Effectiveness of metacognitive interventions for mental disorders in adults: a systematic review (METACOG)

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Citation

Review question(s)
The objective of the systematic review is to assess the effects of metacognitive interventions for adult patients with mental disorders, the review aims:

a) to investigate whether approaches of metacognitive interventions are effective,

b) to investigate whether effectiveness within these approaches varies across mental disorders, and

c) to explore the acceptability of different approaches of metacognitive interventions.

Searches
Electronic database search: Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, ISI Web of Science, BIOSIS, PsycINFO, and CINAHL.

Clinical trial registers: International trial registries via the World Health Organization's trials portal (ICTRP) and ClinicalTrials.gov.

Grey literature: ProQuest Dissertations and theses database, Open Grey (http://www.opengrey.eu/)

Citation search: forward and backward reference search of relevant study reports, including existing reviews on the topic.

Expert contacts: the first author of all included studies for information on unpublished or ongoing studies.

Key author search: search for further publications of the key authors of all forms of metacognitive interventions.

We will restrict the search date to 1994 onwards (unless otherwise stated) which is the year when the metacognitive model of psychological disorders was first presented by Wells and Matthews. There will be no restrictions on language or publication status.

Types of study to be included
Randomized controlled trials (RCTs), including cross-over and cluster RCTs, and non-randomized controlled trials (NRCTs) will be included. For NRCTs, we require that at least two groups of independent participants are compared. No restrictions regarding other design characteristics will be applied.

Condition or domain being studied
Mental disorders (including substance-induced disorders, schizophrenia and other psychotic disorders, affective disorders, anxiety disorders, somatoform disorders, dissociative disorders, sexual disorders, eating disorders, sleep disorders or personality disorders).

Participants/ population
Since meta-cognitive interventions are disseminated throughout diverse and even less frequent mental disorders, studies conducted in adults (>= 18 years) with mental disorders (see Condition) will be considered. The diagnosis either needs to rely on a formal classification system, i.e. the International Classification of Diseases (ICD) or the Diagnostic and Statistical Manual of Mental Disorders (DSM), or on reliable and validated (patient- or observer-reported) scales. Differences in deriving the diagnosis (formal diagnostic criteria vs. validated questionnaires) will be documented and considered in analyses of between-study heterogeneity. We will allow for any co-morbidity and setting (in- and outpatient). Studies in which patients with physical disorders are included will only be considered if patients received a formal diagnosis via one of the before-mentioned classification systems.

**Intervention(s), exposure(s)**
As a distinction from other psychotherapies, metacognitive interventions specifically focus on “knowledge and cognitions about cognitive phenomena” (Flavell, 1979). They highlight the role of maladaptive cognitive processes, as opposed to cognitive contents, in the development, maintenance and treatment of mental disorders. They mainly involve psychological interventions focusing on cognitive processes and related dysfunctional beliefs (e.g., thought suppression and beliefs about its effect in “metacognitive therapy”) or specific cognitive biases (e.g., jumping to conclusions in “metacognitive training” for psychosis). Included metacognitive interventions have to fulfil the following criteria: administered in individual or group format, led by a therapist or as a self-help-program, administered face-to-face or electronically, delivered as stand-alone intervention, as an adjunctive treatment, or delivered in combination with a psychological or pharmacological treatment.

**Comparator(s)/ control**
The comparators may be: another psychological or pharmacological treatment, a combined psychological and pharmacological treatment, treatment as usual (a thorough description will be recorded) or no specific active treatment (e.g., no treatment, wait-list control, placebo).

