OXFORD UNIVERSITY PRESS | Schizophrenia Bulletin

Draft Manuscript for Review. Please review online at http://mc.manuscriptcentral.com/oup/szbltn

The effect of reducing the 'jumping to conclusions' bias on treatment decision-making capacity in psychosis: a randomised controlled trial with mediation analysis

Journal:	*Schizophrenia Bulletin*
Manuscript ID	SZBLTN-ART-18-0236.R2
Manuscript Type:	Regular Article
Date Submitted by the Author:	01-Sep-2018
Complete List of Authors:	Turner, David; Vrije Universiteit Amsterdam, Clinical Psychology MacBeth, Angus; University of Edinburgh, Clinical Psychology Larkin, Amanda; Greater Manchester Mental Health NHS Foundation Trust, Psychosis Unit Moritz, Steffen; University Medical Center Hamburg-Eppendorf, Department of Psychiatry and Psychotherapy Livingstone, Karen; NHS Lanarkshire Campbell, Alison; NHS Lanarkshire Hutton, Paul; Edinburgh Napier University, School of Health and Social Care
Keywords:	capacity, psychosis, RCT, jumping-to-conclusions, meta-cognitive therapy

SCHOLARONE™ Manuscripts

Running head: Effect of reducing the JTC bias on capacity in psychosis

The effect of reducing the 'jumping to conclusions' bias on treatment decision-making capacity in psychosis: a randomised controlled trial with mediation analysis

Dr David Turner, DClinPsy[a,]
Dr Angus MacBeth, PhD[b]
Dr Amanda Larkin, DClinPsy[c]
Prof. Dr. Steffen Moritz, PhD[d]
Dr Karen Livingstone, DClinPsy[e]
Dr Alison Campbell, DClinPsy[e]
Dr Paul Hutton, DClinPsy[f]

[a]Department of Clinical Psychology
Vrije Universitiet, Amsterdam

[b]Department of Clinical and Health Psychology,
School of Health in Social Science, University of Edinburgh

[c]Psychosis Research Unit,
Greater Manchester West Mental Health NHS Foundation Trust

[d]Universitätsklinikum Hamburg-Eppendorf
Klinik für Psychiatrie und Psychotherapie
Arbeitsgruppe Klinische Neuropsychologie

[e]Clinical Psychology, NHS Lanarkshire

[f]School of Health and Social Care,
Edinburgh Napier University

Abstract: 250 words
Text body: 4,000 words

Correspondence to:
Dr David Turner
Department of Clinical Psychology,
Vrije Universitiet,
Van der Boechorststraat 1, 2B81
1081 BT Amsterdam

d.t.turner@vu.nl

Abstract

Background

Evidence-based psychological interventions to support treatment decision-making capacity ('capacity') in psychosis do not currently exist. This study sought to establish whether reducing the extent to which this group form conclusions based on limited evidence, also known as the 'jumping to conclusions' (JTC) bias, could improve capacity.

Methods

In a randomised-controlled open trial, 37 patients aged 16-65 years diagnosed with schizophrenia-spectrum disorders were randomly assigned (1:1) to receive a single-session intervention designed to reduce the JTC bias (MCT-JTC; adapted from Metacognitive Training) or an attention control (AC) condition designed to control for therapist attention, duration, modality and face validity. Primary outcomes were treatment decision-making capacity measured by the MacArthur Competency Assessment Tool for Treatment (MacCAT-T) and the jumping-to-conclusions reasoning bias measured by draws to decision on the Beads task, each of which were administered by the psychologist delivering the intervention.

Results

Those receiving MCT-JTC had large improvements in overall capacity (d=0.96, p<.05) and appreciation (d=0.87, p<.05) compared to those receiving AC. Reduction in JTC mediated a large proportion of the effect of group allocation on understanding, appreciation, reasoning and overall MacCAT-T scores.

Conclusion

This is the first experimental investigation of the effect of a psychological intervention on treatment decision-making capacity in psychosis. It provides early evidence that reducing the JTC bias is associated with large and rapid improvements in capacity. Due to limited resources, assessments were administered by the researchers delivering the intervention. Results should therefore be considered preliminary and a larger, definitive trial addressing methodological limitations is warranted.

Introduction

The concept of treatment decision-making capacity ('capacity') is increasingly important in contemporary mental healthcare and has major implications for treatment, research, policy and legislation.[1] In jurisdictions that have adopted capacity-based mental health legislation, the extent to which a person is judged as having the capacity to make a decision about their psychiatric treatment has important implications not only for their freedom to consent to psychiatric treatment,[2,3] but also for the responsibilities of clinicians who provide treatment. Estimates suggest that 50-80% of inpatients with psychosis have impaired capacity[4] and clinicians are expected to support them to regain capacity, which may include referral for specialist support.[2,3] However, very little robust research exists to inform practice in this area.[5] Although a recent systematic review and meta-analysis found that shared decision-making improved subjective empowerment in psychosis, whether or not it improves capacity is unclear[5,6] and psychiatrists may be reluctant to use this approach when their patients lack capacity.[7] Clinicians may, on the other hand, be willing to provide 'supported decision-making,' where the focus is instead on understanding and enhancing components of their patient's decision-making ability.[8] To aid this work, clinicians need theoretically-driven psychological interventions that have been shown in RCTs to target and improve the mechanisms responsible for impaired capacity. Despite the concept of capacity being in existence for at least 30 years, such interventions are currently lacking for people with psychosis.[5]

