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Effectiveness and feasibility of internet- and mobile-based interventions for individuals experiencing bereavement: A systematic review protocol

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Complete List of Authors:	Luppa, Melanie; University of Leipzig Faculty of Medicine, Institute of Social Medicine, Occupational Health and Public Health Loebner, Margrit; University of Leipzig Faculty of Medicine, Institute of Social Medicine, Occupational Health and Public Health Pabst, Alexander Schlapke, Christiane; University of Leipzig Faculty of Medicine Stein, Janine; University of Leipzig Faculty of Medicine, Institute of Social Medicine, Occupational Health and Public Health Riedel-Heller, Steffi; University of Leipzig, Institute of Social Medicine, Occupational Health and Public Health (ISAP), Medical Faculty
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Effectiveness and feasibility of internet- and mobile-based interventions for individuals experiencing bereavement: A systematic review protocol

Luppa, Melanie; Loebner, Margrit; Pabst, Alexander; Schlapke, Christine, Stein, Janine; Riedel-Heller, Steffi G.

Corresponding author:

Melanie Luppa, PhD

Institute of Social Medicine, Occupational Health and Public Health, University of Leipzig, Faculty of Medicine

Philipp-Rosenthal-Straße 55

04103 Leipzig

Germany

Email: melanie.luppa@medizin-uni-leipzig.de

Phone: +49 341 9715406

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ABSTRACT

Introduction: Internet- and mobile-based interventions (IMIs) provide an innovative and efficient self-management tool for mental health problems. This systematic review aims to summarise and critically evaluate studies addressing the effectiveness and feasibility of IMIs for normal and complicated grief in bereaved adults.

Methods and Analysis: The databases MEDLINE, Cochrane Library, PsycINFO, EMBASE and Web of Science and Google Scholar (for "grey" literature) will be systematically searched for feasibility studies or randomized controlled trials of IMIs for bereaved adults who were experiencing normal/complicated grief. Data will be extracted and evaluated independently by two reviewers from studies eligible for inclusion. Quality of evidence will be assessed, and results will be synthesized qualitatively and pooled meta-analytically, if sufficient outcome data are available. PRISMA standards and GRADE methodology will be used.

Ethics and Dissemination: No primary data will be collected; thus, ethical approval is not required. The results will be disseminated through a peer-reviewed publication and conference presentations.

PROSPERO registration number: CRD42019131428

Keywords: grief, bereavement, systematic review, internet- and mobile-based, effectiveness, feasibility

Strengths and limitations of this study

- first study which provides a comprehensive summary of studies investigating effectiveness and feasibility of internet- and mobile-based interventions (IMIs) for normal and complicated grief in bereaved adults
- possibility of usage of these IMIs in healthcare as additional intervention tools as well as low-threshold treatment options
- application with the necessary caution of these IMIs seems to be required not to interfere with natural grief processes

Background

Self-management is an widely used approach within the medical health care system for improving patients' knowledge, capabilities and skills in managing their health problems. Internet- and mobile-based interventions (IMIs) provide an innovative and efficient self-management tool for mental health problems. In recent years, web-based self-management interventions have gained increasing attention as effective supplementary treatment elements to standard mental health treatment [1].

The effectiveness of IMIs has been shown for treating depression (e.g. [2-4]), anxiety (e.g. [5,6]), post-traumatic stress disorder (PTSD; e.g. [7-9]), and other mental health problems [1]. However, less is currently known about IMIs for individuals experiencing normal or complicated grief.

In general, grief is defined as a typical reaction to the loss of a significant other [10] , and is associated with symptoms such as intense subjective distress, loneliness, and somatic symptoms, e.g. tightness of the throat or need for sighing [11,12]. Recently, the concept of an abnormal reaction to loss has been proposed and is included as a disorder in the *Diagnostic Statistical Manual of Mental Disorders*, 5th Edition (*DSM-V*) and is expected to be included in the *International Statistical Classification of Diseases and Related Health Problems, 11th Revision* (*ICD-11*) as a new diagnosis. The disorders Complicated, Traumatic, or Prolonged Grief (subsequently summarized under complicated grief) and Complicated Grief are described as "a syndrome of prolonged and intense grief that is accompanied by complications that derail the progress of grief" [13]. In contrast to uncomplicated grief, clinically significant impairment in social, occupational, or other important areas of functioning must be present [13,14]. The diagnosis of complicated grief is given only after a period of six months following the index loss event if the person is still suffering from separation stress as well as cognitive, emotional, and behavioral symptoms [14].

Because grief can affect many areas of life [15,16] and is one of the major contributors to the development of mental health disorders, providing IMIs as a low-threshold treatment option may enable more people to receive treatment than through face-to-face interventions alone [17] to prevent the development of mental health disorders. Major Depression, Generalized Anxiety Disorder, and Post-Traumatic Stress Disorder are particularly closely related to the symptoms of complicated grief, but differences between the disorders have also been reported [14,18].

