MENTUPP

Systematic review protocol registered

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Full Name	Short Name	Beneficiary Number	Role
UNIVERSITY COLLEGE CORK – NATIONAL UNIVERSITY OF IRELAND, CORK	UCC	1	Coordinator
EUROPEAN ALLIANCE AGAINST DEPRESSION EV	EAAD	2	Beneficiary
KATHOLIEKE UNIVERSITEIT LEUVEN	KU Leuven	3	Beneficiary
DET NATIONALE FORSKNINGSCENTER FORARBEJDSMILJO	NRCWE	4	Beneficiary
TERVEYDEN JA HYVINVOINNIN LAITOS	THL	5	Beneficiary
THE UNIVERSITY OF STIRLING	NMAHP-RU	6	Beneficiary
SEMMELWEIS EGYETEM	SEM	7	Beneficiary
STICHTING KENNISCENTRUM PHRENOS	PHRENOS	8	Beneficiary
QENDRES SE SHENDETIT DHE MIREQENIES KOMUNITARE	CCHW	9	Beneficiary
ZYRA PER SHENDET MENDOR	ZSMKOS	10	Beneficiary
LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE ROYAL CHARTER	LHSTM	11	Beneficiary
CONSORCIO MAR PARC DE SALUT DE BARCELONA	IMIM	12	Beneficiary
NATIONAL SUICIDE RESEARCH FOUNDATION	NSRF	13	Beneficiary
INTERNATIONAL ASSOCIATION FOR SUICIDE PREVENTION	IASP	14	Beneficiary
PINTAIL LTD	PT	15	Beneficiary
GRIFFITH UNIVERSITY	AISRAP	16	Beneficiary
MATES IN CONSTRUCTION (AUST) LTD	MIC	17	Beneficiary

D3.1 SYSTEMATIC REVIEW PROTOCOL

Version History

Version number (date)	Details
1.0 (01.05.20)	Initial submission to EC
2.0 (19.03.21)	Changed MINDUP to MENTUPP throughout the deliverable

1 Executive Summary

MENTUPP Workpackage 3 focusses on the Development of Interventions for Depressive Disorders and Comorbid Anxiety – or MENTUPP Component B. As a first step to creating the evidence base to inform the MENTUPP Component B tools, the extant literature was reviewed. As no relevant review summarizing the evidence for the prevention and treatment of depression and anxiety in small- and medium-enterprises (SMEs) had already been carried out, a protocol was written and submitted to PROSPERO for a systematic review into this area.

IMIM is leading MENTUPP task 3.1 (Systematic Review) and has designed a search strategy aimed at retrieving studies on interventions to raise awareness and improve early identification of depression and comorbid anxiety among SME employees and employers. This search strategy, together with specific inclusion and exclusion criteria, is an integral part of the protocol that was developed and submitted to the international register PROSPERO (https://www.crd.york.ac.uk/prospero/).

2 Introduction & Background

MENTUPP aims to improve mental health and wellbeing in the workplace by developing, implementing and evaluating a comprehensive, multilevel intervention targeting both clinical (depressive, anxiety disorders) and non-clinical (stress, burnout, wellbeing, depressive symptoms) mental health issues, as well as combating the stigma of mental (ill-) health. WP3 will develop the Component B tools of the MENTUPP intervention, focused on clinical depressive disorders and comorbid anxiety, specifically adapted to employees and employers of SMEs in construction, health and ICT. The developed tools, as well as adapted self-assessment tools for depression and anxiety, will be made available through the MENTUPP-Hub (WP6) and will be optimised by WP2 post-pilot (WPs 7, 8) before implementation in the cRCT (WPs 8, 9). The systematic review protocol is a key first step in defining the evidence base for the development of the Component B tools of the MENTUPP intervention focused on clinical depressive disorders and comorbid anxiety. Input was provided by the staff at IMIM and EAAD and there were no dependencies for this first step on other work packages, although the process was closely aligned to deliverable D2.1 of the systematic review protocol for WP2.

This deliverable (D3.1), the systematic review protocol, spells out the methodology for the systematic reviews. Once accepted in the register, the protocol will remain publicly posted on the PROSPERO website (https://www.crd.york.ac.uk/prospero/) to foster transparency and replicability. The successful completion of this deliverable is directly related to the overall objective of the project to reduce depression, anxiety and suicide in the SME workplace, as a review of the research carried out to date will provide an evidence base for creating the educational material and online tools. Ensuring

a solid evidence base for the intervention package will contribute heavily to the efficacy of the pilot intervention.

