Psychological interventions for psychosis; a meta-analysis of social skills training followed by a randomised controlled experimental study assessing the impact of meta-cognitive training addressing the jumping-to-conclusions bias on capacity

David T. Turner

Doctorate in Clinical Psychology

University of Edinburgh
March 2017
Table of contents

Declaration of own work 3
Research Portfolio Abstract 5
Lay Summary 7

Chapter 1: Systematic review & meta-analysis 9

Abstract 10
Introduction 11
Methods 13
Results 22

Table 1: Social skills training subtypes 19
Table 2: Study characteristics 20
Figure 1: PRISMA flowchart 23
Table 3: Main results 27
Figure 2: Summary forest plot 31
Discussion 32
References 37

Chapter 2: Randomised controlled empirical study 45

Abstract 48
Introduction 52
Method 52

Figure 1: Participant flow diagram 51
Table 1: Demographic and clinical characteristics 53
Table 2: Components of intervention 56
Results 60

Table 3: Main results 61
Table 4: Mediation analysis results 64
Discussion 65
References 69

Appendix 1: Supplementary materials for systematic review 74
Appendix 2: Author guidelines for systematic review 76
Appendix 3: PRISMA checklist 87
Appendix 4: PROSPERO Registration 88
Appendix 5: Author guidelines for empirical study 92
Appendix 6: CONSORT checklist 95
Appendix 7: Empirical Study Protocol 97
Appendix 8: Ethical approval and amendments 129
Appendix 9: Participant information & consent form 146
Appendix 10: Promotional poster 152
Appendix 11: Referrer information sheet 153
Appendix 12: Jumping-to-conclusions worksheets 155
Appendix 13: Demographics form 157

Thesis portfolio references 158
DClinPsychol Declaration of Own Work

Name: David Turner

Title of Work: Psychological interventions for psychosis; a systematic review and meta-analysis of social skills training for psychosis followed by a randomised controlled experimental study applying meta-cognitive training to improve treatment decision-making capacity among psychosis patients

I confirm that this work is my own except where indicated, and that I have:

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- Given the sources of all pictures, data etc. that are not my own
- Not made undue use of essay(s) of any other student(s), either past or present (or where used, this has been referenced appropriately)
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Research Portfolio Abstract

Background

There now exist a range of efficacious options for the treatment of psychosis in mental healthcare. The importance of recovery, empowerment, dignity and choice among patients with severe mental health diagnoses are important topics in contemporary research and practice. This thesis presents a meta-analytic review followed by a randomised controlled experimental study. These address distinct but related questions which aim to further our understanding of the choices available for intervention in psychosis and whether intervention may improve the ability of psychosis patients to make those choices.

Aims

The first objective aimed to offer a comprehensive review of the effectiveness of social skills training (SST), which is a psychological intervention for psychosis. SST has fallen out of favour in the UK and is not widely implemented in practice. We hypothesised that SST would demonstrate superiority for the negative symptoms of psychosis. The second objective was to determine whether decision-making capacity regarding treatment among psychosis patients could be improved by the application of a brief psycho-educational intervention targeting the jumping-to-conclusions (JTC) bias, which is a commonly observed cognitive bias in psychosis. We hypothesised that the intervention would improve decision-making capacity.

Methods

Firstly, a series of 70 meta-analyses are presented in a systematic review assessing the efficacy of social skills training across a number of psychosis outcome domains: positive symptoms, negative symptoms, general symptoms, overall symptoms and social functioning outcomes. Secondly, a randomised controlled experimental study is presented in which 36 psychosis patients in
NHS Lanarkshire and 1 in NHS Dumfries & Galloway were allocated to receive either a brief meta-cognitive training (MCT) intervention or an non-specific control presentation lecture. Capacity was assessed at baseline and post-treatment while the impact of the intervention upon capacity was estimated by ANCOVA. Mediation analyses assessed whether changes in the JTC bias mediated outcome.

Findings

In the meta-analytic review, SST demonstrated superiority over treatment as usual (TAU, \( g = 0.3 \)), active controls \( (g=0.2-0.3) \) and comparators pooled \( (g=0.2-0.3) \) for negative symptoms; and over TAU \( (g=0.4) \) and comparators pooled \( (g=0.3) \) for general psychopathology. In the randomised controlled study, MCT demonstrated large effects on two capacity outcomes; overall capacity \( (d=0.96, p<.05) \) and appreciation \( (d=0.87, p<.05) \). Exploratory analyses suggested a mediating effect of JTC \( (d=0.64, p<.05) \).

Interpretation

SST demonstrates a magnitude of effect for negative symptoms similar to those commonly reported for CBT for positive symptoms and may have potential for wider implementation in mental healthcare settings. The randomised controlled study suggests that psycho-educational interventions targeting capacity have clinical utility and may be developed for implementation. Limitations included lack of blinding, no fidelity checks and inclusion based on clinical diagnosis therefore a larger randomised controlled trial addressing these limitations is warranted.
Lay Summary

Background

There are now a range of choices available to help improve the lives of people diagnosed with psychosis or schizophrenia. The importance of recovery, empowerment, dignity and choice among patients with the most challenging mental health problems are important current topics. This thesis presents a systematic and statistical review of previous research on one method of treatment for psychosis called social skills training (SST) followed by a study which attempts to test a method applied with the intention of improving the ability of psychosis patients to understand treatment options and make choices about treatment.

Aims

The first aim was to determine how effective SST is for patients with psychosis. We predicted that SST would be better than other treatment options for negative symptoms of psychosis. Negative symptoms describe a set of common observations in psychosis that include social withdrawal and lack of conversational ability. The second aim was to test whether engaging people with psychosis in a presentation about decision-making styles could help improve their ability to understand make decisions about their treatment options. We predicted that the presentation would improve decision-making ability more than a presentation not intended to have this effect.

Methods

We used a statistical method called meta-analysis to estimate how effective social skills training was for people with psychosis. This method systematically takes statistics from previously published research and combines it to give an overall score. We also completed a randomised controlled experimental study
including 37 participants with psychosis from the NHS. This means that the participants were randomly selected either to receive a psycho-educational presentation (the intervention group) or a general presentation about psychology (the control group). We then measured whether this had changed their decision-making abilities.

**Findings**

We found that SST was better than other treatment options for negative symptoms and also for general functioning. We also found that the psycho-educational presentation improved people’s ability to understand and make decisions about their treatment more than the control lecture.

**Interpretation**

The findings from the review suggest that SST may be useful to consider for wider use in mental healthcare. The findings from the randomised controlled study suggest that we may be able to improve people’s ability to understand and make decisions on their treatment by providing them with brief interventions. However, our research has some limitations that future research should try to address to ensure that our findings are reliable.
A systematic review and meta-analysis of social skills training and related interventions for psychosis

David Turner, MSc\textsuperscript{a, b} 
Dr Paul Hutton, DClinPsy\textsuperscript{d} 
Edel McGlanaghy\textsuperscript{a} 
Dr Angus MacBeth, PhD\textsuperscript{a}

\textsuperscript{a} Department of Clinical and Health Psychology, School of Health in Social Science, University of Edinburgh

\textsuperscript{b} Clinical Psychology, NHS Lanarkshire

\textsuperscript{c} School of Health and Social Care, Edinburgh Napier University

Correspondence to: 
David Turner (Primary Investigator) 
Department of Clinical and Health Psychology, School of Health in Social Science, University of Edinburgh, Teviot Place, Edinburgh, EH8 9AG 
david.turner17@nhs.net 
+44 (0)131 651 3969

Abstract: 250 words 
Text body: 4,777 words

Prepared in accordance with guidelines for submission to Schizophrenia Bulletin (see Appendix 2).
Abstract

**Objective**: Evidence suggests social skills training (SST) is an efficacious intervention for negative symptoms in psychosis, while evidence of efficacy in other psychosis symptom domains is limited. The current paper reports a comprehensive meta-analytic review of the evidence for SST across relevant outcome measures, control comparisons and follow up assessments. The secondary aim was to identify and investigate the efficacy of SST subtypes.

**Methods**: A systematic literature search identified 27 randomised controlled trials including n=1,437 participants. Trials assessing SST against active controls, treatment as usual (TAU) and waiting list control were included. Risk of bias was assessed using the Cochrane tool generating scores for progressive sensitivity analyses. A series of 70 meta-analytic comparisons provided effect sizes in Hedge's $g$. Heterogeneity and publication bias were assessed.

**Results**: SST demonstrated superiority over TAU ($g=0.3$), active controls ($g=0.2-0.3$) and comparators pooled ($g=0.2-0.3$) for negative symptoms; and over TAU ($g=0.4$) and comparators pooled ($g=0.3$) for general psychopathology. Superiority was indicated in a proportion of comparisons for all symptoms pooled and social outcome measures. SST subtype comparisons were underpowered, although social-cognitive approaches demonstrated superiority versus comparators pooled. SST treatment effects were not maintained at 6-month follow-up.

**Conclusions**: SST demonstrates a magnitude of effect for negative symptoms similar to those commonly reported for CBT for positive symptoms, although unlike CBT, SST is not routinely recommended in treatment guidelines for psychological intervention. SST may have potential for wider implementation. Further stringent effectiveness research alongside wider pilot implementation of SST in in community mental health teams is warranted.

**Keywords**: Social skills training, psychosis, schizophrenia, meta-analysis
Introduction

Social Skills Training (SST) is a psychological intervention focused upon the development or improvement of social interaction, social performance or interpersonal skills, primarily offered to patients diagnosed with schizophrenia-spectrum disorders or psychosis. SST was initially developed in the context of the deinstitutionalisation of psychiatric patients returning to the community in the 1970s and utilised behavioural techniques such as role-play, modelling, coaching, instruction and feedback in an attempt to address interpersonal deficits. Literature from this period described SST as an effective means of reducing social anxiety although suggested that improved generalisability to real-life situations was desirable.¹

Since an initial wave of development in the 1980s and 1990s, SST has diversified meaning that a range of related interventions may now be subsumed within the terminology. The term SST therefore represents a broader spectrum of related interventions within the contemporary literature. These include approaches focused primarily on social cognition that may also integrate technology. Such approaches differ from the similar cognitive remediation methodology by their focus primarily upon social cognitive process and social perception rather than upon improving neuropsychological variables such as memory, attention or executive function.² ³ Similarly, a number of SST approaches assimilate cognitive-behavioural techniques such as cognitive restructuring although follow an SST-style group format as opposed to the typical formulation-based approach of cognitive-behavioural therapy (CBT).⁴ Finally, a number of practically-focused approaches integrating SST with psycho-education, life management skills and relapse prevention strategies also exist.⁵ ⁶

Negative symptoms refer to a specific pattern of commonly observed deficits in psychosis such as passive or apathetic social withdrawal, communication difficulties, blunting of affect and rigid or stereotypical thinking.⁷ Comparatively less research has focused upon the treatment of negative symptoms than
positive symptoms while fewer targeted interventions have been developed. Fusar-Poli et al\textsuperscript{8} assessed the efficacy of pharmacological and psychological interventions for negative symptoms in a large meta-analysis and reported a medium effect size for second-generation antipsychotics versus placebo ($g=0.6, p=<0.05$) while their comparison of 10 RCTs of first-generation antipsychotics versus placebo was not significant ($g=0.05, p=0.69$). Both comparisons displayed a high degree of heterogeneity while for psychological interventions pooled they reported a small to medium effect size ($g=0.4, p=<0.05$) and moderate heterogeneity. The effect size for anti-depressants was smaller ($g=0.3, p=<0.05$). The question of whether medication is more efficacious than psychological interventions pooled is not straightforward since the majority of participants in RCTs for psychological interventions are already maintained on anti-psychotic medication. However, this meta-analytic evidence suggests that differences in efficacy between psychological and pharmacological interventions for negative symptoms are small.\textsuperscript{8}

A recent meta-analysis, reported similar small to medium effect sizes ($g=0.3-0.6$) in favour of SST when compared to other psychological interventions for negative symptoms in psychosis.\textsuperscript{9} Interestingly, the magnitude of the effect size increased with progressive sensitivity analyses to address risk of bias suggesting robustness. Earlier meta-analytic evidence suggested cognitive behavioural therapy (CBT) as efficacious in reducing negative symptoms ($g=0.44, p<.05$) although the review included non-randomised trials.\textsuperscript{66} More recent meta-analyses have been unable to replicate this finding therefore do not suggest CBT as efficacious in the reduction of negative symptoms ($g=0.09, p>.05$).\textsuperscript{67} While SST was initially developed as an intervention targeting primarily social performance, we consider a variety of potential hypotheses regarding its relative efficacy in reducing negative symptoms. Firstly, there exists a considerable degree of crossover between social performance outcomes and PANSS negative symptom items such as rapport, social withdrawal and lack of spontaneity in conversation.\textsuperscript{7} When considering the mechanism of change, the nature of SST treatment plans may also result in patients being supported in overcoming avoidance which is also a key element of cognitive-behavioural
treatment plans. SST may therefore serve as a particularly activating and behavioural intervention providing direct but supportive challenge to difficulties categorised as negative symptoms.\(^7\) The group format of SST interventions may further enhance this process, whereas in contrast behaviourally activating group work is less routinely embedded among CBT interventions due to their predominantly individualised format.\(^9\)

The UK NICE guidelines state that SST should not be offered as a specific intervention for psychosis\(^10\) while the in the USA, guidelines have suggested SST is not an effective means to reduce symptoms.\(^11\) SST is not routinely integrated within adult clinical psychology or community mental health settings in the UK National Health Service (NHS). CBT is the most widely recommended and integrated psychological intervention for psychosis in the UK although many CBT manuals focus primarily on addressing positive rather than negative symptoms of psychosis.\(^12\) The consideration that SST appears relatively more efficacious than CBT in reducing negative symptoms and has produced effect sizes comparable to pharmacological treatments suggests that further examination of its clinical utility is warranted.

The current review aimed to expand upon the promising meta-analytic evidence for SST from our previous comparative meta-analysis of psychological interventions for psychosis by applying a more comprehensive focus on SST and including all comparison conditions rather than only bona fide psychological interventions. To our knowledge it is 8 years since SST has been thoroughly examined via meta-analysis.\(^13\) Given the accumulation of papers since this time means a renewed evaluation of its effectiveness is warranted. Since SST has further diversified into a range of related interventions we aimed to define and assess subtypes of SST as an adjunct to our primary comparisons. We also aimed to account for varying methodological rigour among SST trials since previous reviews did not address risk of bias within RCTs.\(^14,15\) Our overall aim was therefore to provide a detailed meta-analytic review of the contemporary evidence-base for SST, with robust appraisal of risk of bias and methodological quality in RCTs. Our primary objective was to determine whether SST and SST
subtypes demonstrate superiority in reducing negative symptoms against relevant comparison conditions. We hypothesised that SST would demonstrate superiority for negative symptoms across comparisons while superiority would not be demonstrated in other symptom domains.

**Methods**

A systematic literature search and meta-analysis was performed following PRISMA guidelines for the reporting of systematic reviews and meta-analyses.\(^{16}\)

**Protocol**

The objectives and intended methodology of this project were registered via PROSPERO on 9\(^{th}\) May 2016 and can be obtained at the following web location; http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016038872.

**Search strategy**

The systematic literature search completed in May 2016 (with no limits applied for year of publication) identified 2184 references for potential inclusion from four databases: The Cochrane Central Register of Controlled Trials (1722 abstracts), Pubmed (218 abstracts), PsychInfo (131 abstracts) and Embase (113 abstracts). Abstracts were identified by entering text variations of three key terms dependent upon Boolean operators, MeSH terms, exploded terms and limit settings relevant to each database, namely; 1) social skills training and related interventions; 2) psychosis and related diagnoses and 3) randomised controlled trials. Further search strings have been included in supplementary materials. Articles included in published meta-analyses were also considered for inclusion after examination of reference lists.\(^{9,14,15,17,18}\) Trial registrations,
conference abstracts and dissertations were also considered via grey literature checks online.

**Study selection**

Studies were included if they were randomised controlled trials in which social skills training or related interventions were compared against a control condition and applied to a psychosis population. Studies also met the following inclusion criteria: a) the participants were diagnosed with psychotic disorders including schizophrenia, schizoaffective disorder, delusional disorder, brief psychotic disorder or psychosis NOS; b) the intervention was defined as SST or was primarily intended to improve social performance; c) the study was fully randomised and included comparison to an active control, treatment-as-usual or a waiting list control and d) relevant outcome measures assessing psychotic symptoms and/or social performance were reported at post-treatment and/or follow up.

Studies were excluded if: a) participants had alternative or comorbid diagnoses, such as substance abuse or ultra-high risk of psychosis; b) authors mixed various elements of SST into the intervention and/or control condition resulting in difficulty comparing the active SST element and c) missing data could not be obtained by contacting authors. Only studies reported in the English language were included.

**Risk of bias assessment**

For consistency with the previous meta-analysis, RCTs were assessed at the study level against the first four criteria of the Cochrane risk of bias tool; sequence generation, allocation concealment, blinding of assessors and incomplete outcome data. The final two items (selective outcome reporting and other sources of bias) were omitted as there was no evidence of their impact upon validity in meta-analysis. The third item (blinding of assessors) was adapted to include only outcome assessors in blinding since, unlike medication
trials, study therapists and participants cannot be blinded to the intervention being delivered. Two authors (D.T. and E.Mc) calculated risk of bias scores via independent rating and resolution by discussion for 13 (48%) of the included studies while risk of bias assessments for 14 (52%) of studies were utilised from the previously published meta-analysis.

**Data extraction**

Symptom-related outcome data was extracted from 14 studies as part of the previous publication.9 These data were checked for consistency and included in the current analysis. One author (D.T.) extracted symptom-related outcome data from the remaining 13 studies and extracted social performance outcome data for all studies while another (E.Mc) checked consistency. Spreadsheets piloted and utilised in the previous meta-analysis were employed for extraction. We contacted five authors20–23 with requests for missing or unpublished outcome data, resulting in one successful further inclusion.24

All continuous outcome measures relevant to psychotic symptoms, general psychopathology and social performance were extracted. In instances where multiple outcome measures were reported within one domain, all data was extracted and combined to form a pooled effect size for that domain. In a minority of studies, only dichotomous outcome data was available therefore the all symptoms comparison includes relapse, discharge and clinical exacerbation as proxy symptom measures.

**Meta-analyses**

The overall strategy for the meta-analyses was to progress gradually from a broad and inclusive sample of studies toward more methodologically robust comparisons. This meant that for each outcome measure category (all symptoms, positive symptoms, negative symptoms, general symptoms and social performance) or comparison category (all comparators, active controls, TAU and SC only), separate meta-analyses were performed for progressively
decreasing risk of bias (0-4 where 4 indicates the highest risk of bias) when possible based on study availability. Meta-analyses were performed on outcome measures or comparator categories when at least 5 studies were available. Risk of bias sensitivity analyses were performed when at least 4 studies were available.

In order to investigate differences in efficacy between SST variations and related interventions, two authors (D.T. and A.M.) identified subtypes of SST independently and resolved disagreements by discussion before final categorisation. Separate meta-analyses were then performed using the same procedures as above. Similarly, meta-analyses for outcome measures assessed at follow-up were conducted when there were at least four studies available at any given follow-up time-point (e.g. 6 months).

For meta-analyses which did not require the combination of outcome measures at study level, the computer software R Studio version 1.0.136 was used to calculate pooled effect sizes using the packages meta and metafor.\textsuperscript{25,26} For comparisons that included studies where two outcome measures were reported in the same domain (e.g. two measures of negative symptoms), Comprehensive Meta-Analysis, version 3.0 was used due to its ability to provide a combined effect size at the study level. The programmes were checked for consistency of results on a proportion of comparisons. Both software packages provided an aggregated effect size indicating the pooled mean difference between groups at post-treatment or follow-up using Hedge’s $g$. Hedge’s $g$ is an estimate of the standardised mean difference between groups and provides a more accurate estimate of effects in small samples than similar statistics for continuous outcome variables such as Cohen’s $d$.\textsuperscript{27} Alpha was set to 0.05 for all comparisons and 95% confidence intervals were obtained.

**Heterogeneity**

Both software packages calculated chi-square tests to assess the degree of heterogeneity for each comparison. The Q statistic and resultant alpha level
were used to determine the presence of heterogeneity in each comparison. The $I^2$ statistic described the percentage of variance in each comparison that may arise from heterogeneity between studies or outcome measures rather than by chance. For the purpose of assessment, heterogeneity was defined as absent (0%), low (25%), moderate (50%) and high (75%).

**Publication bias**

Publication bias for all meta-analyses was established by examining funnel plots. Duval and Tweedie’s trim and fill procedure was used to estimate effect sizes after accounting for publication bias while Egger’s test of the intercept was applied to quantify bias and assess significance.