To date, a number of IMIs for bereavement problems exist in the international research literature. Internet-based Cognitive Behavioral Therapy (CBT) interventions were reported to be effective in treating patients with complicated grief [19] but not for those with uncomplicated grief [20]. Some researchers have urged caution in implementing interventions too early or across a wide range of bereavement-related distress so as to not interfere with natural grief processes [21,22]. One study showed that IMIs for PTSD improve symptoms of complicated grief [23]. To our knowledge, there are no previous systematic reviews summarizing the effectiveness and feasibility of IMIs for bereaved individuals – for normal as well as complicated grief. The results of this review and meta-analysis will therefore address this gap in the literature. This protocol describes the rationale and design of the planned systematic review and meta-analysis.

OBJECTIVES

The planned review aims to systematically evaluate and synthesize the evidence base of randomized controlled-trials (RCT)s reporting, the effectiveness of IMIs (i.e. improvement of objective parameters), and the feasibility of IMIs (e.g. usability, satisfaction, acceptability, understandability and usefulness) for individuals aged 18 years and older who experienced the death of a significant other. Depending on the number of eligible studies, assessment tools, and quality of the studies reported, we will also combine data across RCTs to estimate pooled effect sizes for the considered outcomes.

METHODS AND ANALYSIS

This protocol outlines the strategies for conducting a systematic review and meta-analysis of RCTs which examined the effectiveness of IMIs for bereavement. It is based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) for systematic review protocols (PRISMA-P) guidelines [24,25]. The protocol describes the planned strategy to systematically evaluate and synthesize data from randomized controlled trials and feasibility studies on IMIs for bereaved individuals. We will apply the four-phase PRISMA flow diagram (figure 1) for our study selection process.

Eligibility criteria

The systematic review will be divided into two parts: effectiveness studies and feasibility studies on IMIs (study design criteria) which include adults (18 years and older), who experienced the death of a significant other and were suffering from normal or complicated grief (participant criteria). Any measures of effectiveness (i.e. improvement of objective parameters) and feasibility (e.g. usability, satisfaction, acceptability, understandability and usefulness) (outcome criteria) of IMIs related to bereavement will be included. Onset data from clinician-rated scales will be prioritized over self-report questionnaires. The intervention must have been a psychological intervention according to Kampling et al. [26] criteria: cognitive behavioral therapy (CBT), psychodynamic psychotherapy, behavior therapy or behavior modification, systemic therapy, third wave cognitive behavioral therapy, humanistic therapy, integrative therapy or to other psychological-orientated interventions and must have been provided in an online setting (intervention criteria). In RCTs, the comparison group must be either 'treatment as usual', 'waiting list', 'attention placebo' (inactivity on the part of both researchers and participants), or 'psychological placebo' (activity on the part of participants and inactivity of researchers). We will consider articles that are written in either English or German (language criteria). The literature search will not be restricted by publication date.

Information sources and search strategy

Systematic literature searches will be conducted in the databases MEDLINE (PubMed interface), Cochrane Library (Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Methodology Register), PsycINFO, EMBASE, Web of Science (Science and Social Science Citation Index) and Google Scholar (for “grey” literature) by ML and CS independently. A combination of the following search terms will be used: (1) bereavement or widowhood or grief; and (2) online or web or computer or mobile or e-health or internet; and (3) intervention or psychotherapy or cognitive behavioural therapy or CBT. If feasible, medical subject headings (MeSH) will be used as search terms. The finalized MEDLINE search strategy will be adapted to the syntax and subject headings specifications of the other databases. We will initially screen titles and abstracts for eligibility. Full texts will then be assessed for criteria, and the reference lists of included articles and systematic reviews will be hand searched to identify further potentially relevant studies. Finally, we will conduct a grey literature search for unpublished studies using Google and Google Scholar with the above-named search terms. If applicable and

necessary, we will contact researchers directly to gather further relevant non-published data. The searches will be re-run just before the final analyses so that more recent studies can be retrieved.

Data management

References and data will be managed using the Review Manager (RevMan) software package version 5.3 (by the Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark, 2014). RevMan is specifically designed for managing and analyzing systematic review data from bibliographical management to data synthesis. If feasible, additional data analyses and meta-analysis will be conducted using Stata 13.1 SE (StataCorp LP, College Station, Texas, USA).

Selection process

All titles and abstracts of articles will be screened independently by two reviewers (ML, CS). At this stage, articles will be divided into potentially relevant, irrelevant or uncertain. Reasons for exclusion of irrelevant articles will be given. Potentially relevant and uncertain articles will be read in full text independently by ML and CS, and study eligibility based on the established criteria specified above will be assessed. At each stage of the selection process, any discrepancies will be discussed between the two reviewers. When discrepancies cannot be resolved, input from a third senior researcher (SRH) will be obtained.

Data collection process and data items

A standardized data extraction form will be used to extract data from included studies. Extracted data will include study characteristics, participant characteristics, methodological factors and outcome data. A pilot version of the data extraction form will be tested independently by the two reviewers (ML, CS) on a subsample of relevant studies to ensure correct extraction of all relevant data. Difficulties with data extraction will be discussed and the form will be adopted accordingly. Data from each study will be extracted by both reviewers (ML, CS) independently, and reliability of data extraction will be checked in a random sample of studies. Discrepancies between the two reviewers will be discussed with a senior researcher (SRH). Missing data will be requested from study authors.

