicated that the metacognitive training was valued, and that participants reported that change had occurred as a result of this intervention.

4.5. Overall conclusion

The study shows that negative symptoms are affected by psychological factors (e.g. internalised stigma, reflective functioning, depression) and that these processes can be

improved in therapy. The promising results in terms of outcomes suggest the intervention should be systematically assessed in future research with a larger sample, a control group, and an independent research group. In addition, the study shows that multilevel modeling is a promising statistical analysis for case series.

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Appendix A. Exclusion criteria for the systematic review

(modified from Ross et al., 2013 and Geddes, 2013)

1. Hornsveld (2005)	No measure of subjective wellbeing
2. Hornsverld (2008)	Patient group (PD rather than psychosis)
3. Ahmed (2015)	Patient group (included non-forensic population)
4. Aho-Mustonen (2008)	Patient group (included non-forensic population)
5. Aho-Mustonen (2010)	No measure of subjective wellbeing
6. Axer (1995)	No quantitative measure
7. Clarke (2010)	No measure of subjective wellbeing
8. Cullen (2012 a,b)	No measure of subjective wellbeing
9. Dean (2013)	Not published in peer-reviewed journal
10. Fahy (2004)	Not published in peer-reviewed journal
11. Garrett (2007)	No quantitative measure
12. Haddock (2009)	Not in a forensic setting
13. Hall (2008)	No measure of subjective wellbeing
14. Hodel (2010)	No measure of subjective wellbeing
15. Kuokkanen (2014)	No measure of subjective wellbeing
16. Kunz (2014)	No quantitative measure
17. Long (2011)	Patient group (PD rather than psychosis)
18. Long (2008)	No data reported
19. Long (2012, 2013, 2015)	Patient group (PD rather than psychosis)
20. Luckhaus (2013)	No measure of subjective wellbeing
21. Naughton (2012)	No measure of subjective wellbeing
22. Nagi (2014)	No measure of subjective wellbeing
23. Mezey (2015)	No quantitative measure
24. Pilarc (2000)	Not a forensic setting
25. Ritchie (2011)	Intervention designed to reduce substance abuse
26. Ree-Jones (2012)	No measure of subjective wellbeing
27. Schanda (1992)	Not in English
28. Siess (2016)	Not in English
29. Sistig (2015)	No measure of subjective wellbeing
30. Slater (2016)	No quantitative measure
31. Tapp (2009)	No measure of subjective wellbeing
32. Taylor (2016)	No measure of subjective wellbeing
33. Tibber (2015)	No measure of subjective wellbeing
34. Völlm (2017)	Not published in peer-reviewed journal
35. Walker (2012)	No measure of subjective wellbeing
36. Williams (2014)	No measure of subjective wellbeing
37. Wynaden (2012)	No measure of subjective wellbeing
38. Yates (2010)	No quantitative measure
39. Yip (2013)	No measure of subjective wellbeing
40. Young (2009)	No measure of subjective wellbeing

Appendix B. Quality Assessment Tool

Study Design and potential bias:

1. Participants were randomly allocated with this process being sufficiently concealed:

Well covered (3)	The method of allocation and concealment are clearly described.
Adequately addressed (2)	The method of allocation and concealment are mentioned but are not described in sufficient enough detail to be clear.
Poorly addressed (1)	The method of allocation or concealment are mentioned but are not sufficiently described. Alternatively, allocation is non-randomised.
Not addressed (0)	The method of allocation and/or concealment is not addressed.
Not reported (0)	The method of allocation and/or concealment is not reported.
Not applicable (0)	The method of allocation and/or concealment is not applicable in this study.

2. An independent concealment of allocation procedure is used:

Well covered (3)	Those administering the outcome measures were blind to the allocation of participants. Alternatively, different people administered the measures and delivered the intervention. The method of this being ensured is clearly described.
Adequately addressed (2)	The method of how researchers were blinded to allocation is described but is not sufficiently detailed in order to fully understand the method by which this was ensured.
Poorly addressed (1)	The blinding of researchers is mentioned but the method is not described.
Not addressed (0)	The blinding of researchers was not discussed.
Not reported (0)	The blinding of researchers was not reported.
Not applicable (0)	The blinding of researchers is not applicable to this study.