**Power analysis**

Due to progressive sensitivity analyses and our identification of SST subtypes, a number of comparisons were likely to be underpowered. We therefore utilised power analysis to determine the approximate number of studies required to identify relevant effects. Previous meta-analysis identified effect sizes ranging from roughly $g = 0.2$-$0.6$ for SST. Based on Cuijpers’ table, for an average $N$ of 30 per group in each study and conservatively assuming .80 power alongside alpha level 0.05, it was estimated that 18 studies would be required to detect an effect size of $g = 0.2$ for comparisons with low between study variance. Comparisons with medium and high variance would require 22 and 26 studies respectively.
Table 1. SST subtype descriptions

<table>
<thead>
<tr>
<th></th>
<th>Definition</th>
<th>$N_{st}$</th>
<th>$N_{p}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cognitive-behavioural social skills training (CBSST): CBSST defined interventions which utilised primarily a social-skills training approach similar to generic SST but also integrated cognitive-behavioural techniques such as cognitive restructuring, thought challenging or behavioural experiments. To limit heterogeneity we attempted to exclude interventions that were primarily structured as formulation-based CBT-based approaches that added aspects of SST since these interventions have less explicit skills training focus.</td>
<td>4</td>
<td>243</td>
</tr>
<tr>
<td>2</td>
<td>Generic social skills training: Generic SST refers to approaches that remain close to the original model of SST emerging in the 1980s. Typically this consists of a behaviourally-oriented, group intervention based upon social learning traditions in which the therapist(s) engage participants in interpersonal training sessions. The focus is typically upon assertiveness, verbal and non-verbal communication, reduction of social distress and learning appropriate contextual responses in social situations. This may be achieved via modelling, role-play, rehearsal, group reflection and discussion or a variety of related methods.</td>
<td>7</td>
<td>287</td>
</tr>
<tr>
<td>3</td>
<td>Social-cognitive skills training (SCST): This category refers to a relatively broad range of interventions that focus primarily on refining social cognitive processes such as emotion perception, theory-of-mind abilities. In order to qualify, interventions were required to include a therapist-led, behavioural or reflective element in order to demonstrate distinction from approaches further on a continuum toward cognitive remediation. SCST may integrate computer programmes or videos in order to facilitate improved training of social responses and may also follow a “drill and repeat” structure.</td>
<td>8</td>
<td>295</td>
</tr>
<tr>
<td>4</td>
<td>UCLA-FAST based: The acronym for this category refers firstly to those interventions explicitly based upon the University of California Los Angeles (UCLA) model of skills training, which integrates traditional SST alongside aspects of psycho-education, relapse prevention and skills in managing daily life tasks such as medication or independent travel. A similar approach is Functional Adaptive Skills Training (FAST) therefore these varieties of SST were combined to form a more practical-skills based category.</td>
<td>8</td>
<td>612</td>
</tr>
</tbody>
</table>

$N_{st}$ = number of studies. $N_{p}$ = number of participants who received each intervention.
<table>
<thead>
<tr>
<th>Study &amp; publications</th>
<th>Country</th>
<th>Sample characteristics</th>
<th>Relevant comparisons &amp; N</th>
<th>Symptom outcome measures</th>
<th>Format</th>
<th>Bias Risk (0-4)</th>
<th>Duration (weeks to PT approx)</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anzai et al 22</td>
<td>Japan</td>
<td>DSM-IV &amp; ICD-10 schizoaffective disorder. Inpatients. Poor insight.</td>
<td>SST (37) vs. OT (15)</td>
<td>Rehab scale, Discharge</td>
<td>Group 4</td>
<td>9</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Bowie et al 36</td>
<td>Canada &amp; USA</td>
<td>Schizophrenia or schizoaffective disorder. Outpatients.</td>
<td>SST (38) vs. CR (38)</td>
<td>PANSS, SSPA</td>
<td>Group 1</td>
<td>12</td>
<td>12 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td>Chien et al 37</td>
<td>Taiwan</td>
<td>DSM-IV schizophrenia. Inpatients.</td>
<td>SST (35) vs. TAU (43)</td>
<td>PANSS, IAS</td>
<td>Group 3</td>
<td>4</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Choi et al 38</td>
<td>South Korea</td>
<td>DSM-IV schizophrenia and schizoaffective disorder. Outpatients.</td>
<td>SST (17) vs. TAU (17)</td>
<td>SBST</td>
<td>Group 4</td>
<td>26</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Dobson et al 39</td>
<td>Canada</td>
<td>DSM-III Schizophrenia. Outpatients. Severe patients excluded.</td>
<td>SST (15) vs. BF (13)</td>
<td>PANSS</td>
<td>Group 3</td>
<td>11</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Gohar et al 40,41</td>
<td>Egypt</td>
<td>DSM-IV schizophrenia and schizoaffective disorder. Outpatients</td>
<td>SCST (22) vs. CST (20)</td>
<td>PANSS, MSCEIT</td>
<td>Group 3</td>
<td>8</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Granholm et al 42</td>
<td>USA</td>
<td>DSM-IV schizophrenia and schizoaffective disorder. Older outpatients 42+</td>
<td>CBST (37) vs. TAU (39)</td>
<td>PANSS</td>
<td>Group 2</td>
<td>24</td>
<td>6, 12 months</td>
<td></td>
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<tr>
<td>Granholm et al 44</td>
<td>USA</td>
<td>Older outpatients 45+, DSM-IV schizophrenia and schizoaffective disorder.</td>
<td>CBST (41) vs. SC (38)</td>
<td>PANSS, SANS</td>
<td>Group 1</td>
<td>36</td>
<td>4,5, 9 months</td>
<td></td>
</tr>
<tr>
<td>Granholm et al 46</td>
<td>USA</td>
<td>DSM-IV schizophrenia and schizoaffective disorder. Outpatients.</td>
<td>CBST (73) vs. SC (76)</td>
<td>PANSS, SANS, MASC, BP RS, SANS, SSS,</td>
<td>Group 1</td>
<td>36</td>
<td>6, 12 months</td>
<td></td>
</tr>
<tr>
<td>Hayes et al 43</td>
<td>Australia</td>
<td>DSM-III-R schizophrenia. Non-current positive symptoms. Recruited from a range of services.</td>
<td>SST (23) vs. SC (22)</td>
<td>Individual</td>
<td>Group 4</td>
<td>18</td>
<td>6 months</td>
<td>N/A</td>
</tr>
<tr>
<td>Hogarty et al 44,45</td>
<td>USA</td>
<td>RDC schizophrenia or schizoaffective disorder. High expressed emotion families. Inpatients.</td>
<td>SST (23) vs. FI (23)</td>
<td>Symptom relapse BP RS, SSPA</td>
<td>Individual 4</td>
<td>104</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Horan et al 3</td>
<td>USA</td>
<td>DSM-IV schizophrenia or schizoaffective disorder. Clinically stable outpatients.</td>
<td>SST (17) vs. PE (17)</td>
<td></td>
<td>Group 2</td>
<td>6</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Horan et al 46</td>
<td>USA</td>
<td>DSM-IV schizophrenia, schizoaffective disorder, delusional disorder or psychosis. Clinically stable outpatients.</td>
<td>SST (19) vs. CR (24)</td>
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<td>Group 2</td>
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<td>Lecomte et al 47,48</td>
<td>Canada</td>
<td>Early psychosis (&lt; 2 years). Current psychotic symptoms. Stabilized outpatients.</td>
<td>CBT (48) vs. SST (54)</td>
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<td>Group 2</td>
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<td>Liberman et al 49-51</td>
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<td>DSM-III schizophrenia. Inpatients.</td>
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<td>PAS</td>
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## Table 2. Continued

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<th>Extracted outcome measures</th>
<th>Format</th>
<th>Bias Risk (0-1)</th>
<th>Duration (weeks to PT)</th>
<th>Follow-up</th>
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<td>Liberman et al 52</td>
<td>USA</td>
<td>Persistent &amp; unremitting schizophrenia. Outpatients.</td>
<td>SST (42) vs. OT (42)</td>
<td>BSI, GAS, BPRS</td>
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<td>Marder et al 53</td>
<td>USA</td>
<td>DSM-III schizophrenia. At least 2 acute episodes or 2 years psychic symptoms. Male outpatients.</td>
<td>SST (13) vs. SC (14)</td>
<td>BPRS Exacerbation s</td>
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<td>Hong Kong</td>
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<td>SST (18) vs. SC (18)</td>
<td>BPRS, SANS, SFS, SBS</td>
<td>Group</td>
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<tr>
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<td>USA</td>
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<td>SST (21) vs. SC (8)</td>
<td>PANSS, SSPA</td>
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<td>Roberts et al 57</td>
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<td>SSA, SSPA, GSFS</td>
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<td>Rus-Calafell et al 58</td>
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<td>DSM-IV-TR schizophrenia or schizoaffective disorder. Clinically stable outpatients.</td>
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<td>PANSS, SFS</td>
<td>Group</td>
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<td>Gil Sanz et al 59</td>
<td>Spain</td>
<td>CIE-10 Schizophrenia. Rehab patients.</td>
<td>SCT (7) vs. TAU (7)</td>
<td>PANSS, WHODAS-II</td>
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<td>Tas et al 60</td>
<td>Turkey &amp; Germany</td>
<td>Persistent &amp; unremitting schizophrenia. Clinically stable outpatients.</td>
<td>SST (22) vs. BF (27)</td>
<td>PANSS, SFS</td>
<td>Group</td>
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<td>Velligan et al 61</td>
<td>USA</td>
<td>DSM-IV schizophrenia or schizoaffective disorder. Clinically stable outpatients.</td>
<td>CBST (26) vs. TAU (25)</td>
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<td>Wang et al 62</td>
<td>China</td>
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<td>China</td>
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<td>SST (50) vs. PE (53)</td>
<td>PANSS, SDSS</td>
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BF, Befriending; BPRS, Brief Psychiatric Rating Scale; BNSS, Brief Negative Symptom Scale; BSI, Brief Symptom Inventory CBT, Cognitive-Behavioural Therapy; CR, Cognitive Remediation; CST, Control Skills Training; FL, Family Intervention; GAS, Global Assessment Scale; GSFS, Global Social Functioning Scale; Ham-D, Hamilton Depression Rating Scale; IAS, Interaction Anxiety Scale; MASC, Maryland Assessment of Social Competence; MSCEIT, Mayer-Salovey Emotional Intelligence Test; N, Number of participants in each treatment group; NSA-16, Negative Symptoms Assessment; OT, Occupational Therapy; PANSS, Positive and Negative Syndromes Scale; PE, Psycho-education; PSP, Personal and Social Performance Scale; PT, Post-treatment; N/A, Not Applicable; SANS, Scale for Assessment of Negative Symptoms; SBS, Social Behaviour Schedule; SBST, Social Behaviour Sequencing Task; SC, Supportive Counselling; SDSS, Social Disability Screening Schedule; SFS, Social Functioning Scale; SSPA, SSIT, Simulated Social Interaction Test; Social Skills Performance Assessment; SST, Social Skills Training; WHO-DAS-II, WHO Disability Scale;
Results

Study selection

Figure 1 illustrates the selection process by which articles were screened for inclusion. Following removal of duplicates, 1972 titles abstracts were screened for relevant characteristics; a further 176 articles were retrieved for closer inspection of inclusion and exclusion criteria. 27 randomised controlled trials qualified for final inclusion resulting in data for $n=1,437$ participants being included across 70 meta-analyses and sensitivity analyses. All included RCTs reported outcome measures at post-treatment while 11 studies (40%) included follow up data ranging from 12 weeks to 18 months.
Fig. 1. PRISMA Flowchart of inclusion of studies

2184 references identified by literature search:
- PubMed: 218
- PsychInfo: 131
- Embase: 113
- Cochrane: 1722

After removal of duplicates: 1972 abstracts

1796 excluded after reading title and abstracts

Excluded:
- Other interventions (20)
- Mixed interventions not definable as SST e.g. including medication (43)
- Comparison of SST variations (13)
- Computerised intervention only (9)
- Secondary papers, protocols or conference abstracts: (18)
- No random assignment: (11)
- No relevant outcome measures: (5)
- Inappropriate sample, e.g. alternative diagnoses (8)
- Review papers: (2)
- Missing outcome data which could not be resolved by contacting authors: (2)
- Non-English language (10)
- Duplicates not detected (5)
- Other reasons: (3)

Included in meta-analyses: 27 randomised trials comparing socials skills training or related interventions to any control condition

176 publications retrieved

Articles identified from previous meta-analyses

2184 references identified by literature search:
Selected characteristics of included studies are available in Table 2. Twenty-Five studies (93%) applied group format only while only 2 applied individual format. Risk of bias scores within studies ranged from 1-4. This meant that no studies achieved the lowest possible risk of bias score and therefore sensitivity analyses could not exclude all risk of bias. Details of risk of bias assessments at the study level are included in supplementary materials. Four broad subtypes of SST were identified as defined in Table 1 and formed the basis of subtype comparisons.

**Effect of SST on psychosis symptoms**

Results for all comparisons of SST against active controls, TAU, SC and all comparators pooled are provided in Table 3. A summary forest plot of significant comparisons is provided in Figure 2. Separate meta-analyses were calculated for each symptom category and followed by risk of bias sensitivity analyses. SST was more efficacious than TAU for all symptoms \((g=0.3, p<.05)\). This effect was robust when removing studies with risk of bias scores of 4 although further sensitivity analyses were not possible. Heterogeneity was absent in the TAU comparison although other non-significant comparisons for all symptoms pooled showed moderate to high heterogeneity. SST did not demonstrate superiority in any comparisons for positive symptoms while heterogeneity was also moderate to high in this domain.

SST was more efficacious for negative symptoms when compared to all comparators pooled, active controls and TAU. SST was more efficacious compared to pooled comparators \((g=0.2 (p<.05)\) when all eligible studies were included in the analysis. When progressive removal of bias risk was implemented the effect size gradually increased to \(g=0.3 (p<.05)\). A similar trend was observed for comparison to active controls, where initial comparisons including all studies approached significance while gradual removal of bias resulted in an effect size of \(g=0.3 (p<.05)\). For comparison to TAU, SST was more efficacious \((g=0.3, p<.05)\) although studies only allowed for
removal of studies with a bias risk score of 4. SST did not demonstrate superiority against SC for negative symptoms but this comparison was underpowered with only 4 studies available. There was no evidence of heterogeneity among negative symptom comparisons.

For PANSS general symptoms, SST demonstrated superiority against comparators pooled \( g=0.3, p<0.05 \) and TAU \( g=0.4, p<0.5 \). The limited number of available studies in this symptom domain meant that sensitivity analyses for risk of bias were not possible. There was no evidence of significant heterogeneity.

**Effect of SST for social performance**

The results for social performance outcome measures are displayed in Table 3. SST was more efficacious when compared to all comparators pooled. This effect size gradually increased from \( g=0.3(p<.05) \) when all eligible studies were included to \( g=0.4, (p<.05) \) when studies scoring >2 on bias risk were excluded. The treatment effect was no longer significant on the final sensitivity analysis for studies scoring >1 on bias risk, although this comparison was underpowered. SST did not demonstrate significant superiority against active controls or TAU although the TAU comparison was particularly underpowered. The majority of comparisons in the social performance domain displayed moderate to high heterogeneity including significant effects.

**Comparison of SST subtypes**

Table 3 provides results of the comparison of the a priori specified SST subtypes. The majority of SST subtype comparisons were underpowered due to limited study availability. In order to assess trends in the data, effects that approached significance \( (p<0.1) \) were noted and the magnitude of non-significant effects were considered. The only subtype that demonstrated significant superiority was SCST, which demonstrated a relatively robust effect
size at >2 and >3 bias levels ($g=0.4, \ p<.05$) against any comparator pooled for all symptom measures pooled. Generic SST demonstrated an effect size that approached significance for all symptoms pooled ($g=0.4, \ p<0.1$) while for negative symptoms a similar magnitude was observed despite the comparison being underpowered ($g=0.3, \ p<0.2$). UCLA-FAST approaches showed a non-significant trend of inferiority for all symptoms pooled versus any comparator while CBSST comparisons were hampered by limited study availability. Comparisons of CBSST showed no evidence of heterogeneity while Generic SST and SCST symptom comparisons did not show significant heterogeneity. Heterogeneity was present for UCLA-FAST comparisons although decreased as bias risk was reduced. Moderate to high heterogeneity was observed across social performance comparisons.

**Follow-up**

Meta-analyses of follow-up data were only possible for the 6 months time-point, due to limited availability at other time points. Limited RCT availability also meant this section was restricted to all comparators pooled rather than allowing TAU or active control comparisons. SST did not demonstrate superiority against comparators pooled in any outcome domain. Follow-up comparisons were underpowered overall, whilst heterogeneity was consistently low.
<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>g</th>
<th>95% CI</th>
<th>Z</th>
<th>Q-value</th>
<th>I² (%)</th>
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<tbody>
<tr>
<td>SST for all symptom measures pooled</td>
<td></td>
<td></td>
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<td>Vs. any comparator</td>
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<td>72.20</td>
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<td>2.61</td>
<td>0.00</td>
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<td>Vs. SC only</td>
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Table 3. Continued

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<th>Q-value</th>
<th>I² (%)</th>
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<tr>
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<td>0.11, 0.70</td>
<td>2.70</td>
<td>2.31</td>
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</tr>
<tr>
<td>SST for social competency outcome measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vs. any comparator</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>all eligible studies</td>
<td>17</td>
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<td>49.60*</td>
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<tr>
<td>excluding risk of bias score of 4</td>
<td>13</td>
<td>0.36*</td>
<td>0.10, 0.63</td>
<td>2.70</td>
<td>37.27*</td>
<td>67.80</td>
</tr>
<tr>
<td>excluding risk of bias score ≥3</td>
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<td>0.37*</td>
<td>0.04, 0.71</td>
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<td>33.20*</td>
<td>75.91</td>
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<tr>
<td>excluding risk of bias score ≥2</td>
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<td>0.19</td>
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<td>5.44</td>
<td>26.48</td>
</tr>
<tr>
<td>Vs. active controls</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>all eligible studies</td>
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<td>-0.23, 0.50</td>
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<td>81.53</td>
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<td>1.12</td>
<td>51.16*</td>
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<tr>
<td>excluding risk of bias score ≥3</td>
<td>8</td>
<td>0.32</td>
<td>-0.10, 0.74</td>
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<td>39.98</td>
<td>82.49</td>
</tr>
<tr>
<td>excluding risk of bias score ≥2</td>
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<td>-0.31, 0.35</td>
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<td>8.86</td>
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<tr>
<td>Vs. TAU</td>
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<tr>
<td>all eligible studies</td>
<td>5</td>
<td>0.20</td>
<td>-0.14, 0.54</td>
<td>1.16</td>
<td>5.31</td>
<td>24.69</td>
</tr>
<tr>
<td>SST subtypes vs. any comparator</td>
<td>N</td>
<td>g</td>
<td>95% CI</td>
<td>Z</td>
<td>Q-value</td>
<td>I² (%)</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>----</td>
<td>-----</td>
<td>--------------</td>
<td>-----</td>
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<td>All symptom measures pooled</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Generic SST, all eligible studies</td>
<td>7</td>
<td>0.17</td>
<td>-0.13, 0.49</td>
<td>1.13</td>
<td>8.70</td>
<td>31.77</td>
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<tr>
<td>Generic SST, excl. risk of bias ≥4</td>
<td>4</td>
<td>0.36**</td>
<td>-0.01, 0.74</td>
<td>1.90</td>
<td>4.21</td>
<td>28.71</td>
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<tr>
<td>Cognitive-behavioural SST, excl. risk of bias ≥3</td>
<td>4</td>
<td>0.15</td>
<td>-0.11, 0.40</td>
<td>1.13</td>
<td>0.59</td>
<td>0.00</td>
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<tr>
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<td>0.270</td>
<td>-0.03, 0.58</td>
<td>1.78</td>
<td>6.40</td>
<td>21.92</td>
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<tr>
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<td>0.39*</td>
<td>0.11, 0.68</td>
<td>2.70</td>
<td>2.48</td>
<td>0.00</td>
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<tr>
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<td>4</td>
<td>0.41*</td>
<td>0.12, 0.71</td>
<td>2.73</td>
<td>2.24</td>
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<tr>
<td>UCLA-FAST, all eligible studies</td>
<td>8</td>
<td>-0.06</td>
<td>-0.39, 0.28</td>
<td>-0.34</td>
<td>25.19*</td>
<td>72.21</td>
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<tr>
<td>UCLA-FAST, risk of bias ≥4</td>
<td>7</td>
<td>-0.18</td>
<td>-0.46, 0.11</td>
<td>-1.21</td>
<td>15.71*</td>
<td>61.81</td>
</tr>
<tr>
<td>UCLA-FAST, excl. risk of bias ≥3</td>
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<td>-0.20</td>
<td>-0.65, 0.25</td>
<td>-0.88</td>
<td>14.65</td>
<td>79.52</td>
</tr>
<tr>
<td>Negative symptoms</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generic SST, all eligible studies</td>
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<td>0.27</td>
<td>-0.14, 0.68</td>
<td>1.28</td>
<td>8.66</td>
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<tr>
<td>Cognitive-behavioural SST, all eligible studies</td>
<td>4</td>
<td>0.15</td>
<td>-0.11, 0.40</td>
<td>1.11</td>
<td>0.46</td>
<td>0.00</td>
</tr>
<tr>
<td>Social-cognitive SST, all eligible studies</td>
<td>5</td>
<td>0.15</td>
<td>-0.21, 0.51</td>
<td>0.80</td>
<td>6.47</td>
<td>38.14</td>
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<td>Social competency outcome measures</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Generic SST, all eligible studies</td>
<td>4</td>
<td>-0.03</td>
<td>-0.32, 0.26</td>
<td>0.21</td>
<td>1.31</td>
<td>0.00</td>
</tr>
<tr>
<td>Social-cognitive SST, all eligible studies</td>
<td>7</td>
<td>0.30</td>
<td>-0.21, 0.81</td>
<td>1.15</td>
<td>23.41*</td>
<td>74.37</td>
</tr>
<tr>
<td>Social-cognitive SST, excl. risk of bias ≥4</td>
<td>6</td>
<td>0.19</td>
<td>-0.34, 0.72</td>
<td>0.70</td>
<td>19.86*</td>
<td>74.02</td>
</tr>
<tr>
<td>Social-cognitive SST, excl. risk of bias ≥3</td>
<td>4</td>
<td>0.48**</td>
<td>-0.02, 0.98</td>
<td>1.89</td>
<td>8.38*</td>
<td>64.18</td>
</tr>
<tr>
<td>UCLA-FAST, all eligible studies</td>
<td>5</td>
<td>0.08</td>
<td>-0.59, 0.75</td>
<td>0.24</td>
<td>36.19*</td>
<td>88.95</td>
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<tr>
<td>UCLA-FAST, excl. risk of bias ≥4</td>
<td>4</td>
<td>0.27</td>
<td>-0.43, 0.97</td>
<td>0.75</td>
<td>27.9*</td>
<td>89.25</td>
</tr>
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</table>

SST vs. any comparator at 6 month follow-up

<table>
<thead>
<tr>
<th>All symptom measures</th>
<th>N</th>
<th>g</th>
<th>95% CI</th>
<th>Z</th>
<th>Q-value</th>
<th>I² (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All symptoms, all eligible studies</td>
<td>8</td>
<td>0.04</td>
<td>-0.15, 0.22</td>
<td>0.37</td>
<td>1.94</td>
<td>0.00</td>
</tr>
<tr>
<td>All symptoms, excl. risk of bias ≥3</td>
<td>6</td>
<td>0.06</td>
<td>-0.14, 0.26</td>
<td>0.60</td>
<td>0.97</td>
<td>0.00</td>
</tr>
<tr>
<td>All symptoms, excl. risk of bias ≥2</td>
<td>4</td>
<td>0.12</td>
<td>-0.12, 0.35</td>
<td>0.97</td>
<td>0.09</td>
<td>0.00</td>
</tr>
<tr>
<td>Positive symptoms, all eligible studies</td>
<td>5</td>
<td>-0.08</td>
<td>-0.32, 0.15</td>
<td>-0.71</td>
<td>1.09</td>
<td>0.00</td>
</tr>
<tr>
<td>Positive symptoms, risk of bias ≥3</td>
<td>4</td>
<td>-0.08</td>
<td>-0.32, 0.17</td>
<td>-0.63</td>
<td>1.06</td>
<td>0.00</td>
</tr>
<tr>
<td>Negative symptoms, all eligible studies</td>
<td>7</td>
<td>0.00</td>
<td>-0.21, 0.21</td>
<td>0.03</td>
<td>4.22</td>
<td>0.00</td>
</tr>
<tr>
<td>Negative symptoms, excl. risk of bias ≥3</td>
<td>5</td>
<td>0.01</td>
<td>-0.02, 0.24</td>
<td>0.05</td>
<td>2.29</td>
<td>0.00</td>
</tr>
<tr>
<td>Social competency outcomes, all eligible studies</td>
<td>4</td>
<td>0.10</td>
<td>-0.19, 0.38</td>
<td>0.67</td>
<td>0.62</td>
<td>0.00</td>
</tr>
</tbody>
</table>