The following data will be extracted:

(1) Study identification items: e.g. first author, year of publication, country

(2) Study design characteristics: e.g. sample size, recruitment strategy, interventions design/type, control group, type of assessment, inclusion/exclusion criteria, duration of intervention, length of follow-up assessments

(3) Participants characteristics: e.g. mean age, age range, gender

(4) Methodological aspects: risk of bias, study limitations

(5) Outcomes: effectiveness (i.e. improvement of objective parameters) and feasibility (e.g. usability, satisfaction, acceptability, understandability and usefulness); (serious) adverse events (e. g. disability, hospitalization, death); onset data from clinician-rated scales will be prioritized over self-report questionnaires. All different time frames of follow-up assessments will be included.

Quality assessment

The methodological quality of included studies will be assessed by two researchers (ML, CS) independently using the Cochrane Collaboration Tool for Assessing Risk of Bias in RCTs [27]. As recommended, each study will be assessed in the following domains: (1) selection bias, i.e. descriptions of the (1a) method of randomisation and (1b) concealment of allocation; (2) performance bias, i.e. description of the methods of blinding participants and researchers; (3) detection bias, i.e. description of the methods of blinding outcome assessment; (4) attrition bias, i.e. description of incomplete outcome data; (5) reporting bias, i.e. description of selective outcome reporting; and (6) other bias, i.e. description of important concerns about other biases. Studies will be rated as 'high', 'low', or 'unclear'. These assessments will be used to inform the corresponding GRADE assessment of study limitations (see table 5.6 of the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) handbook [28]. Specifically, 'low risk of bias' would indicate 'no limitation'; 'unclear risk of bias' would indicate either 'no limitation' or 'serious limitation'; and 'high risk of bias' would indicate either 'serious limitation' or 'very serious limitation' in the GRADE approach. Any disagreement between the two reviewers will be resolved by discussions with involvement of a third review author where necessary. Study authors will be contacted for further methodological information if needed. In the risk of bias table, results of the judgements will be shown for each domain.

Data synthesis and presentation

A detailed description of the results for all included studies will be provided in text and tables. Characteristics of selected studies will be listed and qualitatively described (see listed parameter in "data collection process"). Characteristics of the study, sample, intervention and control condition will be presented first, followed by outcome measurements, effect sizes, and overall results. We will provide a narrative synthesis and if appropriate, a quantitative meta-analysis using funnel and forest plots and pooled statistics. If feasible, results of pooled age- and gender-specific outcomes will be reported.

Data analyses will be performed using Review Manager 5.3 software from the Cochrane Collaboration Tool for Implementing the Characteristics of Studies (Review Manager (RevMan) [Computer program], 2014).

Meta-analysis

Meta-analysis of pooled data will be based on the assessment of clinical, methodological and statistical heterogeneity. According Cochrane standards, meta-analysis will not be performed if high levels of heterogeneity and/or variation in the effects of the interventions are present.

Heterogeneity in study characteristics will be evaluated using forest plots and I^2 statistics. An I^2 of >60% indicates substantial heterogeneity and requires exploration of the sources of heterogeneity in subgroups of studies (Higgins et al. 2011). Depending on the level of observed heterogeneity, fixed-effect, random-effect or mixed-effect models will be used to estimate the pooled effects on outcomes and to quantify the uncertainty of these estimates. If sufficient data are available, subgroup analyses based on the content and form of intervention will be performed. Finally, in order to evaluate the association of sociodemographic variables with pooled effect sizes, meta-regression models will be fitted.

We will follow the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011) to deal with missing data.

Discussion

The planned systematic review will provide a comprehensive summary of the effectiveness and feasibility of internet- and mobile-based interventions for adults who suffer from bereavement.

If treatment programs for bereavement which utilize either the Internet or mobile phone technology show effectiveness and feasibility, this therapeutic delivery method has the potential to become an additional intervention tool. Internet-based interventions can reach more people than face-to-face interventions (Muñoz 2010). Their cost-effectiveness for depression [29] and anxiety disorders [30,31] have also been demonstrated. Because of a prevalence rate of 3.7% for complicated grief in Germany [32], a low-threshold treatment option would enable the provision of adequate care to more bereaved adults.

If there are an insufficient number of studies that have examined gender and age differences, this will be discussed in terms of a need for future research. Second, this review could motivate other researchers to construct and test in randomized trials new or modified internet- or mobile-based interventions for bereaved adults.

Amendments

In the event of protocol amendments, we will provide the date, a description of and rationale for of each amendment.

Abbreviations

CBT – cognitive behavioural therapy

CENTRAL - Cochrane Central Register of Controlled Trials

GRADE - Grades of Recommendation, Assessment, Development and Evaluation

IMI - Internet- and mobile-based interventions

PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analysis

PTSD - post-traumatic stress disorder

RCT - randomized controlled-trials

Declarations section

Ethics Approval and Consent to Participate

Ethical approval and consent to participate are not required as no primary data will be collected. The results of this systematic review are intended to be published in an international peer-reviewed journal. Results may also be presented at relevant professional conferences and meetings.

Availability of supporting data

Not applicable

Competing interest

None declared

Funding

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Author Contributions

ML and CS are the guarantors of the systematic review. ML and CS drafted the manuscript. All authors contributed to the conception and design of the review. ML, MLö and CS developed the search strategy. ML, MLö, AP and CS developed the methodological approach. ML, MLö and SRH critically revised the protocol for important intellectual content.

Acknowledgement

Not applicable

Author's information

All authors approved the final version of the manuscript.

