Data supplement to Larkin & Hutton. Factors helping or hindering treatment decision-making capacity in psychosis: systematic review and meta-analysis**.** Br J Psychiatry
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DS1 Review protocol

Title: Treatment decision making capacity in psychosis: what are the risk factors and correlates?

Reviewers: Amanda Larkin, Paul Hutton

Citation
Amanda Larkin, Paul Hutton. Treatment decision making capacity in psychosis: what are the risk factors and correlates?. PROSPERO 2015:CRD42015025568 Available from http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42015025568

Review question(s)
What are the risk factors and correlates of impaired treatment decision making capacity in people who have experienced psychosis?

Searches
PsycINFO, EMBASE, MEDLINE, theses databases, grey literature. The author also plans to contact researchers in the area as well as hand searching the reference lists of key papers.
The databases will be searched using the keywords "psychosis", "psychotic disorders", "delusions", "hallucinations", "capacity", "decision making", "treatment decision making capacity" "MacCAT-T" "consent" "decisional capacity" "schizophrenia".The search strategy will be amended appropriately for each database.

Types of study to be included
All studies that assess treatment decision making capacity in people who have experienced psychosis. Cross-sectional, correlational studies, cohort studies, case-control studies, audits and prospective studies and trials will be included where other inclusion criteria are met.

Condition or domain being studied
Treatment decision making capacity. Psychosis.

Participants/ population
People who have received a diagnosis of non-affective psychotic disorder

Intervention(s), exposure(s)
Not applicable

Comparator(s)/ control
The reviewer will consider both clinical and non-clinical comparison groups

Context
Studies included will assess capacity in the context of a decision about medical / psychiatric treatment. These decisions may be real or hypothetical.

Outcome(s)

Primary outcomes
Treatment decision making capacity

Secondary outcomes
This review will take an exploratory approach, investigating what factors have been evidenced to be associated with treatment decision making capacity in people who have experienced psychosis. These factors are expected to include insight, symptoms, and cognitive impairment.

Data extraction, (selection and coding)

Studies that include an assessment of treatment decision making capacity in the specified population will be included in the review. Data on the type of study design, measure of capacity used, and strength of association between factors examined and capacity will be extracted. Data relating to the quality of the study will also be extracted including reliability and validity of measures used, characteristics of sample, and power of the sample size to detect effects.

Risk of bias (quality) assessment

Risk of bias will be assessed using a modified tool based on the one developed by the Agency for Healthcare Research and Quality (Williams, Plassman, Burke, Holsinger & Benjamin, 2010). Each study will be given a rating based on the risk of bias in the study. Studies that receive a rating of high risk of bias will be excluded from the review. Included studies will be weighted according to the quality rating and this will be reported.

Strategy for data synthesis

The studies will be reviewed in aggregate. The evidence for each factor that has been examined will be taken in aggregate and reported as such. A narrative review of each of the factors will be undertaken.

Analysis of subgroups or subsets

None planned

Dissemination plans

The completed systematic review will be published in an academic journal.

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Conflicts of interest

None known

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English

Country

Scotland

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Subject indexing assigned by CRD

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Decision Making; Humans; Psychotic Disorders; Risk Factors

Stage of review

Ongoing

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Stage of review at time of this submission	*Started*	*Completed*
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

DS2 Full inclusion and exclusion criteria

Category	Criteria
Study population	Population consisted of people who had been diagnosed with a non-affective psychotic disorder (ICD-10 F20 – F29 diagnoses). Studies that used a mixed population were included if >50% of the population was people diagnosed with non-affective psychotic disorders.
Study geography	Studies from all countries were accepted if they had used a definition of capacity that included at least one of the four accepted factors in capacity as defined above.
Factors / Interventions	Any factors that were measured using a valid measure and had been assessed as contributing to treatment decision-making capacity were included. Baseline and change data from studies of interventions designed to enhance treatment decision-making capacity, or studies which had assessed treatment decision-making capacity pre- and post-intervention were included.
Time period	Studies published between 1947 and October 2015 were included in the review.
Publication language	Studies published in the English language only were included in the review.
Admissible evidence (study design and other criteria)	Case studies and descriptions were excluded from the review.

