



## STUDY PROTOCOL

# REVISED Psychological interventions for mood and cognition after stroke and transient ischaemic attack: A protocol for an umbrella review [version 2; peer review: 2 approved]

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## Abstract

### Background

People who have had a stroke or a Transient Ischaemic Attack (TIA) can experience psychological and/or cognitive difficulties. The body of research for psychological and neuropsychological interventions after stroke is growing, however, published systematic reviews vary in scope and methodology, with different types and severity of strokes included, and at times, diverse conclusions drawn about the effectiveness of the interventions evaluated. In this umbrella review, we aim to systematically summarise the existing systematic reviews evaluating psychological interventions for mood and cognition post-stroke/TIA.

### Methods

We will conduct this umbrella review according to the JBI Manual for Evidence Synthesis. The following databases will be searched from inception: Cochrane Database of Systematic Reviews, Database of

## Open Peer Review

Approval Status

	1	2
<b>version 2</b>		
(revision)		
17 May 2024		
<b>version 1</b>		
20 Mar 2024		

1. **Niamh Kennedy** , Ulster University, Coleraine, UK
2. **Andrea Kusec** , University of Oxford, Oxford, UK  
University of Cambridge, Cambridge, UK

Any reports and responses or comments on the article can be found at the end of the article.

Reviews of Effects (DARE), MEDLINE, Embase, CINAHL, PsycINFO, and Epistemonikos. Systematic reviews with or without meta-analysis published until the search date will be included. Reviews including psychological interventions addressing mood and/or cognition outcomes for any stroke type or severity will be screened for eligibility. A narrative synthesis, including content analysis, will be used. Each stage of the review will be processed by two independent reviewers and a third reviewer will be considered to resolve disagreements. The methodological quality of the included reviews will be assessed using AMSTAR 2.

## **Discussion**

Existing systematic reviews provide varied evidence on the effectiveness of psychological interventions post-stroke/TIA. This umbrella review aims to summarise knowledge and evidence on different types of psychological and neuropsychological interventions targeting mood and cognition. Findings will highlight important knowledge gaps and help prioritise future research questions.

## **Systematic Review Registration**

This protocol was prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO) on November 15, 2022; PROSPERO CRD42022375947.

## **Keywords**

umbrella review, systematic review, stroke, Transient Ischaemic Attack, protocol, overview of systematic reviews, cognition, mood, psychological intervention, cognitive intervention

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**Competing interests:** Dr Eirini Kontou is currently funded through NIHR HEE ICA Clinical Lectureship. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care, UK. Professor Roshan das Nair has received funds (speakers' bureau) for presenting lectures related to psychological and cognitive issues in acquired brain injuries from Novartis, Biogen, and Merck.

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**REVISED Amendments from Version 1**

In Table 1, we added the definition of quasi-RCT designs and added a sentence in the Eligibility criteria section.

In Table 1, we clarified that computerised interventions that are delivered solely via apps or virtual technology will be excluded.

In the 'Synthesis and presentation of results' section, we added a sentence to expand on how content analysis will be implemented in this umbrella review. We explained that quality of life measures will be examined as secondary outcomes only.

We amended the Data Collection Form (see Reporting Guidelines: Additional File 3) and provided the link for the revised version in the Extended Data (v2.0, dated 3.5.24).

**Any further responses from the reviewers can be found at the end of the article**

**List of abbreviations**

CADTH: Canadian Agency for Drugs and Technology in Health

DARE: Database of Reviews of Effects

JBI: Joanna Briggs Institute

PRISMA-P: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols

RCT: Randomised Controlled Trial

SR: Systematic Review

TIA: Transient Ischaemic Attack

VR: Virtual Reality

**Background**

Mood (e.g., depression, anxiety)<sup>1</sup> and cognitive problems (e.g., memory loss, inattention, slow processing)<sup>2</sup> are very common following a stroke and a Transient Ischaemic Attack (TIA). There is now emerging evidence on the prevalence of neuropsychological difficulties (e.g., depression, anxiety, apathy) post-stroke and TIA.<sup>3,4</sup> Interventions for improving psychological and cognitive effects after stroke are still a top research priority for improving rehabilitation care.<sup>5</sup>