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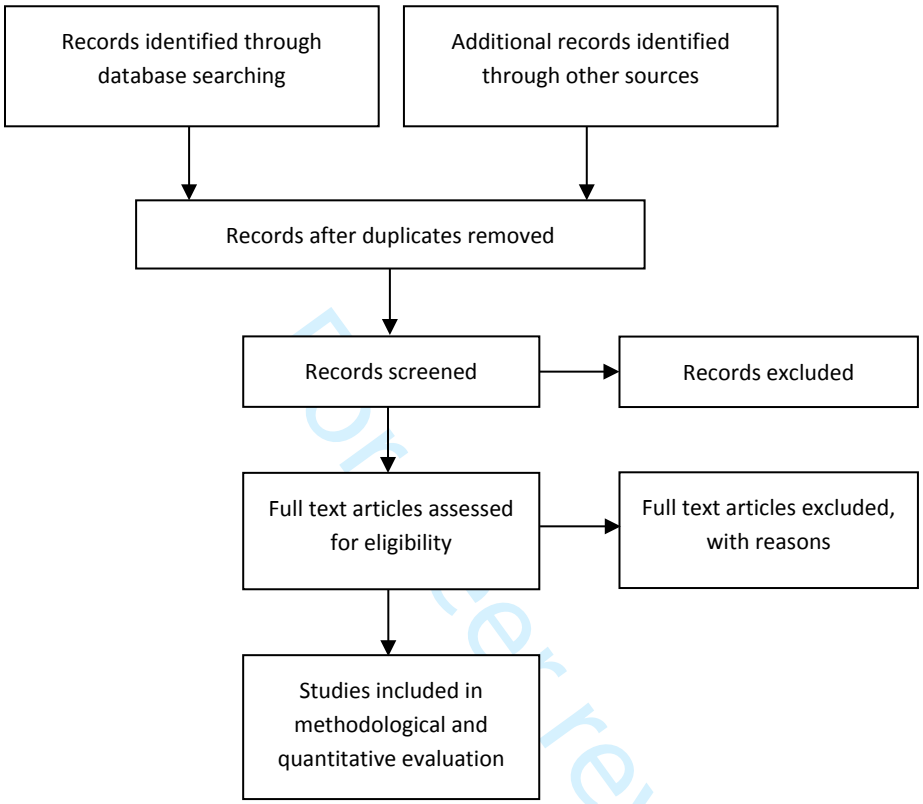

Figure 1. Flow diagram of the planned study selection process adapted from the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement.

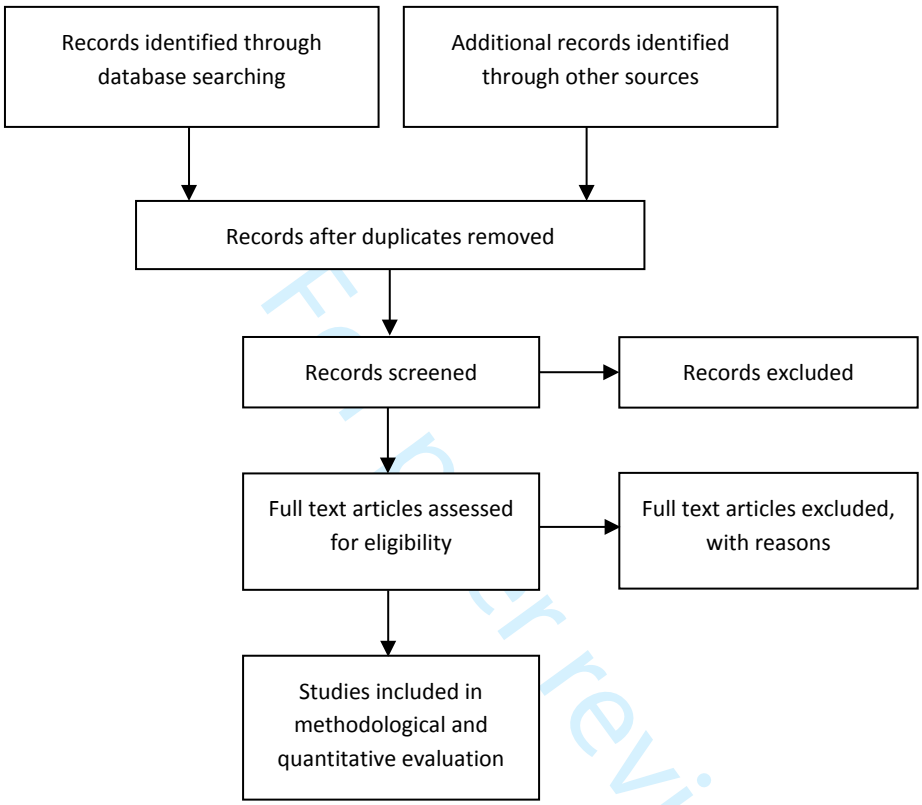

Figure 1. Flow diagram of the planned study selection process adapted from the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement.

PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	x	☐	2
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☐	n/a
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	x	☐	41
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	x	☐	15-22
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	x	☐	392-396
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☐	☐	n/a
Support					
Sources	5a	Indicate sources of financial or other support for the review	x	☐	386-389
Sponsor	5b	Provide name for the review funder and/or sponsor	x	☐	386-389
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	x	☐	386-389
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	x	☐	83-94
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	x	☐	97-103
METHODS					

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	x	☐	128-145
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	x	☐	146-203
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	x	☐	146-203
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	x	☐	206-212
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	x	☐	214-221
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	x	☐	223-245
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	x	☐	247-258
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	x	☐	254-258
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	x	☐	260-286
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	x	☐	288-298
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	x	☐	288-298
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	x	☐	294-295
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	x	☐	288-298
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	x	☐	305-328
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	x	☐	260-286

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Complete List of Authors:	Luppa, Melanie; University of Leipzig Faculty of Medicine, Institute of Social Medicine, Occupational Health and Public Health Loebner, Margrit; University of Leipzig Faculty of Medicine, Institute of Social Medicine, Occupational Health and Public Health Pabst, Alexander; University of Leipzig Faculty of Medicine, Institute of Social Medicine, Occupational Health and Public Health Schlapke, Christiane; University of Leipzig Faculty of Medicine, Institute of Social Medicine, Occupational Health and Public Health Stein, Janine; University of Leipzig Faculty of Medicine, Institute of Social Medicine, Occupational Health and Public Health Riedel-Heller, Steffi; University of Leipzig Faculty of Medicine, Institute of Social Medicine, Occupational Health and Public Health
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Effectiveness and feasibility of internet- and mobile-based interventions for individuals experiencing bereavement: A systematic review protocol

Luppa, Melanie[1]; Loebner, Margrit[1]; Pabst, Alexander[1]; Schlapke, Christiane[1], Stein, Janine[1]; Riedel-Heller, Steffi G. [1]

[1] Institute of Social Medicine, Occupational Health and Public Health, Faculty of Medicine, University of Leipzig

Corresponding author:

Melanie Luppa, PhD

Institute of Social Medicine, Occupational Health and Public Health, Faculty of Medicine, University of Leipzig

Philipp-Rosenthal-Straße 55

04103 Leipzig

Germany

Email: Melanie.Luppa@medizin.uni-leipzig.de

Phone: +49 341 9715406

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ABSTRACT

Introduction: Internet- and mobile-based interventions (IMIs) provide an innovative and efficient self-management tool for mental health problems. This systematic review aims to summarise and critically evaluate studies addressing the effectiveness and feasibility of IMIs for normal and complicated grief in bereaved adults.

Methods and Analysis: The databases MEDLINE, Cochrane Library, PsycINFO, EMBASE and Web of Science and Google Scholar (for "grey" literature) will be systematically searched for feasibility studies or randomized controlled trials of IMIs for bereaved adults who were experiencing normal/complicated grief. Data will be extracted and evaluated independently by two reviewers from studies eligible for inclusion. Quality of evidence will be assessed, and results will be synthesized qualitatively and pooled meta-analytically, if sufficient outcome data are available. PRISMA standards and GRADE methodology will be used.

Ethics and Dissemination: No primary data will be collected; thus, ethical approval is not required. The results will be disseminated through a peer-reviewed publication and conference presentations.

PROSPERO registration number: CRD42019131428

Keywords: grief, bereavement, systematic review, internet- and mobile-based, effectiveness, feasibility

Strengths and limitations of this study

- first study which provides a comprehensive summary of studies investigating effectiveness and feasibility of internet- and mobile-based interventions (IMIs) for normal and complicated grief in bereaved adults
- possibility of usage of these IMIs in healthcare as additional intervention tools as well as low-threshold treatment options
- application with the necessary caution of these IMIs seems to be required not to interfere with natural grief processes

Background

Self-management is a widely used approach within the medical health care system for improving patients' knowledge, capabilities and skills in managing their health problems. Internet- and mobile-based interventions (IMIs) provide an innovative and efficient self-management tool for mental health problems. In recent years, web-based self-management interventions have gained increasing attention as effective supplementary treatment elements to standard mental health treatment[1].

The effectiveness of IMIs has been shown for treating depression (e.g.[2-4]), anxiety (e.g.[5,6]), post-traumatic stress disorder (PTSD; e.g.[7-9]), and other mental health problems[1]. However, less is currently known about IMIs for individuals experiencing normal or complicated grief.

In general, grief is defined as a typical reaction to the loss of a significant other[10] , and is associated with symptoms such as intense subjective distress, loneliness, and somatic symptoms, e.g. tightness of the throat or need for sighing[11,12]. Recently, the concept of an abnormal reaction to loss has been proposed and is included as a disorder in the *Diagnostic Statistical Manual of Mental Disorders*, 5th Edition (*DSM-V*) and is expected to be included in the *International Statistical Classification of Diseases and Related Health Problems, 11th Revision* (*ICD-11*) as a new diagnosis. The disorders Complicated, Traumatic, or Prolonged Grief (subsequently summarized under complicated grief) and Complicated Grief are described as "a syndrome of prolonged and intense grief that is accompanied by complications that derail the progress of grief"[13]. In contrast to uncomplicated grief, clinically significant impairment in social, occupational, or other important areas of functioning must be present[13,14]. The diagnosis of complicated grief is given only after a period of six months following the index loss event if the person is still suffering from separation stress as well as cognitive, emotional, and behavioral symptoms[14].