All comparisons were using random model. Risk of bias and subgroup analyses were only included in instances where at least 4 studies were available for that comparison. *p<0.05. **p<0.1. PANSS, Positive and Negative Syndromes Scale. CI, Confidence Interval. SC, Supportive Counselling. UCLA-FAST, University of California Los Angeles-Functional Adaptive Skills Training.
**Publication bias**

Examination of funnel plots and consideration of the trim and fill procedure for effects that demonstrated statistical significance indicated the presence of publication bias in only one comparison. The funnel plot for SST versus all comparators pooled for general symptoms suggested that one study with negative findings had not been published. The trim and fill procedure trimmed one study causing a marginal reduction in the magnitude of effect size in this comparison from $g=0.32$ ($p<.05$) to $g=0.26$ (95% CI 0.01, 0.53). The classic fail-safe N procedure suggested that it would require 7 missing studies to bring significance below the 0.05 alpha level while Egger’s (2007) test of the intercept did not demonstrate significance.
Figure 2: Summary forest plot of significant main results in Hedge’s g

- vs TAU; all symptoms; any
- vs TAU; all symptoms; <4
- vs ALL; negative; <4
- vs ALL; negative; <4
- vs ALL; negative; <3
- vs ALL; negative; <2
- vs AC; negative; <3
- vs AC; negative; <2
- vs TAU; negative; any
- vs TAU; negative; <4
- vs ALL; general; any
- vs TAU; general; any
- vs ALL; social; any
- vs ALL; social; <4
- vs ALL; social; <3

ALL, all comparators pooled; TAU, treatment-as-usual; AC, active controls; Social, social competency outcomes; General, PANSS general symptoms; Negative, negative symptoms; Any, all eligible studies included; <4, <3 and <2 denote sensitivity analyses progressively removing risk of bias.
Discussion

The current meta-analysis provided a systematic and comprehensive overview of the efficacy of SST for psychosis while also investigating SST subtypes. SST demonstrated superiority for negative symptoms against all comparators pooled, TAU and active controls with small but reliable differences. SST did not demonstrate superiority over SC for negative symptoms although this comparison was very low in power. SST also demonstrated superiority against any comparator and TAU for PANSS general symptoms with small to medium effects. SST was superior to TAU when pooling all symptom measures but did not demonstrate superiority against comparators pooled, active control or SC. There were no significant effects on positive symptoms. SST demonstrated superiority only against comparators pooled for social competency measures although this effect lost significance as bias risk and power decreased. In SST subtype comparisons, only SCST demonstrated superiority to pooled comparators.

As hypothesised, SST demonstrated robust superiority for negative symptoms alongside beneficial effects on those comparisons possible for general symptoms. The overall trend in analyses for both negative and PANSS general symptoms showed that the magnitude of SST effect increased as risk of bias decreased, suggesting these effects may be robust. There was however still a minimal level of risk of bias present in the RCTs pooled to provide these conclusions since no RCT achieved the lowest possible risk of bias score. Comparisons in the social performance domain displayed moderate to high heterogeneity. This heterogeneity may be a result of combining a high number of outcome measures that were not designed to measure a narrowly defined construct. Our combination of these measures may therefore indicate that a number of related but distinct outcomes were included while a lack of significant effects in this domain may also be related to the heterogeneity in the included outcomes.

While SCST demonstrated superiority to pooled comparators again with magnitude increasing as bias decreased, no other SST subtypes demonstrated
superiority in the context of low power. There were a number of trends approaching significance. These favoured generic SST and SCST, while UCLA-FAST performed poorly despite having the highest statistical power. This may therefore suggest that ‘practical’ life skills approaches have less beneficial impact upon symptoms than other subtypes. It is difficult to draw any conclusion regarding CBSST due to limited study availability. The identification of SST subtypes in meta-analysis may therefore become more relevant as the literature develops and future meta-analyses may benefit from increased study availability to bolster categories.

The beneficial effects of SST were not maintained at 6 months follow-up. Comparisons did not approach significance and generally had a low magnitude of effect, therefore low power is unlikely to be the primary reason for null findings. SST has faced criticism that learning does not generalise well to real-life situations.\textsuperscript{33} This finding also has implications for SST developers as it is important that generalizability and longevity are considered closely in SST manuals.

The effect sizes reported for SST for negative symptoms are marginally greater than those reported for CBT for positive symptoms and marginally smaller than those reported for anti-psychotics.\textsuperscript{8,9} If we consider CBT as a targeted intervention for positive symptoms and SST for negative symptoms, each intervention has effects of roughly equivalent magnitude for its target area.\textsuperscript{58}

As discussed, SST is not recommended as a stand-alone intervention by NICE and therefore is not routinely implemented in the NHS.\textsuperscript{10} Furthermore, no UK RCTs met inclusion criteria for this meta-analysis while many meet criteria for CBT meta-analyses.\textsuperscript{9,13,59,60} It is possible that a culture towards cognitive-behavioural, formulation-based interventions is limiting the consideration of alternative approaches that demonstrate similar efficacy. The group-based style of SST may lend itself well to application within a CMHT environment and has the potential to act as a cost-effective means of addressing negative symptoms while improved care matching protocols may develop to help identify which patients...
may benefit most from the range of available interventions and depending on their capacity to engage.\textsuperscript{61}

The positive findings for SST on general psychopathology are also of interest. The PANSS general psychopathology subscale may be conceptualised as a measure of general distress including depression and anxiety, which have been identified as factorial dimensions within psychosis symptomatology.\textsuperscript{62} Understanding of depression as an integral part of psychosis is limited as are targeted interventions. The small to medium effect sizes shown for SST in this domain suggest that targeting general psychopathology is worthy of consideration for the broader recovery agenda\textsuperscript{63} while contemporary research challenges the traditionally prevalent assumption that psychosis and depression are aetio logically distinct.\textsuperscript{62} Considered broadly these findings suggest the importance of developing interventions for psychosis populations that carefully consider the symptom and functioning domains measured by negative and general symptom scales.

On a macro level, this review also provides support that small but reliable differences exist between psychological interventions, particularly in on the outcomes targeted specifically by the intervention. This contradicts the Dodo verdict that all psychological interventions are equivalent since SST retained superiority for negative symptoms observed elsewhere.\textsuperscript{9,64} Small effect sizes and a number of non-significant comparisons versus active controls may also be interpreted as supportive of the premise that interventions are roughly equivalent although the difficulty of low power in these comparisons should not be dismissed. Wampold\textsuperscript{65} highlights the tendency of meta-analyses of psychological interventions to establish targeted, symptom-specific improvement as opposed to improved general functioning. The observed effect on PANSS general symptoms suggests improvement may occur on outcomes capturing comorbidity although our methodology does not have the sophistication to specify the mechanism of such improvements.

There were a number of limitations including those inherent to meta-analyses
and those specific to this review. With regard to the literature, although, 27 RCTs were included participant numbers in many trials were low. Many comparisons were therefore hampered by low power and there were not enough high quality studies minimising bias risk to allow comparison at the lowest risk of bias level. This meant that any significant finding is still susceptible to some degree of potential bias.

Based to our comparison strategy, another limitation was that many RCTs had to be excluded due to the mixed nature of interventions; for example integrating medication, exercise or other psychological therapies alongside SST. It was beyond the scope of this review to consider these interventions although a narrative systematic review may help provide clarity on this burgeoning literature. Similarly, although we attempted to address the issue via joint decision-making, our categorisation of SST subtypes retains a degree of subjectivity while subtypes may contain heterogeneity. Nevertheless, the first meta-analytic consideration of SST subtypes provides guidance for future reviewers as this literature develops.

The lack of translation capability should also be considered a limitation in this review since we were unable to fully assess ten potential papers for inclusion. A final limitation is that a wider range of outcomes are relevant to recovery from psychosis than those included in this review; for example quality of life, neurocognitive function, relapse or employment. Considering all such outcomes was beyond the scope of our project therefore, depending on study availability, future research may consider them.

Taken in the context of wider research findings, the magnitude of effects demonstrated by SST for negative and general symptoms are relatively comparable to other interventions including anti-psychotic and anti-depressant medication. The results of this meta-analysis suggest that SST has the potential for wider clinical application while the level of evidence demonstrated for SST contradicts its exclusion by NICE in the UK. The effect sizes reported are impressive for a group-based psychological intervention suggesting that SST
may have potential as a cost-effective alternative to individual therapies addressing negative and general symptoms and may provide a beneficial adjunct to CBT focused on appraisal and positive symptoms.

Further high-quality outcome research may help clarify doubts regarding the applicability and durability of SST in practice. At the very least, an RCT with stringent methodology applying SST for negative symptoms in a routine mental healthcare setting is warranted. Any future research may also benefit from integrating a cost-effectiveness analysis. Future SST research must focus upon further reducing risk of bias among RCTs and therefore allowing equivalence to CBT methodology alongside addressing the concerns regarding generalisability and longevity. It is therefore important that methodologically stringent RCTs integrate follow-up assessments on primary outcome measures while the integration of booster sessions or any similar attempt to prolong beneficial effects, trouble-shoot and increase applicability to real-life settings may help address existing concerns.

**Acknowledgements**

With thanks to Pim Cuijpers, Mark van der Gaag and Eirini Karyotaki for their contribution to the meta-analysis preceding this work.

**Declaration of interest**

None.
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A randomised experimental manipulation of the jumping-to-conclusions bias in psychosis; impact of brief meta-cognitive training on capacity

David Turner, MSc\textsuperscript{a,b}  
Dr Angus MacBeth, PhD\textsuperscript{a}  
Dr Amanda Larkin, DClinPsy\textsuperscript{c}  
Dr Karen Livingstone, DClinPsy\textsuperscript{b}  
Dr Alison Campbell, DClinPsy\textsuperscript{b}  
Dr Paul Hutton, DClinPsy\textsuperscript{d}

\textsuperscript{a} Department of Clinical and Health Psychology, School of Health in Social Science, University of Edinburgh  
\textsuperscript{b} Clinical Psychology, NHS Lanarkshire  
\textsuperscript{c} Psychosis Research Unit, Greater Manchester West Mental Health NHS Foundation Trust  
\textsuperscript{d} School of Health and Social Care, Edinburgh Napier University

Abstract: 298 words  
Text body: 4,347 words

Correspondence to:  
David Turner (Primary Investigator)  
Department of Clinical and Health Psychology, School of Health in Social Science, University of Edinburgh, Teviot Place, Edinburgh, EH8 9AG  
david.turner17@nhs.net  
+44 (0)131 651 3969

Prepared in accordance with guidelines for submission to \textit{Lancet Psychiatry} (see Appendix 2).
Summary

Background

Limited understanding and impaired capacity regarding treatment-related decisions are prevalent in psychosis. As healthcare systems further consider patient autonomy, dignity and empowerment the capacity to make informed choices regarding mental health treatment is relevant. Cognitive biases including the jumping-to-conclusions (JTC) bias have been implicated in impaired capacity. Preliminary outcome research suggests meta-cognitive therapy (MCT) targeting the JTC bias may improve capacity although no randomised controlled study has directly assessed the effect of MCT on capacity. We hypothesised that brief MCT would improve capacity while outcome would be mediated by changes in the JTC bias.

Methods

A randomised controlled pre-post experimental design allocated inpatients and outpatients from two NHS health boards in Scotland to brief MCT or a non-specific control presentation (NC). English-speaking participants aged 16-65 with a current or historical diagnosis of schizophrenia, schizoaffective disorder or psychosis NOS were included. The non-blinded primary outcome (MacCAT-T) was administered at baseline and post-treatment. Intention-to-treat ANCOVAs estimated the effect of MCT on primary and secondary outcomes while simple mediation analyses examined the JTC bias as a mediator of the effect on capacity. Open Science Framework registration; https://osf.io/kunc4/. The trial is now closed.

Findings

Participants were recruited between January 2016 and February 2017. 19 participants were randomised to MCT and 18 to NC. One participant dropped out but was included in all analyses. MCT demonstrated large effects on two
capacity outcomes; overall capacity \((d=0.96, p<.05)\) and appreciation \((d=0.87, p<.05)\). Exploratory analyses suggested a mediating effect of JTC \((d=0.64, p<.05)\).

**Interpretation**

The study provides preliminary evidence for the efficacy of MCT targeting capacity by addressing the JTC bias in psychosis and suggests that interventions targeting capacity have clinical utility. Limitations included lack of blinding, no fidelity checks and inclusion based on clinical diagnosis. A larger randomised controlled trial addressing our limitations is warranted.

**Funding**

None
Introduction

Capacity to consent to treatment and the related ability to make informed decisions regarding treatment options are important topics in contemporary mental healthcare and research. Capacity (or lack thereof) has important implications regarding patients’ ability to provide informed consent to psychiatric treatment and to understand relevant options based upon their specific needs. Patients deemed to have impaired capacity may be subject to compulsory treatment orders without their consent and against their preferences.

The consideration of impaired capacity is particularly relevant among populations diagnosed with severe mental health disorders such as psychosis (including schizophrenia). Limited understanding regarding diagnosis, limited insight and an impaired capacity to make treatment-related decisions have been repeatedly observed among schizophrenia patients. Estimates suggest that 50-80% of psychosis inpatients have impaired capacity. Meta-analytic data suggests that schizophrenia inpatients are twice as impaired on capacity versus outpatients, although research on the processes underlying impaired capacity remains limited.

Tunzi conceptualised decision-making capacity for medical treatment as consisting of four key components, namely: a) understanding treatment information; b) appreciation of how such information relates to patients’ personal context; c) reasoning ability based upon this information and d) ability to consider and express choice regarding treatment options. Ability in each domain has implications for mental healthcare provision while in many countries, mental capacity legislation relates closely to these domains. These domains also inform the most widely applied assessment of capacity; the MacArthur Competency Assessment Tool for Treatment (MacCAT-T).

In recent years, mental health systems in have developed improved recognition of the importance of autonomy, dignity and empowerment of services users.
Compulsory treatment of patients deemed to lack capacity therefore has important ethical implications for service users and healthcare providers. The capacity to make informed decisions regarding treatment is particularly relevant given varying effectiveness and side effect profiles among anti-psychotics alongside varying efficacy among psychological interventions while cognitive-behavioural therapy (CBT) has shown potential as an intervention for psychosis patients not prescribed medication. The range of options available in contemporary mental healthcare emphasises the importance of informed choice and a better understanding of decision-making capacity among service users. Research on service-user perception of recovery also highlights the importance of choice and understanding in promoting outcomes favourable to psychosis patients.

There exists a developing array of literature on factors that may modulate capacity and the mechanisms by which capacity may be improved. Particular interest has focused upon the role of cognitive bias in decision-making. Impaired reasoning processes including biased appraisal have been implicated in psychosis. One well-researched cognitive bias is the jumping-to-conclusions (JTC) bias, which refers to a tendency to make hasty decisions based upon limited information. JTC has been implicated as influential in delusion formation and maintenance due to the likelihood of inaccurate decisions that exclude relevant information. JTC is prevalent among psychosis populations and is not limited to symptomatic patients; at risk, remitted, schizotypal and familial groups also show elevated levels while longitudinal research indicates the stability of the JTC decision-making style while delusional severity fluctuates. JTC has also been associated with IQ, emotional factors, suspiciousness and a tendency to disregard confirmatory evidence.

In light of the improved understanding of cognitive biases in psychosis, psychological interventions attempting to reduce their impact have been developed. One such intervention is meta-cognitive training (MCT). This psycho-educational, cognitive-behavioural intervention addresses biases implicated in psychosis maintenance including two modules specifically
targeting the JTC bias. MCT has been suggested as efficacious in reducing psychotic symptoms while a small randomised-controlled trial (RCT) demonstrated that a single-session, MCT-based intervention reduced the JTC bias among psychosis patients.

Furthermore, the effect of MCT upon capacity as assessed by the MacCAT-T has also been examined. In a non-randomised prospective cohort trial, MCT demonstrated significant benefits on the understanding and reasoning subscales alongside MacCAT-T total score compared to a waiting-list control among Forensic inpatients, suggesting a beneficial impact of the intervention upon decision-making capacity for treatment. Although the MCT intervention consisted of up to 16 sessions, when considered alongside the Ross et al findings it is reasonable to hypothesise that single-session MCT may have a beneficial effect upon MacCAT-T-assessed capacity. Single-session MCT may therefore have clinical utility in psychiatric settings as means of improving patients’ understanding of treatment options and preparing for intervention.

In light of previous research findings, we aimed to investigate whether a single-session MCT approach similar to that applied by Ross et al may have impact not only on JTC bias severity but also on capacity. The current study represents to our knowledge the first randomised controlled study assessing the impact of single-session, JTC-focused MCT upon treatment-related decision-making capacity. We believe this research is warranted since the aforementioned outcome studies suggest cognitive bias and capacity are relevant treatment targets while the application of a fully randomised methodology focused directly on capacity allows greater inference. We therefore aimed to assess the impact of MCT on capacity as assessed by the MacCAT-T when compared to a non-specific control presentation (NC). Based on previous research, we hypothesised that brief MCT intervention would be more effective in improving capacity. As a secondary research question we also aimed to determine whether any effect of MCT upon capacity was mediated by changes in the JTC bias and hypothesised that reduction in JTC severity would mediate improvements in capacity.
Fig. 1. Flow of participants through the study

Patients contacted by NHS clinical staff to determine interest in participation and basic criteria clarified (estimated n=85)

First contact: Participant information sheet and informed consent (n=43)

Meta-cognitive therapy (n=19)
- Received allocated intervention (n=19)
- Dropped out before completing intervention (n=0)

Non-specific control (n=18)
- Received allocated intervention (n=17)
- Dropped out before completing intervention (n=1)

Session 1: Baseline assessment battery commenced (n=41)

Completed baseline assessment and invited for second session (n=39)

Battery not completed (n=2)

Did not attend second session (n=2)

Randomised on attendance for session 2 (n=37)

Post-treatment assessment (n=19)
- Completed full battery (n=18)
- Partial completion of battery (n=1)

Post-treatment assessment (n=17)
- Completed full battery (n=13)
- Partial completion of battery (n=4)

Analysis
- Included in intention-to-treat analysis (n=19)

Analysis
- Included in intention-to-treat analysis (n=18)
Methods

Design

The study used a randomised controlled pre-post experimental design. Participants were randomly allocated to receive a single-session MCT intervention or a non-specific control presentation. Outcome measures were administered at baseline and post-treatment. Blinding of assessors was not possible due to limitations of the project therefore all outcome measures were administered by the researcher delivering the intervention.

Participants and recruitment

The trial was conducted across NHS Lanarkshire and NHS Dumfries and Galloway health boards, both in Scotland, UK. The majority of recruitment (n=36, 97%) was in NHS Lanarkshire. Recruitment was open between January 2016 and February 2017. Ethical approval was obtained from local NHS Research and Development committees alongside the South of Scotland Research Ethics Committee (REC no. 15/SS/0162) and the University of Edinburgh ethics committee. The study protocol was registered on Open Science Framework (https://osf.io/kunc4/) before randomisation commenced. Outpatients were recruited through contact with Community Mental Health Teams (CMHTs) and Psychological Therapies Teams (PTTs) while inpatients were recruited within both acute and rehab inpatient psychiatric services.

English-speaking participants aged 16-65 were eligible for inclusion if a) they were in contact with NHS mental health services in their respective health board; b) they were assigned a current or historical diagnosis of schizophrenia, schizoaffective disorder, delusional disorder, brief psychotic disorder or psychosis NOS; c) psychosis was not considered the result of a general medical condition or substance misuse disorder; d) the participant was not under care of Forensic mental health services nor involved in on-going legal proceedings; e) the participant had a moderate or severe learning disability or f) there was
deterioration in their condition resulting in participation being judged as potentially detrimental. There was no minimum or maximum symptom threshold while psychosis subtypes (e.g. first episode or treatment-resistant) were not specified. Criteria therefore allowed inclusion of a broad and heterogeneous psychosis population.

To facilitate recruitment, the primary investigator delivered a presentation and Q&A session to a variety of CMHTs, PTTs and psychiatrists that introduced the study alongside the referral procedure. Mental health professionals were requested to identify relevant patients and discuss basic information to determine interest in participation. Staff then provided contact details for interested patients allowing the primary investigator to arrange contact at the patient’s routine mental health facility.

<table>
<thead>
<tr>
<th>Table 1. Demographic and clinical characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (N=37)</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Gender (male:female)</td>
</tr>
<tr>
<td>Ethnicity (white:other)</td>
</tr>
<tr>
<td>Inpatient:outpatient</td>
</tr>
<tr>
<td>Diagnosis</td>
</tr>
<tr>
<td>Schizophrenia</td>
</tr>
<tr>
<td>Schizoaffective</td>
</tr>
<tr>
<td>Psychosis NOS</td>
</tr>
<tr>
<td>Duration</td>
</tr>
<tr>
<td>0-1 years</td>
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<tr>
<td>1-3 years</td>
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<tr>
<td>3-5 years</td>
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<tr>
<td>5-10 years</td>
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<tr>
<td>Over 10 years</td>
</tr>
<tr>
<td>PANSS Positive</td>
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<tr>
<td>PANSS Negative</td>
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<tr>
<td>PANSS General</td>
</tr>
<tr>
<td>PANSS Total</td>
</tr>
<tr>
<td>HADS Total</td>
</tr>
</tbody>
</table>

Note: MCT, Meta-cognitive training. PANSS, Positive and Negative Syndrome Scale. HADS, Hospital Anxiety and Depression Scale. NB, data for Age, PANSS and HADS are reported as mean and standard deviation. Range not reported for age. There were no significant differences between MCT and NC using t-test and chi-squared tests.
Procedures

Participants attended two sessions. For two participants with concentration difficulties an additional session was added to the baseline assessment. Before beginning the first session, participants were provided with a participant information sheet detailing the purpose of the study, implications of participation, confidentiality, possible risks and disadvantages and contact details for an independent advisor and complaints officer. Patients gave informed consent by signature, at which point a unique participant ID number was provided and used on all further documentation.

