

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Identifying optimal frameworks to implement or evaluate digital health interventions: A scoping review protocol
AUTHORS	Soobiah, Charlene; Cooper, Madeline; Kishimoto, Vanessa; Bhatia, R.; Scott, Ted; Maloney, Shelagh; Larsen, Darren; Wijeyesundera, Harindra; Zelmer, Jennifer; SteeleGray, Carolyn; Desveaux, Laura

VERSION 1 – REVIEW

REVIEWER	Anastasia Mallidou University of Victoria, BC Canada
REVIEW RETURNED	02-Mar-2020

GENERAL COMMENTS	<p>Thank you for the opportunity to review this interesting and novel topic of research. The following comments intend to improve the manuscript and clarify some unclear areas.</p> <ol style="list-style-type: none">1. On page 6, the strengths and limitations are not clearly described. It would be useful to be revised.2. On page 8 and page 12 (last paragraph), it is unclear how "The results of this review will provide practical guidance [...and serve as a guide] to researchers, organizations, policy makers and developers interested in implementing or evaluating DHIs." The manuscript would be strengthened if the authors could provide a couple of examples of such "practical guidance".3. A clear search strategy description for the grey literature is required.4. The panel of knowledge users that will be used as advisory committee may a) need a clear description (e.g., who are they? what their role in disseminating the findings?); b) establish the PPI group of this study; and c) need more elaboration whether has already been established or will be done soon. The language used sometimes refers to the past, while other times to the future.
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REVIEWER	Heather May Morgan University of Aberdeen UK
REVIEW RETURNED	30-Mar-2020

GENERAL COMMENTS	<p>This submission promises a useful contribution to the field. Some clarifications are required, however.</p> <p>Abstract: Perhaps not here, and it is picked up later, but more critical and comprehensive choice and definition of the term 'DHI' is required (in relation to the field). When 'healthcare' is stated, is this always formal or does it include informal? This needs thinking through for the whole paper. Is there a specific area of focus? This</p>
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	<p>is very broad. What is 'integrated knowledge translation'? It doesn't mean a lot in the abstract. Re ethical review = yes, none needed, but there may be ethical issues and these are not acknowledged or addressed later (main text p.10). How will the 'practical guidance' manifest/be manifested? Researchers seem to be the target of the output - what about designers/creators/users, etc.? Overall, the abstract needs honing and focus!</p> <p>Main paper: Research seems to be the main focus of this work. What about policy/developer/clinical people????? Which discipline(s) are the identified n=159 frameworks targeted for? This needs attention here and throughout.</p> <p>p.7 (line 47) should be 'this paper outlines the' not 'outlines a'.</p> <p>Also on p.7 - the constructs mentioned - from what discipline/which disciplines?</p> <p>Grey literature needs a mention on p.8, with an emphasis on multidisciplinary (and which disciplines?).</p> <p>What is OSF on p.9?</p> <p>Also on p.9 there is mention of 'Random sample' - by % or n= or?? Please clarify.</p> <p>Who are the appropriate knowledge users? Need to specify on p.10.</p> <p>Re PPI - this is dismissive. Actually, people are involved via included studies and also as stakeholders. Please address.</p> <p>On p.11, consider adding 'application' as well as 'evaluation' of frameworks.</p> <p>Is this work to guide implementation or evaluation or both? Please confirm at p.11/line 32.</p> <p>On p.11/line 44/45 = creates not create.</p> <p>The user panel must involve PPI??? This needs addressing at p.11.</p> <p>DHIs definition - please consider the role off PPI/user group in defining this?</p> <p>Close work with an information specialist is great, but more with other who define DHIs needs to be incorporated throughout.</p> <p>What is this communications and dissemination plan for society???</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1: Comments

Thank you for the opportunity to review this interesting and novel topic of research. The following comments intend to improve the manuscript and clarify some unclear areas.

1. On page 6, the strengths and limitations are not clearly described. It would be useful to be revised.

We have added 5 key points after the abstract to clearly highlight our strengths and limitations (page 4).

Strengths and limitations:

- This will be one of the first scoping reviews to identify frameworks to implement or evaluate digital health interventions on a broad scale.

- The study protocol was informed by the Joanna Briggs Institute approach for scoping reviews and adheres to the PRISMA Extension for Scoping Reviews (PRISMA-ScR)
- Digital health knowledge users, such as policymakers, researchers, clinicians, and developers have been engaged in the design and development of the review since its inception to ensure relevance and scope of project.
- This scoping review will not examine the quality of the included studies or the usability of the frameworks, as such our findings will be limited to descriptive syntheses
- Findings stemming from this review will provide practical guidance for digital health knowledge users and enable them to use evidence informed approaches to select optimal frameworks to implement or evaluate digital health interventions.

2. On page 8 and page 12 (last paragraph), it is unclear how "The results of this review will provide practical guidance [...and serve as a guide] to researchers, organizations, policy makers and developers interested in implementing or evaluating DHIs." The manuscript would be strengthened if the authors could provide a couple of examples of such "practical guidance".

