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

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ABSTRACT

Introduction Whereas the efficacy of cognitive-behavioural therapy has been demonstrated for a variety of mental disorders, there is still need for improvement, especially regarding less prevalent or more severe disorders. Recently, metacognitive interventions have been developed and are now available for a variety of diagnoses. Still, a systematic review investigating the effectiveness of different metacognitive interventions for various mental disorders is missing.

Methods and analysis Randomised controlled trials (RCTs), cross-over and cluster RCTs and non-randomised controlled trials on metacognitive interventions (ie, metacognitive therapy, metacognitive training, others) in adults with any mental disorder will be included. As comparators, another psychological or pharmacological treatment, a combined psychological and pharmacological treatment, treatment as usual or no active treatment are eligible. Outcomes refer to efficacy and acceptability of metacognitive interventions.

Ethics and dissemination In light of the popularity of metacognitive interventions, the systematic review will provide researchers, clinicians and patients with substantial information on the intervention's effectiveness across different mental disorders. Results will be published in peer-reviewed journals and disseminated through a patient workshop.

Strengths and limitations of this study

- We will conduct a comprehensive systematic search including several sources.
- We will take effort to minimise bias by screening full texts, extracting relevant data and assessing risk of bias in duplicate.
- We expect identifying studies with varying patient and intervention characteristics as well as methodological quality, which may complicate drawing clear-cut and easily generalisable conclusions.

INTRODUCTION

Cognitive-behavioural therapy and recent developments

Mental disorders are highly prevalent and often accompanied by comorbidity as well as severe role, functional and health-related quality of life impairments.[1 2] A number of mental disorders share a rather chronic course associated with poor health-related quality of life, poor somatic health and disability.[3 4] Mental disorders are often treated inadequately or not at all.[2 5] An evidence-based psychotherapy for the treatment of most disorders is cognitive-behavioural therapy (CBT)—a scientific and empirical treatment that stems from classical and instrumental conditioning as well as from cognitive approaches.[6] As a family of interventions, it involves different general and disorder-specific interventions and techniques.[7] Evidence supports the use of CBT in the treatment of a variety of mental disorders.[8 9] Limitations refer to insufficient benefits as well as non-response and adverse effects in some patient groups.[10–12] Meta-analyses illustrate methodological shortcomings in psychotherapy studies on less prevalent or more severe mental disorders.[13–15] Due to these limitations, further developments in psychological and specifically psychotherapeutic techniques were achieved including the development of metacognitive interventions.[16]

Metacognitive interventions

During the last 20 years, metacognitive interventions have been developed and disseminated for a variety of mental disorders. They became increasingly popular, and their evidence base has advanced. Nevertheless, quite different psychotherapeutic approaches refer to 'metacognitive' changes, which is why a thorough definition is both warranted and not easy to accomplish.[17]

Metacognitions as described by Flavell[18] refer to 'knowledge and cognitions about

cognitive phenomena' (p 906). As a distinction from other therapies, metacognitive interventions specifically focus on distorted and central metacognitive processes underlying mental disorders. Their primary aim is not to change the cognitive contents, but to apply rather indirect treatment approaches to alter specific metacognitions or their functions.[19–21] In this sense, metacognitions reference thoughts about thoughts, or thinking about one's thinking.[22] Since the above-mentioned definition by Flavell[18] was a major starting point for research on metacognitions also into psychotherapy, we will include metacognitive interventions related to this definition into our systematic review.