The first session consisted of administration of the complete baseline assessment battery meaning all outcome measures listed below were administered alongside a demographic questionnaire. When participants satisfied inclusion criteria and agreed to return for the intervention session, a follow-up appointment within two weeks was arranged.

Randomisation was achieved using the simple randomisation service at sealedenvelope.com, which utilises a permuted random blocks method and provided remote assignment with a digital record of each randomisation. Randomisation was sought by the researcher only when participants arrived to attend the second session. This minimised missing data by ensuring only participants who returned for the intervention session were randomised. Following randomisation, the primary investigator (D.T.) or a collaborator (A.L.) delivered the assigned treatment followed by a reduced battery of primary and secondary outcome measures. In a minority (n=5, 14%) of instances where a participant chose not to continue, some secondary outcome measures were not completed.

Intervention

MCT intervention followed the manual developed by Moritz et al. To provide an effective single-session version of MCT, the primary investigator and the
developer of MCT amalgamated the JTC modules into an hour-long ‘best of’ session. The full MCT manual alongside individual JTC sessions can be obtained at www.uke.de.mkt. The primary investigator and collaborator were trained in the delivery of MCT. Both were final-year Trainee Clinical Psychologists on a Doctoral programme with eight and three years experience delivering cognitive-behavioural interventions respectively.

The MCT session aimed to repeatedly engage the participant in applying an approach contrary to the JTC bias while reflecting on the pitfalls of JTC. Participants were encouraged to assign additional time in decision-making while assessing and interpreting all available evidence in given scenarios. MCT was delivered individually via Powerpoint. Components of the MCT session are provided in Table 2. Patients were encouraged to engage and interact during the session while reflection upon personal examples and misinterpretation of personally significant situations was encouraged.

**Non-specific control presentation (NC)**

To control for therapist attention and time while removing specific intervention factors addressing thinking biases, an hour-long psychology lecture regarding the localisation of brain function was presented individually, including famous cases such as Phineas Gage alongside examples of brain processing across different sensory modalities.
**Table 2.** *Components of meta-cognitive training psycho-educational session*

<table>
<thead>
<tr>
<th>Session duration: one hour (approximate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. An introduction to the jumping-to-conclusions bias in psychosis</td>
</tr>
<tr>
<td>2. Inferences without 100% proof; examples from daily life (2 examples)</td>
</tr>
<tr>
<td>3. Jumping-to-conclusions “in action;” examples from politics and medicine of the pitfalls of using jumping-to-conclusions in decision-making (4 examples)</td>
</tr>
<tr>
<td>4. How jumping-to-conclusions promotes misinterpretation; discussion and examples including a worksheet for personal experiences and alternative interpretation</td>
</tr>
<tr>
<td>5. Jumping-to-conclusion and it’s role in conspiracy theories; illustration via the moon landing conspiracy theory</td>
</tr>
<tr>
<td>6. Worksheet exercise; providing evidence for and against personal delusional beliefs including conviction rating</td>
</tr>
<tr>
<td>7. Picture-identification tasks (3 tasks); participants were required to identify all possible interpretations of images as progressive detail was revealed and state their confidence in their interpretation</td>
</tr>
<tr>
<td>8. Face illusion tasks (3 tasks); participants were required to identify all details or alternative interpretations when presented with images, for example the old woman/young woman/old man face illusion</td>
</tr>
<tr>
<td>9. Scene identification from cut-out (4 tasks); four tasks in which a cut-out image from a larger scene was provided from which participants were required to infer the correct wider context from four options using evidence in the picture and state confidence</td>
</tr>
<tr>
<td>10. Misfits task (5 tasks): presentation of five classic paintings in which participants were required to identify the correct title from four options based upon clues within the painting and state confidence</td>
</tr>
<tr>
<td>11. Summary of jumping-to-conclusions session and suggested tactics</td>
</tr>
</tbody>
</table>
Outcome measures

Primary outcome measure

MacArthur Competency Assessment Tool for Treatment (MacCAT-T)

The MacCAT-T assessed capacity at baseline and post-treatment. The measure was clinician-rated and based on a semi-structured interview schedule covering four domains; understanding information relevant to treatment (0-6); appreciation of diagnostic and treatment information (0-4); reasoning ability regarding treatment options (0-8) and expressing choice regarding treatment (0-2). Although the scale does not provide a total score, to align with previous research an overall capacity score was calculated alongside consideration of the subscales. Each subscale has demonstrated inter-rater reliability of Kappa 0.80 (3–5). Higher scores are indicative of greater capacity. Scale reliability in the current sample was $\alpha = 0.80$.

Secondary outcome measures

Hospital Anxiety and Depression Scale (HADS)

The HADS is a 14-item self-report measure of depressive and anxiety symptoms providing a basic measure of distress. Scale reliability was calculated as $\alpha = 0.83$.

Cognitive Bias Questionnaire for Psychosis (CBQ-p)

The CBP-Q is a 30-item self-report measure, which provided a secondary assessment of the JTC bias alongside four related cognitive distortions. Scale reliability was calculated as $\alpha = 0.89$. 
Beads Task

A computerised version of the beads task was used to assess the JTC bias by recording how many ‘draws to decision’ participants made when judging the relative contents of a jars containing two colours of beads. A 60:40 version of the task was utilised. It has been reliably demonstrated that psychosis samples make hastier decisions based on less draws than healthy controls. Scale reliability was calculated as $\alpha = 0.82$.

Additional measures

Positive and Negative Syndrome Scale (PANSS)

The PANSS was administered at baseline to characterise the sample. 30 clinician-rated items assess positive, negative and general symptoms of psychosis alongside a total score. Higher scores indicate greater severity of symptoms. Scale reliability was calculated as $\alpha = 0.88$ for the total scores.

Statistical Analyses

Participants were randomly allocated on attendance at the single intervention session after which primary and secondary outcome measures were immediately administered. The design meant that missing outcome data was minimised whilst all analyses followed intention-to-treat procedures. Multiple imputation in SPSS was used to estimate missing scores at post-treatment by entering baseline PANSS scores and group assignment as predictors alongside baseline and post-treatment scores for the imputed outcome.

All data were assessed for normality by visual examination of histograms and boxplots alongside calculation of statistically significant skewedness or kurtosis. When significant skewedness or kurtosis suggested potential violation of the assumptions required for ANCOVA, post-hoc non-parametric sensitivity analyses were performed using a Kruskal-Wallis H test in R Studio. The main analyses of
primary and secondary outcome measures were computed in SPSS using ANCOVAs by entering baseline scores as covariates. Controlling for baseline score may improve power and precision in small trials. Each analysis was checked for consistency in both Type I and Type III ANCOVA models while lack of model fit was examined. Partial eta squared effect sizes were converted to Cohen’s $d$ by entering their square root into a purposely-developed spreadsheet.

To investigate the jumping-to-conclusions bias as a potential mediator of the MCT effect on capacity, two methods of simple mediation analyses were performed. First, traditional mediation analyses based upon the linear regression method described by Baron and Kenny was implemented using the RMediation package. Second, causal mediation analyses were conducted following Preacher and Hayes method, using the SPSS PROCESS macro. Causal mediation analysis utilises ordinary least squares path analysis and non-parametric bootstrapping, therefore has higher precision than the Baron and Kenny approach, and may accommodate data violating the assumption of normality. Causal mediation analysis also improves inference regarding causality. The unconventional inclusion of two mediation approaches occurred due to the researcher learning during the project that the Preacher and Hayes approach is considered superior while also attempting to be consistent with the published protocol by retaining the Baron and Kenny approach originally specified. We investigated beads task draws-to-decision at post-treatment as the potential mediator variable across MacCAT-T subscales and total. The CBQP JTC subscale and total were also considered for mediation analyses but did not meet necessary assumptions.

**Power analysis**

The G*Power software was applied to calculate the required sample size to detect a small effect, based on the assumption that a randomised study may observe smaller effects than the large effects ($F=1.29$) reported on MacCAT-T total when adjusting for baseline severity in the non-randomised study by
Naughton et al.\textsuperscript{29} It was estimated that 26 participants would be required in each group to detect an effect of $F=0.4$ for the 0.05 alpha level at 80% power using an ANCOVA including one covariate.

**Results**

**Demographic and clinical characteristics**

Table 1 provides information on demographic and clinical variables at baseline. The majority (n=31, 84%) of participants were male while the majority of females (n=5, 84%) were randomly allocated to the MCT group. All patients were of self-reported white ethnicity. Thirty percent (n=11) of participants were inpatients compared to 70% (n=26) outpatients, while the proportion of inpatients and outpatients was relatively balanced across groups; 74% (n=14) were outpatients in MCT and 67% (n=12) were outpatient in NC. The majority of participants were diagnosed with schizophrenia (n=26, 70%) whilst 14% (n=5) were diagnosed with schizoaffective disorder and 16% (n=6) as psychosis NOS. There were a slightly lower proportion of schizophrenia diagnoses in the MCT group ($p>.05$). The majority of participants' first diagnosis occurred over ten years before baseline (n=27,73%). There were a higher proportion ($p>.05$) of participants with first diagnosis over ten years ago in NC (n=15, 83%) than MCT (n=12, 63%) while only the MCT group included participants with less than one year since their first diagnosis (n=3, 16%, $p>.05$). On average, participants overall fell within the moderate range of the HADS. When comparing the groups, the MCT group fell within the severe range whilst NC participants remained at moderate severity ($p>.05$). PANSS total severity fell below the average provided by Kay et al\textsuperscript{32} across groups. PANSS positive symptom severity was balanced across the groups. PANSS negative symptoms were higher in the NC group ($p>.05$) whilst PANSS general symptom severity, PANSS total score and HADS total score were higher in the MCT group ($p>.05$).
<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Post-treatment</th>
<th>F-Test</th>
<th>Between-group effect size (d)</th>
<th>Post-hoc power</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MCT</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MacCAT-T Understanding</td>
<td>3.62 (1.40)</td>
<td>3.30 (1.46)</td>
<td>4.30 (1.49)</td>
<td>3.59 (1.57)</td>
<td>2.06</td>
</tr>
<tr>
<td>MacCAT-T Appreciation</td>
<td>3.21 (1.08)</td>
<td>2.90 (1.28)</td>
<td>3.86 (0.58)</td>
<td>3.00 (1.35)</td>
<td>6.45*</td>
</tr>
<tr>
<td>MacCAT-T Reasoning</td>
<td>6.2 (1.23)</td>
<td>5.44 (1.89)</td>
<td>6.89 (1.24)</td>
<td>5.56 (2.00)</td>
<td>3.95**</td>
</tr>
<tr>
<td>MacCAT-T Total</td>
<td>14.93 (3.37)</td>
<td>13.58 (4.17)</td>
<td>16.8 (2.83)</td>
<td>13.9 ((4.37)</td>
<td>7.78*</td>
</tr>
<tr>
<td>HADS Anxiety</td>
<td>9.21 (5.39)</td>
<td>7.22 (4.13)</td>
<td>9.158 (4.71)</td>
<td>7.522 (4.55)</td>
<td>2.21</td>
</tr>
<tr>
<td>HADS Depression</td>
<td>6.16 (4.14)</td>
<td>3.39 (2.68)</td>
<td>7.32 (3.60)</td>
<td>3.44 (2.39)</td>
<td>7.63*</td>
</tr>
<tr>
<td>HADS Total</td>
<td>15.38 (8.17)</td>
<td>11.11 (5.40)</td>
<td>16.26 (7.18)</td>
<td>10.99 (5.87)</td>
<td>2.21</td>
</tr>
<tr>
<td>CBQP JTC subscale</td>
<td>11.21 (3.87)</td>
<td>10.56 (2.20)</td>
<td>10.67 (3.05)</td>
<td>10.60 (1.57)</td>
<td>.33</td>
</tr>
<tr>
<td>CBQP Total</td>
<td>48.89 (11.10)</td>
<td>45.44 (9.83)</td>
<td>45.40 (9.42)</td>
<td>43.54 (8.39)</td>
<td>.35</td>
</tr>
<tr>
<td>Beads Task</td>
<td>3.84 (2.91)</td>
<td>3.67 (2.68)</td>
<td>6.16 (4.05)</td>
<td>3.72 (3.36)</td>
<td>7.35*</td>
</tr>
</tbody>
</table>

MCT, Meta-cognitive training; NC, Non-specific control presentation; MacCAT-T, MacArthur Competency Assessment Tool for Treatment; HADS, Hospital Anxiety and Depression Scale; CBQP, Cognitive Biases Questionnaire for Psychosis; JTC, jumping-to-conclusions.

*p<0.05
**p<0.1
Main analysis

Post-hoc power

A total of 37 participants were included in the intention-to-treat analyses. Post hoc power was calculated for all ANCOVA analyses based on our estimated effect sizes at the 0.5 alpha level and is provided in the final column of Table 3.

Between-subject effects

Table 3 provides the results from the ANCOVAs for primary and secondary outcomes. There was a large positive effect of MCT on two capacity outcomes; the Appreciation subscale \( (d=0.87, p<.05) \) and the total score \( (d=0.95, p<.01) \) for the MacCAT-T. There was a medium effect of MCT upon the MacCAT-T Reasoning subscale which approached significance \( (d=0.68, p=.055) \). MCT did not demonstrate superiority on the MacCAT-T Understanding subscale nor for the CBQP JTC subscale or total score. There was a large positive effect of MCT on Beads Task draws-to-decision \( (d=0.93, p<.05) \). There was a large negative effect of MCT on the HADS depression subscale \( (d=0.95, p<.05) \) indicating that treatment resulted in an increase in depressive symptoms while no significant effects were demonstrated on the HADS anxiety subscale or total score.

A significant degree of negative skew was present in the MacCAT-T Appreciation outcome at baseline and post-treatment assessments across MCT and NC groups that potentially violated the assumptions of ANCOVA. Data met the assumptions required for a post-hoc Kruskall-Wallis H test, therefore a sensitivity analysis was performed. The resulting chi-squared statistic was consistent with the main ANCOVA in showing a significant effect favouring MCT \( (x^2=0.11, p<.05) \).
Mediation analysis

Results of both methods of simple mediation analysis are provided in Table 4. The Baron & Kenny\textsuperscript{36} approach found a significant mediating effect of Beads Task draws-to-decision on the MacCAT-T total score at post-treatment ($d=0.64$, $p<.05$) which accounted for 38.7\% of treatment effects. However, this comparison did not meet the assumptions described by Baron and Kenny since the second step in the three-part model, which estimated the effect of draws to decision on MacCAT-T total, was not significant ($p=.06$). There were no significant mediation effects shown on MacCAT-T subscales using the Baron and Kenny approach. The Preacher and Hayes\textsuperscript{38} approach found significant mediating effects of draws-to-decision across all MacCAT-T outcomes at post-treatment; the mediating effect accounted for 63\% of outcome on Understanding ($d=0.45$, $p<.05$), 35.7\% on Appreciation ($d=0.55$, $p<.05$), 28.8\% on Reasoning ($d=0.59$, $p<.05$) and 38.7\% on the total score ($d=0.64$, $p<.05$).
### Table 4. Mediation effects of Post-Treatment Draws to Decision on primary outcome

<table>
<thead>
<tr>
<th></th>
<th>Total effect (SE), ( P )</th>
<th>Direct effect (SE), ( P )</th>
<th>Mediated effect (SE), 95% CI</th>
<th>Proportion mediated, %</th>
<th>( d )</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baron &amp; Kenny method</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MacCAT-T Understanding</td>
<td>-0.71 (0.50), 0.17</td>
<td>-0.26 (0.48), 0.59</td>
<td>-0.45 (0.28), -1.10, 0.00</td>
<td>63</td>
<td>0.45</td>
</tr>
<tr>
<td>MacCAT-T Appreciation</td>
<td>-0.71 (0.34), 0.04*</td>
<td>-0.45 (0.34), 0.19</td>
<td>-0.25 (0.17), -0.66, 0.01</td>
<td>35.7</td>
<td>0.55</td>
</tr>
<tr>
<td>MacCAT-T Reasoning</td>
<td>-1.34 (0.55), 0.02*</td>
<td>-0.95 (0.55), 0.09</td>
<td>-0.39 (0.27), -1.03, 0.02</td>
<td>28.8</td>
<td>0.59</td>
</tr>
<tr>
<td>MacCAT-T Total</td>
<td>-2.89 (1.21), 0.02*</td>
<td>-1.77 (1.14), 0.13</td>
<td>-1.12 (0.69), -2.69, -.00*</td>
<td>38.7*</td>
<td>0.64</td>
</tr>
<tr>
<td><strong>Preacher &amp; Hayes method</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MacCAT-T Understanding</td>
<td>-0.71 (0.50), 0.17</td>
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<td>63*</td>
<td>0.45</td>
</tr>
<tr>
<td>MacCAT-T Appreciation</td>
<td>-0.71 (0.34), 0.04*</td>
<td>-0.46 (0.34), 0.19</td>
<td>-0.25 (0.15), -0.66, -0.04*</td>
<td>35.7*</td>
<td>0.55</td>
</tr>
<tr>
<td>MacCAT-T Reasoning</td>
<td>1.34 (0.55), 0.02*</td>
<td>-0.95 (0.55), 0.09</td>
<td>-0.39 (0.25), -1.08, -0.03*</td>
<td>28.8*</td>
<td>0.59</td>
</tr>
<tr>
<td>MacCAT-T Total</td>
<td>-2.89 (1.21), 0.02*</td>
<td>-1.77 (1.14), 0.13</td>
<td>-1.12 (0.65), -2.86, -0.14*</td>
<td>38.7*</td>
<td>0.64</td>
</tr>
</tbody>
</table>

MacCAT-T, MacArthur Competency Assessment Tool for Treatment. SE, standard error. CI, confidence interval. \( P \), probability level. Mediation model: \( x = \) group, \( y = \) MacCAT-T, \( M = \) draws to decision at post-treatment.
Discussion

This randomised controlled experimental study was the first to examine the effects of brief MCT on decision-making capacity regarding treatment in psychosis. Results identified large significant effects of MCT on two capacity-related outcomes in patients diagnosed with psychosis, namely their appreciation of diagnosis and treatment ($d=0.87$) and overall capacity ($d=0.96$). A large effect of MCT on reasoning ability regarding treatment-related information approached significance while the MCT group also showed significant increases in depressive symptomatology at post-treatment ($d=0.95$). These results are broadly consistent with a previous non-randomised trial.\textsuperscript{29} Results of our study also suggested that the treatment effects of MCT were mediated by changes in the jumping-to-conclusions bias although effects were more robust using the Preacher and Hayes\textsuperscript{38} method than Baron and Kenny.\textsuperscript{36}

The indication that a brief MCT intervention had a beneficial impact on patients capacity use information regarding their treatment and mental health diagnosis has important implications for our understanding of capacity in psychosis since limited insight, understanding and decision-making have been repeatedly observed.\textsuperscript{3,6} Our findings are preliminary evidence that targeted psychological intervention for cognitive bias modification can improve capacity and contribute to the developing literature implicating cognitive biases in impaired capacity.\textsuperscript{42} The mediating effect demonstrated by the JTC bias also implies that a causal relationship may exist between cognitive bias and capacity although we acknowledge the exploratory nature of our comparisons.

A somewhat unexpected finding was the negative effect of MCT upon depressive symptoms compared to NC, suggesting that MCT increased self-reported symptomatology. However, the ‘insight paradox’ of increasing emotional distress and lower self-esteem as insight improves has been well researched in psychosis while recent capacity research has indicated that anxiety may increase as capacity improves.\textsuperscript{3,43-45} Moreover, this finding suggests that the negative effects on HADS depression be a by-product of improving capacity.
therefore interventions targeting JTC may consider methods of mitigating such effects.

We emphasise that a number of limitations mean the results of this study should be interpreted with caution. An important limitation was the lack of blind assessment or fidelity checks and the involvement of the primary researcher in the vast majority of recruitment, assessment and treatment. A related limitation was the therapy-therapist confound, although the didactic and structured nature of MCT may limit potential bias. It was not possible to provide financial reward for participation, therefore recruitment relied on clinical staff identifying participants who may tolerate and enjoy participation. This method had the potential to introduce selection bias since those considered for inclusion may have been better primed for the intervention while there is the possibility that the direct dynamic between the primary researcher, clinical teams and patients could impact participant performance.

Similarly, a broad definition of psychosis was utilised, meaning that patients with historical diagnoses of psychosis were included even when their symptoms had been well controlled by anti-psychotic medication for many years. This resulted in a high average age, a lack of first-episode psychosis and a predominance of participants first diagnosed over ten years ago. Inclusion in the study was also based upon pre-assigned psychiatric clinical diagnosis and satisfaction of current DSM-5 criteria was not fully confirmed by researchers although PANSS baseline severity was assessed. Contrasting the narrower Forensic-only population included by Naughton et al., our sample was heterogeneous in that patients at opposing poles of the psychosis and capacity continuum were included; from severe inpatients scoring at the minimum for capacity and high on PANSS positive symptoms to participants high in capacity who had not experienced positive symptoms for many years. The relatively low average on PANSS negative symptoms suggests the sample were not overall characteristic of the deficit syndrome of schizophrenia. The study was also underpowered; the protocol power calculation identified that 26 participants would be required in each group to provide adequate power to identify small
effect sizes. The resultant group sizes of 19 and 18 for MCT and NC respectively therefore meant that there was a possibility of Type II errors missing small to medium effects in comparisons that did not demonstrate statistical significance; specifically the MacCAT-T Understanding, HADS total, HADS anxiety and CBQP outcomes. Caution should therefore be employed when interpreting of these results.

We should also consider the implications of the absence of any pre-recruitment screening measure to quantify the severity of the JTC bias among participants. This introduced the possibility that not all participants currently demonstrated the JTC bias, and therefore might not have had the impairment the intervention sought to treat. The finding that MCT significantly reduced the JTC bias and the concurrent evidence of a mediating relationship between the JTC bias and capacity therefore becomes potentially more impressive since not every case may have been ‘treatable.’