The body of research for psychological interventions after stroke is growing, and our initial scoping search in the Cochrane Database of Systematic Reviews suggested that there were at least seven published Cochrane systematic reviews on the effectiveness of interventions for depression,<sup>6,7</sup> anxiety<sup>8</sup> and various types of cognitive problems.<sup>9–12</sup> However, these published systematic reviews varied in scope and methodology, with different types and severity of strokes included, and at times, diverse conclusions drawn about the effectiveness of the range of interventions evaluated. Until now, there has been no published overview of systematic reviews of interventions for neuropsychological difficulties after stroke and TIA. We propose an umbrella review approach<sup>13</sup> (a term used to describe an overview of systematic reviews) that will be used to systematically summarise the methodological and reporting characteristics of existing systematic reviews on psychological interventions for mood and cognition after stroke/TIA.

This umbrella review aims to summarise and synthesise the published evidence on psychological interventions for neuropsychological (specifically mood and cognition) difficulties after stroke/TIA. Furthermore, when information is available in the identified systematic reviews, we will attempt to systematically evaluate the quality of the evidence and the extent of potential methodological limitations on this topic.

In the present protocol, we describe how this review will aim to address the following questions:

- 1) What are the available psychological interventions for addressing difficulties with mood (depression and anxiety) and cognition (all cognitive domains including language) after stroke/TIA?
- 2) Which of these interventions, if any, are effective for which stroke survivors (stroke type, severity) and for which outcome measures (mood, individual cognitive domains, quality of life)?

**Methods**

The protocol is based on the guidelines provided by the JBI (Joanna Briggs Institute) Manual for Evidence Synthesis<sup>14</sup> and in accordance with PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols) guidelines<sup>15</sup> (see *Reporting Guidelines, Additional File 1*). Our protocol was prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO CRD42022375947 on 15 November 2022).

### Search strategy

The following databases will be searched from inception until the search date: Cochrane Database of Systematic Reviews, Database of Reviews of Effects (DARE), Ovid MEDLINE, Ovid Embase, CINAHL, Ovid PsycINFO, and Epistemonikos.

Our search algorithm will be developed, peer-reviewed and undertaken by two Information Specialists (FS, NT). We will use the Canadian Agency for Drugs and Technology in Health (CADTH) (<https://searchfilters.cadth.ca/>) systematic review search filters and the Cochrane Stroke group search strategy for identifying studies on stroke and TIA (for MEDLINE, Embase, CINAHL, PsycINFO).

The search terms will include the following themes, with synonyms to describe each: psychotherapies, depression, anxiety, cognition, and stroke. Full details and search strategies can be found in *Reporting Guidelines: Additional File 2*.

### Eligibility criteria

Psychological interventions with a variety of theoretical underpinnings will be considered. The main types of psychological interventions that will be identified for inclusion in our umbrella review will be *psychotherapy/talking therapy* interventions (including psychoeducation), *cognitive rehabilitation* and *neuropsychological rehabilitation* interventions. We will include only articles published in English. Only full-text systematic reviews published in peer-reviewed journals will be considered for inclusion. Systematic reviews will be included based on the following eligibility criteria. See [Table 1](#).