Currently, two main approaches of therapy and research on metacognitions in mental disorders are prominent: (1) The transdiagnostic 'metacognitive therapy' focuses on core cognitive processes and dysfunctional beliefs in mental disorders in general.[19 23] Metacognitive therapy as developed by Wells mainly addresses dysfunctional beliefs about thinking.[23] It describes cognitive processes like worrying, rumination, dysfunctional threat monitoring or thought suppression as well as dysfunctional beliefs about these processes (like 'rumination is helpful to avoid threat') as key in mental disorders.[19 24] These cognitive processes and beliefs are addressed via interventions like the attention training technique or behavioural experiments.[19] Although metacognitive therapy is rooted in CBT, it differs from traditional CBT in several aspects like its focus on inflexible cognitive processes (instead of cognitive contents), or on how metacognitions influence thoughts and emotions.[23] (2) The more disorder-specific 'metacognitive training' as developed by Moritz and colleagues[25] focuses on the alteration of specific cognitive biases (eg, jumping to conclusions or externalising attributions in schizophrenia) in the development, maintenance and treatment of specific disorders such as psychosis or borderline personality disorder.[20 21] In experimental psychology, confidence is regarded a central aspect of metacognition, which is picked up by metacognitive training aiming to 'sow the seeds of doubt', that is to decrease overconfidence by challenging cognitive biases.[26] It challenges symptoms rather indirectly by treating cognitive biases instead of challenging the core symptoms of mental disorders directly ('backdoor approach').[20] Unlike metacognitive therapy, metacognitive training can be administered either as an adjunct to traditional CBT or as a stand-alone intervention.[21 25] Both approaches may be conducted in an individual or group format.

Due to ongoing development, further interventions involving metacognitions become available, especially for patients with schizophrenia.[17 27] Therefore, we will only include psychotherapeutic interventions focusing on metacognitive change (as defined by Flavell[18]) as the central mechanism.

Evaluation studies on metacognitive interventions have been conducted in patients with generalised anxiety, obsessive–compulsive and social anxiety disorder, post-traumatic stress disorder, depression and schizophrenia,[19 25] and applications to new populations, like chronic fatigue syndrome, body dysmorphic disorder, emotional instability or alcohol abuse are under way.[19] The evidence update of the British National Institute for Health and Clinical Excellence incorporates Wells' metacognitive therapy already as step-three intervention into the treatment guideline for adults with generalised anxiety disorders.[28]

Existing evidence and rationale for the present review

As there was an increase in evaluation studies on metacognitive interventions during the last years, it is one aim of the current review to summarise the empirical evidence on metacognitive interventions.

Some previous reviews on metacognitive interventions were done narratively, rather than systematically, and conclude encouraging positive effects.[11 19 25] Methodological shortcomings of these reviews are in limited search strategies, the mix of high-quality and low-quality primary studies, no exploration of heterogeneity between primary studies and no comparison of types of metacognitive interventions. One systematic review on 'third wave' therapies explicitly excluded metacognitive interventions.[29] Two consecutive Cochrane reviews on 'third wave' therapies for the acute phase treatment of depressive disorders focused on randomised controlled trials (RCTs) and included only outpatients, and thus were not able to include all metacognitive interventions.[30 31]

Furthermore, meta-analyses on metacognitive interventions have demonstrated inconsistent findings. A meta-analysis on metacognitive therapy including uncontrolled trials yielded large significant effects.[32] Since the literature search of this review was conducted 3 years ago and was limited to anxiety and depression, we will cover current studies by an update that also includes other mental disorders. Regarding metacognitive training, by using different inclusion criteria, outcomes and assessment methods, meta-analyses reached very different results, from non-significant,[33] over mixed[34] to significant small to moderate effects.[35] The latter set of meta-analyses focused exclusively on patients with schizophrenia, as metacognitive training for depression and borderline personality disorder has so far only been addressed by single studies.[36 37] Moreover, current studies are available on a self-help version of metacognitive training for OCD.[38 39]

Therefore, a comprehensive and methodologically sound systematic review on metacognitive interventions is needed. Separate meta-analyses will be conducted to estimate the effects of the different approaches including 'metacognitive therapy' and 'metacognitive training'. If trials on other 'metacognitive' interventions fulfil our inclusion criteria, their conceptual background will be analysed carefully. Following this, they will either be allocated to one of the above-mentioned approaches or to a new category. Additional subgroup analyses shall reveal if there are differential effects in groups of mental

disorders. Information on randomised and non-randomised controlled trials will be incorporated to gain a more comprehensive picture of the evidence base. By this systematic review, clinicians may be supported in the assessment of newly developed psychological treatments.

Objectives

The objective of the systematic review is to assess the effects of metacognitive interventions for adult patients with mental disorders. In detail, 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.