The importance of respecting autonomy and minimising compulsory, coercive or paternalistic care means the development of these interventions is crucial, as is the development of an enhanced understanding of clinical and psychological mechanisms maintaining incapacity in psychosis. A recent meta-analytical review found that increased psychotic symptom severity, poorer verbal cognitive functioning and fewer years of education were robustly associated with impaired capacity.[5] However, aside from an established literature on the role of reduced insight in capacity, only two small studies have examined the potential contribution of other psychological factors to capacity.[9,10] One found that metacognitive awareness of cognitive functioning had a stronger relationship with capacity than actual cognitive functioning.[9] Another found that improvements in capacity in psychosis were correlated with the provision of Metacognitive Training (MCT).[10] This was first developed as a group psychological intervention aiming to raise awareness of cognitive biases and decision-making styles known to be robustly and specifically associated with their psychotic symptoms.[11] A later version, "MCT+," adapted the package to target patients' specific delusional ideas via an individualised approach.[12]

One bias that MCT aims to reduce is the 'jumping to conclusions' (JTC) bias, which refers to a tendency to make decisions based upon minimal evidence.[13,14] Our meta-analysis of 55 studies found that individuals with psychosis were 4 to 6 times more likely to demonstrate the JTC bias than healthy individuals or people with non-psychotic mental health problems.[14] As predicted by the cognitive model of psychosis,[15] there was evidence for specificity to delusions. Together with the Naughton *et al* finding that an intervention targeting the JTC bias (and others) may improve capacity,[10] the results suggest the possibility that the JTC bias may be involved in maintaining impaired capacity. As a consequence of forming conclusions too quickly, a person with the JTC bias may be limited in the degree to which they understand all the issues relevant to a particular decision and may struggle to properly weigh up and appreciate the relevant evidence. JTC may also contribute to impaired capacity via the formation of capacity-limiting delusional appraisals (e.g. "my doctor is trying to kill me").

We tested this hypothesis recently, finding that the degree to which people with psychosis could understand treatment-relevant information was both directly and indirectly associated with the degree to which they gathered data before reaching a decision (A. Larkin, D. Turner, K. Whyte and P. Hutton. Unpublished data, 2017). It has been hypothesised that the JTC bias and similar data-gathering biases have origins in a "liberal acceptance" belief appraisal process among people with psychosis compared to non-psychotic individuals, which suggests that a lowered-decision threshold leads to premature acceptance of hypotheses, subsequent bias in seeking hypothesis disconfirmation and overconfidence in errors.[16]

If these preliminary observational findings reflect underlying causal relationships, then this has important implications for efforts to support decision-making in this group. If the JTC bias *does* contribute to impaired capacity, then simple interventions that successfully ameliorate this bias may improve capacity and support informed decision-making. A non-randomised controlled trial has previously demonstrated a therapeutic effect of an adapted single-session MCT intervention targeting JTC and belief flexibility upon severity and conviction of delusions, insight and cognitive biases.[17] The aim of this study was to determine whether a brief psychological intervention could improve capacity under experimental conditions.[18] In the first study of its kind, people with psychosis were randomly assigned to receive either an intervention designed solely to reduce the JTC bias or a suitable control intervention, with the effect upon on their capacity assessed. We worked with the developer of MCT to identify its most effective components in reducing JTC and reasoned that if greater improvements in capacity occurred in those who received this 'MCT-JTC' intervention, then this would be strong evidence that the JTC bias is related to capacity in this group. We also reasoned that if changes in the amount of data people gathered before making a decision mediated the effect of group allocation, then this would be even stronger evidence that data-gathering is an important mechanism underlying capacity in this group.

Methods

Patients

People with psychosis were eligible to take part in the study if they were aged 16-65, English-speaking, in contact with NHS mental health services, had a diagnosis of schizophrenia, schizoaffective disorder, delusional disorder, brief psychotic disorder or psychosis NOS. Capacity to consent to participation was assessed via clinical judgement by the patients' respective NHS psychiatrist and confirmed by the researcher. Patients were unable to participate if their psychotic symptoms were the result of a general medical condition or substance misuse disorder, if they were under care of forensic mental health services or involved in on-going legal proceedings, if they had a moderate or severe learning disability, or if there had been a deterioration in their condition which suggested participation could be detrimental. Given the primary outcome was treatment decision-making capacity, no minimum or maximum symptom threshold or stage of illness was specified. The study was conducted across NHS Lanarkshire and NHS Dumfries and Galloway Health Boards (Scotland, UK), with the majority of participants (n=36, 97%) being recruited from NHS Lanarkshire, hence the research clinician based in NHS Lanarkshire assessed and treated the majority of participants. Recruitment was open between January 2016 and February 2017. Outpatients were recruited through contact with Community Mental Health Teams (CMHTs) and Psychological Therapies Teams (PTTs) while inpatients were recruited within both acute and rehabilitation inpatient psychiatric services. A presentation and Q&A session was delivered to CMHTs, PTTs and psychiatrists introducing the study aims and referral procedure. The overall study aims were fully communicated to clinical staff while

participants were informed that the study aimed to investigate how people with psychosis make decisions regarding their treatment.

Ethical approval was obtained from the South of Scotland Research Ethics Committee (REC no. 15/SS/0162) and the University of Edinburgh. All patients provided written informed consent.

Study Design

The study used a randomised controlled parallel experimental design. Participants were randomly assigned to receive a single-session of MCT-JTC or an attention control, specially designed to control for time and therapist attention. Outcome measures were administered at baseline and post-treatment. To minimise attrition bias from missing data, randomisation was performed by the researcher only when participants arrived to attend the single intervention or control session. This was carried out in session using an online randomisation service (sealedenvelope.com), which randomised participants according to a permuted random blocks randomisation sequence concealed from the investigator, the participant and clinical staff. Participants, but not clinical staff, were blind to the study hypothesis. Participants and clinical staff were blind to allocation, however the same researcher carried out the assessments and delivered the interventions. Participants were fully debriefed about the study hypothesis at the end of the study.