DS3 Excluded studies

The following table details studies or reports excluded after inspection of the full-text report, or via correspondence with authors. Studies or reports excluded on basis of title or abstract alone are not detailed as these are too numerous and the vast majority were of different conditions or were otherwise unrelated to the review question.

Study ref	Reason for exclusion
1. Ackerman et al. (2015)	Case description
2. Ang et al. (2009)	Case description
3. Baklar (1998)	Editorial
4. Bingham (2012)	Case description
5. Bitter et al. (2015)	No measure of capacity or did not examine correlates
6. Bowen & Barnes (1994)	No measure of capacity or did not examine correlates
7. Bunn et al. (1997)	No measure of capacity or did not examine correlates
8. Bursztajn et al. (1991)	Case description
9. Burton & Twamley (2015)	No measure of capacity or did not examine correlates
10. Dudzinski & Sullivan (2004)	Case description
11. Falzer & Garman (2012)	No measure of capacity or did not examine correlates
12. Gray & O'Reilly (2009)	Case description
13. Grimes et al. (2000)	No measure of capacity or did not examine correlates
14. Grisso & Appelbaum (1995)	No measure of capacity or did not examine correlates
15. Grisso & Appelbaum (1995) (2)	Brief report – no usable data
16. Hamann et al. (2011)	No measure of capacity or did not examine correlates
17. Irwin, Knight, & Pirl (2014)	No measure of capacity or did not examine correlates
18. Jacob et al. (2005)	Sample <50% psychosis or schizophrenia
19. Jeste, Depp, & Palmer (2006)	Review paper
20. Karel et al. (2010)	Sample <50% psychosis or schizophrenia
21. Krogsgaard Bording, Munk-Jorgensen, & Puschner (2012)	No measure of capacity or did not examine correlates
22. Lee et al. (2010)	No measure of capacity or did not examine correlates
23. Linden & Chaskel (1991)	No measure of capacity or did not examine correlates
24. Mahone (2004)	No measure of capacity or did not examine correlates
25. Mandarelli et al. (2014)	No measure of capacity or did not examine correlates
26. Maxmin et al. (2009)	Sample <50% psychosis or schizophrenia
27. McSherry & Bruckard (2009)	Editorial
28. Meszaros et al. (2011)	No measure of capacity or did not examine correlates
29. Moye et al. (2008)	No measure of capacity or did not examine correlates
30. Parsons & Kennedy (2007)	No measure of capacity or did not examine correlates
31. Paul & Oyebode (1999)	No measure of capacity or did not examine correlates
32. Roth et al. (1982)	Sample <50% psychosis or schizophrenia
33. Schlecter (2008)	Case description
34. Seeman (2014)	Case description
35. Shek, Lyons, & Taylor (2010)	No measure of capacity or did not examine correlates
36. Vollman et al. (2003)	No measure of capacity or did not examine correlates
37. Weinstock, Copelan, & Bagheri (1984)	No measure of capacity or did not examine correlates
38. Wirshing et al. (1998)	Research decision making capacity
39. Wirshing, Sergei, & Mintz (2005)	Research decision making capacity
40. Zalpuri et al. (2015)	Case description

DS4 Study quality assessment tool

We adapted a tool for assessing the methodological quality of observational studies that has been successfully employed in prior research undertaken by the Agency for Healthcare Research and Quality (AHRQ). The main methodological quality criteria were retained but the underlying factors related to each study quality criterion were adapted in some instances for this specific context. Each study is assessed on a number of methodological quality criteria (for example, unbiased selection of groups, sample-size calculations, and so on) that are rated as being met, not met, partially met, or being unclear.

General instructions: Grade each criterion as 'Yes', 'No', 'Partially', or 'Can't tell'. Factors to consider when making an assessment are listed under each criterion. Where appropriate (particularly when assigning a 'No', 'Partially', or 'Can't tell' score), please provide a brief rationale for your decision (in parentheses) in the evidence table.

1. Unbiased selection of the cohort?
Factors that help reduce selection bias:
○ Inclusion/exclusion criteria:
○ Recruitment strategy
▪ Clearly described.
▪ Relatively free from bias (selection bias might be introduced, for example, by recruitment via advertisement).

2. Selection minimizes baseline differences in prognostic factors?
Factors to consider:
○ Was selection of the comparison group appropriate?
○ Is the comparison group matched with the clinical group on key demographics (that is age and gender)?