3 Approach

To define the approach for the systematic review protocol, the work was based on the attached guidelines for formulating systematic reviews created by a member of the IMIM group Joan Carles Medina titled “Easy guide for reviews and meta-analyses” (Appendix 1). Firstly, staff at IMIM and EAAD reviewed existing literature to see if any current reviews existed on the search topic. While the extant literature has numerous reviews into workplace-based interventions into symptoms of anxiety and depression, only one review had focused on clinical depression and none were in the context of SMEs. Thus, there was a clear need to focus the systematic review in interventions in this context and the review’s main objective was decided. Next, staff at IMIM carried out a scoping review using different search terms to optimise the search strategy. Once the review question and search strategy were clearly defined, the PROSPERO protocol was filled out and submitted on 28/10/2019. This protocol was developed after the MENTUPP Grant application was approved but before the start date of the project. IMIM performed this initial work to get started with tasks for the systematic review in WP3, without cost to the commission.

4 Results

The final output of this process was the completion of the Prospero draft, completed on 28th October 2019, please see Appendix 2. Based on the scoping search, the review protocol was created to answer the questions of 1) how effective are work-based psychosocial interventions in improving symptoms of depression, anxiety and/or suicidal ideation in employees and owners/managers of small- and medium-sized enterprises, as compared to controls, and 2) in addition, of work-based psychosocial interventions shown to be effective in the reduction of symptoms of depression, anxiety and/or suicidal ideation, does the evidence support one intervention as being more effective than others?

It was decided in the protocol to search a wide range of databases (PsycINFO, Pubmed, Scopus) as well as grey literature sources (BIOSIS Previews, Clinical Trials, Cochrane CENTRAL, ISRCTN Registry) to source the widest range of available literature. The systematic review protocol states the review will be carried out according to PRISMA guidelines. Articles in English or Spanish will be screened in a two phase procedure independently by two researchers with discrepancies resolved in a consensus meeting with a third researcher. The data to be extracted will be: 1) number of participants (intention-to-treat and completers); (2) type and characteristics of intervention; (3) type and characteristics of control intervention (if any); (4) relevant outcomes in terms of depression, anxiety and suicidal

ideation; (5) instruments used to measure outcomes. In order to assess the quality of all included studies with measurable mental health outcomes, the Quality Assessment Tool for Quantitative Studies (QATQS; https://merst.ca/ephpp/) will be used.

5 Impact & Conclusion

Once the Prospero protocol was registered, Prospero advised there was a delay on approvals and work could begin immediately on carrying out the systematic review before Prospero acceptance. Therefore, the team at IMIM and EAAD were able to carry out the review in alignment with the submitted protocol. The results of this review will feed directly into the consultation with experts (D3.2) and publishing of the systematic review (D3.4), and the results of this deliverable and D3.2 combined will inform the content for the educational material and online tools package for the pilot (D3.3), prior to tools being optimised (D3.5) and implemented on a wider scale (D3.6). This deliverable is also aligned directly with the systematic review protocol deliverable for WP2 (D2.1).

In conclusion, meeting this deliverable is a key first step in the development of the Component B MENTUPP tools.

6 Appendices

Appendix 1 ‘Easy guide for reviews and meta-analyses’ by Joan Carles Medina

Appendix 2 Systematic Review Protocol submitted to Prospero

Appendix 3 Acknowledgement from Prospero/registration number

EASY PATHWAY TO SYSTEMATIC REVIEWS AND META-ANALYSES

A 22-step guide

Joan C. Medina, Ph.D.

1. Check if it has already been done recently (search Scopus, MEDLINE, PsycInfo…) or is currently being done (search PROSPERO; https://www.crd.york.ac.uk/PROSPERO/). If so, seek alliances with authors!

2. Read PRISMA guidelines (http://www.prisma-statement.org/) and prepare your future manuscript.

3. Write a draft PROSPERO protocol using the PICOS (i.e., Population, Intervention, Comparison, Outcomes and Study design) for your research question and design the search strategy (i.e., search terms).

4. Conduct a scoping search: light search to refine your search strategy and to anticipate how much literature is available (this may influence your PROSPERO draft). Repeat steps 3 and 4 until the search strategy is optimal.