Interventions

MCT-JTC; The intervention was derived from the MCT manual developed by Moritz *et al.*[19] To provide an effective single-session version of MCT, the primary investigator (DT) and the developer of MCT (SM) amalgamated the JTC modules into an hour-long 'best of' intervention. The intervention aimed to repeatedly engage the participant in 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. The intervention was delivered individually via Powerpoint. Key components are provided in Table 2. Due to the utilisation of individual format, the method of delivery was closest to the "MCT+" variant of MCT.[12] Participants were encouraged to engage and interact during the session while reflection upon personal examples and misinterpretation of personally significant situations was encouraged.

Control condition; To control for therapist attention and time, whilst removing specific intervention factors addressing thinking biases, an individually-delivered educational talk on the localisation of brain function was provided. Participants were informed that the presentation was "about how different parts of the brain have different functions." This condition was also delivered individually using Powerpoint and lasted 1 hour, ensuring that both conditions were closely matched for modality of presentation, time spent by the researcher with the participant and non-specific interaction factors. The content of the presentations was carefully chosen to ensure participants were masked to which was the active intervention.

Study evaluation

The first session consisted of administration of the complete baseline assessment battery. A follow-up appointment within two weeks was arranged to carry out the experimental procedures and post-intervention assessment. The MacArthur Competency Assessment Tool for Treatment (MacCAT-T)[20] was used to assess capacity at baseline and post-treatment. This

semi-structured interview schedule covers 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). Both raters (DT and AL) were trained in the administration of all clinical scales by the primary project supervisor (PH), who also supervised assessments and scoring while remaining blind to treatment allocation. Participants were first presented with an overview of their psychiatric diagnosis, three of its features and its expected course. Their capacity to accurately understand and retain information regarding the diagnostic information was then assessed. Participants were then introduced to two hypothetical treatment options relevant to their diagnosis (taking anti-psychotics versus no medication) and the risks and benefits of each option. They were again assessed on their capacity to retain and understand this information. Participants were then asked to choose which treatment option seemed best for them based on the information provided. They were finally assessed on reasoning ability and ability to generate consequences of their choice. Although the scale does not provide a total score, in order to align with previous research an overall capacity score was calculated alongside the consideration of subscales.[5] Each subscale has demonstrated inter-rater reliability of Kappa 0.80.[4,21,22] Higher scores are indicative of greater capacity. MacCAT-T scale reliability (internal consistency) in the current sample was α= 0.80.

A computerised version of the 'beads task' (described in detail elsewhere)[23] was used to assess the JTC bias by recording how many pieces of information a participant required before making a decision regarding the jar of origin of the coloured beads presented. We utilised the 60/40 version, which was chosen for consistency with other on-going research within the project team. Participants were informed they could view as many beads as they wished until they were certain about their origin. The total number of beads a person requests before making their decision ('draws-to-decision'; DTD) was taken as an index of data-gathering and the JTC bias. The Cognitive Bias Questionnaire for Psychosis (CBQ-p) provided a secondary assessment of the JTC bias alongside related cognitive distortions.[24] The scale reliability of this 30-item self-report measure was α= 0.89 in the current sample. The Positive and Negative Syndrome Scale (PANSS)[25] was administered at baseline to characterise the clinical profile of the sample. Thirty 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 α= 0.88 for the sample. The Hospital Anxiety and Depression Scale (HADS)[26] provided a basic measure of depressive and anxiety symptoms. Scale reliability of this 14-tem measure was α= 0.83 for this sample.

Statistical Analyses

G*Power software[27] was used to calculate the required sample size to detect a statistically significant effect, based on the assumption that a randomised study may need to able to detect smaller effects than the large effects (F=1.29) reported on MacCAT-T total scores in the non-randomised study by Naughton *et al.*[10] 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 with one covariate.

All analyses followed intention-to-treat procedures.[28] Multiple imputation 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 through visual examination of histograms and boxplots, alongside calculation of statistically significant skewedness or kurtosis. When significant skewedness or kurtosis suggested violation of the assumptions required for

ANCOVA, post-hoc non-parametric sensitivity analyses were performed using a Kruskal-Wallis H test in R. The main analyses of primary and secondary outcome measures were computed in SPSS using ANCOVAs by entering baseline scores as covariates to improve power and precision.[29] Baseline scores correlate with magnitude of change, meaning they should be utilised as covariates when comparing groups on mean change and are important in guarding against floor and ceiling effects. To satisfy the assumption of independence of covariate and treatment effect,[30] ANCOVA was only performed when group differences at baseline were not significant. When baseline differences were significant, a simple analysis of group differences in mean change in the variable was conducted instead. 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*.

To investigate whether changes in data-gathering mediated the effect of group allocation on capacity, two methods of simple mediation analyses were performed. Mediation analyses based upon the linear regression method described by Baron and Kenny[31] were implemented using the RMediation package.[32] Causal mediation analyses were also conducted following Preacher and Hayes method[33] using the SPSS PROCESS-4 macro.[34,35] Causal mediation analysis utilises ordinary least squares path analysis and non-parametric bootstrapping, has higher precision than the Baron and Kenny approach, may accommodate data violating the assumption of normality, and improves inferences regarding causality.[36]

Pre-registration

The study protocol was pre-registered on the Open Science Framework before randomisation and recruitment commenced (Open Science Framework registration; https://osf.io/kunc4/).

Results

Patients

As shown in Figure 1, 37 participants were randomised within the recruitment window. Resource and time constraints led to this smaller than planned sample size, but it was deemed sufficient to detect clinically meaningful effects. 19 participants were allocated to MCT-JTC and 18 were allocated to the control group. Missing data was minimal (3%) for the primary outcome, suggesting high acceptability and a very low risk of attrition bias.