The study design also had a number of strengths that increase the likelihood that findings are robust for the sample included. The NC condition was closely matched to count for common factors of the MCT intervention while omitting any specific factors targeting JTC meaning that any effect on capacity should be specific to MCT rather than contextual. The design also meant that it was unlikely that many participants were fully aware whether they had been randomly assigned to treatment or control since the procedure was identical other than the content of the treatment and control conditions. Allocating randomisation on attendance at the single intervention session also meant that missing data was minimal.

It is also relevant to consider our application of the MacCAT-T as primary outcome. The measure was developed primarily in a legal context and has faced criticism for missing the complexity of decision-making in practice by assuming centrality of cognitive ability without addressing the impact of emotional or contextual factors. Our finding that self-reported depressive symptomatology increased as capacity improved supports the continuing development of
comprehensive, multifactorial capacity assessment models allowing greater specification of the components that contribute to impaired capacity.

In light of the promising findings reported, a methodologically stringent RCT addressing the aforementioned limitations is warranted to help determine whether the effect of MCT in improving capacity is robust. A future trial may improve validity by stricter inclusion criteria based upon current diagnosis, blind assessment, treatment fidelity checks, inclusion of additional therapists and a recruitment method less reliant on personal relationships. The limitations mean our study may be conceptualised as providing an effectiveness rather than a strict efficacy trial therefore future replication attempts may focus upon this distinction.\textsuperscript{48}

This randomised experimental study provides preliminary evidence for the efficacy of a brief psycho-educational intervention targeting capacity by addressing the JTC bias in psychosis. That capacity may be improved by such intervention has implications for our understanding of the factors that modulate capacity and holds promise that capacity can be improved by psychological intervention. This has further implication for autonomy, empowerment and the joint decision-making in psychiatric treatment. The applicability of brief MCT intervention suggests that these methods have potential for integration as a first-step in treatment pathways that help improve understanding and aid service-user decision-making, which may improve engagement and care matching given the range of available treatment options.\textsuperscript{15,16}

**Declaration of interest**

None

**Acknowledgements**

With huge thanks to my family, my supervisors and all the NHS Lanarkshire staff who helped make this project possible as without the trust and huge level of support from each of these sources this project would not have been possible.
References


48. Gartlehner G, Hansen RA, Nissman D, Lahr KN, Carey TS. Criteria for distinguishing effectiveness from efficacy trials in systematic reviews. Agency for Healthcare Research and Quality (US); 2006;
Appendix 1: Supplementary materials for systematic review

Search strategy for 4 included databases

1. PubMed

**Main dialog box:** Schizophrenia and Disorders with Psychotic Features AND (social skills training OR functional skills training OR social cognitive skills training OR skills training OR functional adaptation skills training OR social cognition training OR social skills)

**Limits:** limited to randomised controlled trials

**Result:** 218 articles

2. Psychinfo

**Main search (all terms entered in separate dialog boxes):** Schizophrenia OR psychosis AND social skills training OR functional skills training OR social cognitive skills training OR skills training OR functional adaptation skills training OR social cognition training OR social skills

**Limits:** Limited to treatment outcome/clinical trials

Result: 131 articles

3. Embase

**Main dialog box:** Schizophrenia OR psychosis AND (social skills training OR functional skills training OR social cognitive skills training OR skills training OR functional adaptation skills training OR social cognition training OR social skills)
Limits: Limited to randomised controlled trials and Embase listings only (excluding PubMed)

Result: 113 articles

**4. Cochrane Register**

**Main dialog box:** Schizophrenia OR psychosis AND "social skills training" OR "functional skills training" OR "social cognitive skills training" OR "skills training" OR "functional adaptation skills training" OR "social cognition training" OR "social skills" AND "randomised controlled trial"

**Limits:** Limit to trials

**Result:** 1722 articles
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+, high risk of bias. -, low risk of bias. Item 1, random sequence generation. Item 2, allocation concealment. Item 3, blinding of assessors. Item 4, incomplete outcome data. Total risk of bias was calculated as the sum of high risk items to provide an overall risk score. Unclear risk of bias category was disregarded therefore when no information on an item was included in report, high risk of bias was assumed.
Appendix 2: Author guidelines for systematic review

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Clinical laboratory data may be expressed in conventional rather than Système International (SI) units.

Acknowledgments
These should be as brief as possible but include the names of sources of logistical support.

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Appendix 3: PRISMA checklist

### PRISMA 2009 Checklist

<table>
<thead>
<tr>
<th>Section/topic</th>
<th># Checklist item</th>
<th>Reported on page #</th>
</tr>
</thead>
<tbody>
<tr>
<td>TITLE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Identify the report as a systematic review, meta-analysis, or both.</td>
</tr>
<tr>
<td>ABSTRACT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured summary</td>
<td>2</td>
<td>Provide a structured summary including, as applicable: background, objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.</td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rationale</td>
<td>3</td>
<td>Describe the rationale for the review in the context of what is already known.</td>
</tr>
<tr>
<td>Objectives</td>
<td>4</td>
<td>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).</td>
</tr>
<tr>
<td>METHODS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol and registration</td>
<td>5</td>
<td>Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>6</td>
<td>Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.</td>
</tr>
<tr>
<td>Information sources</td>
<td>7</td>
<td>Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.</td>
</tr>
<tr>
<td>Search</td>
<td>8</td>
<td>Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.</td>
</tr>
<tr>
<td>Study selection</td>
<td>9</td>
<td>State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).</td>
</tr>
<tr>
<td>Data collection process</td>
<td>10</td>
<td>Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.</td>
</tr>
<tr>
<td>Data items</td>
<td>11</td>
<td>List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.</td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>12</td>
<td>Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.</td>
</tr>
<tr>
<td>Summary measures</td>
<td>13</td>
<td>State the principal summary measures (e.g., risk ratio, difference in means).</td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>14</td>
<td>Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I²) for each meta-analysis.</td>
</tr>
<tr>
<td>RESULTS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias across studies</td>
<td>15</td>
<td>Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).</td>
</tr>
<tr>
<td>Additional analyses</td>
<td>16</td>
<td>Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.</td>
</tr>
<tr>
<td>DISCUSSION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of evidence</td>
<td>24</td>
<td>Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).</td>
</tr>
<tr>
<td>Limitations</td>
<td>25</td>
<td>Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).</td>
</tr>
<tr>
<td>Conclusions</td>
<td>26</td>
<td>Provide a general interpretation of the results in the context of other evidence, and implications for future research.</td>
</tr>
<tr>
<td>FUNDING</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Funding</td>
<td>27</td>
<td>Describe sources of funding for the systematic review and other support (e.g., supply of data), role of funders for the systematic review.</td>
</tr>
</tbody>
</table>

Appendix 4: PROSPERO Registration

Social skills training for psychosis: a comprehensive meta-analysis
David Turner, Edel McGlone, Paul Hutton

Citation

Review question(s)
What is the efficacy of social skills training for psychosis?

For what outcomes are social skills training most efficacious?

Are some forms of social skills training more efficacious than others?

Has social skills training for psychosis been underused in comparison to other interventions?

Should social skills training be recommended for negative symptoms in psychosis?

Searches
PubMed, PsycINFO, Embase and the Cochrane Central Register for Controlled Trials (CENTRAL) will be searched.

The inclusion lists from previous reviews will also be considered while those social skills studies meeting the criteria for inclusion in the Turner et al. (2014) meta-analysis will also be included.

The search terms will relate to specific MeSH criteria for each database but will roughly include terms to encompass psychotic disorders and any name variations of social skills training, for example: Schizophrenia and Psychotic Disorders AND (social skills training OR social cognitive training OR social skills therapy).

There will be no period of restriction upon searches.

The search will be limited to the English language, but if papers are uncovered during the search in different languages which are readily translatable by the review team they may be considered for inclusion.

Types of study to be included
Only randomised controlled trials will be included in this review. The randomisation process is required to be reported clearly as quasi-randomised trials will not meet criteria. In the case that randomisation quality is unclear, sensitivity analyses may be performed when excluding such studies.

Condition or domain being studied
The problem being studied is psychosis, including schizophrenia and other psychotic disorders.

Participants/population
Participants in RCTs aged 18 and above who are diagnosed with schizophrenia, psychosis or psychotic disorders.

Studies will not be included if the majority proportion of the cases are mood disorder patients with psychosis, e.g. bipolar or psychotic depression. The percentage of affective psychosis cases in any study must therefore be below 50%. In cases where it is indicated that between 25-49% of cases are affective psychosis, sensitivity analyses will be calculated. Prodromal or ultra-high risk participants will not be included. Studies of psychosis related primarily to general medical causes or substance use will not be included.
Intervention(s), exposure(s)
The review will include any intervention applied to psychosis in the domain of social skills training. This was defined by Turner et al (2014) as "behavioural intervention based on behavioural and social learning traditions in which participants' social functioning is targeted in order to improve their ability to perform in social situations, manage daily life tasks and reduce social distress. Importance is typically placed on verbal and non-verbal communication alongside learning, appropriate perception and responses to social cues. The intervention may also include training in independent living skills."

If sufficient power/literature is available, separate analyses may also be run for varying models of social skills training.

Comparator(s)/control
Various comparison conditions will be included. Bona fide alternative interventions such as cognitive behavioural therapy or cognitive remediation will be included as will attention-control conditions, treatment-as-usual and waiting list control. It is likely that analyses will be run for all comparators pooled alongside separate analyses for each type of comparator/control although whether this is possible depends on power and study availability.

Context
Participants will have been diagnosed as having psychosis schizophrenia or related disorders by health professionals. They may be inpatients or outpatients of varying severity.

Outcome(s)
Primary outcomes
The primary outcome will be negative symptoms as measured by various scales for psychotic symptoms. These include the Positive and Negative Syndromes Scale (PANSS), Brief Psychiatric Ratings Scale (BPRS) and Scale for Assessing Negative Symptoms (SANS).

Data will be extracted for baseline, post-treatment and any follow-up data available. Follow-up data will be stratified into comparable groups for analysis.

Secondary outcomes
All outcome measures featuring data on psychological symptoms, e.g. positive symptoms or depression and anxiety, will be extracted and when possible analyses will be run. Alternative outcome measures such as social functioning (e.g. SOFAS) or quality of life measures will also be extracted and analyses run when possible. Similarly, dichotomous outcomes such as relapse rates and hospitalisation will also be considered. When available, data on adverse outcomes and treatment engagement will be considered.

Data will be extracted for baseline, post-treatment and any follow-up data available. Follow-up data will be stratified into comparable groups for analysis.

Data extraction, (selection and coding)
Two researchers will be involved in data extraction for the study, while sections of the data have already been extracted for the previous meta-analysis by Turner et al (2014). The data from the previous meta-analysis was extracted by one author (D.T.) and checked by a co-author Eleni Karyotaki, who will have no direct involvement in the current review. Further data extracted only for this review will be checked for consistency by E.McG. (co-author on this review). Discrepancies will be resolved via discussion. Data will be extracted to sheets developed for the previous review.

Risk of bias (quality) assessment
As in Turner et al (2014) risk of bias will be assessed using the four relevant items of the Cochrane Risk of Bias tool. The Cochrane GRADE principles will also be applied to evaluate the quality of evidence.

Strategy for data synthesis
The Comprehensive Meta-Analysis software package will be used to analyse data. Meta-analyses will be performed on sub-groups only when at least three RCTs are available. Aggregated effect sizes indicating pooled difference.
between interventions at post-treatment and follow-up intervals will be calculated using Hedge's g. Standardised mean difference will be calculated using a 95% CI and random effects model, while odds ratio will be used for dichotomous outcomes. As is standard, heterogeneity will be investigated via a Chi-squared test, Q statistic and I-squared while publication bias will also be assessed.

Analysis of subgroups or subsets
A variety of sub-group analyses will be conducted as indicated in previous sections. Sub-group analyses will be performed for the varying levels of risk of bias. They will also be performed for any perceived differences between social skills training interventions, when study availability allows. Sub-group analyses will also be performed for different types on control conditions (e.g. TAU, Active controls etc) and various outcome measures.

Dissemination plans
The review will aim for publication in a relevant peer-reviewed journal.

Contact details for further information
David Turner
david.turner17@nhs.net

Organisational affiliation of the review
School of Health in Social Science, University of Edinburgh
http://www.ed.ac.uk/health

Review team
Mr David Turner, University of Edinburgh/NHS
Miss Edel McGlinchey, University of Edinburgh/NHS
Dr Paul Hutton, University of Edinburgh

Details of any existing review of the same topic by the same authors

This is not an update of this review but aspects of the former review relevant to social skills training will be utilised.

Anticipated or actual start date
09 May 2016

Anticipated completion date
21 October 2016

Funding sources/sponsors
David Turner is a Trainee Clinical Psychologist on the Doctorate in Clinical Psychology at Edinburgh University and is funded on this programme via NHS Education for Scotland.

Dr Paul Hutton is academic supervisor as part of this programme.

Conflicts of interest
None known

Language
English

Country
Scotland
Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Humans; Psychotic Disorders; Social Adjustment; Social Skills; Treatment Outcome

Stage of review
Ongoing

Date of registration in PROSPERO
09 May 2016

Date of publication of this revision
11 May 2016

<table>
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<th>Stage of review at time of this submission</th>
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<th>Completed</th>
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</thead>
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<tr>
<td>Preliminary searches</td>
<td>No</td>
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</tr>
<tr>
<td>Piloting of the study selection process</td>
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</tr>
<tr>
<td>Formal screening of search results against eligibility criteria</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Data extraction</td>
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<td>No</td>
</tr>
<tr>
<td>Risk of bias (quality) assessment</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Data analysis</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

PROSPERO
International prospective register of systematic reviews
The information in this record has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.
Appendix 5: Author guidelines for empirical study

Randomised trials in *The Lancet*: formatting guidelines

To assist authors with submission and to streamline the peer review and editing process, we have compiled the following guidelines for reporting of randomised trials in *The Lancet*. Please provide a non-declaratory title, including the trial descriptor (eg, Once-weekly dulaglutide versus once-daily liraglutide in patients with type 2 diabetes (AWARD-6): a randomised, open-label, phase 3, non-inferiority trial). A structured summary should be included, of maximum length 300 words. The main text of the Article should be 3000 words, but can be extended up to 4000 words for randomised trials, with up to 30 references. All reports of randomised trials should include a trial profile, table of baseline characteristics, and a panel that puts their results in context with previous work. Extra description or analyses can be included as an appendix. Please submit your test and tables in a Word document (removing Endnote or other referencing software), and your figures as editable files (eg, eps, pdf). Reports of trials must conform to CONSORT 2010 guidelines. Abstracts, cluster-randomised trials, and trials that report harms must be reported according to CONSORT extended guidelines.

**Authors:** Please include first names and surnames for all authors. Affiliations and degrees should be supplied as shown in the margins; only one degree is listed per author, and indicate any full professors. For papers with more than 30 authors we suggest that a collaborative group authorship is considered, to be listed at the end of the paper or in an appendix, dependent on length. Collaborators listed in this way are recognized by PubMed. Authors statement forms and International Committee of Medical Journal Editors conflict of interest forms should be submitted and should match summary statements at the end of your paper. Please list one corresponding author and state their preferred title, postal address including zip code or postcode, and email address.

**Summary** (maximum length 300 words)

**Background**
- State briefly why the study was done, followed by a specific aim or hypothesis; do not include references here.

**Methods**
- State study design (eg, randomised, parallel, cluster, non-inferiority, open-label, double-blind).
- Indicate the setting (community, hospital) where participants were recruited (which countries, how many centres or hospitals), and the key participants eligibility criteria.
- Explain the groups participants were randomly assigned to, and provide information about the methods of randomisation, masking, and stratification. How were participants allocated to groups and by whom? Were participants, investigators, and those assessing outcomes masked to group assignments?
- Give details of interventions (type, method of delivery, duration). For drugs provide the generic name (rINN), dose, route, and schedule of administration.
- What was the main outcome of this report and when was it assessed? We do not as standard include additional outcomes in the Summary.
- State who was included in primary and safety analyses (eg, intention to treat, per protocol, all participants who received one dose of study drug).
- For non-inferiority studies, state the margin used to establish non-inferiority.
- Provide the trial registration number, name of registry, and trial status (is the trial closed to new participants?).

**Findings**
- Provide exact dates between which participants were recruited and the number of participants assigned and analysed in each group, accounting for dropouts.
- For the primary outcome give a result for each group (provide actual numbers of participants or events alongside any percentages), and estimated effect size (eg, odds ratio) and its precision (eg, 95% CI, p value). Report SDs for mean values and IQRs for medians, and give exact p values unless p<0.001. Use SI units. For risk changes or effect sizes, give absolute values rather than relative changes.
- Summarise adverse events (actual numbers and percentages in both groups; include treatment-related deaths).
- Results stated should agree with what is in the main paper, and all data here should also appear in the main paper.

**Interpretation**
- Provide a general interpretation of the results and their significance rather than repeating them. Mention any key limitations and strengths of the study. The interpretation should be justified by the results and should explain their importance or relevance to clinical practice.

**Funding**
- Source of funding (if none, say so).

www.thelancet.com November 2005
Methods

Study design
- Start with the study descriptor (randomised, parallel, cluster, non-inferiority, open-label, double-blind, etc.).
- Indicate where the study was done (community, hospital), in which countries, and in how many centres or hospitals.
- State the centre where ethics approval was obtained.
- Provide a link to the study protocol if available online.

Participants (or patients)
- Describe the planned population, with inclusion and exclusion criteria and how participants were recruited.
- State whether participants gave written or oral informed consent.

Randomisation and masking
- Explain the groups to which participants were randomly assigned, describe the method of randomisation—in that used to generate the sequence with which participants are allocated to comparison groups (eg, computer, random-number tables, coin-toss), including details of the methods used to restrict the randomisation (block, stratification) and any stratification or minimisation factors.
- State method of allocation concealment (eg, sealed opaque envelopes).
- State who generated the sequence, who enrolled participants, and who assigned them to the trial groups and whether they had any involvement in the rest of the trial.
- Describe how masking (blinding) was achieved (eg, tablets with identical appearance, syringe taped up to conceal colour of liquid inside). Include a statement of whether participants, people giving the interventions, those assessing outcomes, and those analysing the data were masked to group assignment, and how the success of masking was assessed.

Procedures
- Give details of interventions (type, method of delivery, duration). For drugs please provide the recommended international non-proprietary name, manufacturer and place of manufacture.
- State the follow-up intervals and assessments done at each visit.

Outcomes
- State the primary outcome (for multicentre trials, whether this was centrally assessed).
- List secondary outcomes (a complete list).
- Describe assessment of safety and adverse events.
Statistical analysis
- Indicate how the target sample size was calculated and what power the study had to detect a significant difference between treatment groups.
- Give details of main comparative analyses.
- State which participants were included in primary and safety analyses (eg, by intention to treat, per protocol, including only participants who received at least one dose of study drug).
- State statistics program and version number used for analyses.
- For non-inferiority studies, state the margin used to establish non-inferiority.
- State whether a data monitoring committee oversaw the study.
- List trial registration number and name of registry.

Role of the funding source
- Include standard statement (if funder had no role in study) or amend as necessary: “The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.”
- If the study had no funder, state “There was no funding source for this study”. Information about access to data and responsibility for submission are still required.

Results
- Paragraphs in this section should follow the order: a description of number of participants recruited and included in analysis; baseline characteristics; findings for the primary outcome, secondary outcomes, adverse events, and finally any post-hoc or sensitivity analyses. No subheadings should be used in the Results or the Discussion sections.
- The first paragraph should state the exact dates (eg, Jan 1, 2013, to Dec 31, 2014) between which participants were recruited, and include with a trial profile (see figure 1 for an example; template available online) the number of participants assessed for eligibility, the number ineligible, the number randomised to each group, the number of exclusions or dropouts at each stage, and the number assessed for the primary endpoint.
- Details of participants’ baseline characteristics should be provided (table), but a formal statistical comparison (p value) should not be given because any differences between groups at this point must arise by chance (if randomised properly).
- The main outcome measures must include a point estimate (eg, relative risk, hazard ratio) plus a measure of precision (95% CI) of the difference between groups.

### Table 1. Baseline characteristics of the intention-to-treat population

<table>
<thead>
<tr>
<th></th>
<th>Drug A (n=500)</th>
<th>Drug B (n=500)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>247 (49%)</td>
<td>253 (50%)</td>
</tr>
<tr>
<td>Female</td>
<td>253 (51%)</td>
<td>247 (50%)</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-15</td>
<td>62 (12.4%)</td>
<td>67 (13.4%)</td>
</tr>
<tr>
<td>16-34</td>
<td>246 (49%)</td>
<td>244 (49%)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
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</tr>
<tr>
<td>White</td>
<td>240 (48%)</td>
<td>246 (49%)</td>
</tr>
<tr>
<td>Black</td>
<td>151 (30%)</td>
<td>154 (31%)</td>
</tr>
<tr>
<td>Asian</td>
<td>197 (39%)</td>
<td>98 (20%)</td>
</tr>
<tr>
<td>Other</td>
<td>11 (2%)</td>
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</tr>
<tr>
<td><strong>CD4 performance status</strong></td>
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<tr>
<td>0</td>
<td>235 (47%)</td>
<td>240 (48%)</td>
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<tr>
<td>1</td>
<td>161 (32%)</td>
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<td><strong>BMI (kg/m²)</strong></td>
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<tr>
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<tr>
<td>median (IQR)</td>
<td>245 (145)</td>
<td>252 (150)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>250 (150)</td>
<td>255 (150)</td>
</tr>
</tbody>
</table>

Panel: Research in context

**Evidence before this study**
This section should include a description of all the evidence that the authors considered before undertaking this study. Authors should briefly state the sources (databases, journal or book reference lists, etc.) searched, the criteria used to include or exclude studies (including the exact start and end dates of the search), which should not be limited to English language publications; the search terms used; the quality (risk of bias) of that evidence; and the pooled estimate derived from meta-analysis of the evidence, if appropriate.

**Added value of this study**
Authors should describe here how their findings add value to the existing evidence.

**Implications of all the available evidence**
Authors should state the implications for practice or policy and future research of their study combined with existing evidence. Research in context panels should not contain references; key studies mentioned here should be referenced in the main text.

- Use SI units. State a baseline number of participants or events alongside percentages. Mean values should be accompanied by SDs or 95% CI, and medians by IQRs. Supply exact p values unless p<0.001.
- Estimates of survival (either median or at a specific time point) should be accompanied by 95% CI.
- Ensure that any Kaplan-Meier survival curves (figure 2) have unbroken y axes, include numbers at risk below the x axis, and state a measure of effect (usually log rank p, plus hazard ratio and...
Articles

95% CI on the graph. Similar guidance applies to cumulative incidence figures.