3. Acceptable and comparable attrition rates between groups:

Well covered (3)	Details are given regarding the drop out rates for both groups. These are similar for each group (from pre- post intervention within 10% of each other and 20% of total participants).
Adequately addressed (2)	Details are given regarding the drop out rates for both groups. These rates are somewhat alike between groups (within 20% of each other and less than 30% of total participants from pre- to post-intervention).
Poorly addressed (1)	Details are given regarding the drop out rates for both

	groups. There are high drop out rates in general or uneven drop out rates.
Not addressed (0)	Dropout rates are mentioned but not clearly described.
Not reported (0) Not applicable (0)	Dropout rates are not reported. Dropout rates are not applicable in this study.

4. Follow-up assessment at a suitable time period completed:

Well covered (3)	Described sufficiently well to determine that follow-up period after the intervention is reasonable. At least 6 months post end of intervention. Follow-up data must include outcome measures used at baseline.
Adequately addressed (2)	Described sufficiently well to determine that follow-up period after the intervention is adequate. At least 3-6 months post end of intervention. Follow-up data must include outcome measures used at baseline.
Poorly addressed (1)	Described sufficiently well to determine that follow-up period after the intervention is inadequate. Follow up less than 3 months post end of intervention. Follow-up data must include outcome measures used at baseline.
Not addressed (0)	Follow-up is mentioned but is not described in sufficient detail to determine time period.
Not reported (0)	Follow-up assessment not reported.
Not applicable (0)	Follow-up assessment not applicable in this study.

Outcomes:

5. Outcome measures for subjective wellbeing are evidenced to be both valid and reliable and psychometric values are specified by the authors:

Well covered (3)	Outcome measures are used with their psychometric properties being well reported. Details of their validity and reliability within a forensic psychiatric population are also reported.
Adequately addressed (2)	Outcome measures are used with their psychometric properties being reported less well. Details of their validity and reliability within a forensic psychiatric population are less clear.
Poorly addressed (1)	The use of outcome measures is mentioned but with little information given about the measures or their psychometric properties.
Not addressed (0)	The use of outcome measures is mentioned but no further information is provided.
Not reported (0)	The use of outcome measures is not reported.
Not applicable (0)	The use of outcome measures is not applicable in this study.

6. The outcome is relevant and meaningful to the intervention:

Well covered (3)	The outcome is described and is relevant to both the intervention and the evaluation of this within the context of subjective wellbeing in forensic patients.
Adequately addressed (2)	The outcome is described but is less relevant either to the specific intervention being delivered or within the context of subjective wellbeing in forensic patients.
Poorly addressed (1)	The outcome is mentioned but is less well covered and its usefulness to the evaluation of the intervention or broader context of subjective wellbeing in forensic patients is less clearly described.
Not addressed (0)	The overall outcome is not related to the intervention specifically or the broader context of subjective wellbeing in forensic patients.
Not reported (0)	How the outcome is related to the intervention and evaluation is not reported.
Not applicable (0)	How the outcome is related to the intervention and evaluation is not applicable in this study.

7. Study is adequately powered to detect the effect of the intervention:

Well covered (3)	A power calculation was completed using a reasonable effect size estimation and is clearly reported along with sufficient sample size within each group.
Adequately addressed (2)	A power calculation is carried out, however, arbitrary effect size estimation used.
Poorly addressed (1)	Power calculation is completed, however, effect size estimation is not mentioned and no evidence of this having informed the sample size in each group.
Not addressed (0)	Power calculation not completed or paper failed to meet the power calculation with sufficient sample size meaning any difference is not statistically significant.
Not reported (0)	Power calculation is not reported.
Not applicable (0)	Power calculation is not applicable in this instance.

8. Appropriate analysis for outcome measures used and p values, confidence intervals and effect sizes reported where appropriate:

Well covered (3)	Method of quantitative analysis used provides meaningful results of outcome and the confidence intervals, p-values and effect sizes are reported where appropriate. The analysis is described in sufficient detail so as statistical significance as well as descriptive information is clearly presented.

Adequately addressed (2)	The quantitative analysis used provides meaningful results, however, the details of this such as the p-values, confidence intervals and effect sizes are less well covered.
Poorly addressed (1)	The method of analysis used has not been well considered and does not provide the best presentation of results from the study. The p values, effect sizes and confidence intervals may have mentioned but are not sufficient in this case.
Not addressed (0)	There has not been any quantitative analysis used in this case, rather inconclusive findings have been provided.
Not reported (0)	The methods of analysis have not been reported.
Not applicable (0)	The methods of analysis are not applicable in this instance.