Table 1 provides information on demographic and clinical variables. The majority (n=31, 84%) of participants were male and all patients were of self-reported white ethnicity. Thirty percent (n=11) were inpatients and 70% (n=26) were outpatients. The majority were diagnosed with schizophrenia (n=26, 70%) whilst 14% (n=5) were diagnosed with schizoaffective disorder and 16% (n=6) as psychosis NOS. First diagnosis occurred over ten years before baseline for the majority of participants (n=27,73%). On average, HADS scores fell within the moderate range.[37] PANSS total scores indicated that participants were mildly to moderately ill on average.[38] The majority of participants (81.1%) showed at worst mild impairment on the lack of judgement and insight item of the PANSS (see supplementary materials).

Primary outcomes

As shown in Table 3, there was a large positive effect of MCT-JTC on the 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-JTC upon the MacCAT-T reasoning subscale which approached significance (d=0.68, p=.055). MCT-JTC did not demonstrate

superiority from control on the MacCAT-T understanding subscale. A significant degree of negative skew was present for the MacCAT-T Appreciation at baseline and post-treatment across MCT-JTC and control groups, potentially violating the assumptions for 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-JTC (x^2=4.89, p<.05).

Secondary outcomes

MCT-JTC did not have a significant effect on the CBQP JTC subscale or total. There was however a large positive effect of MCT-JTC on DTD, as assessed by the Beads tasks (d=0.93, p<.05). No significant group differences were found on the HADS anxiety subscale or total score. Although MCT-JTC participants had higher HADS depression subscale at post-intervention, they also had significantly higher HADS depression scores at baseline (p=0.022). It was not possible to adjust for these with ANCOVA, since doing so would violate the assumption of the independence of covariate and treatment effect.[30] An analysis of mean change did not detect any significant group differences. The number of new cases of at least mild depression, defined as moving from a score of less than 8 on the HADS depression subscale at baseline to a score of 8 or more at post-treatment, was 3 and 2 for MCT-JTC and control respectively. To examine whether participants became more depressed or anxious following the trial, post-hoc within-group t-tests and Wilcoxon Signed Ranks Tests were conducted on HADS total and subscale scores for the sample as a whole and per group. No significant differences were detected (all comparisons p<0.10). No other adverse effects were reported.

Mediation analysis

Results of both methods of simple mediation analysis are provided in Table 4. The pre-specified Baron and Kenny[31] analysis found that post-intervention draws-to-decision significantly mediated the effect of group allocation on the MacCAT-T total score at post-treatment (d=0.64, p<.05), accounting for 39% 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 was not significant (p=<.06). No significant mediating effects of post-intervention draws-to-decision were observed on the MacCAT-T subscales. A post-hoc Preacher and Hayes[33] analysis of mediation was also performed since this approach does not require data to be normally distributed and incorporates bootstrapping, meaning it has increased power to detect effects in smaller samples.[39] The magnitude of the mediation effects in this analysis were the same as those observed with the Baron and Kenny approach, however using the Preacher and Hayes approach all were significant. Post-intervention draws-to-decision accounted for 63%, 36%, 29% and 39% of the effect of group allocation on understanding (d=0.45, p<.05), appreciation (d=0.55, p<.05), reasoning (d=0.59, p<.05) and overall MacCAT-T scores (d=0.64, p<.05) respectively.

Discussion

This study represents the first randomised controlled investigation of the effect of a psychological intervention on capacity in psychosis and provides evidence that data-gathering is associated with capacity in this group. Hypotheses, methodology, outcomes and analytical plan were pre-registered in the public domain, reducing the risk of selective reporting bias. The duration of the intervention, use of late randomisation and use of intention to treat analysis also minimised the risk of attrition bias. Late randomisation, together with the careful

design of the control intervention and the brief nature of the intervention, helped to ensure participants and clinicians were masked to allocation, therefore minimising performance bias. The close matching of the control and experimental interventions in relation to duration, modality and researcher-participant interaction also greatly reduced the risk of group differences being attributable to non-specific therapeutic factors. Nevertheless, firmer conclusions await larger trials which could address the limitations of this study, most notably lack of rater blinding.

The findings were broadly consistent with previous observational research.[10] The relative magnitude and significance of the effect on the Appreciation subscale over the Reasoning subscale contrasts with the findings of a previous non-randomised trial, although the medium magnitude of the non-significant effect on Reasoning, alongside small samples sizes in each trial, suggests the possibility of type II error. It should also be noted that because outcome measures were administered directly following the treatment, the current RCT does not demonstrate a persistent effect of MCT-JTC but rather a snapshot of capacity at post-intervention. Naughton *et al* (2012) were able to demonstrate a dose-response relationship between changes in MacCAT-T reasoning and the number of sessions completed. These changes were also associated with changes in general functioning. Consequently the opportunity remains to investigate such effects via a randomised trial integrating multiple sessions. Although we expected differences on the MacCAT-T total, we did not make specific a-priori predictions of differences across subscales. Nevertheless, we hypothesise that a positive impact on the JTC bias, as demonstrated by the effect on the beads task, may be influential in increasing meta-cognitive awareness of the pitfalls of one's own biased decision-making process. This in turn may lead to greater (and less biased) appreciation regarding one's own disorder and treatment options. A larger trial administering multiple sessions with session-by-session outcome measures may have the potential to shed further light on this possibility alongside the sustainability of such effects.

The prediction that change in data-gathering would mediate the effect of group assignment on capacity was confirmed, therefore suggesting that MCT-JTC successfully changed this mechanism, and that this change accounted for the observed improvements. Importantly, the non-invasive and brief nature of the MCT-JTC made it highly acceptable to participants. By operating at the metacognitive level, MCT-JTC avoided protracted discussions of the evidence for and against particular beliefs. By focusing on decision-making, emotive discussion of the merits or otherwise of psychiatric treatments was also avoided. The focus of MCT-JTC on only one mechanism – the JTC bias – makes it unlikely that changes in other psychological variables accounted for the changes in capacity.