**Table 1. Umbrella review eligibility criteria.**

Inclusion criteria	
Study type	Systematic reviews with or without a meta-analysis that include randomised controlled trial (RCT) designs and quasi-RCT designs (e.g., participants allocated to different arms of the trial using a method of allocation that is not truly random)
Population	Participants with a confirmed diagnosis of stroke and/or TIA Mixed population systematic reviews with stroke participants totalling at least 70% of the population
Condition	Any type and severity of stroke including TIA Reviews with mixed stroke subtypes
Intervention	Neuropsychological (psychological and cognitive) interventions focusing on addressing mood and/or cognition Psychological (psychotherapy/talking therapy) interventions designed to improve mood and/or cognition Cognitive rehabilitation therapies designed to improve cognitive functioning using a range of restorative or compensatory strategies Interventions providing advice, support or education designed to address mood and/or cognition that are based on psychological principles and specify the theoretical model (e.g., Cognitive Behavioural Therapy) Reviews including music therapy, mental imagery meditation, relaxation, tai-chi, or yoga, will be included if delivered within a psychological intervention (e.g., Compassionate Focused Therapy or Mindfulness-based Therapies) Family/carer interventions (e.g., dyadic) if outcomes are reported separately for stroke participants Mixed intervention reviews will be included if at least 50% of the interventions are psychologically based and are separately reported
Comparison	Any type of control/comparison (usual care, no intervention, waiting list, or attention control)
Context	Any healthcare or community settings Interventions delivered remotely
Outcome	Mood (e.g., depression, low mood, anxiety, stress) Cognition (e.g., memory, attention, executive function)

**Table 1.** *Continued*

Exclusion criteria	
Study type	Lack of quality appraisal in methodology
Population	Focus on subarachnoid haemorrhage only
Intervention	Music therapy, mental imagery meditation, relaxation, tai-chi, or yoga as a standalone intervention
	Computerised-cognitive rehabilitation interventions (e.g., computer games, virtual reality, or technology-based interventions)
	Non-invasive brain stimulation interventions (e.g., electroconvulsive therapy, transcranial magnetic stimulation)
	Psychological interventions combined with another component (e.g., a pharmacological intervention)
	Those focused on prevention, not treatment
	Computerised interventions delivered solely via apps or virtual technology

We will consider the consensus definition of a systematic review used in overviews of systematic reviews.<sup>16</sup> Where a systematic review has been updated, we will include the updated version in preference to the original publication. If the authors of a systematic review did not define a quasi-RCT, this will be noted, but it will not be a reason for exclusion.

### Data extraction and management

Two authors will screen the titles and abstracts (EK, FS), and full-text papers, with discrepancies being resolved through either consensus or with a third author (NC, MW). Two authors (NC, MW) will independently extract relevant characteristics of the reviews, including title, author, year of publication, databases searched, years searched, inclusion criteria, intervention details, outcomes assessed, type of data synthesis performed, results from methodological quality assessments, quantitative and descriptive results relating to the outcome measures. Any disagreement will be resolved after consulting with a third author (EK). Data extraction will be conducted using a bespoke data extraction form (*see Reporting Guidelines: Additional File 3*) created for the purpose of this review and based on the JBI Data Extraction Form for Review for Systematic Reviews and Research Syntheses. In the data extraction process, we will consider adapting and piloting the data extraction form with at least 10% of the reviews included.

### Quality assessment

Two authors will independently assess the methodological quality of the included reviews using the AMSTAR 2<sup>17</sup> appraisal tool since this tool can be used for RCTs. Variations in the assessment of quality between the two authors (NC, MW) will be addressed through discussion or the involvement of a third author (EK). It is not recommended to combine AMSTAR 2 individual item ratings to produce an overall score. The proposed scheme proposed by Shea et al. (2017)<sup>17</sup> for interpreting weaknesses detected in critical items of a systematic review will be considered for assessing the overall quality of the reviews included (i.e., high, moderate, low or critically low). The core study team (EK, AD, TQ, RdN, FS) will seek consensus on the items that are most important for the reviews considered for this topic area.

### Synthesis and presentation of results

A narrative synthesis will be performed to look systematically at the data and to describe each review. Patterns in the data will be identified through tabulation and visual representation of the results. The commonality in results between the reviews will be identified using content analysis based on an inductive approach (deriving concepts from the data). Content analysis will be applied as a systematic and replicable method to the synthesis of findings from multiple reviews without preconceived categories or theories (for example, the analysis would be developed without a set of a priori themes to guide data extraction and analysis from the outset).