3. Sample size calculated?
Factors to consider:
○ Did the authors report conducting a power analysis or describe some other basis for determining the adequacy of study group sizes for the primary outcome(s) of interest to us?
○ Where a power calculation is presented, do the final numbers obtained match up to this (for example, within 10% of required numbers)?

4. Adequate description of the cohort?
Consider whether the cohort is well-characterized in terms of baseline:
○ Age
○ Sex
○ Ethnicity
○ Diagnosis/clinical status

5. Validated measure of treatment decision making capacity or of domains of treatment decision making capacity?
Factors to consider:
○ Was the method used to assess treatment decision making capacity clearly described (details should be sufficient to permit replication in new studies)?
○ Was a valid and reliable measure used to assess treatment decision making capacity (subjective measures based on self-report tend to have lower reliability and validity than objective measures such as clinical interview)?

6. Validated measures for assessing associated factors of interest?
Factors to consider:
○ Where possible studies should use validated measures to assess factors, for example a validated measure of depression rather than a subjective rating of mood.
○ Were these measures implemented consistently across all study participants?

7. Outcome assessment blind to exposure? (Note: subsequently excluded from overall assessment of study quality)
Factors to consider:

○ Were the study investigators who assessed outcomes blind to whether participants had impaired treatment decision making capacity and vice versa?

8. Analysis controls for confounding?
Factors to consider for controlled studies:
○ If groups were not matched as baseline, did the analysis control for any baseline differences between groups?
○ Does the study identify and control for important confounding variables and effect modifiers (for example, IQ)?

9. Analytic methods appropriate?
Factors to consider:
○ Was the kind of analysis done appropriate for the kind of outcome data (categorical, continuous, and so on)?
○ Was the number of variables used in the analysis appropriate for the sample size (the statistical techniques used must be appropriate to the data and take into account issues such as controlling for small sample size, clustering, rare outcomes, multiple comparison, and number of covariates for a given sample size)?

For intervention studies (non-randomised controlled trials only) the following additional criteria were rated:

10. Adherence to intervention?
Factors to consider:

- Was the intervention manualised?
- Did all participants receive the same number of sessions / intensity of intervention?

11. Adequate follow-up period?
Treatment decision making capacity is time and decision specific. As such it is expected to change over time. To ensure that the change in capacity can be attributable to the intervention studied, a short follow up period is more valid than a longer follow up period.

Factors to consider:

- How long was the follow up period? Maximum follow up period – 2 weeks

12. Completeness of follow up?
Factors to consider:

- Did attrition from any group exceed 30%? (Attrition is measured in relation to the time between baseline/allocation and outcome measurement. Where different numbers of patients are followed up for different outcomes, use the number followed up for the primary outcome for this calculation.)
- Did attrition differ between groups by more than 10% percent?

DS5 GRADE assessment criteria

Outcomes where more than one study contributed evidence were assessed for overall quality using the GRADE approach. The rating of quality was conducted by the first author, and discussed with second author PH. The following criteria for downgrading were applied to each outcome.

Study limitations
Individual studies were rated for risk of bias using a tool adapted from Williams et al. (2010) (1). We downgraded by 1 point if three of the parameters in our risk of bias assessment had ≥50% studies with at least one 'no' or 'unclear' rating, and 2 points if four or more parameters had ≥50% studies with ratings of 'no or unclear'.

Imprecision
Imprecision was judged by examining the 95% CI of the effect sizes for the outcome of interest across studies. We downgraded 1 point for imprecision when optimal sample size had not been reached.

Inconsistency
For outcomes included in meta-analysis where the I^2 statistic was calculated we downgraded by 1 point for inconsistency if the I^2 statistic was ≥40% in the context of an unclear direction of effect or ≥75% in the context of a clear direction of effect. We downgraded by 2 points if the I^2 statistic was ≥75% in the context of an unclear direction of effect. For outcomes included in the narrative review, we downgraded by 1 point for inconsistency in cases where 95% CI did not overlap, and heterogeneity could not be explained.

Indirectness
The review was exploratory in nature, therefore outcomes had not been pre-specified. However, for outcomes that had used significantly different measures of the same construct, we downgraded by 1 point for indirectness.