- Any histology figures should include magnification bars, and images of patients should only be used with signed consent from the patient or their representative (please do not send signed forms to The Lancet; please instead complete the patient consent section of the author statement form while returning copies of the signed patient forms).

Discussion

- The Discussion section should contain a full description and discussion of the context.
- Start with a sentence summarizing your main findings and move on to relate your results to your hypothesis and data previously published. Authors must either to report their own, up-to-date systematic review or cite a recent systematic review of other trials as part of a panel putting your research into context with existing evidence (see panel for details). No subheadings should be used in this section.
- Discuss limitations and strengths of your study, noting sources of bias or imprecision.
- Discuss any controversies raised by this study.
- Consider possible underlying mechanisms for your findings.
- Suggest future research directions.
- State general interpretation of data in light of all evidence available, noting the clinical significance and effects on patient care and policy, expanding on the summary provided in your Research in context panel.

Contributions

Provide a statement outlining what each author contributed to the start of the article contributed to the study—e.g., AS led the statistical analysis. DC wrote the first draft of the report with input from B.

Declaration of Interests

Declare any competing interest for all authors, if none then add “I declare no competing interests.” This statement must match what is reported on the signed forms submitted for all authors.

Acknowledgements

State the funding source for your work, including grant numbers here if applicable. If you wish to thank or acknowledge any individuals, please provide signed statements from them agreeing to be cited in your Article.

References (maximum of 16 for primary research articles)

- Cite references in the text sequentially in the Vancouver numbering style, as a superscript number after any punctuation mark—e.g., as reported by Smith and colleagues. Two references are cited separately by a comma, with no space. Three or more consecutive references are given as a range. Reference to tables, figures, and panels should be in numerical order according to where the item is cited in the text. Do not include references in the Summary. See below the formatting examples of different reference types.
- Journal references
  - In press—e.g., Author A. Author B. Title. Journal Name; volume (2023): page range. doi: xxxxxx.
  - Published on-line before print—e.g., Author A. Author B. Title. Journal Name; published on-line month day, DOI xxxxxx.
  - Journal names are abbreviated in their standard form as in Index Medicus.
  - If there are six authors or fewer, list all six in the format: Smith B, Jones R, Brown D, Green A. If there are seven or more give the first three, followed by et al.
  - If the reference is an abstract, we note that after the page range—e.g., (OJ 1998 2(4) 25–26).
- Book or published report references
  - For references to a whole book or report, list the authors or editors and the publisher, the city of publication, and year of publication—e.g., Editor A, Editor B, eds. Title of book. City of publication: Publisher. Year of publication.
  - For a chapter or section of a book or report, also give the authors and title of the section, and the page numbers—e.g., Author A, Author B. Title of chapter. In: Editor A, Editor B, eds. Title of book. City of publication: Publisher. Year of publication: page range of chapter.
- Other
  - For the online material, please cite the authors of the page, the title, and the date created, along with the URL and the date you accessed the website—e.g., Author A, Author B (if available). Title of document. Date (if available). URL (accessed month day year).
  - Unpublished material is cited in the text as: unpublished if it is the author’s own observation, or as a personal communication from a named individual with their permission, and if it is by someone else. Written permission is needed to cite personal communications.
  - References that have been submitted to a journal but not accepted for publication should be cited as unpublished data in the text and not included in the reference list. References that have been accepted by a journal and are in press can be included in the list; please supply a copy of the letter of acceptance.
### Appendix 6: CONSORT checklist

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item No</th>
<th>Checklist item</th>
<th>Reported on page No</th>
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<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
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<td></td>
<td>1a</td>
<td>Identification as a randomized trial in the title</td>
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<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)</td>
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<tr>
<td><strong>Introduction</strong></td>
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<tr>
<td>Background and objectives</td>
<td>2a</td>
<td>Scientific background and explanation of rationale</td>
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<td>Specific objectives or hypotheses</td>
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<tr>
<td><strong>Methods</strong></td>
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<tr>
<td>Trial design</td>
<td>3a</td>
<td>Description of trial design (such as parallel, factorial) including allocation ratio</td>
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<td></td>
<td>3b</td>
<td>Important changes to methods after trial commencement (such as eligibility criteria), with reasons</td>
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<td>Participants</td>
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<td>Eligibility criteria for participants</td>
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<td>Setting and locations where the data were collected</td>
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<td>Interventions</td>
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<td>The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</td>
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<tr>
<td>Outcomes</td>
<td>6a</td>
<td>Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed</td>
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<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
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<td>Sample size</td>
<td>7a</td>
<td>How sample size was determined</td>
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<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
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<td><strong>Randomisation</strong></td>
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<td>Sequence generation</td>
<td>8a</td>
<td>Method used to generate the random allocation sequence</td>
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<td>8b</td>
<td>Type of randomisation; details of random restriction (such as blocking and block size)</td>
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<tr>
<td>Allocation</td>
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<td>Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), concealment mechanism</td>
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<td>Describing any steps taken to conceal the sequence until interventions were assigned</td>
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<td>Implementation</td>
<td>10</td>
<td>Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
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<tr>
<td>Blinding</td>
<td>11a</td>
<td>If done, who was blinded as to interventions (for example, participants, care providers, those assessing outcomes) and how</td>
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<td>11b</td>
<td>If relevant, description of the similarity of interventions</td>
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<td><strong>Statistical methods</strong></td>
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<td>Statistical methods used to compare groups for primary and secondary outcomes</td>
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<td>12b</td>
<td>Methods for additional analyses, such as subgroup analyses and adjusted analyses</td>
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<td><strong>Results</strong></td>
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<tr>
<td>Participant flow (a diagram is strongly recommended)</td>
<td>13a</td>
<td>For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome</td>
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<td></td>
<td>13b</td>
<td>For each group, losses and exclusions after randomisation, together with reasons</td>
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<tr>
<td>Recruitment</td>
<td>14a</td>
<td>Dates defining the periods of recruitment and follow-up</td>
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<td>14b</td>
<td>Why the trial ended or was stopped</td>
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<tr>
<td>Baseline data</td>
<td>15</td>
<td>A table showing baseline demographic and clinical characteristics for each group</td>
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<tr>
<td>Numbers analysed</td>
<td>16</td>
<td>For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups</td>
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<td>17a</td>
<td>For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)</td>
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<tr>
<td>Ancillary analyses</td>
<td>17b</td>
<td>For binary outcomes, presentation of both absolute and relative effect sizes is recommended</td>
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<tr>
<td>Outcomes and estimation</td>
<td>18</td>
<td>Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory</td>
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<td>19</td>
<td>All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)</td>
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<tr>
<td><strong>Discussion</strong></td>
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<tr>
<td>Limitations</td>
<td>20</td>
<td>Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses</td>
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<tr>
<td>Generalisability</td>
<td>21</td>
<td>Generalisability (external validity, applicability) of the trial findings</td>
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<tr>
<td>Interpretation</td>
<td>22</td>
<td>Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence</td>
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<td>Other information</td>
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<tr>
<td>Registration</td>
<td>23</td>
<td>Registration number and name of trial registry</td>
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<tr>
<td>Protocol</td>
<td>24</td>
<td>Where the full trial protocol can be accessed, if available</td>
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<tr>
<td>Funding</td>
<td>25</td>
<td>Sources of funding and other support (such as supply of drugs), role of funders</td>
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</tbody>
</table>

*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 randomized trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming; for these and for up-to-date references relevant to this checklist, see www.consort-statement.org.*
Appendix 7: Empirical Study Protocol

Doctorate in Clinical Psychology

This form should be completed and submitted as the assessment for Research 1. It will then be reviewed by a member of the academic team and will receive a grade and detailed feedback. The feedback will include an evaluation of the viability of the project and any recommendations. If there are significant concerns about viability, the project will be flagged to the research director and the research committee will decide whether the project can proceed in its current form.

Provisional Thesis Title: A randomised experimental manipulation of the jumping-to-conclusions bias in psychosis: Effect on capacity to consent to treatment

Exam number: R1

Allocated Thesis Project Supervisors

Clinical Dr Karen Livingstone

Academic 1 Dr Paul Hutton

Proposed setting(s): Outpatient and inpatient mental health services in NHS Lanarkshire

Anticipated Month & Year of Submission of Thesis: 1st March 2017

(Must be in final year for full time trainees. For flexible trainees, the month & year of submission will depend on their Individual Training and Development Plan. Trainees from 2011 intake onwards must submit in May, trainees who started in 2010 or earlier are advised to submit in May to reduce potential for HPC registration difficulties)
**Please Note:** Whilst this is not an ethics review process, where questions have some similarities to questions contained in the NHS IRAS Research Ethics form, the corresponding IRAS question numbers are given in parentheses. This is intended to facilitate completion of NHS ethics where such approval is needed.

Version (date): 25<sup>th</sup> August 2015

**Researchers**

**David Turner** *
Trainee Clinical Psychologist  
NHS Lanarkshire & University of Edinburgh

**Dr. Paul Hutton (Academic Supervisor)**  
University of Edinburgh

**Dr. Karen Livingstone (Clinical Supervisor)**  
NHS Lanarkshire

* Main researcher and protocol author

**Word count:**  
5,645
**Abbreviations**

CBT- Cognitive behavioural therapy

MacCAT-T- MacArthur Capacity Assessment for Treatment

JTC- Jumping to conclusions

CBQP- Cognitive Biases Questionnaire for Psychosis

MCT- Meta-cognitive training

CMHT- Community mental health team

PTT- Psychological therapy team

IPS- Inpatient psychiatric services

ICD-10- International Classification of Diseases 10th Edition

PANSS- Positive and Negative Syndromes Scale

HADS- Hospital anxiety and depression scale

ANCOVA- Analysis of co-variance

NHS- National Health Service

CBTp- Cognitive behavioural therapy for psychosis

ITT- Intention-to treat-analysis
Introduction

Capacity to consent to treatment in mental health

Decision-making capacity regarding consent to treatment and choice of intervention is an important topic in contemporary psychiatry. In many countries, mental health legislation may justify medical or psychiatric intervention without consent of the patient if they are judged to have impaired capacity to make informed treatment choices in their own best interests. Decision-making capacity has been conceptualised as consisting of four components or abilities, namely; a) understanding of treatment-related information; b) appreciation by the patient of how this information applies to their situation; c) ability to reason based on this information and d) ability to make and express choices about treatment (Tunzi, 2001). The extent to which patients have capacity in these domains has implications for the provision and implementation of mental health care. In England and Wales, the Mental Capacity Act (2005) relates closely to the above components and therefore states that to have capacity, an individual must understand information relevant to treatment decisions, must be able to retain that information and must have the ability to use or reason with that information when making decisions based upon it. The Adults with Incapacity (Scotland) Act (2000) is based upon similar principles.

Capacity in psychosis

There are ethical implications surrounding the issue of capacity to consent to treatment in psychosis and in recent decades, health systems in developed countries have become more conscious of the role of patient autonomy and the importance of dignity, empowerment and agency in psychiatric treatment (Holmes & Ssleeby, 1993. The Schizophrenia Commision, 2012). Psychotic disorders are particularly relevant when considering decision-making capacity in mental health treatment since limited insight about the diagnosis and impaired capacity have repeatedly been observed in schizophrenia patients.
Limited capacity in psychosis patients has often led to compulsory psychiatric treatment via anti-psychotic medication (Gisev et al, 2014. Schulte et al, 2007). There have been well-documented problems with anti-psychotics such as side effects, symptoms being resistant to change and dissatisfaction among users, which may lead to a high level of discontinuation of assigned treatments (Lieberman, 2007).

Contemporary psychiatric and psychological research now emphasises a range of efficacious treatment options in psychosis including a variety of psychological interventions (Turner et al, 2014), while a ground-breaking study by Morrison et al (2014) suggests that cognitive-behavioural therapy (CBT) may act as an efficacious intervention in the absence of medication. CBT may therefore offer an alternative without the risk of serious side effects often associated with anti-psychotics (Wayne et al, 2009). Such findings have implications for patient autonomy and exemplify the need for an improved understanding of capacity to consent and the ability to make choices regarding treatment options among psychosis patients.

Capacity in mental health has typically been assessed using the MacArthur Competency Assessment Tool for Treatment (MacCAT-T), which is a clinician-administered semi-structured interview assessing the four aforementioned components of capacity (Grisso, et al, 1997). A number of studies have utilised the MacCAT-T to assess the prevalence of impaired capacity among psychosis patients, with estimates of around 50-80% among inpatient samples (Owen et al, 2008. Okai et al, 2007. Cairns et al, 2005). Meta-analysis has also suggested that inpatients diagnosed with schizophrenia are twice as impaired on capacity compared to outpatients (Jeste et al, 2006). Although diagnosis with a psychotic disorder does not guarantee a patient has impaired decision-making capacity, estimates therefore suggest that a majority of psychotic inpatients and many outpatients have limited understanding of their diagnosis, its implications for mental health care, the choices available for intervention and ability to make appropriate choices. Nevertheless, understanding of the processes underlying impaired capacity in psychosis remains limited (Raffard et al, 2013).
Impaired cognitive processes have been implicated as influential in the development and maintenance of psychosis, including the impact of biased cognitive appraisal and reasoning or *cognitive bias* (Garety *et al.*, 2001). One particular cognitive bias for which an evidence base has developed is the jumping-to-conclusions (JTC) bias, which refers to a tendency to make decisions based upon limited evidence (Ross *et al.*, 2015). A consequence is that those displaying JTC are more likely to make false conclusions or exclude relevant information; therefore JTC has been implicated in the development and maintenance of delusions in schizophrenia (Moritz *et al.* 2010). Conceptualised as a data-gathering bias, the JTC bias has traditionally been assessed via a beads gathering task in which participants are requested to judge the relative amount of coloured beads in a jar. JTC may also be investigated using the Cognitive Bias Questionnaire for Psychosis (CBQP. Peters *et al.*, 2014). A dose-response relationship has been demonstrated between the JTC bias and familial trait liability to psychosis (van Dael *et al.*, 2006), while the basis of JTC has been suggested as an over-estimation of conviction in choices alongside use of less information to make decisions (Rubio *et al.*, 2011). Suspiciousness, a tendency to disregard evidence, emotional factors and IQ are also predictive of the JTC bias (Jolley *et al.*, 2014). The JTC bias has been demonstrated as present in a wide range of psychosis-related populations including symptomatic, at risk, remitted and schizotypal groups (Peters *et al.*, 2014). Longitudinal studies suggest stability of the JTC bias over time while delusional conviction varies (So *et al.*, 2012).

*Interventions with potential impact on capacity in psychosis*

Meta-cognitive therapy (MCT) is a psycho-educational intervention based on cognitive-behavioural principles alongside elements of cognitive remediation (Moritz *et al.*, 2010). MCT specifically targets the cognitive biases hypothesised as maintaining delusions in psychosis and contains two specific modules focusing on reduction of the JTC bias. Each module presents examples and discusses consequences of making hasty decisions based upon limited evidence.
MCT has been suggested as efficacious in the reduction of delusions and positive symptoms (Moritz et al, 2011). Current research suggests that JTC is amenable to intervention and may be modified using brief psycho-educational interventions based upon MCT. Ross et al (2011) conducted a randomised controlled trial in which they investigated the effects of a single session MCT-based intervention on data gathering and reasoning among individuals with delusions and schizophrenia-spectrum diagnoses. Compared to a non-specific control presentation group, those receiving MCT significantly increased their data gathering by roughly 50% compared to the control group although there were only non-significant benefits upon their belief flexibility or delusional belief conviction. However, the study included only 17 participants in each group therefore had limited power to detect effects. Nevertheless, the results suggest that brief, targeted intervention may have a positive impact upon the JTC bias and therefore have implications for our study.

A further study suggested that not only is the JTC bias amenable to intervention but that interventions targeting the JTC bias may also improve the capacity of psychosis patients. Naughton et al (2012) conducted a prospective naturalistic cohort effectiveness trial in a forensic setting. The study reported a significant effect for benefits of MCT compared to the non-specific control presentation on MacCAT-T total score alongside significant effects on the understanding and reasoning subscales. One considerable difference between the Naughton et al study and the proposed research is the frequency and duration of intervention since participants received MCT twice weekly for eight weeks, resulting in up to 16 sessions compared to one session in the proposed research. This has implications for the anticipated results of the proposed research since limited time and resources mean it is not possible to include an equivalent intervention. However, based upon the results of Ross et al (2011) in which a single-session intervention had impact upon the JTC bias it is reasonable to hypothesis that brief MCT specifically targeted to the JTC bias may improve capacity.

Implications of current knowledge for the proposed research
The combined findings of the two aforementioned studies utilising brief MCT-based interventions suggest that the proposed research is warranted since cognitive bias and capacity appear to be amenable to improvement. Furthermore, the Naughton *et al* study was not considered a randomised controlled trial since an opportunistic waiting list was used rather than random allocation while the study was also underpowered. Further review of currently available research therefore suggests that the proposed study would be the first fully randomised experimental study investigating the impact of an MCT-based psycho-educational intervention for the JTC bias upon capacity in psychosis.

**Research Questions / Objectives:**

The primary objective is to investigate whether the application of a brief, MCT-based psycho-educational intervention for the JTC bias can improve treatment decision-making capacity in psychosis patients when compared to an inactive non-specific control presentation condition.

3) What are the secondary research questions / objectives if applicable? *(IRAS A11)*

A secondary objective is to investigate whether baseline psychosis severity or JTC bias severity predicts treatment response on decision-making capacity scores.

A further objective is to examine whether the MCT-based psycho-educational intervention will improve JTC bias severity among psychosis patients when compared to an inactive non-specific control presentation condition.
An additional objective is to examine whether changes in the JTC bias mediate any relationship between group assignment (MCT vs. control) and treatment decision-making capacity.

A final objective is to consider how results from our attempt to modify treatment decision-making capacity by using a cognitive bias intervention may be utilised to further develop models of capacity in psychosis.

**Methodology**

*Design*

The design will consist of a randomised experimental design in which participants are randomly assigned to either of two conditions: a) a brief adaptation of the MCT JTC modules or b) an non-specific control presentation using a non-specific psychology-related presentation without JTC information to control for researcher contact and time. A randomised experimental design was chosen since a strong randomisation process means we can assume that groups are equivalent at baseline, therefore any differences in outcome measures post-treatment are caused by the experimental manipulation rather than any confounding variable(s).

*Participants and recruitment*

Participants will be outpatients and inpatients diagnosed with schizophrenia-spectrum disorders, attending community mental health teams (CMHT), psychological therapy teams (PTT) or inpatient psychiatric services (IPS) in the
NHS Lanarkshire catchment area. The main researcher will make contact with lead clinical and administrative staff in relevant mental health facilities across NHS Lanarkshire to inform them of the project and attempt to gain their cooperation in identifying relevant participants for the study. In order to facilitate this process, presentations and training will be provided at each relevant location.

Clinical staff in contact with psychosis patients in CMHTs, PTTs or IPS will be requested to refer relevant participants to the study. Staff will be provided with training on the identification of appropriate cases and means by which to refer participants to the study. They will be requested simply to refer participants who have been identified as psychotic. Consideration of remaining inclusion/exclusion criteria would then be made during the first meeting with the main researcher. This will include the administration of a brief self-report screening tool using only the JTC items from the CBQP. Psychotic participants who score 7 or more from a possible 18 would be considered, which will indicate the minimum presence of the JTC bias. This will act to help identify participants as appropriate before formal consideration of the remaining inclusion/exclusion criteria by the researcher.

Randomisation and blinding

Following the procedure applied by Ross et al (2011), a randomisation schedule will be generated using randomization.com. Participants will first attend the initial session at which baseline outcome measures will be administered whereas the randomisation, intervention and post-treatment assessments will take place at a second session. When it is clear that participants meet the full inclusion criteria following the baseline assessment session, an appointment for a second session will be agreed with the participant at the end of the first session. Participants will not be randomised until they attend the second session, at which point the main researcher will obtain their allocation. This procedure is intended to minimise the likelihood of missing data since those
participants who do not attend the second session will not have been randomised and can be excluded from data analysis.

Due to the limitations of the project, the main researcher is required to administer outcome measures at baseline and post-treatment alongside delivering the experimental and control conditions, therefore completely blind assessment at post-treatment is not possible. However, in order to improve validity, a proportion (approximately 10%) of the MacCAT-T interview at post-treatment will be audio recorded and then rated by another researcher blind to the participants’ allocation. Following the review of these recordings they will be destroyed. This method is intended to limit the potential for bias in post-treatment outcome measures, since limited resources mean it is only possible that the main researcher delivers the experimental and control conditions then follows this by administering the post-treatment outcome measures. Although there remains the possibility of therapy-therapist confound since the main researcher will deliver the intervention and also facilitate the control condition, the psycho-educational nature of the experimental condition and non-active role of the researcher in the non-specific control presentation condition mean that risk of bias in this domain is minimised.

*Experimental and control conditions*

The experimental treatment will consist of an amalgamation of the two JTC modules from the Metacognitive Training package (Moritz *et al*, 2011). The format will be a one-to-one power point presentation during which the main researcher talks the participant through the module slide by slide and will last approximately one hour. MCT will be delivered on a one-to-one basis in order to allow equivalence to the control condition. The participants will be permitted to ask questions specific to the JTC presentation. Any request or question by the participant regarding personal mental health difficulties will be (when possible) deferred for attention by members of the relevant CMHT, PTT or IPS.
The inactive non-specific control presentation condition will consist of a non-specific presentation about psychology but without any information on the JTC or anything intended to change capacity or symptoms. This is designed to control only for participant effort, researcher attention and engagement without delivering any active intervention. The presentation will be administered on a one-to-one basis to provide equivalent contact to the experimental condition.

Inclusion and exclusion criteria

Participants will be eligible for inclusion when:
   a) their case is currently open to adult mental health services;
   b) they meet ICD-10 criteria for one of the following psychotic disorders: schizophrenia, schizo-affective disorder, delusional disorder, brief psychotic disorder;
   c) they show evidence of the JTC bias as assessed by selected items of the CBQP;
   d) they are aged 16-65.
   e) they have capacity to consent to research participation, as judged by clinical team and researcher (note: the decision to participate in this research is likely to require much less decisional capacity than decisions about medical treatment)

Participants will be excluded from the study when:
   a) they do not show evidence of the JTC bias;
   b) there is a comorbid diagnosis of alcohol or substance misuse;
   c) they have a moderate or severe learning disability;
   d) psychotic symptoms are best explained by a general medical condition;
   e) there is an on-going legal case or involvement with forensic services;
   f) they do not speak English fluently (due to inability to complete standardised outcome measures and participate in intervention);
   g) they lack capacity to consent to research or;
h) they are experiencing a significant deterioration in their condition and the clinical team or researcher judges participation in this research to cause them or others harm

Participants will not be excluded based upon scores on the MacCAT-T measure of capacity since a continuum rather than a categorical approach will be taken to capacity, meaning that an arbitrary cut-off range for capacity will not be applied. This means an assumption will be made that, due to evidence of participants displaying JTC alongside a psychosis diagnosis, the majority of participants included in the study will either have significantly impaired treatment-related capacity or would reside at a higher severity point on a capacity continuum when compared to healthy controls.