Quality of reporting:

9. The TREND, CONSORT and STROBE statement guidelines for reporting have been adhered to in the RCT's, non-randomised trials and observational studies (guidelines included within appendices):

Well covered (3)	The reporting and layout of the article has strictly followed the relevant statement guideline.
Adequately addressed (2)	The layout of the article is not in exactly the same format as that provided by the relevant guideline; however, the content required by the guideline is present.
Poorly addressed (1)	The guideline of reporting has not been adhered to successfully. There is evidence that aspects of the guideline have been considered but has not been sufficiently followed.
Not addressed (0)	There is no evidence that the guideline has been considered when the article has been developed.
Not applicable (0)	Adherence to the relevant guideline is not applicable in this study.

Quality of the intervention:

10. The intervention has been appropriately defined:

Well covered (3)	The intervention is covered in sufficient detail including reference to the theoretical underpinnings and the potential impact the intervention could have on subjective wellbeing. The content and procedures of the intervention are clearly described so as it could be replicated by the reader.
Adequately addressed (2)	The intervention is described in relatively sufficient detail, although is less well covered. The theoretical underpinnings and potential impact the intervention could have on subjective wellbeing is discussed but in less detail. The content and procedures are also mentioned but lack the detail necessary for the intervention to be accurately

	replicated.
Poorly addressed (1)	The intervention is described; however, there is a lack of reference to the theoretical underpinnings and potential impact on subjective wellbeing. The content and procedures are not discussed.
Not addressed (0)	The aims of the intervention are mentioned but the underpinnings and procedures of the intervention are lacking.
Not reported (0)	Details of the intervention itself are not reported.
Not applicable (0)	Details of the intervention are not applicable in this study.

11. The intervention is both sufficiently defined and delivered as planned (i.e. demonstrates good fidelity):

Well covered (3)	Details of how the treatment was operationalised (e.g. treatment manual) are provided and adhered to, as are fidelity checks (e.g. supervision and/or reflective practice).
Adequately addressed (2)	Details of how the treatment was operationalised (e.g. treatment manual) are provided and adhered to but there are no fidelity checks.
Poorly addressed (1)	Details of how the treatment was operationalised are given but there is no evidence of this being adhered to and/or no evidence of fidelity checks
Not addressed (0)	Operationalisation of the intervention and/or fidelity checks are mentioned but no further detail is given.
Not reported (0)	Operationalisation of the intervention and/or fidelity checks are not reported.
Not applicable (0)	Operationalisation of the intervention and/or fidelity checks are not applicable in this study.

Generalisability:

12. The intervention has been implemented in a way that would be considered routine practice:

Well covered (3)	The intervention took place in a forensic psychiatric setting and the article discusses external validity and the relevance of the intervention to this setting.
Adequately addressed (2)	The paper describes external validity and the relevance of this intervention to a forensic psychiatric setting, however, the intervention did not take place in this setting.
Poorly addressed (1)	The paper does not discuss external validity and the intervention did not take place in a forensic psychiatric setting.
Not addressed (0)	Neither external validity nor intervention setting was addressed in the paper.
Not reported (0)	Neither external validity nor intervention setting was reported in

	the paper.
Not applicable (0)	Neither external validity nor intervention setting was applicable in this study.

Appendix C. TREND, CONSORT, and STROBE Statement Checklists

TREND Statement Checklist

Paper Section/ Topic	Item No	Descriptor	Reported? ✓	Reported? Pg #
Title and Abstract				
Title and Abstract	1	• Information on how unit were allocated to interventions		
		• Structured abstract recommended		
		• Information on target population or study sample		
Introduction				
Background	2	• Scientific background and explanation of rationale		
		• Theories used in designing behavioral interventions		
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)		
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented		
		• Recruitment setting		
		• Settings and locations where the data were collected		
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:		
		o Content: what was given?		
		o Delivery method: how was the content given?		
		o Unit of delivery: how were the subjects grouped during delivery?		
		o Deliverer: who delivered the intervention?		
		o Setting: where was the intervention delivered?		
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?		
		o Time span: how long was it intended to take to deliver the intervention to each unit?		
		o Activities to increase compliance or adherence (e.g., incentives)		
Objectives	5	• Specific objectives and hypotheses		
Outcomes	6	• Clearly defined primary and secondary outcome measures		
		• Methods used to collect data and any methods used to enhance the quality of measurements		
		• Information on validated instruments such as psychometric and biometric properties		
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules		
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)		
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)		
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)		