Because grief can affect many areas of life[15,16] and is one of the major contributors to the development of mental health disorders, providing IMIs as a low-threshold treatment option may enable more people to receive treatment than through face-to-face interventions alone[17] to prevent the development of mental health disorders. Major Depression, Generalized Anxiety Disorder, and Post-Traumatic Stress Disorder are particularly closely related to the symptoms of complicated grief, but differences between the disorders have also been reported[14,18].

To date, a number of IMIs for bereavement problems exist in the international research literature. Internet-based Cognitive Behavioral Therapy (CBT) interventions were reported to be effective in treating patients with complicated grief[19] but not for those with uncomplicated grief[20]. Some researchers have urged caution in implementing interventions too early or across a wide range of bereavement-related distress so as to not interfere with natural grief processes[21,22]. One study showed that IMIs for PTSD improve symptoms of complicated grief[23]. To our knowledge, there are no previous systematic reviews summarizing the effectiveness and feasibility of IMIs for bereaved individuals – for normal as well as complicated grief. The results of this review and meta-analysis will therefore address this gap in the literature. This protocol describes the rationale and design of the planned systematic review and meta-analysis.

OBJECTIVES

The planned review aims to systematically evaluate and synthesize the evidence base of randomized controlled-trials (RCT)s reporting, the effectiveness of IMIs (i.e. improvement of objective parameters), and the feasibility of IMIs (e.g. usability, satisfaction, acceptability, understandability and usefulness) for individuals aged 18 years and older who experienced the death of a significant other. Depending on the number of eligible studies, assessment tools, and quality of the studies reported, we will also combine data across RCTs to estimate pooled effect sizes for the considered outcomes.

METHODS AND ANALYSIS

This protocol outlines the strategies for conducting a systematic review and meta-analysis of RCTs which examined the effectiveness of IMIs for bereavement. It is based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) for systematic review protocols (PRISMA-P) guidelines[24,25]. The protocol describes the planned strategy to systematically evaluate and synthesize data from randomized controlled trials and feasibility studies on IMIs for bereaved individuals. We will apply the four-phase PRISMA flow diagram (figure 1) for our study selection process.

Eligibility criteria

The systematic review will be divided into two parts: effectiveness studies and feasibility studies on IMIs (study design criteria) which include adults (18 years and older), who experienced the death of a significant other and were suffering from normal or complicated grief (participant criteria). Any measures of effectiveness (i.e. improvement of objective parameters) and feasibility (e.g. usability, satisfaction, acceptability, understandability and usefulness) (outcome criteria) of IMIs related to bereavement will be included. Onset data from clinician-rated scales will be prioritized over self-report questionnaires. The intervention must have been a psychological intervention according to Kampling et al.[26] criteria: cognitive behavioral therapy (CBT), psychodynamic psychotherapy, behavior therapy or behavior modification, systemic therapy, third wave cognitive behavioral therapy, humanistic therapy, integrative therapy or to other psychological-orientated interventions and must have been provided in an online setting (intervention criteria). In RCTs, the comparison group must be either 'treatment as usual', 'waiting list', 'attention placebo' (inactivity on the part of both researchers and participants), or 'psychological placebo' (activity on the part of participants and inactivity of researchers). We will consider articles that are written in either English or German (language criteria). The literature search will not be restricted by publication date.

Information sources and search strategy

Systematic literature searches will be conducted in the databases MEDLINE (PubMed interface), Cochrane Library (Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Methodology Register), PsycINFO, EMBASE, Web of Science (Science and Social Science Citation Index) and Google Scholar (for “grey” literature) by ML and CS independently. A combination of the following search terms will be used: (1) bereavement or widowhood or grief; and (2) online or web or computer or mobile or e-health or internet; and (3) intervention or psychotherapy or cognitive behavioural therapy or CBT. The draft of the full MEDLINE search strategy is available in online supplementary appendix 1. If feasible, medical subject headings (MeSH) will be used as search terms. The finalized MEDLINE search strategy will be adapted to the syntax and subject headings specifications of the other databases. We will initially screen titles and abstracts for eligibility. Full texts will then be assessed for criteria, and the reference lists of included articles and systematic reviews will be hand searched to identify further potentially relevant studies. Finally, we will conduct a grey literature search for unpublished studies

using Google and Google Scholar with the above-named search terms. If applicable and necessary, we will contact researchers directly to gather further relevant non-published data. The searches will be re-run just before the final analyses so that more recent studies can be retrieved.

Data management

References and data will be managed using the Review Manager (RevMan) software package version 5.3 (by the Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark, 2014). RevMan is specifically designed for managing and analyzing systematic review data from bibliographical management to data synthesis. If feasible, additional data analyses and meta-analysis will be conducted using Stata 13.1 SE (StataCorp LP, College Station, Texas, USA).

Selection process

All titles and abstracts of articles will be screened independently by two reviewers (ML, CS). At this stage, articles will be divided into potentially relevant, irrelevant or uncertain. Reasons for exclusion of irrelevant articles will be given. Potentially relevant and uncertain articles will be read in full text independently by ML and CS, and study eligibility based on the established criteria specified above will be assessed. At each stage of the selection process, any discrepancies will be discussed between the two reviewers. When discrepancies cannot be resolved, input from a third senior researcher (SRH) will be obtained.