METHODS AND ANALYSIS

Criteria for selecting studies for this review

Types of studies

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

Types of participants

As metacognitive interventions target diverse and several less frequent mental disorders, studies conducted in adults (≥18 years) with 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) will be considered. The diagnosis either needs to rely on a formal classification system, that is the International Classification of Diseases[40] or the Diagnostic and Statistical Manual of Mental Disorders [41] or on reliable and validated (patient-reported 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 comorbidity and setting (inpatient and outpatient). Studies in which patients with physical disorders are included will only be considered if patients received a formal diagnosis of a mental disorder via one of the before-mentioned classification systems.

Types of interventions

As a distinction from other psychotherapies, metacognitive interventions specifically focus on 'knowledge and cognitions about cognitive phenomena'.[18] 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 (eg, thought suppression and beliefs about its effect in 'metacognitive therapy') or specific cognitive biases (eg, jumping to conclusions in 'metacognitive training' for psychosis). Included metacognitive interventions have to fulfil the following criteria:

- administered in individual or group format,
- lead by a therapist or as a self-help-programme,
- administered face-to-face or electronically,
- delivered as stand-alone intervention, as an adjunctive treatment or in combination with a psychological or pharmacological treatment.

Types of comparators

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 (eg, no treatment, wait-list control (WL), placebo).

Types of outcome measures

The primary efficacy outcome will refer to changes in metric outcomes on disorder-specific, comprehensive and validated symptom rating scales (eg, Psychotic Symptom Rating Scales (PSYRATS) delusion score for schizophrenia or other psychotic disorders[42] or Hamilton Rating Scale for Depression (HRSD) for depressive disorders[43]) at the end of treatment. If necessary, subscales relating to relevant symptom domains rather than global symptom burden will be considered. If several symptom rating scales are available for one disorder, they will be ordered and included according to psychometric criteria and frequency of their application. If the original authors report patient-reported and observer-reported outcomes, we will give preference to observer-rating scales as they may be blinded.

The primary acceptability outcome will be treatment dropout, defined as the number of participants who dropped out of the allocated treatment for any reason.

Secondary efficacy outcomes will include treatment response as defined by the study authors (often as a minimum decrease in a symptom scale score from baseline to post-treatment/follow-up), improvement in overall symptomatology (measured for example by the Clinical Global Impressions (CGI) scale[44]), changes in metacognitive processes (measured for example by the Metacognitions Questionnaire (MCQ-30)[45]), satisfaction with treatment (measured for example by the Patient Satisfaction Questionnaire(PSQ)[46]) and quality of life (measured for example by the WHO-QoL-BREF[47]).

Beyond, applicability of metacognitive interventions (ie, applicability and transfer in everyday life or in crises; measured for example by single items) and autonomy (as measured for example by the subscale level of independence of the WHO-QoL[48]) will be included. These secondary outcomes have been identified as clinically relevant outcomes by means of a patient involvement workshop and focus group with seven adult patients with different mental disorders, which was held in December

2015 at the Department of Medical Psychology at the University Medical Center Hamburg-Eppendorf.

Secondary acceptability outcomes will refer to adverse events and adverse effects (like suicide attempts or worsening of symptoms).

Outcomes will be evaluated at the end of treatment for the main outcomes. Additionally if follow-up assessments are reported, they will be analysed with their timing categorised as short term (up to 6 months post-treatment), medium term (7 to 12 months post-treatment) or long term (longer than 12 months).

Search methods for identification of studies

Several methods will be used to retrieve potentially relevant articles. In addition to standard electronic medical databases clinical trial registers and sources of grey literature will be searched. The 'ancestry approach' (forward and backward reference search) will be applied by examining reference lists and performing citation searches. In addition, relevant experts will be contacted.

Bibliographic database search

The following databases will be searched: Cochrane Central Register of Controlled Trials, Medline, ISI Web of Science, Biological Abstracts/Previews Archive (BIOSIS), PsycINFO and Cumulative Index to Nursing and Allied Health Literature. All databases will be searched using both relevant subject headings (controlled vocabularies) and keywords (free text). For searches, an intervention-component will be combined (AND) with a design component.

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.[49] There will be no restrictions on language or publication status applied to the searches.

Search in clinical trial registers

We will search International trial registries via the WHO's trials portal International Clinical Trials Registry Platform (ICTRP) and ClinicalTrials.gov to identify additional unpublished or ongoing studies.