TREND Statement Checklist

Blinding (masking)	9	• Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed.		
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)		
		• If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)		
Statistical Methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data		
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis		
		• Methods for imputing missing data, if used		
		• Statistical software or programs used		
Results				
Participant flow	12	• Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended)		
		o Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study		
		o Assignment: the numbers of participants assigned to a study condition		
		o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention		
		o Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition		
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition		
		• Description of protocol deviations from study as planned, along with reasons		
Recruitment	13	• Dates defining the periods of recruitment and follow-up		
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition		
		• Baseline characteristics for each study condition relevant to specific disease prevention research		
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition		
		• Comparison between study population at baseline and target population of interest		
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences		

TREND Statement Checklist

Numbers analyzed	16	• Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible		
		• Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses		
Outcomes and estimation	17	• For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision		
		• Inclusion of null and negative findings		
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any		
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory		
Adverse events	19	• Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)		
DISCUSSION				
Interpretation	20	• Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study		
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations		
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation		
		• Discussion of research, programmatic, or policy implications		
Generalizability	21	• Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues		
Overall Evidence	22	• General interpretation of the results in the context of current evidence and current theory		

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

STROBE Statement Checklist

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

Appendix D. The International Journal of Forensic Mental Health author guidelines

> ***Formatting and templates***

Papers may be submitted in any standard file format, including Word and LaTeX. Figures should be saved separately from the text. The main document should be double-spaced, with one-inch margins on all sides, and all pages should be numbered consecutively. Text should appear in 12-point Times New Roman or other common 12-point font.

Style guidelines

Submissions to *International Journal of Forensic Mental Health* should follow the style guidelines described in the *APA Publication Manual* (6th ed.). *Merriam-Webster's Collegiate Dictionary* (11th ed.) should be consulted for spelling.

References

References should be cited parenthetically in the text by author surname(s) and year, in accordance with *APA Publication Manual* guidelines. References should be listed in a separate section at the end of the main text. All references in the list should be ordered alphabetically by the first author's surname.

1. **Author details**. Please include all authors' full names, affiliations, postal addresses, and email addresses on the cover page. One author will need to be identified as the corresponding author, with their email address normally displayed in the published article. Authors' affiliations are the affiliations where the research was conducted.

2. **Abstract.** This summary of your article is normally no longer than 100 words.

3. **Keywords.** Keywords are the terms that are most important to the article and should be terms readers may use to search. Authors should provide 3 to 5 keywords.

Appendix E. The Clinical Psychology & Psychotherapy author guidelines

PREPARING THE SUBMISSION

Title Page

The title page should contain:

- A short informative title containing the major key words. The title should not contain abbreviations;
- A short running title of less than 40 characters;
- The full names of the authors;
- The author's institutional affiliations where the work was conducted, with a footnote for the author's present address if different from where the work was conducted;

Abstract

Enter an abstract of up to 150 words for all articles. An abstract is a concise summary of the whole paper, not just the conclusions, and is understandable without reference to the rest of the paper. It should contain no citation to other published work

Keywords

Please provide five to six keywords.

Main Text

The language of the journal is English. 12-point type in one of the standard fonts: Times, Helvetica, or Courier is preferred. Please double-line space your manuscript. Tables must be on separate pages after the reference list, and not be incorporated into the main text. Figures should be uploaded as separate figure files

References

References should be prepared according to the Publication Manual of the American Psychological Association (6th edition). This means in text citations should follow the author-date method whereby the author's last name and the year of publication for the source should appear in the text, for example, (Jones, 1998). The complete reference list should appear alphabetically by name at the end of the paper. Please note that for journal articles, issue numbers are not included unless each issue in the volume begins with page 1, and a DOI should be provided for all references where available.

Tables

Tables should be self-contained and complement, not duplicate, information contained in the text. They should be supplied as editable files, not pasted as images. Legends should be concise but comprehensive – the table, legend, and footnotes must be understandable without reference to the text. All abbreviations must be defined in footnotes. Footnote symbols: †, ‡, §, ¶, should be used (in that order) and *, **, *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the headings.

Figure Legends

Legends should be concise but comprehensive – the figure and its legend must be understandable without reference to the text. Include definitions of any symbols used and define/explain all abbreviations and units of measurement.

Figures

Although authors are encouraged to send the highest-quality figures possible, for peer-review purposes, a wide variety of formats, sizes, and resolutions are accepted.