Rating up the quality of evidence
In the context of a large effect size, we upgraded by 1 point where the effect size calculated was consistently large. Using Cohen's criteria (2), an effect size of $r \geq .50$ or $d \geq .80$ was considered large.

DS6 Narrative synthesis of results from individual studies

Executive functioning
In a very small study, Koren et al (2005) (3) found that executive functioning had non-significant moderate correlations with the three MacCAT-T subdomains of understanding (r = -0.35, 95% CI -0.68, 0.10; trials to first category), appreciation (0.41, 95% CI -0.03, 0.72; N categories), and reasoning (r = 0.31, 95% CI -0.14, 0.65; N categories) whereas Mandarelli et al (2012) (4) found that poor executive functioning was significantly associated with large reductions in understanding (d = 1.13, 95% CI 0.49, 1.77) and appreciation (d = 0.86, 95% CI 0.24, 1.49), but not reasoning, where the reduction was small and non-significant (d = 0.32, 95% CI -0.28, 0.92). The inconsistent and very imprecise findings meant the overall quality of evidence was rated as very low in quality.

Insight
Five studies examined the relationship between insight and treatment decision making capacity. Each assessed different aspects of insight, so were not conceptually similar enough to combine in meta-analysis. In a study of 112 inpatients, Cairns et al (2005) (5) found incapacity was associated with a large reduction in insight, as measured by the Expanded Schedule for the Assessment of Insight (χ^2 162.50, $p < 0.001$). Capdevielle et al (2009) (6) found that understanding and the ability to express a choice, as measured by the MacCAT-T, had moderate correlations with each of the Scale to Assess Unawareness of Mental Disorder (SUMD) subscales (higher scores equal poorer insight, hence correlations are negative), with correlations ranging from -0.32 (95% CI -0.53, -0.07) for the association between understanding and 'awareness' of symptoms to -0.44 (95% CI -0.62, -0.21) for the association between being able to express a choice about treament and being aware of the social consequences of their disorder. Both the reasoning and appreciation domains had large correlations with all SUMD subscales, ranging from -0.61 (95% CI -0.75, -0.42) for the correlation between reasoning and awareness of symptoms, to -0.80 (95% CI -0.88, -0.69) for the correlation between appreciation and awareness of effects of medication. Owen et al (2009) (7) used the Expanded Schedule for the Assessment of Insight (SAI-E) and found a very large difference in insight between those who were judged to have and not have intact capacity (Hedge's g =-2.19 95% CI -1.83, -2.55). Finally, Elbogen et al (2007) (8) used the Insight and Treatment Attitudes Questionnaire (ITAQ) and again found that insight was positively associated with reasoning ($\beta = 0.36$, $p < 0.05$).

Raffard et al (2013) (9) examined the relationship between MacCAT-T ratings and scores on the Beck Cognitive Insight Scale (BCIS), a measure which assesses self-certainty and self-reflectiveness. For degree of self-certainty, they reported small positive (r = 0.12, 95% CI -0.14, 0.36; understanding) to small negative (r = -0.21, 95% CI -0.44, 0.05; reasoning) correlations with the MacCAT-T subscales, none of which were statistically significant in this sample of 60 participants. For degree of self-reflectiveness, they reported correlations that ranged from small and non-significant (r = 0.18, 95% CI -0.08, 0.42; ability to express a choice) to moderate and significant (r = 0.43, 95% CI 0.20, 0.62; reasoning, r = 0.33, 95% 0.08, 0.54; appreciation).

Overall we judged the evidence on insight to be of moderate quality, and consistent with the view that insight is associated with improved capacity, in particular reasoning ability.

Duration of illness
Two studies provided low quality data on the relationship between duration of illness (years since diagnosis) and capacity (10, 11) Raffard et al (2013) (12) did not find significant correlations, with estimates ranging from -0.09 (95% CI -0.34, 0.17; appreciation) to -0.19 (95% CI -0.42, 0.06), whereas Wong et al., (2005)(13) reported a small yet significant relationship with understanding (r = -0.24, 95% CI -0.02, -0.44).

Metacognitive ability
In one small study, Koren et al (2005) (14) found that metacognitive ability was significantly associated with the ability of participants to understand information relating to treatment (r = 0.60, 95% CI 0.23, 0.82 for control sensitivity). Although not significant, correlations of similar magnitude were observed for appreciation (r = 0.40, 95% CI -0.04, 0.71 for monetary gains) and reasoning (r = 0.43, 95% CI -0.00, 0.73).