Search in sources of grey literature

We will search two sources of grey literature for metacognitive interventions (1994 onwards): the ProQuest Dissertations and theses database (http://www.proquest.com/libraries/academic/dissertation-theses/), and Open Grey (http://www.opengrey.eu/).

Ancestry approach

We will check the reference lists of all included studies and relevant systematic reviews to identify additional studies potentially missed from the original electronic searches (for example unpublished or in-press citations). We will also conduct a cited reference search of reports of included studies, including existing reviews on the topic.

Expert contacts

Further, we will contact the first author of all included studies for information on unpublished or ongoing studies.

Key author search

As in some circumstances, publications on metacognitive interventions were not termed as such, we will search for further publications of the key authors of all metacognitive interventions.

Study selection and data extraction

Study selection

At first, we will screen titles and abstracts for inclusion and code studies as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve' (ineligible). We will then retrieve the full texts (study reports respective publications), and two review authors will independently screen the full texts and determine studies for inclusion. Reasons for exclusion of ineligible studies will be recorded. We will resolve any disagreement through discussion or, if required, consult a third reviewer. Multiple reports that relate to the same study will be collated so that each study rather than each report is the unit of interest of the review. We will record the selection process in sufficient detail to complete a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram.[50] Literature records will be managed using EndNote software.[51]

Data extraction

To extract study characteristics and outcome data, we will use a structured data collection form, which will be piloted on at least three studies in the review. Two review authors will independently extract study characteristics and outcome data from the included studies. Data on the following study characteristics will be collected:

1. Methods: study design, total duration of study, location, date of study (year).
2. Participants: number of participants (N), diagnosis, age range, % female.
3. Interventions: metacognitive approach (eg, metacognitive therapy, metacognitive training), extent (eg, stand-alone intervention, active ingredient of a larger intervention), intensity of contact (eg, therapist led, self help), intervention dose (eg, frequency or duration of sessions).
4. Outcomes: scale for measurement of primary outcome.
5. Comparator.

We will note in the 'Characteristics of included studies' table if outcome data were not reported in a usable way. We will resolve disagreements by consensus or by involving a third reviewer.

Assessment of methodological quality

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*.[52] Risk of

bias will be assessed according to the following domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting and other bias.

The Risk Of Bias in Non-randomized Studies - of Interventions (ROBINS-I)[53] for assessing the quality of non-randomised studies in meta-analyses will be used to assess the quality of non-randomised controlled trials.[52] We will assess recruitment bias, baseline imbalance, loss of clusters, incorrect analysis and comparability with individually randomised trials in cluster-randomised trials. Any disagreements will be resolved by discussion or by involving a third reviewer. We will judge each potential source of bias according to the grading of the relevant risk of bias tool (eg, high, low or unclear risk).

Data synthesis

Planned treatment comparisons

Separate meta-analyses will be calculated for the different conceptual backgrounds, like for the 'metacognitive therapy' or the 'metacognitive training' approaches. For each mental disorder, the following main comparisons are planned based on clinical importance and expected frequency of the comparisons in clinical trials:

- metacognitive intervention versus other psychological treatment.
- metacognitive intervention versus pharmacological treatment.
- metacognitive intervention versus no specific active treatment (no treatment, WL, treatment as usual (TAU)).
- metacognitive intervention versus placebo.
- metacognitive intervention in combination with another psychological treatment, with pharmacological treatment or with no specific active treatment versus another psychological treatment, another pharmacological treatment, another unspecific active treatment or placebo.

Meta-analysis

Effectiveness measures for dichotomous outcomes will be pooled as ORs. We will analyse continuous data as mean differences (MD). If different rating scales were used to assess the same outcome in the included studies, standardised MD will be calculated.

Meta-analyses will be undertaken only if it is meaningful, that is if treatments, participants and the underlying clinical question are similar enough for pooling.[54] We will narratively describe skewed data reported as medians and interquartile ranges.

To broaden the evidence base of the planned review, data from non-randomised controlled trials, cluster-randomised trials and cross-over trials will be included in addition to individually randomised parallel trials. Cluster-randomised trials will be included if proper adjustment for the intracluster 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.

In case of missing or unclear data, we will contact the first/corresponding author respective study funder to obtain key study characteristics and outcome data (eg, when a study is identified as abstract only). All requests and correspondences will be documented.