Appendices

Appendices will be published after the references. For submission they should be supplied as separate files but referred to in the text.

General Style Points

The following points provide general advice on formatting and style.

Abbreviations: In general, terms should not be abbreviated unless they are used repeatedly and the abbreviation is helpful to the reader. Initially, use the word in full, followed by the abbreviation in parentheses. Thereafter use the abbreviation only.

Units of measurement: Measurements should be given in SI or SI-derived units.

Numbers: numbers under 10 are spelled out, except for: measurements with a unit (8mmol/l); age (6 weeks old), or lists with other numbers (11 dogs, 9 cats, 4 gerbils).

Trade Names: Chemical substances should be referred to by the generic name only. Trade names should not be used. Drugs should be referred to by their generic names. If proprietary drugs have been used in the study, refer to these by their generic name, mentioning the proprietary name and the name and location of the manufacturer in parentheses.

Appendix F. Ethical approval, Patient Information Sheet, Consent Form, and Interview Schedule

Lothian NHS Board

South East Scotland Research Ethics Committee 02

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 536 9000

www.nhslothian.scot.nhs.uk

Date 26 February 2016
Your Ref
Our Ref

Enquiries to: Joyce Clearie
Extension: 35674
Direct Line: 0131 465 5674
Email: Joyce.Clearie@nhslothian.scot.nhs.uk

26 February 2016

Ms Linda Eriksson
Department of Psychology, 2nd Floor Mackinnon House
Royal Edinburgh Hospital, Tipperlinn Road
Edinburgh
EH10 5HF

Dear Ms Eriksson

Study title: **Modified Metacognitive Therapy for negative symptoms in psychotic disorders**
REC reference: **16/SS/0046**
IRAS project ID: **189645**

The Research Ethics Committee reviewed the above application at the meeting held on 24 February 2016. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Ms Joyce Clearie, joyce.clearie@nhslothian.scot.nhs.uk. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

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

- Please do final typographical and grammatical check of participant documentation and amend appropriately e.g. favourable rather than favorable etc.
-

<u>Participant information sheet</u>

- Should explain the fate of the audio recordings etc.

- PIS Where will my data be stored section – Please amend wording along the lines….*in future ethically approved studies.* A bullet point should also be added to the consent form to allow for this.
- What do I have to do section should make it clearer the number of visits required i.e. 2
- Please consider road testing participant information.
- Please reconsider extending the amount of time allocated to allow for filling in questionnaires. 45 minutes seems optimistic? Please justify or extend.

- IRAS A29 – The Committee were not entirely clear who will be making the initial approach /obtaining consent. Please confirm

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

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

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

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

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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

Ethical review of research sites

NHS Sites

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

Non NHS sites

The Committee has not yet completed any site-specific assessment(s) (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Summary of discussion at the meeting

Ethical issues, noted and resolved in preliminary discussion

- **Social or scientific value; scientific design and conduct of the study**
  Overall the study's scientific value, scientific design and the conduct was considered to be acceptable. They had few significant ethical concerns over the project.

- **Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)**
  This was considered acceptable

- **Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity**
  Overall this was considered acceptable

- **Suitability of the applicant and supporting staff**
  This was considered acceptable

- **Independent review**
  This was considered acceptable

- **Suitability of supporting information**
  This was considered acceptable

- **Other general comments**
  No other general comments

- **Suitability of the summary of the research**
  This was considered acceptable

- **Recruitment arrangements and access to health information, and fair participant selection**
  A29 – The Committee were not entirely clear who will be making the initial approach /obtaining consent and it was agreed that this should be clarified.

Ethical issues raised by the Committee in private discussion, together with responses given by the researcher when invited into the meeting. The Chair welcomed Ms Linda Eriksson to the meeting

- **Informed consent process and the adequacy and completeness of participant information**

  The Committee asked if the PISs had been road tested?

  The CI confirmed they had not.

  The Committee commented that it would have been good for the investigators to try road-testing the PIS for comprehensibility and to prove that the questionnaires actually could be done in 45 minutes.

  The CI noted this.

  The Committee advised the CI that the PIS should explain the fate of the audio recordings e.g. destruction after transcription.