Data collection

Data for the analysis will be gathered on the primary outcome measure (MacCAT-T) at two time points; baseline (during session one) and post-treatment (during session two). During the baseline assessment, a demographic questionnaire will be administered alongside the Positive and Negative Syndrome Scale (PANSS) as a measure of baseline severity and the Hospital Anxiety and Depression Scale (HADS) as a measure of baseline emotional distress. The JTC beads task will also be administered at each session. It is not expected that psychotic symptom severity will be influenced by a brief psycho-educational intervention therefore in the interests of time management, the PANSS will not be re-administered at post-treatment. This is consistent with results from Naughton et al (2012) in which PANSS scores showed no significant changes. Unfortunately blind assessment of outcome measures will not be possible within the scope of the study since practicalities only allow that the main researcher is responsible for collection of data, data analysis and facilitation of the experiment.

Primary outcome measure
The MacArthur Competence Assessment Tool for Treatment (MacCAT-T)

The MacCAT-T will be used to assess decision-making regarding capacity to consent for treatment at baseline and post-treatment for all participants. The MacCAT-T is a clinician-administered, semi-structured interview schedule. The tool assesses four specific components of decision-making, which are reflected in the sub-scales; understanding information relevant to treatment (rated 0 to 6); appreciation of the significance of diagnostic and treatment-related information regarding the patient’s situation (rated 0 to 4); reasoning ability when deciding upon treatment options (rated 0 to 8) and expressing a choice regarding treatment (rated 0 to 2). The test is tailored to each participant since information from review of the patient’s file is required to inform the process. The scale does not provide an overall total score and instead provides ratings on each area, although previous studies have also included analysis and results using the total score (e.g. Naughton et al, 2012). Inter-rater reliability has been demonstrated as Kappa above 0.80 for each subscale (Cairns et al, 2005. Okai et al, 2007. Raffard et al, 2013) while initial indications have been described as favourable (Appelbaum et al, 1997. Zapf & Roesch, 2005). Preparation for the MacCAT-T assessments may require access to participants’ medical notes.

Secondary outcome measures

Beads Task

A computerised version of the beads task will be used to assess the JTC bias (Moritz et al, 2007). The beads task in various forms is the standard means by which to assess probabilistic reasoning in the JTC bias and has traditionally recorded how many beads or ‘draws to decision’ it takes participants to make a judgement regarding the contents of a jar. Participants with psychosis have been shown to make decisions based on less draws compared to healthy controls or psychiatric controls (Moritz & Woodward, 2005).
Positive and Negative Syndrome Scale (PANSS)

The PANSS (Kay et al, 1988) is a 30-item, clinician-administered interview schedule designed to assess positive, negative and general symptoms of psychosis which are reflected in its subscales. A total score indicating overall severity of psychosis is also provided. The PANSS was selected due to having been most utilised in relevant previous research. The scale has demonstrated inter-rater reliability as Kappa over 0.80 while support has been shown for criterion and construct validity (Kay et al, 1988).

Hospital Anxiety and Depression Scale (HADS)

The HADS (Zigmund & Snaith, 1983) is a brief 14-item scale assessing depression and anxiety severity. A review of 747 papers utilising the HADS found good discriminant validity and internal consistency alongside appropriate balance between sensitivity and specificity (Bjelland et al, 2002)

Demographic questionnaire

A basic demographic questionnaire will be developed in order to characterise the sample based upon those administered by Ross et al (2011) and Naughton et al (2012). Areas covered by the questionnaire will include age, gender, ethnicity, inpatient/outpatient status, diagnosis, medication use and duration of illness.

Sample Size

The G*Power software (Faul et al, 2007) was used to calculate the required sample size. The study by Naughton et al (2012) applied the complete MCT package for the treatment group compared to a waiting list control and reported a large effect size of $F = 1.29$ for MacCAT-T total when adjusting for baseline severity. Based on the assumption that we are aiming to detect a smaller effect size of $F = 0.4$ (which is considered a large effect size for $F$ values
by Cohen (1988)), G*Power calculated that 26 participants will be required in each group when probability was set at the 0.05 level alongside 80% power for an ANCOVA with 1 covariate.

The regression analysis is a secondary research question therefore will be exploratory in nature and not based upon expected effect sizes from previous research. G*Power estimated that based on a sample size of 52, a linear multiple regression using a fixed model and the $R^2$ deviation from zero method would be able to detect an effect size of $F = 0.26$ with 95% power and the probability set at the 0.05 level. This suggests that it would be worthwhile to attempt the regression analysis if the appropriate sample size is achieved for the main analysis. However, for the most relevant comparisons only participants in the experimental group will be relevant for analysis since this would allow understanding of the characteristics of participants that interacted best with the intervention and would allow only 26 participants. Based on a sample size of 26, the regression will only able to detect a large effect size of $F = 0.55$ with 95% power and the probability set at the 0.05 level. As this is an exploratory analysis it shall still be conducted although with the knowledge that it is underpowered.

**Sample size justification**

The NHS Lanarkshire catchment area covers a large geographical region serving approximately 652,230 people. The majority of the population reside in large former industrial towns to the east of the city of Glasgow while the region also extends to include rural communities and former mining villages. The majority of adult mental health services are based in community or psychiatric settings across ten localities located in the main population centres. The NHS Information Analyst for mental health provided statistics of the diagnoses of inpatients at discharge, which showed that across all localities 293 patients were discharged from IPS with psychotic disorders between 1st January and 31st December 2014. Figures are not currently available for the number of psychotic patients under the care of CMHTs or PTTs but it is likely that a higher number of
psychosis patients will be managed within the community without presenting at IPS within a given year.

The main researcher has thus far approached one CMHT, which was receptive to the proposed research and agreed to participate. It was agreed that training on the study protocol alongside education on the JTC bias and capacity will be provided by the main researcher to the CMHT, with the aim of facilitating appropriate recruitment and providing a beneficial continued professional development opportunity for staff. The training and education model will be piloted in this CMHT before being rolled out across CMHTs in the wider NHS Lanarkshire region after feedback from staff. The clinical supervisor holds the position of CBT for psychosis (CBTp) “champion” within NHS Lanarkshire and coordinates a wider group of clinicians trained in CBTp in each locality. The main researcher will therefore present at CBTp meetings in order to promote the study and facilitate recruitment and will also contact individual PTTs with the possibility of presentations in departments if required alongside meetings with individual clinicians. Similarly, contact will be made with psychiatric services with the possibility of presenting at area-wide meetings to facilitate recruitment. In order to recruit sufficient participants, an average of 4 per month would have to be recruited over a 13-month period. Ideally in initial months a minimum of 5 patients would be recruited in order to allow leeway. If recruitment appears slow (<15 participants) after an initial 3-month trial period, the research team will consider recruitment in neighbouring NHS Greater Glasgow and Clyde or NHS Lothian.

Analysis

An Analysis of Covariance (ANCOVA) will be conducted for the main analysis. The categorical independent variable will be treatment type (MCT versus non-specific control presentation) while the dependent variables will be the continuous outcomes from the MacCAT-T, including subscales and a total score
as calculated by Naughton et al (2012). Baseline MacCAT-T scores will act as
the covariate in the ANCOVA model. This technique has been suggested as
improving statistical power when comparing two treatments (Moritz et al,
2011). In order to assess the impact of MCT upon the JTC bias, a further
ANCOVA will be conducted identical to the above procedure although with
scores from the beads task substituted for MacCAT-T scores as the dependent
variable. Furthermore, the regression-based procedure outlined by Baron and
Kenny (1986) will be applied to examine whether changes in beads task scores
mediate the effect of group (MCT vs. no MCT) upon MacCAT-T scores.

Intention-to-treat (ITT) analysis will be utilised in the case of any missing data.
It is unlikely that there will be a significant proportion of missing data since
randomisation will occur directly before the single experimental intervention
session, after which post-treatment assessments will be immediately
administered. The only likely opportunity for attrition is between session one
(baseline assessment only) and session two (randomisation, intervention and
post-treatment assessment) before any intervention has taken place and during
any contact until this point allocation will be unknown. In the unlikely instance
that there is drop out between part one and part two of session two, ITT will be
conducted using baseline scores.

For the exploratory linear regression analysis, baseline severity on the PANSS,
HADS, beads task scores and relevant demographic data will be entered as
predictor variables while MacCAT-T capacity subscales and total alongside the
beads task scores will be entered as dependent variables. Simple correlations
will also be conducted to examine whether an association exists between the
various outcome measures.

**Project Management: Timetable**

Ethics submission: July 2015

Start of data collection: October 2015
End of data collection: November 2016

Data analysis: November-December 2016

Write-up of final paper: January-February 2017

Completion of systematic review: October 2016

**Management of Risks to Project**

1) There is risk that NHS Lanarkshire mental health services to be contacted for participation in the study will not be receptive to involvement. This could potentially make recruitment of sufficient participants difficult. There has thus far been a very positive reaction to involvement from those contacted while the clinical supervisor also has well-developed links to psychosis-related services within the region. In the case that an adequate number of services do not participate, there is the possibility of recruitment in neighbouring health boards.

2) There exists risk that the intended sample size will not be obtained during the specified time period even when mental health services participate. For this reason, the main researcher requested that the proposal could be submitted and returned earlier than was scheduled to allow for earlier submission of ethics and data collection. This will allow over one year for data collection and widening of the area of recruitment in the case that referrals are slow over an initial period.

3) There is risk that the study will not receive ethical approval at either University or NHS level. This is considered unlikely since projects studying capacity and the JTC among a similar population have been approved within the past year as part of the Doctorate in Clinical Psychology programme. A key
difference in this project is that participants will be randomised to receive to different experimental conditions. This should not provide ethical difficulties since the experimental intervention is not hypothesised as having a therapeutic effect and during a similar previous application did not reduce or increase psychotic symptoms (Naughton et al, 2012). This negates the necessity of providing the brief MCT-based intervention for the control group after post-treatment. Should this be problematic, the brief MCT-based intervention can be offered to the control group as a group PowerPoint lecture at each research site.

Knowledge Exchange

The results of this study will be reported in the form of a journal manuscript and will be submitted for consideration to a peer-reviewed international journal in the area of psychosis, for example Schizophrenia Bulletin or Schizophrenia Research. Each of these journals have a large international readership and an impact factor of 8.6 and 4.4 respectively, although in the instance that results are not relevant to these journals another appropriate one shall be sought. Should results from secondary regression analyses prove particularly interesting these have the potential to form a separate paper although this is unlikely due to being underpowered. This article will also form part of the doctoral thesis submitted as part of the Doctorate in Clinical Psychology at the University of Edinburgh. Results will also be communicated via email to participating CMHTs, PTTs and IPS in NHS Lanarkshire while staff will be given the opportunity to attend a lecture within the NHS Lanarkshire area summarising the results and implications.

Anticipated benefits or implications for services of the project

The results of this project may be relevant to model building regarding capacity in psychosis and the understanding of how capacity may be improved. This has various implications for how psychological or psychiatric services may work with psychotic patients in terms of offering choice of interventions and understanding factors which may limit or improve capacity. There are now a number of on-going projects at the University of Edinburgh investigating
aspects of capacity in relation to cognitive biases and the JTC therefore alongside these projects, there may be potential for the development of treatment protocols aimed at improving capacity in psychosis. Such a protocol would have benefit for individuals with psychosis and their ability to make autonomous decisions regarding their treatment. There are also potential benefits to the NHS since improved capacity, autonomy and patient choice may result in better treatment engagement and improved outcomes following intervention (Martin et al, 2000).

Potential costs

There will likely be only limited costs in this project. The primary area of potential cost is travel expenses accumulated between study sites during NHS working hours and participant travel expenses. The NHS Lanarkshire area of main population is relatively compact and is well connected by roads while the data collection will take place over around one year, meaning approximately 50 possible days during which travel may be claimed. However, expenses from home to base are not eligible for claim therefore only in instances in which there are two study sites to visit within one day will incur expenses to the NHS while other travel will be self-funded by the main researcher. The aim is that the main researcher will primarily base himself in different health localities for discrete periods in order to maximise potential recruitment and minimise costs. It is also assumed that travel expenses reimbursed to participants will be minimal. Two reasons for this are the convenient location of the majority of NHS Lanarkshire mental health facilities centrally within local communities alongside the likelihood that many participants in the study already qualify for free public transport.

The MacCAT-T and PANSS are already available in the Department while the CBQP, HADS and beads task are free of charge therefore there will be minimal costs incurred for use of outcome measures. Similarly, the MCT package is freely available therefore can be adapted for use without cost. Further associated costs to the NHS will include use of computers, printers, postage and
telephones to arrange appointments. The researcher already has access to all relevant programs for data analysis therefore no additional costs are anticipated in this domain.

References


Raffard, S. Fond, G. Brittner, M. Bortolon, C. Macgregor, A. Boulenger, J. P. ... & Capdevielle, D. (2013). Cognitive insight as an indicator of competence to consent to treatment in schizophrenia. *Schizophrenia research, 144*(1), 118-121.


17) Confirmation of Supervisors’ Approval
I confirm that both my academic and clinical supervisors have seen and approved this research proposal and have both completed the supervisors’ appraisal forms below.
(Insert ‘yes’ below if true)

Appendix 1:  

**Methodological Review**

**Main Academic Thesis Supervisor’s Appraisal of Project Risk**

Supervisor’s Name: Dr Paul Hutton

*Do you consider that the project should proceed in broadly its current form?*

(Delete as appropriate)

Yes  Yes, subject to revisions outlined below  No

Please outline the reasons for your response. In particular, highlight any areas of risk to the completion of the project that have not been fully addressed within the proposal and any steps that could be taken to reduce risks:

The project is an ambitious one in terms of recruitment and time required for assessment, however I have a lot of confidence in David as a researcher. He has arrived at Edinburgh with a track record of managing and publishing high-impact research. He has already made substantial progress in engaging key stakeholders and making preparatory enquiries regarding feasibility. His clinical supervisor (Karen Livingstone) is also very well-established within the psychosis treatment field, with excellent links, and has been very supportive in proposal development. The total contact time per participant is also brief and comparable to other trainee projects currently underway with this population. My main concern (and this applies to almost all Edinburgh trainee projects that involve patients and quantitative analysis) is ensuring David has access to a qualified statistician before submitting the project to REC. This is not because I doubt David’s statistical knowledge and ability (which is high), but that the RECs are quite often now asking trainees to obtain a review by qualified statisticians before they will approve projects.

Date: 27th May 2015

Appendix 2:
Methodological Review

Clinical Thesis Supervisor’s Appraisal of Project Risk

Supervisor’s Name: Dr Karen Livingstone

Position: Clinical Psychologist, NHS Lanarkshire

Do you consider that the project should proceed in broadly its current form?
(Delete as appropriate)

Yes ✗ Yes, subject to revisions outlined below ☐ No

Please outline the reasons for your response. In particular, highlight any areas of risk to the completion of the project that have not been fully addressed within the proposal and any steps that could be taken to reduce risks:

It will be challenging to ensure David is able to access enough participants for his study design however given that we have just over 1 year to collect data I am relatively optimistic that we will be able to recruit the numbers required. Reviewing 3 months in to the project whether it appears that there will be enough participants seems a helpful step and allows time to make links with other health boards.

As David has noted I have good links with other clinicians who are working with clients presenting with psychosis, work very closely with the local CMHT and also within the North Lanarkshire rehab unit. The Airdrie CMHT was very supportive in helping my previous trainee recruit participants for her research project (which looked at a different client group) and I would anticipate they will also be interested in this research project.

Date: 28/05/15
Doctorate Research Agreement

Supervisor and Trainee Responsibilities: Research Agreement

(This research agreement is provided as a sample only and supervisors / trainees may use any variations that are mutually agreed)

Trainee / Student name: David Turner

Title of Research Project: A randomised experimental manipulation of the jumping-to-conclusions bias in psychosis: Effect on capacity to consent to treatment

Academic Supervisor(s):
Name: Paul Hutton  Position: Chancellor’s Fellow & Clinical Psychologist
Affiliation: Clinical and Health Psychology, University of Edinburgh

Clinical Supervisor:
Name: Karen Livingstone  Position: Clinical Psychologist
Affiliation: NHS Lanarkshire
Responsibilities/expectations:

(1) **Student / Trainee:**

(a) To conduct suitable literature searches and prepare a well grounded proposal for research which could contribute to clinical practice and / or knowledge.

(b) To obtain suitable ethical approval for the study (& other approval where applicable).

(c) To adhere to relevant university regulations for the preparation and submission of theses.

(d) To have responsibility and ownership of all data collection and data analysis, to manage personal data appropriately, to adhere to research governance guidance regarding storage and archiving of unidentifiable research data and to prepare chapters for the thesis.

(e) To submit draft chapters to supervisors on agreed dates.

(f) To make amendments to the thesis in accordance with comments from examiners and university regulations.

(g) To disseminate findings appropriately in consultation with supervisors / other collaborators. Where appropriate, supervisors should be recognised as co-authors in any journal or conference papers or other outputs (see Handbook Section R.5).

(2) **Academic Supervisor(s):**

(a) To provide advice / comments upon proposals, study design, ethics applications, research data archiving and other aspects of the thesis project.

(b) To agree to meet regularly to discuss study progress (where sufficient notice is given and at convenient times).

(c) To read a draft version of each proposal or chapter and provide detailed comments within four weeks of receipt (where drafts are received on mutually agreed dates).

(d) To read and comment upon a second version of each chapter, either individually or as part of the full draft of the thesis received at least one month prior to the submission date.

(e) To provide advice on any amendments required subsequent to viva.

(f) To facilitate dissemination of findings where applicable and comment upon manuscripts submitted for publication.

(3) **Clinical Supervisor / Research Collaborator*: (where applicable)

(a) To provide advice / comments upon proposals, study design & ethics applications.

(b) To agree to meet regularly to discuss study progress (where sufficient notice is given and at convenient times).

(c) To facilitate access and recruitment of client groups.

(d) By arrangement, to read and comment upon draft chapters

(e) To facilitate dissemination of findings where applicable and comment upon manuscripts submitted for publication.

**Other Responsibilities:** (add any additional responsibilities)

Please note that it is not the role of supervisor(s) to proof read chapters. The onus is on students / trainees to ensure that proposals and chapters are well written.
Ethical Knowledge Exchange

There is an ethical responsibility to appropriately disseminate research findings where these would contribute to clinical practice and/or understanding. Studies usually involve notable investments of time and other resources from health care professionals, supervisors, and patients – most of whom participate on the understanding that the findings might benefit others. Naturally findings can only be of benefit to others if the results are appropriately disseminated via presentations and/or publication.

Dissemination may take many forms, such as the presentation of results to local health care professionals, patient groups or other interested parties; talks or posters at relevant meetings or conferences; or more widely via publication as journal articles. The trainee, all supervisors and any other relevant collaborators* should be recognised as authors in any publications or other outputs (e.g. posters/presentations) derived from the project where their involvement would meet criteria for authorship.

Preferably, the student/trainee should be first author and should prepare the manuscript, receiving suitable advice, assistance and encouragement from supervisors and other collaborators as relevant. All such publications/presentations should be circulated to all authors for comment prior to being submitted/presented.

It is suggested that if the student/trainee is unable to prepare work to a standard suitable for submission to relevant conference(s) or journal(s) within one year of completing the project (or another agreed time-frame), then with the agreement of the student/trainee and the other authors the academic supervisor may endeavour to prepare and submit findings that would make a reasonable contribution to the literature. In these circumstances, particularly if substantial rewriting is required, the academic supervisor may become the first author and the student/trainee would be an author on the paper.

It is recommended that supervisors and students/trainees discuss dissemination and agree respective roles/expectations regarding dissemination of results early in the supervision process. This conversation should involve all others contributing to the project and aim to reach a clear agreement about authorship or acknowledgment.

*: Note that the term collaborator is used here to refer to someone who has given substantial intellectual contribution to the project which would warrant recognition as co-author in relevant outputs. Others might contribute to the project in other ways which might be more appropriately recognised as an acknowledgement.

Confirmation of agreement (completed by trainee)

I confirm that each of the following have agreed this version of the research agreement and have agreed to meet the above responsibilities and expectations:

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<thead>
<tr>
<th>Name(s)</th>
<th>Agree with above statement</th>
<th>Date</th>
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<tbody>
<tr>
<td>Trainee / student:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>David Turner</td>
<td>Yes</td>
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<tr>
<td>Academic supervisor(s)</td>
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<td></td>
<td>Paul Hutton</td>
<td>Yes</td>
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<td>Clinical Supervisor(s)</td>
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<td>Karen Livingstone</td>
<td>Yes</td>
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<td>Research collaborator(s)</td>
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<td>(if any)</td>
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(All parties should be sent a copy of the final version of this agreement by the trainee)
Appendix 8: Ethical Approval and amendments

Lothian NHS Board

South East Scotland Research
Ethics Committee 01
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 636 9000
www.nhslothian.scot.nhs.uk

Date 24 September 2015
Your Ref
Our Ref

Enquiries to: Sandra Wylie
Extension: 35473
Direct Line: 0131 465 5473
Email: Sandra.Wylie@nhslothian.scot.nhs.uk

Mr David T Turner
Trainee Clinical Psychologist
NHS Lanarkshire
Department of Clinical Psychology
Kirklands Hospital, Fallside Road
Bothwell
G71 8BB

Dear Mr Turner

Study title: A randomised experimental manipulation of the jumping-to-conclusions bias in psychosis: Effect on capacity to consent to treatment
REC reference: 15/SS/0182
Protocol number: JTC_PROT_25.8.15v2.0
IRAS project ID: 186919

Thank you for your letter of 18 September 2015, responding to the Committee’s request for further information on the above research and submitting revised documentation.