Data collection process and data items

A standardized data extraction form will be used to extract data from included studies. Extracted data will include study characteristics, participant characteristics, methodological factors and outcome data. A pilot version of the data extraction form will be tested independently by the two reviewers (ML, CS) on a subsample of relevant studies to ensure correct extraction of all relevant data. Difficulties with data extraction will be discussed and the form will be adopted accordingly. Data from each study will be extracted by both reviewers (ML, CS) independently, and reliability of data extraction will be checked in a random sample of studies. Discrepancies between the two reviewers will be discussed with a senior researcher (SRH). Missing data will be requested from study authors.

The following data will be extracted:

(1) Study identification items: e.g. first author, year of publication, country

(2) Study design characteristics: e.g. sample size, recruitment strategy, inclusion/exclusion criteria, circumstances of the loss (e.g. violent death, suicide), control group, diagnostic criteria/assessment of normal/prolonged/complicated grief, assessment of co-occurring conditions (e. g. Major Depression, Posttraumatic stress disorder, concurrent pharmaco-/psychotherapy), assessment of suicidal ideation or behaviour, interventions design/type, duration of intervention, length of follow-up assessments

(3) Participants characteristics: e.g. mean age, age range, gender

(4) Methodological aspects: risk of bias, study limitations

(5) Outcomes: (a) Effectiveness: Primary outcome measures: reduction of grief symptoms; Secondary outcome measures: reduction of depression, anxiety, somatization or PTS symptoms or suicidal ideation or behaviour) and (b) feasibility: usability, satisfaction, acceptability, understandability and usefulness;; onset data from clinician-rated scales will be prioritized over self-report questionnaires. All different time frames of follow-up assessments will be included.

Quality assessment

The methodological quality of included studies will be assessed by two researchers (ML, CS) independently using the Cochrane Collaboration Tool for Assessing Risk of Bias in RCTs[27]. As recommended, each study will be assessed in the following domains: (1) selection bias, i.e. descriptions of the (1a) method of randomisation and (1b) concealment of allocation; (2) performance bias, i.e. description of the methods of blinding participants and researchers; (3) detection bias, i.e. description of the methods of blinding outcome assessment; (4) attrition bias, i.e. description of incomplete outcome data; (5) reporting bias, i.e. description of selective outcome reporting; and (6) other bias, i.e. description of important concerns about other biases. Studies will be rated as 'high', 'low', or 'unclear'. These assessments will be used to inform the corresponding GRADE assessment of study limitations (see table 5.6 of the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) handbook[28]. Specifically, 'low risk of bias' would indicate 'no limitation'; 'unclear risk of

bias' would indicate either 'no limitation' or 'serious limitation'; and 'high risk of bias' would indicate either 'serious limitation' or 'very serious limitation' in the GRADE approach. Any disagreement between the two reviewers will be resolved by discussions with involvement of a third review author where necessary. Study authors will be contacted for further methodological information if needed. In the risk of bias table, results of the judgements will be shown for each domain.

Data synthesis and presentation

A narrative synthesis for all included studies and relevant characteristics listed under 'data collection process' will be provided in text and 'summary of findings' tables. Characteristics of the study, sample, intervention and control condition will be presented first, followed by outcome measurements, effect sizes, and overall results.

Only studies that provide a quantitative measure of grief symptoms will be included in the meta-analysis. We will analyze heterogeneity by providing I^2 statistics and funnel and forest plots. According to the Cochrane standards, we suppose a moderate level of heterogeneity between studies for I^2 values ranging from 30% to 60%[29]. If studies fail to show sufficient heterogeneity (I^2 <60%) in at least two trials[30], meta-analytic pooling will not be undertaken. However, inconsistency may occur from differences in study characteristics[29]. Therefore, we will explore sources of heterogeneity in subgroups of studies in terms of type of grief or intervention type. A random effects model will be applied. We will estimate standardized mean difference values and the respective 95% confidence intervals. We will follow the Cochrane Handbook for Systematic Reviews of Interventions[27] to deal with missing data.

Data analyses will be performed using Review Manager 5.3 software from the Cochrane Collaboration Tool for Implementing the Characteristics of Studies (Review Manager (RevMan) [Computer program], 2014).

Patient and Public Involvement

No patient involved. Discussion

The planned systematic review will provide a comprehensive summary of the effectiveness and feasibility of internet- and mobile-based interventions for adults who suffer from bereavement.

If treatment programs for bereavement which utilize either the Internet or mobile phone technology show effectiveness and feasibility, this therapeutic delivery method has the potential to become an additional intervention tool. Internet-based interventions can reach more people than face-to-face interventions[17] . Their cost-effectiveness for depression[31] and anxiety disorders[32,33] have also been demonstrated. Because of a prevalence rate of 3.7% for complicated grief in Germany[34], a low-threshold treatment option would enable the provision of adequate care to more bereaved adults.

If there are an insufficient number of studies that have examined gender and age differences, this will be discussed in terms of a need for future research. Second, this review could motivate other researchers to construct and test in randomized trials new or modified internet- or mobile-based interventions for bereaved adults.

Amendments

In the event of protocol amendments, we will provide the date, a description of and rationale for of each amendment.