  The CI accepted this

Decision

The Committee gave a favourable opinion of the application (with additional conditions)

- Please do final typographical and grammatical check of participant documentation and amend appropriately e.g. favourable rather than favorable etc.
-

Participant information sheet

- Should explain the fate of the audio recordings etc.
- PIS Where will my data be stored section – Please amend wording along the lines….*in future ethically approved studies.* A bullet point should also be added to the consent form to allow for this.
- What do I have to do section should make it clearer the number of visits required i.e. 2
- Please consider road testing participant information.
- Please reconsider extending the amount of time allocated to allow for filling in questionnaires. 45 minutes seems optimistic? Please justify or extend.

- IRAS A29 – The Committee were not entirely clear who will be making the initial approach /obtaining consent. Please confirm

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*

Copies of advertisement materials for research participants	1	01 February 2016
GP/consultant information sheets or letters	1	01 February 2016
Interview schedules or topic guides for participants		
Other [Second supervisor CV]		
Other [EL Cert]		
Other [PL-Confirmation]		
Other [Clinical Trial liability]		
Other [Professional Indemnity]		
Other [Demographicdata]		
Participant consent form	1	01 February 2016
Participant information sheet (PIS)	1	01 February 2016
Participant information sheet (PIS) [Debrief Patients]	1	01 February 2016
REC Application Form [REC_Form_09022016]		09 February 2016
Research protocol or project proposal		
Summary CV for Chief Investigator (CI)		01 February 2016
Summary CV for student		
Summary CV for supervisor (student research)		01 February 2016
Validated questionnaire [BIPQ]		
Validated questionnaire [BNSS]		
Validated questionnaire [CDSS]		
Validated questionnaire [GAF]		
Validated questionnaire [MAS-A]		
Validated questionnaire [PANSS]		
Validated questionnaire [Q-LES-Q-18]		
Validated questionnaire [RFQ]		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

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

After ethical review

Reporting requirements

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

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

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

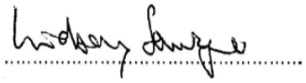
HRA Training

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

16/SS/0046	**Please quote this number on all correspondence**

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

Yours sincerely



Professor Lindsay Sawyer
Chair
E-mail: joyce.clearie@nhslothian.scot.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers" [*SL-AR2 for other studies]*

Copy to:

Jo-Anne Robertson, University of Edinburgh
Mr Gavin Robertson, NHS Lothian

University Hospitals Division

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

NHS Lothian

FM/GM/Approval

17th March 2016

Ms Linda Eriksson
Department of Psychology,
2nd Floor Mackinnon House
Royal Edinburgh Hospital
Tipperlinn Road
EH10 5HF

Research & Development
Room E1.12
Tel: 0131 242 3330

Email:
R&DOffice@nhslothian.scot.nhs.uk

Director: Professor David E Newby

Dear Ms Eriksson,

Lothian R&D Project No: 2016/0070

Title of Research: Modified Metacognitive Therapy for negative symptoms in psychotic disorders

REC No: 16/SS/0046

Participant Information Sheet:
Version 2.0 Dated 14th March 2016

Consent Form:
Version 2.0 Dated 14th March 2016

Protocol: Version 1.0 Dated 6th January 2016

I am pleased to inform you that this study has been approved for NHS Lothian and you may proceed with your research, subject to the conditions below. This letter provides Site Specific approval for NHS Lothian.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Lothian.

Substantial amendments to the protocol will require approval from the ethics committee which approved your study and the MHRA where applicable.

Please inform this office when recruitment has closed and when the study has been completed.

I wish you every success with your study.

Yours sincerely

Fiona McArdle.

Ms Fiona McArdle
Deputy R&D Director

Lothian NHS Board

South East Scotland Research Ethics Committee 02

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 536 9000

www.nhslothian.scot.nhs.uk

Date: 27 June 2016
Your Ref
Our Ref

Enquiries to: Joyce Clearie
Extension: 35674
Direct Line: 0131 465 5674
Email: joyce.clearie@nhslothian.scot.nhs.uk

27 June 2016

Ms Linda Eriksson
Department of Psychology, 2nd Floor Mackinnon House
Royal Edinburgh Hospital, Tipperlinn Road
Edinburgh, EH10 5HF

Dear Ms Eriksson,

Study title:	**Modified Metacognitive Therapy for negative symptoms in psychotic disorders**
REC reference:	**16/SS/0046**
Amendment number:	**1 (09/06/16) 16/SS/0046AM01**
Amendment date:	**9 June 2016**
IRAS project ID:	**189645**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

No significant ethical issues were raised with this amendment.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)		10 June 2016
Research protocol or project proposal	2.0	09 June 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