5. Register the protocol in PROSPERO and wait for acceptance (SAVE BOTH DATES): REGISTERED: dd/mm/yyyy – ACCEPTED: dd/mm/yyyy – REGISTRATION NUMBER:

6. Conduct the search (SAVE THE DATE: dd/mm/yyyy), taking notes on the number of studies retrieved in each source, and exporting results in all cases (WITH ABSTRACT). The search typically includes **Scopus**, **MEDLINE** and **PsycInfo** [primary literature]; as well as **BIOSIS**, **Clinical Trials**, Cochrane **CENTRAL**, and **ISRCTN** Registry [grey literature].

6.1. Results from all primary literature sources and Cochrane CENTRAL can be exported in **".ris"** format.

6.2. BIOSIS results can be exported in **".ciw"** format.

6.3. Differently, Clinical Trials and the ISRCTN Registry require a more manual approach. Chose to search only trials with results and distribute the terms of your search strategy among the different boxes available. Once done, write down the number of entries retrieved by each search. Afterwards, check study by study to see if they inform on any published article with results.

6.3.1. If that is the case, find the article and save it.

6.3.2. If not, several actions can be taken. For example, search on Scopus, MEDLINE and PsycInfo the registration number of the study or its title to see if any publication appears. Study authors can also be contacted and, finally, the study results' page can be saved in PDF for now (in case authors have not published the results but are willing to share their data, request information on step 17 below). Write down also the studies whose authors did not reply.

6.4. Store all export files. At some point, for example a journal reviewer might want to know which documents were found in grey literature sources. We always need to have access to the original data.

7. Upload everything into a Mendeley folder and delete duplicates. Pay attention to the number of documents retained in Mendeley afterwards to know the number of duplicates deleted at this point (compare it to the sum of all step 6 results). Then, export all references to a **".ris"** file.

8. Open and share a project in Rayyan (BLIND ON) with the reviewers (https://rayyan.qcri.org/). Import the **".ris"** file from Mendeley. Wait some hours (ideally until next day) for the software to identify all remaining duplicates.

9. Review duplicates proposed by Rayyan ("Unresolved" section) to decide which are real and which are not. To do so, click on an article, click on "Resolve duplicate", and chose "Delete" in those studies you want to discard. The software may have deleted automatically articles with 100% similarity, you can check them on "2 exact matches". Add the number of duplicates deleted in Rayyan to those deleted in Mendeley to obtain the final number of duplicates (if more are detected in the future do not worry, add them later).

10. Prepare a list with the inclusion criteria described in PROSPERO for your review/meta-analysis. You can follow the same order used there (typically PICOS order) or rank the criteria according to their relevance for your research question. Share this list with reviewers for them to have it easily accessible.

---------- Here starts the first phase of independent work by 2 blind reviewers ----------

11. First stage review: Read title and abstract of each document and take decisions on inclusion or exclusion (accept those in doubt avoiding the use of the "?" option, more information will be available in the full-text stage). Exclusion is always related to the violation of one or more of the inclusion criteria listed in step 10. Use Rayyan's "Labels" tool to specify which one in each case (e.g. not psychological intervention, not depression outcomes). It is important to assign ONLY ONE label to each excluded article, otherwise Rayyan generates duplications. Therefore, in case of more than one, assign the label for the criterion that is higher on the list described in step 10 (this instruction must be given to reviewers in advance to avoid misunderstandings).

11.1. As mentioned, only the failure to meet an inclusion criterion leads to the exclusion of a document. This means that features such as format (e.g., poster, communication) does not necessarily excludes a study, since we have searched grey literature. But, what to do with any previous review or meta-analysis retrieved by the search? This is a delicate issue that may be managed in several ways, here we propose to apply exactly the same procedure described in step 11. This means that, if it is deemed susceptible to contain articles meeting our inclusion criteria, we give the review access to the 2nd stage. This will allow reading the full-text and checking the articles cited (see step 13).

---------- Here finishes the first phase of independent work by 2 blind reviewers ----------

12. Schedule a meeting with both reviewers. Set Rayyan to BLIND OFF and take notes on the number of articles in which they agreed (both in accepting and rejecting), and those they did not

for interrater agreement estimation. Discussion will then be needed for those in which they disagreed, leading to final decisions regarding their inclusion/exclusion. In case they do not reach an agreement, invite a third reviewer. Then take notes on inclusion/exclusion final numbers, the labels for exclusion, and the number of documents in each one. If only one label per study has been used, the sum of all them should be equal to the number of documents excluded in this first stage. All this information will be used in the PRISMA flow diagram.