Taken together, these findings lend encouragement to researchers, clinicians and legal experts who are interested in developing effective strategies to support treatment decision-making in psychosis. The complexity of psychosis means it is very unlikely that the JTC bias alone accounts for impaired capacity, therefore studies investigating the potential role of other psychological variables including attributional biases, self-esteem and metacognitive awareness of cognitive impairment are also required. The results of this study demonstrate the advantage of considering how the processes underlying a particular condition might also adversely affect decision-making and autonomy. As the concepts of capacity and supported decision-making become increasingly important in mental health legislation, so too will the need for empirical evidence. Application of an interventionist-causal framework[18] to generating this evidence may help to accelerate the development of effective decision-support interventions.[5]

Study limitations

Our study had several further limitations. It had limited power therefore the estimates of effect were imprecise. Achieving adequate precision must await studies with larger sample sizes.[40] As indicated, limited resources precluded researcher blinding therefore there was a high risk of detection bias.[41] The use of masked raters is associated with a reduction in effect sizes of 9-17% across medicine,[42] therefore we emphasise that the large effects we observed here, while promising, should be treated as preliminary until replicated independently by larger rater-blind studies. Further questions for future research include whether our findings can be generalised to populations with early psychosis, those presenting with more severe symptoms, or samples in which capacity is more severely impaired at baseline. We also note minor imbalances at baseline on secondary outcome measures- namely the HADS and PANSS subscales, which a larger trial may help resolve.

These limitations notwithstanding, the study provides evidence that a widely studied psychological mechanism associated with psychotic symptoms, the JTC bias,[13,14] may influence treatment decision-making capacity in this group. In addition, the study has also demonstrated that capacity in psychosis is modifiable by intervention, which is consistent with previous observational research,[43] and that it is feasible to perform RCTs with capacity as a primary outcome.

Author contribution statement

DT conceived of and designed the study, secured ethical approval, recruited participants, gathered and analysed the data and wrote the manuscript. AM helped with recruitment of participants, analysis of data and contributed to the manuscript. AL helped with recruitment of participants and gathering of data and contributed to the manuscript. SM helped to design the intervention and contributed to the manuscript. KL helped to design the study, helped with recruitment of participants and contributed to the manuscript. AC helped with recruitment of participants and contributed to the manuscript. PH conceived of and helped to design the study, helped secure ethical approval, helped with recruitment of participants, helped to analyse the data and helped to write the final manuscript.

Conflict of interest statement

Authors DT, AM, AL, KL and AC report no competing or conflicting interests. SM is the originator of Metacognitive Therapy for psychosis, and has conducted a number of studies and trials to examine its efficacy. He reports no author competing or conflicting interests. PH has been a co-investigator on research grants from the National Institute of Health Research to evaluate the efficacy of cognitive therapy for people with psychosis who are not taking antipsychotic medication and is a member of a committee developing National Institute for Clinical and Social Care Excellence (NICE) guidelines on supporting decision-making for people who may lack mental capacity.

Funding

There was no funding for this work.

References

1. Owen SG, Freyenhagen F, Richardson G, Hotopf M. Mental Capacity and Decisional Autonomy: An Interdisciplinary Challenge. *Inquiry*. 2009;52(1):79-107. doi:10.1080/00201740802661502.
2. Department of Health. Mental Capacity Act. *London Stationery Office*. 2005.
3. Executive S. Adults with Incapacity (Scotland) Act 2000. *Stationery Office Edinburgh*. 2000.
4. Cairns R, Maddock C, Buchanan A, David AS, Ward PHAY, Richardson GA. Prevalence and predictors of mental incapacity in psychiatric in-patients. *Br J Psychiatry*. 2005;187(4):379-385
5. Larkin A, Hutton P. A systematic review and meta-analysis of factors that help or hinder treatment decision-making capacity in psychosis. *Br J Psychiatry*. 2017;211(4):205-215.
6. Stovell D, Morrison AP, Panayiotou M, Hutton P. Shared treatment decision-making and empowerment-related outcomes in psychosis: Systematic review and meta-analysis. *Br J Psychiatry*. 2016;209(1):23-28. doi:10.1192/bjp.bp.114.158931.
7. Hamann J, Mendel R, Cohen R, et al. Psychiatrists' use of shared decision making in the treatment of schizophrenia: patient characteristics and decision topics. *Psychiatr Serv*. 2009;60(8):1107-1112. doi:10.1176/appi.ps.60.8.1107.
8. Drake RE, Deegan PE, Rapp C. The promise of shared decision making in mental health. *Psychiatr Rehabil J*. 2010;34(1):7-13.
9. Koren D, Poyurovsky M, Seidman LJ, Goldsmith M, Wenger S, Klein EM. The neuropsychological basis of competence to consent in first-episode schizophrenia: a pilot metacognitive study. *Biol Psychiatry*. 2005;57(6):609-616.
10. Naughton M, Nulty A, Abidin Z, Davoren M, O'Dwyer S, Kennedy HG. Effects of group metacognitive training (MCT) on mental capacity and functioning in patients with psychosis in a secure forensic psychiatric hospital: a prospective-cohort waiting list controlled study. *BMC Res Notes*. 2012;5(1):302. doi:10.1186/1756-0500-5-302.
11. Moritz S, Andreou C, Schneider BC, et al. Sowing the seeds of doubt: A narrative review on metacognitive training in schizophrenia. *Clin Psychol Rev*. 2014;34(4):358-366. doi:10.1016/j.cpr.2014.04.004.
12. Vitzthum FB, Veckenstedt R, Moritz S. Individualized Metacognitive Therapy Program for Patients with Psychosis (MCT+): Introduction of a Novel Approach for Psychotic Symptoms. *Behav Cogn Psychother*. 2013;42(1):105-110. doi:10.1017/S1352465813000246.
13. Huq SF, Garety PA, Hemsley DR. Probabilistic judgements in deluded and non-deluded subjects. *Q J Exp Psychol Sect A*. 1988;40(4):801-812. doi:10.1080/14640748808402300.
14. Dudley R, Taylor P, Wickham S, Hutton P. Psychosis, delusions and the "Jumping to Conclusions" reasoning bias: A systematic review and meta-analysis. *Schizophr Bull*. 2016;42(3):652-665. doi:10.1093/schbul/sbv150.
15. Garety PA, Kuipers E, Fowler D, Freeman D, Bebbington PE. A cognitive model of the positive symptoms of psychosis. *Psychol Med*. 2001;31(2):189-195. doi:10.1017/S0033291701003312.
16. Moritz S, Balzan RP, Kulagin SC, Andreou C. A New Paradigm to Measure Probabilistic Reasoning and a Possible Answer to the Question Why Psychosis-Prone Individuals Jump to Conclusions. *J Abnorm Psychol*. 2017;126(4):406.
17. Balzan RP, Delfabbro PH, Galletly CA, Woodward TS. Metacognitive training for patients with schizophrenia: Preliminary evidence for a targeted, single-module