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

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Mrs Sandra Wylie, sandra.wylie@nhslothian.scot.nhs.uk.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Headquarters
Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG

Chair Mr Brian Houston
Chief Executive Tim Davison
Lothian NHS Board is the common name of Lothian Health Board
Conditions of the favourable opinion

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

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

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

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

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

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

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 within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

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 contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

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, 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).
Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

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Statement of compliance

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

After ethical review

Reporting requirements

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

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

15/55/0162 Please quote this number on all correspondence

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

Yours sincerely

Dr Chee Wee Tan
Vice Chair

Email:sandra.wylie@nhslotian.scot.nhs.uk

Enclosures: “After ethical review – guidance for researchers”

Copy to: Mrs Jo-Anne Robertson
Mr Raymond Hamill, NHS Lanarkshire - Primary Care Division
Dear Mr Turner

Study title: A randomised experimental manipulation of the jumping-to-conclusions bias in psychosis: Effect on capacity to consent to treatment

REC reference: 15/SS/0162
Protocol number: JTC_PROT_25.8.15v2.0
Amendment number: 01
Amendment date: 08 January 2016
IRAS project ID: 186919

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.

The Committee had no ethical concerns regarding this amendment.

Approved documents

The documents reviewed and approved at the meeting were:

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Membership of the Committee

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

Headquarters
Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG
Chair Mr Brian Houston
Chief Executive Tim Davison
Lothian NHS Board is the common name of Lothian Health Board
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/

15/SS/0162: Please quote this number on all correspondence

Yours sincerely

Mr Chee-Wee Tan
Chair

E-mail: sandra.wyllie@nhslothian.scot.nhs.uk

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

Copy to: Mr RAymond Hamill, NHS Lanarkshire - Primary Care Division
Mrs Jo-Anne Robertson
South East Scotland REC 01
Attendance at Sub-Committee of the REC

Committee Members:

<table>
<thead>
<tr>
<th>Name</th>
<th>Profession</th>
<th>Present</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr George Howat</td>
<td>Retired - Computing Services</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Mr Chee-Wee Tan</td>
<td>Lecturer in Physiotherapy</td>
<td>Yes</td>
<td>(Chair)</td>
</tr>
</tbody>
</table>

Also in attendance:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position (or reason for attending)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mrs Sandra Wylie</td>
<td>REC Manager</td>
</tr>
</tbody>
</table>
24 February 2016

Mr David T Turner
Trainee Clinical Psychologist
NHS Lanarkshire
Department of Clinical Psychology
Kirklands Hospital, Fallside Road
Bothwell
G71 8BB

Dear Mr Turner,

Study title: A randomised experimental manipulation of the jumping-to-conclusions bias in psychosis: Effect on capacity to consent to treatment
REC reference: 15/SS/0162
Protocol number: JTC_PROT_25.8.15v2.0
Amendment number: 02
Amendment date: 02 February 2016
IRAS project ID: 186919

Thank you for your email of 23 February 2016, notifying the Committee of the above amendment.

The Committee does not consider this to be a “substantial amendment” as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice of Minor Amendment – from Sponsor</td>
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<td>02 February 2016</td>
</tr>
<tr>
<td>Other [Notification of new collaborator.]</td>
<td></td>
<td>23 February 2016</td>
</tr>
</tbody>
</table>

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.
Yours sincerely

Sandra Wyllie
REC Manager

Email: sandra.wyllie@nhslothian.scot.nhs.uk

Copy to: Mr Raymond Hamill, NHS Lanarkshire - Primary Care Division
         Mrs Jo-Anne Robertson
29 February 2016

Mr David T Turner
Trainee Clinical Psychologist
NHS Lanarkshire
Department of Clinical Psychology
Kirklands Hospital, Fallside Road
Bo'ness
G71 8BB

Dear Mr Turner

Study title: A randomised experimental manipulation of the jumping-to-conclusions bias in psychosis: Effect on capacity to consent to treatment

REC reference: 15/SS/0162
Protocol number: JTC_PROT_25.8.15v2.0
Amendment number: 03
Amendment date: 24 February 2016
IRAS project ID: 196919

Thank you for submitting the above amendment, which was received on 25 February 2016. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Documents received

The documents to be reviewed are as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
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</thead>
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<td></td>
</tr>
<tr>
<td>Other [Confidence Task]</td>
<td>Version 1</td>
<td>23 February 2016</td>
</tr>
<tr>
<td>Research protocol or project proposal</td>
<td>Version 5</td>
<td>23 February 2016</td>
</tr>
</tbody>
</table>

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

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 for the research.

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/
Yours sincerely

Sandra Wyllie
REC Manager

Email: sandra.wyllie@nhslothian.scot.nhs.uk

Copy to: Mr Raymond Hamill, NHS Lanarkshire - Primary Care Division
Mrs Jo-Anne Robertson
Research and Development Support Unit
Ground Floor
Dumfries and Galloway Royal Infirmary
Bankend Road
Dumfries
DG1 4AP

Mr David T Turner
NHS Lanarkshire
Department of Clinical Psychology
Kirklands Hospital
Fallside Road
Bothwell
G71 8BB

Date: 20th April 2016
Our ref: 16/DGY/019
Study title: A randomised experimental manipulation of the jumping-to-
conclusions bias in psychosis: Effect on capacity to consent to treatment
Protocol version approved: Version 4
Amendments included: SA01 & SA02

Dear Mr Turner

Thank you for sending me details of your study with a request for management
approval. I can confirm that the study review team has reviewed the documentation
and on this basis I am pleased to inform you that your study has management
approval for commencement within NHS Dumfries and Galloway.

It is a condition of this approval that everyone involved in this study abides by the
guidelines/protocols laid down by this Health Board in respect of confidentiality and
Research Governance. It is your responsibility to ensure you are familiar with these;
please do not hesitate to seek advice if you are unsure. (Copies of Research
Governance Framework documents are available via the website
www.ethd.scot.nhs.uk/eso and then use the publications link.

We also note that it is the sponsor’s responsibility to ensure that appropriate training
is in place for all local investigators. It is important that all research must be carried
out in compliance with the Research Governance Framework for Health and
Community Care and the new EU Clinical Trials Directive (for clinical trials
involving investigational medicinal products).

As part of the Health Board’s responsibilities under Research Governance a sample of
studies will be monitored, and it is therefore important that all records in connection
with the study are kept up to date and available for review. We are also required to
inform you that details of your study will be entered onto our R&D database. As
custodian of the information collated during this research project, you are responsible
for ensuring the security of all personal information collected, in line with NHS
Scotland IT Security Policies, until the destruction of this data.
If your study is adopted by UKCRN into a portfolio then please advise this department of recruitment figures by adding accrual data to that database on a monthly basis.

Please notify the R&D office immediately you become aware of any serious adverse events associated with this research.

You must contact the R&D Department if/when the project is subject to any minor or substantial amendments so that these can be appropriately assessed, and approved, where necessary. I understand that performance of this study will not infringe on NHS Dumfries and Galloway’s ability to deliver our usual level of service.

May I take this opportunity to wish you every success with your project. Please do not hesitate to seek help and advice from the R&D Support Unit (ext 33165/33815) if there is anything you feel you require assistance with. I look forward to hearing about your work and would appreciate a short annual report and a final report when the study is complete.

Yours Sincerely

Dr GJ Baxter
Research Lead

cc: SREDA Database
Dear David

Project title: A randomised experimental manipulation of the jumping-to-conclusions bias in psychosis: Effect on capacity to consent to treatment

R&D ID: L15066

Amendment number: NSA, dated 02.02.16

Local PI/Collaborator: Mr David Turner

Date 09 March 2016

Enquiries to Elizabeth McConigal, R&D Facilitator

Direct Line 01236 712459

Email elizabeth.mcconigal@lanarkshire.scot.nhs.uk

I am writing to you as Chief Investigator of the above study in reference to the above Amendment as approved in the Ethics Acknowledgement letter dated 24 February 2016. Any documents approved are listed in Table 1, overleaf.

I confirm that your original R&D Management Approval has not been affected by this Amendment, and it can therefore be implemented within NHS Lanarkshire as detailed above, subject to all regulatory approvals. NHS Lanarkshire reserves the right to revoke Management Approval should any unfavourable opinions be received.

I note that it is the responsibility of the Principal Investigator(s) to carry out any changes to be made to the project as a result.

Yours sincerely,

Raymond Hamill – Corporate R&D Manager

PLEAS NOTE: It is the responsibility of the Principal Investigator to inform the R&D Department of any significant findings identified as a result of a Monitoring Visit.
Table 1. Documents approved by the NHS REC as part of this amendment

☑️ No additional documents were approved as part of the amendment

<table>
<thead>
<tr>
<th>NAME</th>
<th>TITLE</th>
<th>CONTACT ADDRESS</th>
<th>ROLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Karen Livingstone</td>
<td>Clinical Psychologist</td>
<td><a href="mailto:Karen.livingstone@lanarkshire.scot.nhs.uk">Karen.livingstone@lanarkshire.scot.nhs.uk</a></td>
<td>Supervisor</td>
</tr>
<tr>
<td>Mrs Jo-Anne Robertson</td>
<td></td>
<td><a href="mailto:researchgovernance@ed.ac.uk">researchgovernance@ed.ac.uk</a></td>
<td>Sponsor Contact</td>
</tr>
</tbody>
</table>
Mr David Turner  
Trainee Clinical Psychologist  
NHS Lanarkshire  
Department of Clinical Psychology  
Kirklands Hospital  
Fallside Road  
Bothwell  
G71 8BB  

R&D Department  
Corporate Services Building  
Monklands Hospital  
Monkscourt Avenue  
AIRDRIE  
ML6 0JS  

Date  
09 March 2016  
Enquiries to  
Elizabeth McGonigal, R&D Facilitator  
Direct Line  
01236 712459  
Email  
elizabeth.mcgonigal@lanarkshire.scot.nhs.uk  

Dear David  

Project title: A randomised experimental manipulation of the jumping-to-conclusions bias in psychosis: Effect on capacity to consent to treatment  

R&D ID: L15066  
Ethics number: 15/SS/0162  

Amendment number: Amendment 01, dated 08.01.16  
Ethics Approval date: 15.01.16  

Local PI/Collaborator: Mr David Turner  
NHSL Site(s): NHS Lanarkshire  

I am writing to you as Chief Investigator of the above study in reference to the above Amendment as approved in the Ethics Approval letter dated 15 January 2016. Any documents approved are listed in Table 1, overleaf.  

I confirm that your original R&D Management Approval has not been affected by this Amendment, and it can therefore be implemented within NHS Lanarkshire as detailed above, subject to all regulatory approvals. NHS Lanarkshire reserves the right to revoke Management Approval should any unfavourable opinions be received.  

I note that it is the responsibility of the Principal Investigator(s) to carry out any changes to be made to the project as a result.  

Yours sincerely,  

Raymond Hamill – Corporate R&D Manager  
ct. – see overleaf  

PLEASE NOTE: It is the responsibility of the Principal Investigator to inform the R&D Department of any significant findings identified as a result of a Monitoring Visit.
**Table 1. Documents approved by the NHS REC as part of this amendment**

The following documents were approved as part of the amendment:

<table>
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<th>Document</th>
<th>Revision</th>
<th>Date</th>
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<tbody>
<tr>
<td>Notice of Substantial Amendment (non-CTIMP)</td>
<td></td>
<td>08 January 2016</td>
</tr>
<tr>
<td>Participant consent form</td>
<td>Version 4</td>
<td>23 December 2015</td>
</tr>
<tr>
<td>Participant information sheet (PIS)</td>
<td>Version 4</td>
<td>23 December 2015</td>
</tr>
<tr>
<td>Research protocol or project proposal</td>
<td>Version 4</td>
<td>23 December 2015</td>
</tr>
</tbody>
</table>

**C.C.**

<table>
<thead>
<tr>
<th>NAME</th>
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<td><a href="mailto:karen.livingstone@lanarkshire.scot.nhs.uk">karen.livingstone@lanarkshire.scot.nhs.uk</a></td>
<td>Supervisor</td>
</tr>
<tr>
<td>Mrs Jo-Anne Robertson</td>
<td></td>
<td></td>
<td>Sponsor Contact</td>
</tr>
</tbody>
</table>


Appendix 9: Participant information and consent form

Participant Information Sheet and Consent Form

Decision-making about treatment in psychosis

You are being invited to take part in a research study. Before you decide whether or not 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. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The purpose of the study is to help inform our understanding of how people who experience psychosis (or schizophrenia) make decisions about their treatment choices and to investigate whether providing a short presentation on decision-making can help them to have better decision-making capacity.

Why have I been asked to take part?

You have been asked to take part as you have been previously diagnosed with psychosis and are in contact with mental health services in NHS Lanarkshire.

Do I have to take part?

No, it is up to you to decide whether or not to take part. 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, or your legal rights.
What will happen if I take part?

If you are interested in taking part in the study, a staff member from your NHS mental health team or psychological therapy team will give you this form and discuss with you whether you would like to consent to the study. If you meet the criteria for the study, you will then be contacted by the main researcher to arrange an appointment for the initial meeting within an NHS Lanarkshire facility that is accessible for you. If you do not have access to free transport, travel expenses can be reimbursed.

There will be two sessions for the study. The aim is that these sessions occur within the space of 1-2 weeks. In the first session, you will be interviewed to provide information about your psychosis. You will also be asked questions about decision-making and well-being. In the second session, you will be randomly allocated to either a). a presentation about decision-making or b). another presentation about psychology. “Randomly allocated” means that you have an equal chance of going into either of these options, which will be decided by computerised sequence similar to tossing a coin. All sessions will be carried out by the same researcher.

Parts of the session may be recorded in order that an academic supervisor can check that the work is being done properly but you can opt out from recordings if you prefer. Recordings will be stored securely on NHS or University of Edinburgh computers and will be destroyed once they have been checked by the supervisor. Recordings will not be transcribed. You will also be asked for permission that the main researcher can access to your medical notes so that preparation can be made before the first meeting.

Each session is intended to last between 1.5 and 2 hours. You will have a break and tea, coffee, water and snacks will be provided. Your standard care will not be affected by this project and for any matters related to your mental health or well-being, your mental health team, psychological therapies practitioner or GP will remain your first point of contact.

What are the possible benefits of taking part?

The results of this study may be very helpful to understanding people with psychosis and how to improve their ability to make decisions regarding their psychiatric treatment. This may contribute to better mental health care and treatment for people experiencing similar difficulties.

Who is doing this study?

I (David Turner) am a Trainee Clinical Psychologist based in NHS Lanarkshire and affiliated to the University of Edinburgh. This study is part of my training for the Doctorate in Clinical Psychology programme. I work within mental health services in NHS Lanarkshire.
What are the possible disadvantages and risks of taking part?

It is not thought that there are many disadvantages of participation. The study will involve attending two meetings and is intended to take up at the most four hours of your time. Efforts will be made to make this time as comfortable as possible for you.

There is a very small risk that you could become distressed during the study. If any aspect of the study causes your distress or you become upset or anxious, this will be communicated to your mental health team or psychological therapies team so that they can follow up with you. If it appears that you present a risk to yourself or to other people, this will also be communicated and standard NHS procedures would be followed.

What if there is a problem?

If you have a concern about any aspect of this study please contact David Turner at david.turner@lanarkshire.scot.nhs.uk or 01698 426753. He will do his best to answer your questions.

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

What happens when the study is finished?

Your direct involvement in the study finishes after the second session. You will retain standard contact with your mental health team or psychological therapies team as appropriate.

At the end of the research we will analyse the data from all the participants and write a report. Your data will be made anonymous as soon as possible and less than three months after the session. The anonymous data will be kept for 7 years.

You may be provided with a paper copy of the presentation if you wish to review it following the session. You can also choose to have a summary of the results and outcome of the study sent to you once the research has been completed. The researcher will ask whether you would like to opt in to receiving this summary.

Will my taking part in the study be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. 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 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.
Should information come to light from disclosure during the study suggesting that you, another adult or a child is at risk or harm, standard NHS procedures would be followed to address this risk which may limit confidentiality. Any such disclosure would be handled within NHS policy and would protect confidentiality as best possible.

All identifiable information used at the beginning of the study will be destroyed as soon as possible and replaced with anonymous identifiers. All identifiable information will be kept in NHS Lanarkshire sites and safely transported between sites using a locked briefcase.

**What will happen to the results of the study?**

The study will be written up as a scientific journal article. You will not be identifiable in any published results. You will have the option that a general plain language summary of the results is sent to you.

**Who is organising the research and why?**

This study is being organised and sponsored by the University of Edinburgh.

**Who has reviewed the study?**

The study proposal has been reviewed by representatives from the University of Edinburgh and NHS Lanarkshire. 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 West of Scotland REC. NHS management approval has also been obtained.

**If you have any further questions about the study please contact [David Turner] on: 01698 426 753 or email: [david.turner@lanarkshire.scot.nhs.uk]**

If you would like to discuss this study with someone independent of the study please contact:

Dr Ethel Quayle (University of Edinburgh)
Ethel.Quayle@ed.ac.uk
0131 650 4272

If you wish to make a complaint about the study please contact NHS Lanarkshire:

Laura Jack
Patient Affairs Manager
NHS Lanarkshire Headquarters
Kirklands,
Fallside Road
Bothwell
G71 8BB
Tel: 01698 858321
laura.bryan@lanarkshire.scot.nhs.uk
Thank you for taking the time to read this information sheet.
CONSENT FORM
Decision-making about treatment in psychosis

Participant ID: __________________________

David Turner
david.turner@lanarkshire.scot.nhs.uk
01698 426 753

Please initial box

1. I confirm that I have read and understand the information sheet (as specified in this document header) 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 any 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 Sponsor, from the NHS organisation or other authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.

4. I agree to my General Practitioner being informed of my participation in this study.

4. I agree that audio recordings may be made of parts of my sessions to help monitor the project (optional).

5. I agree to take part in the above study.

__________________________  __________________________  __________________
Name of Participant                    Date                        Signature

__________________________  __________________________  __________________
Name of Person taking consent   Date                        Signature

1x original – into Site File; 1x copy – to Participant;
Appendix 10: Promotional poster

Do you have a diagnosis of psychosis or schizophrenia?

If so, would you be interested in participating in research to help us understand the impact of your condition on decision-making?

We are running a study investigating ways to improve understanding of mental health treatment and decision-making for treatment options. The study would involve two meetings with a researcher in an NHS Lanarkshire facility that suits you.

If you are interested in participation, please inform an NHS Lanarkshire staff member involved in your mental health care or treatment. This person might be your NHS CPN, psychologist, psychiatrist or other therapist.
Appendix 11: Referrer information sheet

Referrer Information Sheet

Decision-making about treatment in psychosis

Purpose of research

The purpose of the study is to help inform our understanding of how people who experience psychosis (or schizophrenia) make decisions about their treatment choices and to investigate whether providing a short presentation on decision-making can help them to have better decision-making ability.

Referral Criteria

Patients are considered eligible for the study if:

1. They have a diagnosis of psychosis or related disorders, such as schizophrenia, schizo-affective disorder, delusional disorder etc
2. They are aged 16-65
3. They are in contact with NHSL mental health services

If you are unsure whether a patient is suitable, please get in touch so that I can discuss this with you. Please also consider that a patient does not require to be actively psychotic to meet criteria so long as the person has experienced psychosis and has received care in NHSL for this reason.

What will happen when participants take part?

If you identify a participant, upon receiving the person’s details I will arrange an initial meeting. There will likely be two sessions for each person. The aim is that these sessions occur within the space of 1-2 weeks. In the first session, the participant will be interviewed to provide baseline information about their psychosis, their decision-making and well-being. In the second session, the persons will be randomly allocated to either a). a presentation about decision-making or b). another presentation about psychology. Each session is intended to last between 1.5 and 2 hours. A break with tea, coffee, water and snacks will be provided.
To refer a participant or for further questions contact David Turner on:

01698 426 753

Or email: david.turner17@nhs.net
Appendix 12: Jumping-to-conclusions worksheets

Worksheet 1 How jumping to conclusions promotes misinterpretations, e.g. during psychosis – own examples

<table>
<thead>
<tr>
<th>Event (e.g.: &quot;I heard footsteps right behind me that became faster and faster, but I did not dare to turn around&quot;)</th>
<th>Interpretation during psychosis (e.g.: &quot;M15 has found me, they will restrain and arrest me at this very moment&quot;)</th>
<th>Other explanations (e.g.: &quot;Somebody wanted to catch the bus; I could have imagined it&quot;)</th>
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</tbody>
</table>

worksheet for therapy unit 5: making decisions
**Therapy Unit: Jumping to Conclusions**

**Worksheet 2 Own Ideas**

**What speaks for and against your own particular ideas?**

Idea/Assumptions:

---

Degree of conviction: ______ %

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>(What speaks for it?)</td>
<td>(What speaks against it?)</td>
</tr>
</tbody>
</table>

Degree of conviction: ______ %

---
## DEMOGRAPHIC INFORMATION

### PARTICIPANT ID:

### PLEASE CIRCLE AS APPROPRIATE

<table>
<thead>
<tr>
<th>AGE RANGE</th>
<th>16-21</th>
<th>22-31</th>
<th>32-41</th>
<th>42-51</th>
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<tbody>
<tr>
<td>52-65</td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### GENDER:

- MALE
- FEMALE

### ETHNICITY:

- WHITE
- BLACK AFRICAN
- BLACK CARIBBEAN
- ASIAN
- OTHER

### TYPE OF CONTACT WITH MENTAL HEALTH SERVICES:

- INPATIENT
- OUTPATIENT

### DIAGNOSIS:

- SCHIZOPHRENIA
- SCHIZO_AFFECTIVE DISORDER
- BRIEF PSYCHOTIC DISORDER
- DELUSIONAL DISORDER
- PSYCHOSIS

### HOW MANY YEARS SINCE YOUR FIRST DIAGNOSIS:

- 0-1 YEARS
- 1-3 YEARS
- 3-5 YEARS
- 5-10 YEARS
- OVER 10 YEARS

### ARE YOU CURRENTLY PRESCRIBED ANTI-PSYCHOTIC MEDICATION?

- YES
- NO

### MEDICATION NAME (IF KNOWN):

---------------------------------------------
Thesis Portfolio References


http://doi.org/10.1093/schbul/sbr036


http://doi.org/10.1093/schbul/sbu047


Liberman, R. P., Wallace, C. J., Blackwell, G., Kopelowicz, a, Vaccaro, J. V, & Mintz,


intervention for schizophrenia patients improves delusional symptoms.

*Psychological Medicine, 41*(9), 1823–32.

http://doi.org/10.1017/S0033291710002618


http://doi.org/10.1017/S0033291708004637

patients with psychosis: a preliminary study using the MacCAT-T and HCAT. *The American Journal of Geriatric Psychiatry, 10*(2), 207–211.