13. If any previous systematic review or meta-analysis has made it to this step, read them carefully. If the cited articles are already among those included by reviewers, no action is required except the exclusion of the review/meta-analysis from the second stage records (taking notes on everything). On the contrary, if any citation seems likely to meet the criteria for our research and has not been found by our search, download and include them in the second stage records, excluding the review/meta-analysis afterwards (taking notes again). Therefore, this procedure will lead to the recalculation of documents for the 2nd stage (i.e., previous reviews out, new potential articles in), it may be described in the future article, and will leave for the blind reviewers the decision on the final inclusion of these studies.

14. Search and download the full version of all articles retained and upload them to a Mendeley folder (https://www.mendeley.com/). Check that authors, title, year, etc. are correct and share it with reviewers to facilitate reading, but warn them against modifying either the folder or articles to preserve blind review. Export the references to a **".ris"** file again and upload it to a second Rayyan project, share it with reviewers (BLIND ON). Give the software some hours to be sure no duplicates are found. If so, follow the same process described in step 9.

---------- Here starts the second phase of independent work by 2 blind reviewers ----------

15. Second stage review: Read full texts in Mendeley (especially methods section) and take decisions on inclusion or exclusion in Rayyan following the same procedure described in step 11. Use the "?" option only when it is strictly necessary.

---------- Here finishes the second phase of independent work by 2 blind reviewers ----------

16. Schedule a meeting with both reviewers and set Rayyan to BLIND OFF. Take notes again on the number of articles in which they agreed (accepting and rejecting), and those they did not. Discussion will then be needed for those in disagreement, leading to final decisions regarding their inclusion/exclusion. In case they do not reach an agreement, invite the same third reviewer. Then take notes on inclusion/exclusion final numbers, the labels for exclusion, and the number of documents in each one. If only one label per study has been used, the sum of all them should be equal to the number of documents excluded in this second stage. Create a subfolder in Mendeley for the finally included studies and build the PRISMA flow diagram.

17. Create an Excel file to code all relevant variables from included documents. It may be less exhaustive for systematic reviews, but for meta-analyses we suggest at least: (1) Author and year; (2) type of study design; (3) number of experimental participants (initial and analysed); (4) number of control participants (initial and analysed); (5) type of intervention; (6) number of sessions and length; (7) type of control; (8) number of sessions and length; (9) relevant outcomes; (10) instruments applied to measure outcomes; (11) country; (12) and mean and

standard deviation of all study groups in the relevant outcomes at all assessment times to be analysed. At this point, write authors if needed to request not provided relevant information. Take notes on the number of requests and the reply (or absence of reply).

18. Quality rating using QATQS (substitute by an equivalent tool in case of qualitative studies). We will create an Excel file to rate QATQS (https://www.nccmt.ca/knowledge-repositories/search/14) and send a copy to each reviewer. After describing the tool, we will give them a sample article (not from our research) for training purposes. Together we will compare their scores and solve doubts.

---------- Here starts the third phase of independent work by 2 blind reviewers ----------

18.1. In case they do not have it already, give the reviewers access to the included articles in Mendeley, but warn them against modifying either the folder or articles. Each one must score all QATQS categories for all studies and send the Excel back to you.

---------- Here finishes the third phase of independent work by 2 blind reviewers ----------

19. Compare both files and take notes on the number of QATQS categories they disagreed on in each study (this procedure does not include subcategories) for interrater agreement estimation. Then, schedule a meeting with reviewers for them to discuss the categories they rated differently, reaching final decisions by consensus or inviting of a third reviewer again.

20. Create a R script to analyse interrater agreement for the inclusion/exclusion of documents both at the first and second stage, as well as for the QATQS scores. Use for example the “irr” package (Gamer, Lemon, Fellows, & Singh, 2012). In turn, in case of meta-analysis, use for example the “Meta” package (Schwarzer, 2007). Create funnel plots to study reporting bias and forest plots to study efficacy.

21. Rate quality of evidence for each outcome under study with GRADEpro (https://gradepro.org/) and export and adapt the “Summary of Findings” tables for reporting of results.

22. Write the articles!!

If you have doubts regarding this guide do not hesitate to contact jc.medina.alcaraz@gmail.com

Systematic review

This record cannot be edited because it is being assessed by the editorial team

1. * Review title.