programme. *Aust N Z J Psychiatry*. 2014;48(12):1126-1136. doi:10.1177/0004867413508451.

18. Kendler KS, Campbell J. Interventionist causal models in psychiatry: repositioning the mind–body problem. *Psychol Med*. 2009;39(06):881. doi:10.1017/S0033291708004467.
19. Moritz S, Woodward TS, Burlon, M. Metacognitive training for patients with schizophrenia (MCT). Manual. *VanHam Campus Verlag, Hamburg*. 2007.
20. Grisso T, Appelbaum PS. *MacArthur Competence Assessment Tool for Treatment (MacCAT-T).* Professional Resource Press/Professional Resource Exchange; 1998.
21. Raffard S, Fond G, Brittner M, et al. Cognitive insight as an indicator of competence to consent to treatment in schizophrenia. *Schizophr Res*. 2013;144(1-3):118-121. doi:10.1016/j.schres.2012.12.011.
22. Cairns R, Maddock C, Buchanan A, et al. Reliability of mental capacity assessments in psychiatric in-patients. *Br J Psychiatry*. 2005;187(OCT.):372-378. doi:10.1192/bjp.187.4.372.
23. Moritz S, Woodward TS. Jumping to conclusions in delusional and non-delusional schizophrenic patients. *Br J Clin Psychol*. 2005;44(2):193-207. doi:10.1348/014466505X35678.
24. Peters ER, Moritz S, Schwannauer M, et al. Cognitive Biases Questionnaire for Psychosis. *Schizophr Bull.* 2013;40(2):300-313. doi:10.1093/schbul/sbs199.
25. Kay SR, Flszbein A, Opfer LA. The positive and negative syndrome scale (PANSS) for schizophrenia. *Schizophr Bull*. 1987;13(2):261.
26. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand*. 1983;67(6):361-370. doi:10.1111/j.1600-0447.1983.tb09716.x.
27. Faul F, Erdfelder E, Lang AG, Buchner A. G* Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods*. 2007;39(2):175-191. doi:10.3758/BF03193146.
28. White IR, Carpenter J, Horton NJ. Including all individuals is not enough: Lessons for intention-to-treat analysis. *Clin Trials*. 2012;9(4):396-407. doi:10.1177/1740774512450098.
29. Borm GF, Fransen J, Lemmens WAJG. A simple sample size formula for analysis of covariance in randomized clinical trials. *J Clin Epidemiol*. 2007;60(12):1234-1238. doi:10.1016/j.jclinepi.2007.02.006.
30. Field A. *Discovering Statistics Using IBM SPSS (4th Edition). Sage, London. 2013*
31. Baron RM, Kenny D. The Moderator-Mediator Variable Distinction in Social Psychological Research: Conceptual, Strategic, and Statistical Considerations. *J Pers Soc Psychol*. 1986;51(6):1173-1182. doi:10.1037/0022-3514.51.6.1173.
32. Tofighi D, MacKinnon DP. RMediation: an R package for mediation analysis confidence intervals. *Behav Res Methods*. 2011;43(3):692-700. doi:10.3758/s13428-011-0076-x.
33. Preacher KJ, Hayes AF. Asymptotic and resampling strategies for assessing and comparing indirect effects in multiple mediator models. *Behav Res Methods*. 2008;40(3):879-891. doi:10.3758/BRM.40.3.879.
34. Preacher KJ, Hayes AF. SPSS and SAS procedures for estimating indirect effects in simple mediation models. *Behav Res methods, instruments, Comput*. 2004;36(4):717-731. doi:10.3758/BF03206553.
35. Hayes AF. Introduction to mediation, moderation, and conditional process analysis: A regression based approach. New York NY, Guilford Press 2013
36. MacKinnon DP, Fairchild AJ, Fritz MS. Mediation analysis. *Annu Rev Psychol*. 2007;58:593-614.

37. Breeman S, Cotton S, Fielding S, Jones GT. Normative data for the Hospital Anxiety and Depression Scale. *Qual life Res*. 2015;24(2):391-398. doi:10.1007/s11136-014-0763-z.
38. Leucht S, Kane JM, Kissling W, Hamann J, Etschel E, Engel RR. What does the PANSS mean? *Schizophr Res*. 2005;79(2-3):231-238. doi:10.1016/j.schres.2005.04.008.
39. Fritz MS, MacKinnon DP. Required sample size to detect the mediated effect. *Psychol Sci*. 2007;18(3):233-239. doi:10.1111/j.1467-9280.2007.01882.x.
40. Guyatt GH, Oxman AD, Kunz R, et al. GRADE guidelines 6. Rating the quality of evidence - Imprecision. *J Clin Epidemiol*. 2011;64(12):1283-1293. doi:10.1016/j.jclinepi.2011.01.012.
41. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. . *Br Med J*. 2011;343:889-893. doi:doi: 10.1136/bmj.d5928.
42. Higgins JPT, Altman DG SJ. *Cochrane Handbook for Systematic Reviews of Interventions*.; 2011. www.cochrane-handbook.org.
43. Fernandez C, Kennedy HG, Kennedy M. The recovery of factors associated with decision- making capacity in individuals with psychosis. 2017:113-119. doi:10.1192/bjpo.bp.116.004226.