We will investigate reasons for differences in the magnitude of each outcome measure (mood and cognition) through investigating within-review differences, e.g., psychological therapy versus cognitive rehabilitation. Quality of life measures will be examined as secondary outcomes only. A summary of findings table will be created to provide an overview of the findings from the reviews, which will comprise the intervention, relevant reviews and outcome measure using a 'stop-light' indicator, where green indicates the intervention is beneficial, amber is no differences, and red suggests the intervention is detrimental. It is anticipated that there will be discordant/inconsistent findings between included systematic reviews on the same research topic. In these instances, this will be clearly reported and the assignment of the 'stop-light' indicator will be fully described.

In the synthesis stage, we will describe and explain any overlap from the same primary studies reported across the included systematic reviews. We will attempt to visually present the amount of overlap using a table or a matrix. As there is currently no standard methodological approach recommended for managing overlap, we will choose an appropriate method based on the number of included reviews and their primary studies.<sup>18</sup>

Subgroup analysis will be used, if possible, to investigate whether there are differences in the effectiveness of the psychological interventions by population (stroke versus TIA/minor stroke).

A complete list of the different types of psychological interventions included will be considered when presenting the findings of our review. Reasons for excluding any reviews based on our eligibility criteria will be reported.

## Discussion

Considering the high prevalence of psychological and cognitive difficulties reported in the stroke literature and the varied evidence on the effectiveness of available interventions, this umbrella review aims to summarise the current state of the evidence on psychological interventions for people with stroke/TIA. It will attempt to identify what the different types of psychological interventions are for addressing the most common neuropsychological difficulties (primarily mood and cognition) following a diagnosis of stroke/TIA. The quality of the included systematic reviews will be discussed, and recommendations for future research will be provided. Finally, the findings from this review will be used to inform the development and evaluation of a psychological care pathway for people experiencing less severe strokes.

## Study status

Ongoing. At the time of submission, the umbrella review will be progressing at data extraction stage.

## Data availability

### Underlying data

No data are associated with this article.

## Extended data

**Medline Search Strategy (Additional File 2)** for Psychological interventions for mood and cognition after stroke and transient ischaemic attack: a protocol for an umbrella review, <https://doi.org/10.6084/m9.figshare.24939081.v1>.<sup>19</sup>

**Data Extraction Form (Additional File 3)** for Psychological interventions for mood and cognition after stroke and transient ischaemic attack: a protocol for an umbrella review, <https://doi.org/10.6084/m9.figshare.25746573.v1>.<sup>20</sup>

## Reporting guidelines

**PRISMA-P Checklist (Additional File 1)** for Psychological interventions for mood and cognition after stroke and transient ischaemic attack: a protocol for an umbrella review, <https://doi.org/10.6084/m9.figshare.24938931>.

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](https://creativecommons.org/licenses/by/4.0/) (CC-BY 4.0)

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# Open Peer Review

Current Peer Review Status:  

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## Version 2

Reviewer Report 29 May 2024

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**Andrea Kusec** 

<sup>1</sup> University of Oxford, Oxford, UK

<sup>2</sup> University of Cambridge, Cambridge, England, UK

The authors have address my initial comments and manuscript is suitable for indexing.

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** stroke, mental health, cognition, mood disorders, clinical trials, neuropsychological rehabilitation,

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

Reviewer Report 21 May 2024

<https://doi.org/10.5256/f1000research.166176.r279666>

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**Niamh Kennedy** 

Ulster University, Coleraine, Northern Ireland, UK

I'm happy that authors have addressed the concerns.

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Stroke, Neurorehabilitation, Psychology

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

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**Version 1**

Reviewer Report 11 April 2024

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**Andrea Kusec** 

<sup>1</sup> University of Oxford, Oxford, UK

<sup>2</sup> University of Cambridge, Cambridge, England, UK

This paper describes a protocol for an umbrella review of psychological interventions for cognition and mood after stroke in order to harmonize the increasing amount of research focused on this topic. In general, the protocol is clear, and I mainly have suggestions to strengthen the potential quality of the umbrella review.