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

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

16/SS/0046:	**Please quote this number on all correspondence**

Yours sincerely,

Mr Lindsay Murray
Chair

E-mail: joyce.clearie@nhslothian.scot.nhs.uk

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Mr Gavin Robertson, NHS Lothian*
Jo-Anne Robertson, University of Edinburgh

University Hospitals Division

NHS Lothian

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

KS/LM

11 September 2017

RESEARCH & DEVELOPMENT
Room E1.16
Tel: 0131 242 3330
Email:
R&DOffice@nhslothian.scot.nhs.uk

Director:
Professor Tim Walsh

Ms Linda Eriksson
NHS Lothian, University of Edinburgh
Department of Psychology, 2nd Floor Mackinnon House
Royal Edinburgh Hospital
Tipperlinn Road
Edinburgh
EH10 5HF

Dear Ms Eriksson

REC No:	16/SS/0046
R&D Project ID No:	2016/0070
Amendment:	Minor amendment dated 15 August 2017
Title of Research:	Modified Metacognitive Training for negative symptoms in psychotic disorders

I am writing in reply to recent correspondence in relation to an amendment(s) to the above project and the subsequent updated documents as follows.

- Consent Form Version 3.0, dated 23 August 2017
- Debrief Sheet Version 3.0, dated 23 August 2017
- Demographic Info Version 3.0, dated 23 August 2017
- GP Letter Version 3.0, dated 23 August 2017
- Patient Information Sheet Version 3.0, dated 23 August 2017
- Poster Version 3.0, dated 23 August 2017
- Protocol Version 3.0, dated 23 August 2017
- Qualitative Interview Questions Version 2.0, dated 23 August 2017
- Questionnaire - RFQ

We have now assessed any consequential changes and can confirm that NHS Lothian management approval is extended to cover the specific changes intimated.

Yours sincerely

pp K Kwak

Mr Kenny Scott
NRS Generic Review Manager

Patient Information Sheet

Study Title: Metacognitive Training for negative symptoms in psychotic disorders

We would like to invite you to take part in a research project being conducted by the University of Edinburgh and NHS Lothian as part of a Clinical Psychology doctoral thesis. Before you decide if you would like to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. If you are interested in taking part, there will be an opportunity to discuss the research before you make your final decision.

What is the purpose of the study?
The project will focus on the treatment of negative symptoms in psychotic disorders, for example: loss of interest and motivation in life and activities; lack of concentration; being less likely to initiate conversations; and feeling uncomfortable with people. Specifically, we will investigate whether Metacognitive Training (teaching you to think about and change your thinking patterns) is an effective treatment for negative symptoms in psychosis.

Why have I been asked to take part?
We are asking clients diagnosed with psychotic disorders in Lothian to take part in this study.

Do I have to take part?
No, it is up to you whether you take part or not. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive.

What do I have to do?
If you decide you are interested in taking part, a researcher will contact you to arrange two initial meetings.

At the first meeting you will sign a consent form and will have the opportunity to ask questions about the research. This meeting will last 10 minutes.

At the second meeting you will be interviewed and asked to complete a few questionnaires with the assistance of the researcher. The interview will be audio recorded on an encrypted digital recorder. This meeting will last 45-50 minutes in total.

We will then ask you to attend 8 sessions of Metacognitive Training. At the beginning of each session we will ask you questions about how you been since the last session and will ask you to complete some questionnaires. Each therapy session will last around 45 minutes, including the time needed to complete the questionnaires.

After completing the eight sessions, you will be asked to complete a few questionnaires and will be interviewed about what you thought of the therapy. This interview will be audio recorded. This meeting will last approximately 55-60 minutes in total.

A final meeting will be arranged 12 weeks later and will involve a short interview and the completion of some questionnaires with the assistance of the researcher. The interview will be audio recorded. This meeting will last 45-50 minutes in total.

What are the possible benefits and disadvantages of taking part?
We hope that both the treatment and assessments will be helpful to you, but this cannot be guaranteed. It is possible that talking about your mental health issues may be upsetting. You will have the opportunity to discuss any concerns you have with the researcher and you are free to withdraw from the study at any point. You can also talk to your mental health clinician about participation in this study and any concerns you may have.

What if there is a problem?
In the unlikely event that something goes wrong and you are harmed during the research and this is due to negligence then you may have grounds for legal action against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

If you have any concerns about aspects of the study please contact Linda Eriksson (Trainee Clinical Psychologist) on 0131 537 6916 who will do her best to answer your questions.