Give the working title of the review, for example the one used for obtaining funding. Ideally the title should state succinctly the interventions or exposures being reviewed and the associated health or social problems. Where appropriate, the title should use the PI(E)COS structure to contain information on the Participants, Intervention (or Exposure) and Comparison groups, the Outcomes to be measured and Study designs to be included.

A systematic review into the efficacy of work-based psychosocial interventions targeted at improving mental health in terms of symptoms of depression, anxiety and/or suicidal ideation in small and medium-sized enterprises (SMEs).

2. Original language title.

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3. * Anticipated or actual start date.

Give the date when the systematic review commenced, or is expected to commence.

01/10/2019

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

31/03/2020

5. * Stage of review at time of this submission.

Indicate the stage of progress of the review by ticking the relevant Started and Completed boxes. Additional information may be added in the free text box provided.

Please note: Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. Should evidence of incorrect status and/or completion date being supplied at the time of submission come to light, the content of the PROSPERO record will be removed leaving only the title and named contact details and a statement that inaccuracies in the stage of the review date had been identified.

This field should be updated when any amendments are made to a published record and on completion and publication of the review. If this field was pre-populated from the initial screening questions then you are not able to edit it until the record is published.

The review has not yet started: No

Review stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here (e.g. Funded proposal, protocol not yet finalised).

6. * Named contact.

The named contact acts as the guarantor for the accuracy of the information presented in the register record.

Bridget Hogg

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:
Bridget

7. * Named contact email.

Give the electronic mail address of the named contact.

bhogg@imim.es

8. Named contact address

PLEASE NOTE this information will be published in the PROSPERO record so please do not enter private information

Give the full postal address for the named contact.

C/ Llull 410, 08019, Barcelona, Spain

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

(0034) 933268500 ext 8403

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

Hospital del Mar Research Institute (IMIM)

Organisation web address:
www.imim.es

11. * Review team members and their organisational affiliations.

Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong. **NOTE: email and country are now mandatory fields for each person.**

Ms Bridget Hogg. Hospital del Mar Research Institute (IMIM)

Dr Joan Carles Medina. Institut d'Investigació Biomèdica de Bellvitge

Dr Ana Moreno-Alcázar. Hospital del Mar Research Institute (IMIM)

Ms Itxaso Gardoki.Souto. Hospital del Mar Research Institute (IMIM)

Professor Ella Arensman. National Suicide Research Foundation and Department of Epidemiology and Public Health, University College Cork

Professor Ulrich Hegerl. University of Leipzig, Medical Faculty

Dr Benedikt L. Amann. Parc de Salut Mar; Hospital del Mar Research Institute (IMIM)

12. * Funding sources/sponsors.

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Include any unique identification numbers assigned to the review by the individuals or bodies listed.

EU Horizon 2020 Grant: Mental Health Promotion and Intervention in Occupational Settings: MENTUPP (SEP-210574882; call: H2020-SC1-BHC-2018-2020)

Grant number(s) 848137

13. * Conflicts of interest.

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

None

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. **NOTE: email and country are now mandatory fields for each person.**

15. * Review question.

State the question(s) to be addressed by the review, clearly and precisely. Review questions may be specific or broad. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS where relevant.

- How effective are work-based psychosocial interventions in improving depressive symptoms in employees and owners/managers of small- and medium-sized enterprises, as compared to controls?
- How effective are work-based psychosocial interventions in improving anxiety symptoms in employees and owners/managers of small- and medium-sized enterprises, as compared to controls?
- How effective are work-based psychosocial interventions in improving symptoms of suicidal ideation in employees and owners/managers of small- and medium-sized enterprises, as compared to controls?
- Of work-based psychosocial interventions shown to be effective in the reduction of symptoms of depression, anxiety and/or suicidal ideation, does the evidence support one intervention as being more effective than others?

16. * Searches.

State the sources that will be searched. Give the search dates, and any restrictions (e.g. language or publication period). Do NOT enter the full search strategy (it may be provided as a link or attachment.)

The following sources will be searched: Scopus, PubMed, PsycINFO, Clinical Trials, the International Standard Randomised Controlled Trial Number (ISRCTN) Registry, BIOSIS Previews, and the Cochrane Central Register of Controlled Trials (CENTRAL). Hand tracking will also be used to find relevant publications. All searches will include entries from the beginning of records to the date of the search. The following inclusion criteria will be applied: (1) Study sample are employees or owners/managers of SMEs; (2) the study tests a psychosocial intervention in at least one arm; (3) the study measures mental health outcomes in terms of symptoms of depression, anxiety and/or suicidal ideation/behaviour; (4) published in English or Spanish language, and (5) the intervention is delivered through the workplace.