Perceived coercion
Moderate quality evidence from Cairns et al., (2005) (15) suggested that participants judged to have impaired capacity were more likely to report higher levels of perceived coercion (Mann-Whitney U = 422.5, $p < 0.001$).

Anxiety

Moderate quality evidence from two studies suggests state and trait anxiety may be positively associated with aspects of capacity – i.e., greater anxiety was linked to greater treatment decisional capacity (16, 17). State anxiety was significantly and moderately correlated with appreciation in both studies (r = 0.27, 95% CI 0.02, 0.49;(18) r = 0.36, 95% CI 0.12, 0.56(19)), whereas trait anxiety was only significantly associated with appreciation in one (r = 0.33, 95% CI 0.08, 0.54;(20) r = 0.22, 95% CI -0.04, 0.45(21)). A similar pattern of findings was observed for the relation between state anxiety and reasoning (r = 0.32, 95% CI 0.07, 0.53;(22) r = 0.27, 95% CI 0.02, 0.49(23)) and trait anxiety and reasoning (r = 0.38, 95% CI 0.14, 0.58;(24) r = 0.15, 95% CI -0.11, 0.39(19)). In both studies, non-significant small correlations were reported for state and trait anxiety and understanding and expressing a choice.

Table DS1 Assessment of quality of cross-sectional observational studies

Study ref	Unbiased selection of cohort?	Selection minimises baseline differences in prognostic factors?[1]	Sample size calculation?	Adequate description of the cohort?	Validated method for assessing capacity?	Validated methods for ascertaining correlates?	Outcome assessments blind to clinical status?	Analysis controls for confounding?	Analytic methods appropriate?
Cairns et al. (2005)	Yes	Yes	No	Yes	Yes	Yes	Can't tell	No	Yes
Capdevielle 2009	Yes	Yes	Partial	Yes	Yes	Yes	Yes	No	Yes
Di 2013	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes
Grisso 1991	No	No	No	Yes	Yes	Yes	Can't tell	No	Yes
Grisso 1995	No	Yes	Partial	Yes	Yes	Yes	No	No	Yes
Grisso 1997	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes
Howe 2005	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes
Koren 2005	Yes	Yes	No	Yes	Yes	Partial	Yes	No	Yes
Mandarelli 2012	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes
Owen 2009	Yes	Yes	Partial	Yes	Yes	Yes	No	Yes	Yes
Raffard 2013	Yes	Yes	No	Yes	Yes	Yes	Partial	Yes	Yes
Rutledge 2008	No	No	Partial	Yes	Yes	Yes	No	No	Yes
Schachter 1994	No	Yes	No	Yes	No	Yes	Yes	Yes	Yes
Wong 2005	No	Yes	No	Yes	No	Yes	No	No	Yes

Table DS2 Assessment of quality of non-randomised or uncontrolled intervention studies

Study ref	Unbiased selection of cohort?	Selection minimises baseline differences in prognostic factors?[1]	Sample size calculation?	Adequate description of the cohort?	Adherence to intervention?	Valid measure of capacity?	Blind outcome assessment?	Adequate follow-up period?
Dornan 2015	No	No	No	Yes	Partial	Yes	Partial	Can't tell
Kennedy 2009	No	No	No	Yes	Yes	Yes	No	Yes
Kleinman 1996	Yes	Yes	No	Yes	Yes	No	No	No
Munetz 1985	Yes	Yes	No	Yes	Yes	No	No	Yes
Naughton 2012	No	No	No	Yes	Yes	Yes	No	No
Owen 2011	Yes	Yes	No	Yes	N/A	Yes	No	Yes
Palmer 2002	No	No	No	Yes	Yes	Yes	Partial	Yes
Wong 2000	No	No	No	Yes	Yes	Yes	Can't tell	Yes

Table DS3 Risk of bias assessment for randomised controlled trials

Study ref	Sequence generation	Allocation concealment	Blinding	Attrition	Selective reporting	Other
Elbogen 2007	Yes	Yes	Unclear	No	No	Yes
Hamann 2011	Yes	Yes	No	Yes	No	Yes

DS7 Additional references

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