Substitution of missing data will follow current guidelines, for example, calculating standard errors from exactly reported t-values or estimating dichotomous from metric outcomes.[52 55 56] For all studies, effect sizes will be calculated using the intention-to-treat principle, that is, analysing all subjects allocated to a study arm. For all outcomes, the definition of the intention-to-treat sample provided by the authors will be followed.

Statistical heterogeneity between study results will be tested for significance using Cochran's Q-test and quantified using the I^2-statistic.[52] I^2-values will be interpreted as follows: 0%–40%: might not be important; 30%–60%: may represent moderate heterogeneity; 50%–90%: may represent substantial heterogeneity; 75%–100%: considerable heterogeneity. Substantial and considerable statistical heterogeneity needs further exploration, but magnitude and direction of effects and the strength of evidence for heterogeneity will be taken into account as well.

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 10 studies is to be included in the meta-analysis.

All analyses will be performed using a random effects model, assuming that included studies will not be functionally equivalent and will show some clinical (concerning population, intervention) and methodological heterogeneity.[54] Results will be displayed as forest plots. If it will not be possible to combine studies via meta-analysis, a narrative summary will be provided.[52 57]

Subgroup analysis and investigation of heterogeneity

To identify possible treatment effect moderators, a priori defined subgroup analyses (in case of categorical predictors) or metaregression 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 (eg, therapist-led or self-help intervention) or intervention dose (eg, frequency or duration of sessions). Differences between subgroups will be tested formally.[58 59]

Metaregression analysis will be performed using the restricted maximum likelihood estimate method, a

recommended random effects approach accounting for residual between-trial heterogeneity.[60]

In case of considerable heterogeneity between study results that cannot be explained by the a priori defined subgroup and metaregression analyses, a series of a posteriori (explorative) metaregression analyses will be performed to identify sources of heterogeneity. A priori and a posteriori analyses will be clearly labelled as such.

Sensitivity analysis

We will conduct sensitivity analyses regarding the primary effectiveness and acceptability outcomes. Sensitivity analyses will be performed excluding studies with a high or unclear risk of bias (separately for each of the seven domains according to the risk of bias tool of the *Cochrane Handbook*[52]) and/or with outlying findings. Additional sensitivity analyses will be performed excluding non-randomised trials to control for possible design effects. Further, differences in making the diagnosis will be addressed in sensitivity analyses by excluding those studies that did not use formal diagnostic criteria.

Ethics and dissemination

The systematic review aims to synthesise the current available evidence according efficacy and acceptability of metacognitive interventions for mental disorders. Our work intends to contributing to minimise a research gap and thereby enabling patients, physicians, guideline developers and policy-makers to make evidence-based decisions regarding treatment selection. The protocol of this review has been registered with the International Prospective Register of Systematic Reviews (PROSPERO), Protocol No. CRD42016051006. The review's start date was 15 November 2016, and it is expected to be completed by the end of 2017. The set of extracted data will be published as online supplementary material or will be available from the corresponding author.

We will ensure the dissemination of our results using multiple strategies including peer-reviewed open-access journal publications, conference presentations and executive summaries. Further, dissemination of results will be discussed in a second workshop with patients with mental disorders. The planned publication will be prepared according to the PRISMA statement.[50] Changes to this study protocol along with the rationale will be reported, if necessary.

Correction notice This paper has been amended since it was published Online First. Owing to a scripting error, some of the publisher names in the references were replaced with 'BMJ Publishing Group'. This only affected the full text version, not the PDF. We have since corrected these errors and the correct publishers have been inserted into the references.

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Contributors FK is the guarantor. All authors made substantial contributions to the conception and design of the work. LK provided statistical expertise, SM expertise on metacognitive interventions. FK, RM, AJ and LK drafted the article, and MH and SM revised it critically for important intellectual content. All authors read, provided feedback and approved the final manuscript.

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Competing interests SM has developed a metacognitive intervention and tested it in several studies as primary investigator. He will not select which trials to include, extract data from trials, undertake risk of bias assessments or carry out analyses. His participation will mainly focus on the contribution and discussion of clinical issues. LK has participated in the evaluation of a 22 metacognitive interventions as independent statistician. The other authors declare no conflicts of interest.

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