**Outcome(s)**

**Primary outcomes**
Primary efficacy outcome: changes in metric outcomes on disorder-specific, comprehensive and validated symptom rating scales

Primary acceptability outcome: treatment drop-out (i.e. the number of participants who dropped out of the allocated treatment for any reason)

**Secondary outcomes**
Secondary efficacy outcomes: treatment response as defined by the study authors, improvement in overall symptomatology, changes in metacognitive processes, satisfaction with treatment, quality of life, applicability of metacognitive interventions, and autonomy

Secondary acceptability outcomes: adverse events, adverse effects

**Data extraction, (selection and coding)**
Study selection: first, titles and abstracts for inclusion will be screened and coded as eligible/potentially eligible or ineligible by one reviewer; then full texts will be retrieved and screened independently by two reviewers, who determine studies for inclusion. Reasons for exclusion of ineligible studies will be recorded.

Data extraction: basic data and results will be extracted independently by two reviewers using a structured form which will be piloted on at least three studies. Disagreement will be resolved by consensus or by involving a third reviewer.

Outcomes will be extracted from publications with estimation and substitution of missing data according to current guidelines.

**Risk of bias (quality) assessment**
Two review authors will independently assess risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2011) and in the ROBINS-I tool (Sterne et al., 2016) for assessing the quality of non-randomized studies. Moreover, we will assess recruitment bias, baseline
imbalance, loss of clusters, incorrect analysis, and comparability with individually randomized trials in cluster-randomized trials (Higgins & Green, 2011). Disagreements will be resolved by discussion or by involving a third reviewer. Potential sources of bias will be assessed overall by classifying in categories of high, low, or unclear risk of bias.

**Strategy for data synthesis**

If applicable, separate meta-analyses will be calculated for the different conceptual backgrounds, like for the “metacognitive therapy” or the “metacognitive training” approaches. Effectiveness measures for dichotomous outcomes will be pooled as odds ratios. We will analyze continuous data as mean differences (MD). If different rating scales were used to assess the same outcome in the included studies, standardized mean differences (SMD) will be calculated. Cluster-randomized trials will be included if proper adjustment for the intra-cluster correlation can be calculated. Regarding cross-over trials, we will include data from the first active treatment phase. Concerning studies with multiple treatment groups, for each of the main objectives addressed in our review, only data from the comparison of interest will be considered. If the study provides more than one comparison of interest for one of the main objectives, we will divide the number of participants in the arm used several times by the number of arms for all analyses to avoid including participants more than once in the analysis. For all studies, effect sizes will be calculated using the intention-to-treat principle. Statistical heterogeneity between study results will be tested for significance using Cochran's Q-test, and quantified using the I-squared statistic. Possible reporting bias and small-study effects will be tested using visual examination of funnel plots and by performing Egger's test, if a minimum of ten studies is to be included in the meta-analysis. All analyses will be performed using a random effects model. Results will be displayed visually as forest plots. If it will not be possible to combine studies via meta-analysis, a narrative summary will be provided.

**Analysis of subgroups or subsets**

In order to identify possible treatment effect moderators, a priori defined subgroup analyses (in case of categorical predictors) or meta-regression analyses (in case of metric predictors) will be performed. These analyses will relate to the primary effectiveness and acceptability outcomes and consider diagnosis subtype, intervention extent (stand-alone intervention or active ingredient of a larger psychological treatment), intensity of contact (e.g., therapist-led or self-help intervention), or intervention dose (e.g., frequency or duration of sessions). Differences between subgroups will be tested formally.

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15 November 2016

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30 September 2017

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Conflicts of interest
SM has developed a metacognitive intervention and tested it in several studies as primary investigator.

LK has participated in the evaluation of a metacognitive intervention as independent statistician.

The other authors report no conflict of interest.

Language
English

Country
Germany

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Adult; Humans; Mental Disorders

Any other information
The secondary outcomes of applicability and autonomy have been identified as clinically relevant outcomes by means of a patient involvement workshop and focus group with adult patients with different mental disorders, which was held at the Department of Medical Psychology at the University Medical Center Hamburg-Eppendorf.

Reference and/or URL for protocol

http://bmjopen.bmj.com/content/7/6/e015428

Stage of review
Ongoing

Date of registration in PROSPERO
08 November 2016

Date of publication of this revision
26 July 2017

Stage of review at time of this submission

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**PROSPERO**

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