Abbreviations

CBT – cognitive behavioural therapy

CENTRAL - Cochrane Central Register of Controlled Trials

GRADE - Grades of Recommendation, Assessment, Development and Evaluation

IMI - Internet- and mobile-based interventions

PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analysis

PTSD - post-traumatic stress disorder

RCT - randomized controlled-trials

Declarations section

Ethics Approval and Consent to Participate

Ethical approval and consent to participate are not required as no primary data will be collected. The results of this systematic review are intended to be published in an international peer-reviewed journal. Results may also be presented at relevant professional conferences and meetings.

Availability of supporting data

Not applicable

Competing interest

None declared

Funding

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Author Contributions

ML, CS, AP, MLö, JS, SRH contributed substantially to the conception of the work; ML and CS drafted the manuscript; AP, MLö, JS, SRH revised the manuscript critically for important intellectual content; ML, CS, AP, MLö, JS, SRH finally approved the version to be published. ML, CS, AP, MLö, JS, SRh gave agreement to be accountable for all aspects of the work.

Acknowledgement

Not applicable

Author's information

All authors approved the final version of the manuscript.

Figure legend

Figure 1. Flow diagram of the planned study selection process adapted from the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement

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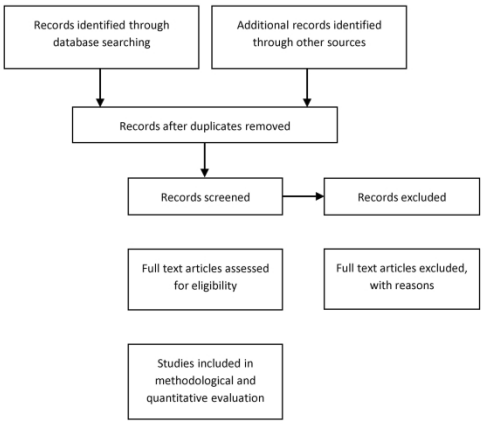

Figure 1. Flow diagram of the planned study selection process adapted from the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement

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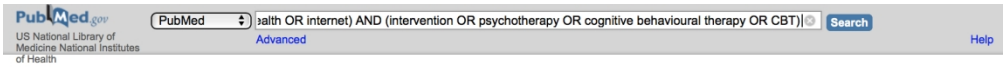

Search Details

Query Translation:

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(("bereavement"[MeSH Terms] OR "bereavement"[All Fields]) OR
("widowhood"[MeSH Terms] OR "widowhood"[All Fields]) OR ("grief"
[MeSH Terms] OR "grief"[All Fields])) AND (online[All Fields] OR
web[All Fields] OR ("computers"[MeSH Terms] OR "computers"[All
Fields] OR "computer"[All Fields]) OR mobile[All Fields] OR e-
health[All Fields] OR ("internet"[MeSH Terms] OR "internet"[All
Fields])) AND (("methods"[MeSH Terms] OR "methods"[All Fields] OR
"intervention"[All Fields]) OR ("psychotherapy"[MeSH Terms] OR
"psychotherapy"[All Fields]) OR ("cognitive behavioral therapy"
[MeSH Terms] OR ("cognitive"[All Fields] AND "behavioral"[All
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Search URL

Result:

273

Translations:

bereavement	"bereavement"[MeSH Terms] OR "bereavement"[All Fields]
widowhood	"widowhood"[MeSH Terms] OR "widowhood"[All Fields]
grief	"grief"[MeSH Terms] OR "grief"[All Fields]
computer	"computers"[MeSH Terms] OR "computers"[All Fields] OR "computer"[All Fields]
internet	"internet"[MeSH Terms] OR "internet"[All Fields]
intervention	"methods"[MeSH Terms] OR "methods"[All Fields] OR "intervention"[All Fields]
psychotherapy	"psychotherapy"[MeSH Terms] OR "psychotherapy"[All Fields]
cognitive behavioural therapy	"cognitive behavioral therapy"[MeSH Terms] OR ("cognitive"[All Fields] AND "behavioral"[All Fields] AND "therapy"[All Fields]) OR "cognitive behavioral therapy"[All Fields] OR ("cognitive"[All Fields] AND "behavioural"[All Fields] AND "therapy"[All Fields]) OR "cognitive behavioural therapy"[All Fields]

Database:

PubMed

User query:

(bereavement OR widowhood OR grief) AND (online OR web OR computer OR mobile OR e-health OR internet) AND (intervention OR psychotherapy OR cognitive behavioural therapy OR CBT)

PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	x	☐	2
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☐	n/a
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	x	☐	41
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	x	☐	15-22
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	x	☐	392-396
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☐	☐	n/a
Support					
Sources	5a	Indicate sources of financial or other support for the review	x	☐	386-389
Sponsor	5b	Provide name for the review funder and/or sponsor	x	☐	386-389
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	x	☐	386-389
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	x	☐	83-94
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	x	☐	97-103
METHODS					

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	x	☐	128-145
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	x	☐	146-203
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	x	☐	146-203
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	x	☐	206-212
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	x	☐	214-221
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	x	☐	223-245
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	x	☐	247-258
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	x	☐	254-258
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	x	☐	260-286
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	x	☐	288-298
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	x	☐	288-298
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	x	☐	294-295
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	x	☐	288-298
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	x	☐	305-328
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	x	☐	260-286