Figure 1. Flow of participants through the study

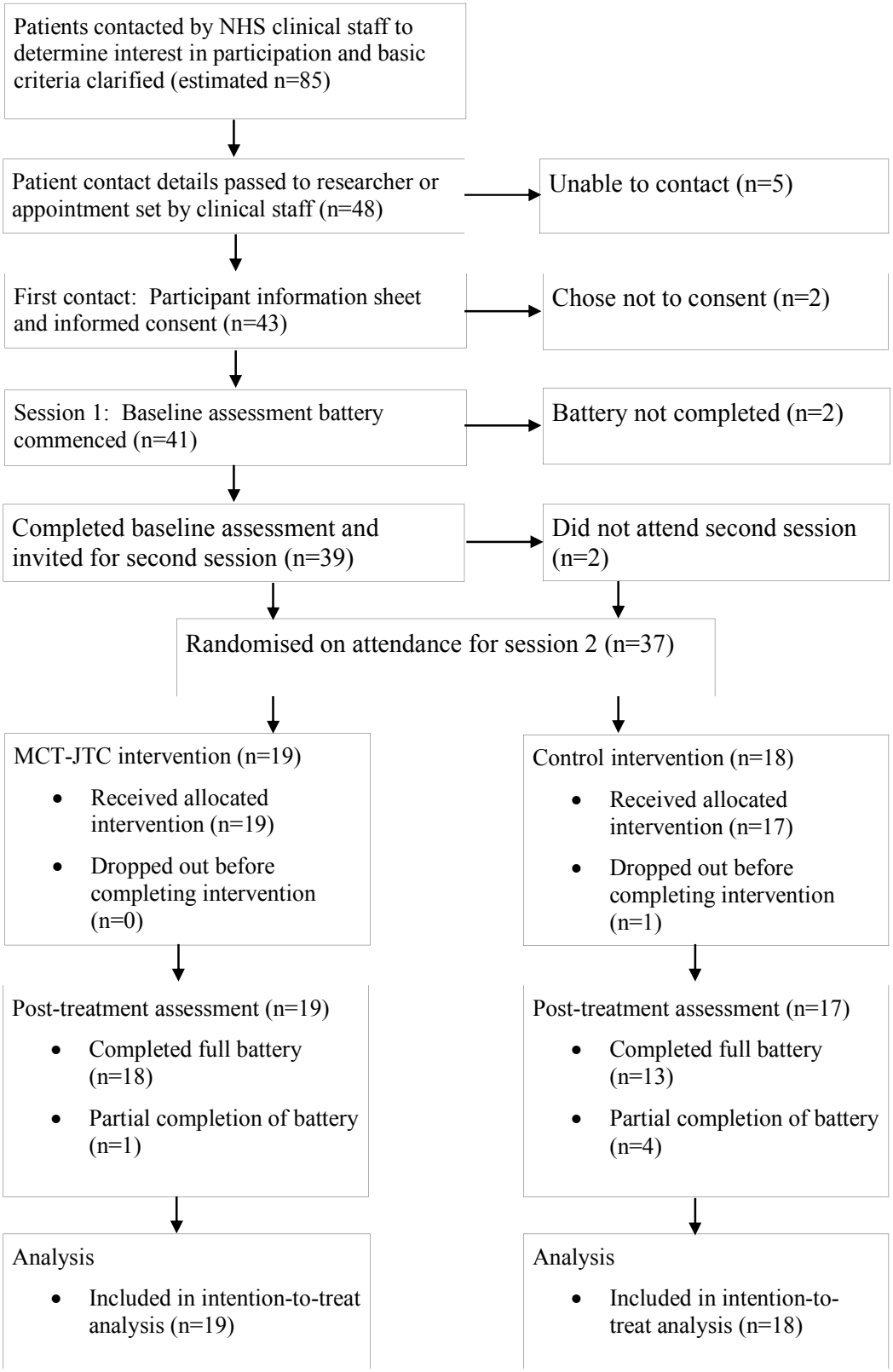

Table 1. Demographic and clinical characteristics

	Overall (N=37)	Experimental (N=19)	Control (N=17)
Age, mean (SD)	44.7 (12.8)	45.3 (13.0)	44 (12.9)
Gender (male:female)	31:6	14:5	17:1
Ethnicity (white:other)	37:0	19:0	17:0
Inpatient:outpatient	11:26	5:14	6:12
Diagnosis			
Schizophrenia, N (%)	26 (70%)	12 (63%)	14 (78%)
Schizoaffective, N (%)	5 (14%)	3 (16%)	2 (11%)
Psychosis NOS, N (%)	6 (16%)	4 (21%)	2 (11%)
Duration			
0-1 years, N (%)	3 (8%)	3 (16%)	0 (0%)
1-3 years, N (%)	3 (8%)	2 (11%)	1 (6%)
3-5 years, N (%)	2 (5%)	1 (5%)	1 (6%)
5-10 years, N (%)	2 (5%)	1 (5%)	1 (6%)
Over 10 years, N (%)	27 (73%)	12 (63%)	15 (83%)
PANSS Positive, mean (SD)	17.2 (7.1)	17.2 (8.1)	17.2 (6.1)
PANSS Negative, mean (SD)	15.1 (5.2)	13.7 (4.4)	16.6 (5.8)
PANSS General, mean (SD)	36.2 (7.4)	38.1 (7.2)	34.3 (7.3)
PANSS Total, mean (SD)	68.8 (16.5)	69.5 (16.8)	68.1 (16.7)
HADS Total, mean (SD)	13.30 (7.2)	15.4 (8.2)	11.1 (5.4)
PANSS Insight, mean (SD)	2.51 (1.39)	2.37 (1.38)	2.67 (1.41)

Note: PANSS, Positive and Negative Syndrome Scale. HADS, Hospital Anxiety and Depression Scale. Insight = Item 12 of PANSS General subscale. NB, data for Age, PANSS and HADS are reported as mean and standard deviation. There were no significant differences between groups using t-test and chi-squared tests.