17. URL to search strategy.

Give a link to a published pdf/word document detailing either the search strategy or an example of a search strategy for a specific database if available (including the keywords that will be used in the search strategies), or upload your search strategy.

Do NOT provide links to your search results.

https://www.crd.york.ac.uk/PROSPEROFILES/156275_STRATEGY_20191028.pdf

Yes I give permission for this file to be made publicly available

18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

Depression, anxiety, subsyndromic depression and subsyndromic anxiety, as defined by DSM-V, suicidal ideation and behaviour.

19. * Participants/population.

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

Inclusion criteria for the participants of this review are: (1) be an employee or owner/manager of a small- or medium-sized enterprise; (2) be in a company which has offered a work-based intervention with mental health outcomes. Exclusion criteria are: (1) working for a company with 250 or more employees; (2) have participated in an intervention not run through the workplace.

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the nature of the interventions or the exposures to be reviewed.

The interventions to be reviewed are any type of psychosocial intervention delivered through a SME workplace, with an outcome related to depression, anxiety or suicidal ideation/behaviour.

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

The review is expected to be inclusive, therefore, other active arms, placebo, wait-list, and treatment as usual will all be considered as control conditions.

22. * Types of study to be included.

Give details of the types of study (study designs) eligible for inclusion in the review. If there are no restrictions on the types of study design eligible for inclusion, or certain study types are excluded, this should be stated. The preferred format includes details of both inclusion and exclusion criteria.

As determined by a scoping review, there is limited data available for SMEs, so both qualitative and quantitative data from any experimental, quasi-experimental and correlational study is in scope.

23. Context.

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

24. * Main outcome(s).

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

Primary outcomes in this review will be symptoms of (1) depression, (2) anxiety and/or (3) suicidal ideation/behaviour.

* Measures of effect

Outcomes may be measured using either validated self-report scales or through a validated clinician-administered scale or interview; both will be included in the review and should be measured at a minimum of two time points (pre- and post), and may include further follow-up data.

25. * Additional outcome(s).

List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state ‘None’ or ‘Not applicable’ as appropriate to the review

N/A

* Measures of effect

N/A

26. * Data extraction (selection and coding).

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

Two of the team members of this review (BH and IGS) will conduct the search of the studies in the aforementioned databases. All results will be exported to Rayyan (https://rayyan.qcri.org/), a free online software specialized in accelerating systematic reviews. Using Rayyan tools, BH and IGS will screen results for duplicates and, once removed, will independently review the remaining records against the inclusion- and exclusion-criteria, following a two-stage procedure: (1) a first selection will be conducted after reading the title and abstract of all studies, and (2) full-text publication of the remaining articles will be read in order to decide if they meet all the inclusion criteria. Afterwards they will meet to compare the studies retained, and in the case of discrepancy, a final decision will be taken with the contribution of JCM.
The data to be extracted from all studies will be, at least: (1) number of experimental participants (intention-to-treat and completers); (2) type and characteristics of intervention; (3) type and characteristics of control intervention (if any); (4) relevant outcomes in terms of depression, anxiety and suicidal ideation; (5) instruments used to measure outcomes.

27. * Risk of bias (quality) assessment.

Describe the method of assessing risk of bias or quality assessment. State which characteristics of the studies will be assessed and any formal risk of bias tools that will be used.

In order to counteract any possible publication bias, trials meeting all the inclusion criteria will be searched in the following electronic databases: Clinical Trials, the International Standard Randomised Controlled Trial Number (ISRCTN) Registry, BIOSIS Previews, and the Cochrane Central Register of Controlled Trials (CENTRAL). In order to assess the quality of all included studies with measurable mental health outcomes, the Quality Assessment Tool for Quantitative Studies (QATQS) will be used. This tool will measure methodological rigor in six different areas: (1) selection bias; (2) design; (3) confounders; (4) blinding; (5) data collection method; and (6) withdrawals and dropouts. The score in each of these domains will be aggregated to compute a total quality score for every study included in the review. The results will be interpreted in the light of these scores in the final publication of this systematic review.

28. * Strategy for data synthesis.

Provide details of the planned synthesis including a rationale for the methods selected. This **must not be generic text** but should be **specific to your review** and describe how the proposed analysis will be applied to your data.