What happens to the information collected about me in the study?
Following the completion of the study your information will be anonymised and will be stored in a research database at the University of Edinburgh for 10 years. After those 10 years have elapsed all the information will be destroyed. Personal information (written and audio-taped) gathered during the study will be held for a period of 6-12 months after the study is completed and will then be destroyed. During the study and for the 6-12 month storage period your personal data will be treated in the same confidential manner as your medical records.

With your consent we will inform your GP that you are taking part.

To ensure that the study is being run correctly, we will ask for your consent for responsible representatives from the Sponsor and NHS Institution to access your medical records and data collected during the study, where it is relevant to you taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

Although direct quotes will be used in publications, participants will not be identified in any way.

The information that you provide (research data such as questionnaires and audio recordings) will not be shared with other people (i.e. medical staff or people involved in your care) unless you consent. The only instance in which information you provide may be shared is if you provide us with information that indicates that either yourself or another person is at risk of danger. Your safety and that of others is very important to us so we would need to share this information. This would normally be shared with somebody already involved in your care such as your mental health clinician or your GP. However, we will always discuss this with you beforehand.

If you lose your capacity to consent whilst participating in the study, you will be withdrawn from the study; identifiable data already collected with consent would be retained and used in the study. However, no further data would be collected and no further research procedures would be carried out from that point.

Where will my data be stored?
The questionnaires you complete will be kept in locked filing cabinets, to which only the researchers will have access. The recording is to be stored on the chief investigator's (Linda Eriksson) password protected NHS shared drive and deleted from the encrypted recorder immediately after uploading to the shared drive. Following completion of the study anonymous data will be stored electronically at the University of Edinburgh. It will not be possible to link you to this data in any way. It is possible that the anonymised data will be used in future ethically approved studies.

What will happen to the results of the research study?
We are happy to provide you with a summary of the results of the study. The final results and conclusions of the study will be published as a university thesis and will be shared at conferences and in peer reviewed scientific journals. You will not be identified in any publication.

Who is organising the research?
This study is being organised and sponsored by The University of Edinburgh and NHS Lothian.

Who has reviewed the study proposal?
The University of Edinburgh and NHS Lothian have reviewed the study proposal. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained from South East Scotland REC. NHS management approval has also been obtained.

If you have any further questions about the study please contact Linda Eriksson (Trainee Clinical Psychologist) by phone on 0131 537 6916

If you would like to discuss this study with an independent researcher please contact:

Emily Newman (Lecturer in Clinical Psychology)
School of Health in Social Science
Doorway 6, Medial Quad, Room 2.1, Teviot Place,
Edinburgh
EH8 9AG
Tel: 0131 651 3945

If you wish to make a complaint about the study please contact NHS Lothian:
NHS Lothian Complaints Team
2nd Floor
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 536 3370
Email: feedback@nhslothian.scot.nhs.uk

Thank you very much for reading this and for any further involvement with this study.

Participant Consent Form

Study Title: Modified Metacognitive Training for negative symptoms in psychotic disorders

Participant ID: ……

Name of Researcher: ……..

Please initial box

1. I confirm that I have read and understand the Patient Information Sheet (Version 3.0; 23.08.17) for the above study and have had the opportunity to consider the information and ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the regulatory authorities and from the Sponsor(s) (NHS Lothian and the University of Edinburgh) where it is relevant to this research. I give permission for those individuals to have access to my records. ☐
4. I understand that my data will be anonymised and transferred from NHS Lothian facilities to a research database at the University of Edinburgh. ☐
5. I understand that the anonymised data kept in the research database at the University of Edinburgh may be used in future ethically approved studies ☐
6. I agree to my General Practitioner being informed of my participation in this study. ☐
7. I agree to information (such as age, gender, medication, diagnosis, and previous psychological treatment) being collected from my medical notes ☐
8. I agree to parts of the interviews being audio recorded and that the audio recording will be transcribed and then deleted. ☐
9. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

 Original (x1) to be retained in site file. Copy (x1) to be retained by the participant.

1) How did you find the therapy?

2) Have you noticed any changes after completing the therapy?

3) Do you find yourself doing things differently after completing the therapy?

4) Do you find yourself looking at things differently?

5) What did you find least useful with the therapy?

6) What did you find most useful with the therapy?