Table 2. Components of 1-hour MTC-JTC intervention

1. An introduction to the jumping-to-conclusions bias in psychosis
2. Inferences without 100% proof; examples from daily life (2 examples)
3. Jumping-to-conclusions "in action;" examples from politics and medicine of the pitfalls of using jumping-to-conclusions in decision-making (4 examples)
4. How jumping-to-conclusions promotes misinterpretation; discussion and examples including a worksheet for personal experiences and alternative interpretation
5. Jumping-to-conclusion and it's role in conspiracy theories; illustration via the moon landing conspiracy theory
6. Worksheet exercise; providing evidence for and against personal delusional beliefs including conviction rating
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
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
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
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
11. Summary of jumping-to-conclusions session and suggested tactics

Effect of reducing the JTC bias on capacity in psychosis

Table 3. Main ANCOVA results for all outcome measures by treatment group (intention-to-treat)

	Baseline		Post-treatment		*F*-Test	Between-group effect size (*d*)
	MCT-JTC	AC	MCT-JTC	AC	Group effect (*F*)	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		
MacCAT-T Understanding	3.62 (1.40)	3.30 (1.46)	4.30 (1.49)	3.59 (1.57)	2.06	.49
MacCAT-T Appreciation	3.21 (1.08)	2.90 (1.28)	3.86 (0.58)	3.00 (1.35)	6.45*	.87*
MacCAT-T Reasoning	6.2 (1.23)	5.44 (1.89)	6.89 (1.24)	5.56 (2.00)	3.95**	.68**
MacCAT-T Expressing Choice	1.95 (0.23)	1.89 (0.32)	1.95 (0.23)	1.93 (0.24)	†	†
MacCAT-T Total	14.93 (3.37)	13.58 (4.17)	16.8 (2.83)	13.9 (4.37)	7.78*	.96*
HADS Anxiety	9.21 (5.39)	7.22 (4.13)	9.16 (4.71)	7.52 (4.55)	2.21	-.18
HADS Depression	6.16 (4.14)	3.39 (2.68)	7.32 (3.60)[1]	3.44 (2.39)[1]	†	.30
HADS Total	15.38 (8.17)	11.11 (5.40)	16.26 (7.18)	10.99 (5.87)	2.21	-.51
CBQP JTC subscale	11.21 (3.87)	10.56 (2.20)	10.67 (3.05)	10.60 (1.57)	.33	.20
CBQP Total	48.89 (11.10)	45.44 (9.83)	45.40 (9.42)	43.54 (8.39)	.35	.20
Beads Task	3.84 (2.91)	3.67 (2.68)	6.16 (4.05)	3.72 (3.36)	7.35*	.93*

Effect of reducing the JTC bias on capacity in psychosis

Note: MCT, Meta-cognitive training; AC, Attention control; 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
[1]Mean change for MCT-JTC and control was 1.16 (SD 3.17) and 0.05 (SD 3.09), respectively. †Data violated necessary assumptions therefore ANCOVA was not possible. Between group difference for MacCAT-T Expressing Choice was non-significant.

Table 4. Data gathering as a mediator of group allocation on capacity

	Total effect (SE), *P*	Direct effect (SE), *P*	Mediated effect (SE), 95% CI	Proportion mediated, %	*d*
Baron & Kenny method					
MacCAT-T Understanding	-0.71 (0.50), 0.17	-0.26 (0.48), 0.59	-0.45 (0.28), -1.10, 0.00	63	0.45
MacCAT-T Appreciation	-0.71 (0.34), 0.04*	-0.45 (0.34), 0.19	-0.25 (0.17), -0.66, 0.01	35.7	0.55
MacCAT-T Reasoning	-1.34 (0.55), 0.02*	-0.95 (0.55), 0.09	-0.39 (0.27), -1.03, 0.02	28.8	0.59
MacCAT-T Total	-2.89 (1.21), 0.02*	-1.77 (1.14), 0.13	-1.12 (0.69), -2.69, -.00*	38.7*	0.64
Preacher & Hayes method					
MacCAT-T Understanding	-0.71 (0.50), 0.17	0.26 ((0.48), 0.59	-0.45 (0.28), -1.19, -0.05*	63*	0.45
MacCAT-T Appreciation	-0.71 (0.34), 0.04*	-0.46 (0.34), 0.19	-0.25 (0.15), -0.66, -0.04*	35.7*	0.55
MacCAT-T Reasoning	1.34 (0.55), 0.02*	-0.95 (0.55), 0.09	-0.39 (0.25), -1.08, -0.03*	28.8*	0.59
MacCAT-T Total	-2.89 (1.21), 0.02*	-1.77 (1.14), 0.13	-1.12 (0.65), -2.86, -0.14*	38.7*	0.64

Note: 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

Supplementary Materials

Table 5: *Distribution of scores for PANSS item 12: Lack of judgment and insight*

Score (1-7)	Overall (N=37)		Experimental (N=19)		Control (N=17)	
	n	%	*n*	%	*n*	%
1	7	18.9	5	26.3	2	11.8
2	18	48.6	8	42.1	9	52.9
3	5	13.5	3	15.8	2	11.8
4	2	5.4	1	5.3	1	5.9
5	3	8.1	1	5.3	2	11.8
6	2	5.4	1	5.3	1	5.9
7	0	0	0	0	0	0