- The search terms seem largely appropriate; given the second research question of the protocol focus on which outcome measures demonstrate benefit for stroke/TIA survivors, will the authors consider reviews which focus on interventions to improve quality of life post-stroke?
- How will the authors consider the role of time post-stroke in their umbrella review – some interventions may be delivered very early on in stroke or in chronic stages and this could impact interpretation of results
- Why are the authors including articles where 70% of the sample in included reviews has a stroke – this seems like a large number given that many neuropsychological rehabilitation reviews focus on acquired brain injury more generally and might exclude potentially useful information about neuropsychological interventions. Further, given that mixed health care services exist that work with stroke and other acquired brain injury survivors the potential overlap does not seem irrelevant in the context of this review, which aims to describe mood and cognitive interventions in a broad sense.

**Is the rationale for, and objectives of, the study clearly described?**

Yes

**Is the study design appropriate for the research question?**

Yes

**Are sufficient details of the methods provided to allow replication by others?**

Yes

**Are the datasets clearly presented in a useable and accessible format?**

Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** stroke, mental health, cognition, mood disorders, clinical trials, neuropsychological rehabilitation,

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.**

Author Response 07 May 2024

**Eirini Kontou**

We are grateful to the expert reviewer for their interest in this topic and for taking the time to review our manuscript. We appreciate their helpful and thorough comments. A revised version was submitted and a detailed response to each comment.

**Background/Methods**

**Comment:** The search terms seem largely appropriate; given the second research question of the protocol focus on which outcome measures demonstrate benefit for stroke/TIA survivors, will the authors consider reviews which focus on interventions to improve quality of life post-stroke?

**Reply:** Thank you for this comment. This review was commissioned to primarily examine mood and cognition. Thus, interventions are not the focus of this umbrella review, which is a work package for a larger research study evaluating psychological care pathways for people after TIA and minor stroke. Quality of life measures will be examined as secondary outcomes only.

**Results/Synthesis**

**Comment:** How will the authors consider the role of time post-stroke in their umbrella review – some interventions may be delivered very early on in stroke or in chronic stages and this could impact interpretation of results

**Reply:** Thank for this suggestion. We want to clarify that the recovery stage will be reported. For example, we will aim to map and present findings to time post diagnosis e.g., Acute <1 month, Early subacute, 3-6 months, Late/chronic, > 6 months. This approach has been taken by other authors on the topic of psychological interventions after stroke/TIA.

**Methods / Eligibility Criteria**

**Comment:** Why are the authors including articles where 70% of the sample in included reviews has a stroke – this seems like a large number given that many neuropsychological

rehabilitation reviews focus on acquired brain injury more generally and might exclude potentially useful information about neuropsychological interventions. Further, given that mixed health care services exist that work with stroke and other acquired brain injury survivors the potential overlap does not seem irrelevant in the context of this review, which aims to describe mood and cognitive interventions in a broad sense.

**Reply:** The reason for excluding Acquired Brain Injury (ABI) in general is because this review was funded to focus on stroke and TIA. Thus, we wanted to identify interventions that might be suitable, and considered best practice interventions, for people after stroke/TIA, rather than for all ABI survivors. This is because, depending on the type and severity of their injury, their difficulties and needs are likely to be different and broader. Additionally, this was also a pragmatic decision because of the heterogeneity of reviews and the primary studies included.

**Competing Interests:** No competing interests were disclosed.

Reviewer Report 01 April 2024

<https://doi.org/10.5256/f1000research.160420.r258061>

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**Niamh Kennedy** 

Ulster University, Coleraine, Northern Ireland, UK

This paper provides a protocol for an umbrella review of psychological interventions for mood and cognition after stroke and transient ischaemic attack. They propose conducting an umbrella review (along established guidelines) to help synthesise the existing systematic reviews, evaluating psychological interventions for mood and cognition. They present a robust methodology, searching a range of relevant databases, using clear eligibility criteria and search terms. Quality assessment will be conducted using AMSTAR 2, to establish quality of the included systematic reviews. A narrative synthesis will be used to collate findings, establishing commonality between findings and to investigate any potential differences in the effectiveness of interventions. This is a relevant and useful paper for this field. The importance of psychological and mood interventions has been frequently highlighted by stroke survivors, their families and health care professionals as a major concern post stroke. Currently there is little consensus or structured recommendation on what interventions/approaches are most appropriate to this population. There is some published findings in the area but its lacking in agreement and this is needed to help drive this clinical area forward. This paper provides an opportunity to address some of these gaps.