Due to the scarcity of literature in SMEs as discovered in a preliminary scoping search, a meta-analytic approach will not be used, instead using a data synthesis approach for randomized trials, referring to the quality of the study as assessed through the risk of bias tool previously mentioned and the strength of the results. Data which cannot be synthesized through this approach will be summed up using a narrative synthesis.

29. * Analysis of subgroups or subsets.

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach.

No separate analyses for subgroups of participants are foreseen.

30. * Type and method of review.

Select the type of review and the review method from the lists below. Select the health area(s) of interest for your review.

Type of review

Cost effectiveness	No
Diagnostic	No
Epidemiologic	No
Individual patient data (IPD) meta-analysis	No
Intervention	No
Meta-analysis	No
Methodology	No
Narrative synthesis	No
Network meta-analysis	No

Pre-clinical	No
Prevention	No
Prognostic	No
Prospective meta-analysis (PMA)	No
Review of reviews	No
Service delivery	No
Synthesis of qualitative studies	No
Systematic review	Yes
Other	No

Health area of the review

Alcohol/substance misuse/abuse	No
Blood and immune system	No
Cancer	No
Cardiovascular	No
Care of the elderly	No
Child health	No
Complementary therapies	No
Crime and justice	No
Dental	No
Digestive system	No
Ear, nose and throat	No
Education	No
Endocrine and metabolic disorders	No
Eye disorders	No
General interest	No
Genetics	No
Health inequalities/health equity	No
Infections and infestations	No
International development	No

Mental health and behavioural conditions	Yes
Musculoskeletal	No
Neurological	No
Nursing	No
Obstetrics and gynaecology	No
Oral health	No
Palliative care	No
Perioperative care	No
Physiotherapy	No
Pregnancy and childbirth	No
Public health (including social determinants of health)	No
Rehabilitation	No
Respiratory disorders	No
Service delivery	No
Skin disorders	No
Social care	No
Surgery	No
Tropical Medicine	No
Urological	No
Wounds, injuries and accidents	No
Violence and abuse	No

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.

English

There is not an English language summary

32. * Country.

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved.

Spain

33. Other registration details.

Give the name of any organisation where the systematic review title or protocol is registered (such as with The Campbell Collaboration, or The Joanna Briggs Institute) together with any unique identification number assigned. (N.B. Registration

details for Cochrane protocols will be automatically entered). If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

34. Reference and/or URL for published protocol.

Give the citation and link for the published protocol, if there is one

No I do not make this file publicly available until the review is complete

35. Dissemination plans.

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

Do you intend to publish the review on completion?

Yes

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords will help users find the review in the Register (the words do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

Depression, Anxiety, Suicide, intervention, SME

37. Details of any existing review of the same topic by the same authors.

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

38. * Current review status.

Review status should be updated when the review is completed and when it is published. For newregistrations the review must be Ongoing.

Review_Ongoing

39. Any additional information.

Provide any other information the review team feel is relevant to the registration of the review.

40. Details of final report/publication(s).

This field should be left empty until details of the completed review are available.

De: CRD-REGISTER [irss505@york.ac.uk]
Enviado: lunes, 28 de octubre de 2019 10:42
Para: Hogg -, Bridget
Asunto: PROSPERO acknowledgement of receipt [156275]

Dear Registrant,

Thank you for submitting details of your systematic review for registration in PROSPERO.

We will check the information supplied to

- make sure that your systematic review is within scope

- ensure that the fields have been completed appropriately.

PLEASE NOTE THAT THESE CHECKS DO NOT CONSTITUTE PEER REVIEW OR IMPLY
APPROVAL OF YOUR SYSTEMATIC REVIEW METHODS.

We will let you know when your record has been published on PROSPERO, or alternatively ask for further information or clarification. If your application is rejected we will advise you of the reasons for non-publication (usually this will be if your review is out of scope).

With the current extremely high demand for registration, we will aim to respond within 10 working days for UK submissions but for submissions from outside the UK it will be considerably longer - possibly around three months.
But we will process your application as soon as possible. During this time the record will be locked and you will not be able to access it.

Please note that this does not stop you working on your review.

Yours sincerely,
PROSPERO Administrator
Centre for Reviews and Dissemination
University of York
York YO10 5DD
t: +44 (0) 1904 321049
e: CRD-register@york.ac.uk
www.york.ac.uk/inst/crd