Abstract is appropriately detailed, covering all main areas. Background is sufficiently detailed, provides a rationale for the study, identifying the need for this study (and using this methodology). Methods; Good level of detail, sufficient for replication. Clear thought has been applied to use of the research team, with good use of double screening, extraction etc. Good

explanation and description of data extraction and quality assessment procedures.  
Supplementary material- clear, useful and appropriate.

#### Major Points

No major points.

#### Minor Points

- The research questions in the paper differ slightly from those stated in PROSPERO I suggest editing these (on pro perso) to ensure consistency.
- Quasi-RC isn't defined or further detail on what may fall under this category, isn't provided which may be useful (especially for replication).
- Could you provide a justification for exclusion of Computerised-cognitive rehabilitation interventions?
- A line or two of additional detail on how " using content analysis based on an inductive approach" will be implemented would be helpful for the reader.
- No participant details such as average age, gender are being recorded in the data extraction form, I find this unusual especially if one of the aims is to look at potential subgroups analysis. I believe these details should be extracted.

I recommended some minor comments.

#### **Is the rationale for, and objectives of, the study clearly described?**

Yes

#### **Is the study design appropriate for the research question?**

Yes

#### **Are sufficient details of the methods provided to allow replication by others?**

Yes

#### **Are the datasets clearly presented in a useable and accessible format?**

Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Stroke, Neurorehabilitation, Psychology

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

Author Response 07 May 2024

#### **Eirini Kontou**

We thank the reviewer for spending time on our review and for providing helpful comments. We have made minor amendments to the manuscript addressing their recommendations.

#### **Background**

**Comment:** The research questions in the paper differ slightly from those stated in PROSPERO I suggest editing these to ensure consistency.

**Reply:** Thank you for noting this. We will request to amend on PROSPERO, in order to ensure we are consistent.

### Methods

**Comment:** Quasi-RC isn't defined or further detail on what may fall under this category, isn't provided which may be useful (especially for replication).

**Reply:** This refers to studies that were included in a systematic review and referred to as 'quasi-RCT designs'. We have added a sentence to clarify that if the authors of a systematic review did not define or further detail what they meant by a Quasi RCT (e.g., participants allocated to different arms of the trial using a method of allocation that was not truly random) on their eligibility criteria, this will be noted but will not constitute a reason for exclusion.

### Methods / Eligibility criteria

**Comment:** Could you provide a justification for exclusion of Computerised-cognitive rehabilitation interventions?

**Reply:** We added that computerised interventions that are delivered solely via apps or virtual technology will be excluded. This is due to differences in the way they approach the content and delivery of the intervention compared with other cognitive rehabilitation interventions (via Zoom or Teams), as well as significant heterogeneity between the interventions themselves (e.g., the use of computer games, virtual reality platforms or other remote tasks).

### Results/Synthesis

**Comment:** A line or two of additional detail on how " using content analysis based on an inductive approach" will be implemented would be helpful for the reader.

**Reply:** We have added a sentence to expand on how this will be implemented in the context of this umbrella review.

### Methods/Data extraction

**Comment:** No participant details such as average age, gender are being recorded in the data extraction form, I find this unusual especially if one of the aims is to look at potential subgroups analysis. I believe these details should be extracted.

**Reply:** Thank you for this very helpful observation. We have extracted this information (age and gender) under the 'Participant Characteristics'. During the piloting process of the extraction form it was noticed that, for several systematic reviews, gender was not adequately reported under participant characteristics. Given this variability it may not be possible to extract this information for all the systematic reviews included in our umbrella review. We acknowledge that this is not currently explicit in the Data Extraction Form – we

added this in the details and uploaded a revised version.

**Competing Interests:** No competing interests were disclosed.

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