Thank you for your comment, we have revised this section to provide more clarity:

Page 6, paragraph 1: *"The results of this review will provide practical guidance and support for researchers, clinicians, organizations, policymakers and developers in selecting the most appropriate framework for DHIs, which will support evidence-based approaches in relation to implementation and evaluation efforts."*

Page 11, paragraph 1: *"To our knowledge, this is the first scoping review to examine the use of frameworks to guide implementation or evaluation of DHIs on a broad scale. A clear understanding of which frameworks can be used for development, feasibility, implementation and evaluation of will facilitate decision making by making evidence-based approaches available to policymakers, researchers, clinicians and developers."*

3. A clear search strategy description for the grey literature is required.

We have revised the section to include the following:

Page 7, Paragraph 3: *"We will use keywords such as digital health, frameworks, benefits evaluation to refine our supplementary search. In addition, we will also scan reference lists of included studies and conduct a forward citation search (i.e., examine studies that reference the included studies) in Web of Science using the cited reference search feature. This will ensure our approach is comprehensive."*

4. The panel of knowledge users that will be used as advisory committee may a) need a clear description (e.g., who are they? what their role in disseminating the findings?); b) establish the PPI group of this study; and c) need more elaboration whether has already been established or will be done soon. The language used sometimes refers to the past, while other times to the future.

We agree. The digital health knowledge user panel was established before the scope of the project was finalized. To clarify, we have revised the Ethics and Dissemination section and added our advisory panel to the subsequent section on Patient and Public Involvement.

Page 9, Paragraph 2: *"We employed an integrated knowledge translation strategy to engage digital health knowledge users in the review process to ensure the scope of the project met the needs of*

various end-users. Knowledge users are defined as individuals who are likely to use the findings to inform health decision making.² A priori, we decided to engage senior leaders and policymakers at organizations that promote or support implementation of digital health solutions, as well as researchers, clinicians, and developers evaluating DHIs in real world settings. An advisory panel of digital health knowledge users was established to provide input at strategic phases of the scoping review.

Potential panelists were identified through organizational networks and were invited to participate via email. Six members agreed to participate (CSG, TS, HCW, JZ, SM, DL) on the advisory panel. Panelists and the research team convened a meeting and discussed the strategic steps and opportunities for involvement and input in the review. Specifically, the advisory panel will support refinement of inclusion criteria, prioritization of data abstraction elements, assist in interpretation of findings and develop dissemination strategies. Panelists have national and international networks that will ensure the scope of the review reflects the knowledge needs of a diverse audience, which is directly in line with the stated aim of providing practical guidance on the selection and application of frameworks for DHIs. As the intended audience of this paper does not include patients and members of the general public, they were not included as part of the advisory panel. The perspectives of patients and the general public will be incorporated through their participation and involvement in the respective studies included as part of this review.”

Reviewer 2: Comments

This submission promises a useful contribution to the field. Some clarifications are required, however.

Abstract: Perhaps not here, and it is picked up later, but more critical and comprehensive choice and definition of the term ‘DHI’ is required (in relation to the field). When ‘healthcare’ is stated, is this always formal or does it include informal? This needs thinking through for the whole paper. Is there a specific area of focus? This is very broad. What is ‘integrated knowledge translation’? It doesn’t mean a lot in the abstract. Re ethical review = yes, none needed, but there may be ethical issues and these are not acknowledged or addressed later (main text p.10). How will the ‘practical guidance’ manifest/be manifested? Researchers seem to be the target of the output - what about designers/creators/users, etc.? Overall, the abstract needs honing and focus!

We appreciate your thoughtful comments. We have further described the term DHI in the abstract, removed reference to the integrated knowledge translation approach, and added details in the main text to expand on the points raised.

Abstract, Introduction: *“Digital health interventions (DHIs) are defined as health services delivered electronically through formal or informal care. DHIs can range from electronic medical records used by providers to mobile health apps used by consumers to maintain wellness.”*

Abstract, Ethics and Dissemination: *“We have engaged an advisory panel of digital health knowledge users (i.e., policymakers, researchers and developers of DHIs) to provide input at strategic stages of the scoping review to enhance the relevance of findings and their uptake, including tailored dissemination activities. Specifically, they will provide feedback on the eligibility criteria, data abstraction elements, interpretation of findings and assist in developing key messages for dissemination. This study does not require ethical review. Findings from this review will support decision making when selecting appropriate frameworks to guide the implementation or evaluation of DHIs.”*

Page 6, Paragraph 3: *“We will use the WHO definition of healthcare which encompasses physical, mental and social well-being and spans across multiple disciplines such as psychology, sociology or medical sciences.¹¹ DHI was defined as any health service or treatment delivered using technology that aims to facilitate, capture, or exchange knowledge (formally or informally).⁵ DHI definition was generated from a search of the literature and consultations with digital health knowledge users, including policymakers, researchers, clinicians and developers.”*

Main paper: Research seems to be the main focus of this work. What about policy/developer/clinical people????? Which discipline(s) are the identified n=159 frameworks targeted for? This needs attention here and throughout.

Thank you for this suggestion. The review is targeting researchers, clinicians, policymakers, and developers as knowledge users, which has been further clarified this in the main text as outlined below:

Page 5, Paragraph 1: *“Frameworks help to systematically organize and link research objectives or constructs, and provide useful insights in quantitative and qualitative analyses, which can inform interpretation or decision-making.^{1,2} The Medical Research Council (MRC) categorizes frameworks into four distinct groups: 1) development frameworks, which can model processes and outcomes; 2) feasibility frameworks, which can guide pilot testing of an intervention; 3) implementation frameworks to guide evidence into clinical practice; and 4) evaluation frameworks, to determine intervention effectiveness.³*

A recent scoping review, identified over 159 knowledge translation frameworks to guide implementation and evaluation of health interventions in clinical practice settings, presenting a plethora of options for the implementation and evaluation of digital health interventions (DHIs).⁴ Implementation and evaluation frameworks present an opportunity to address gaps relating not only to whether an intervention works but provide actionable insights for how to support their uptake in practice.”

Page 6, Paragraph 1: *“The results of this review will provide practical guidance and support for researchers, clinicians, organizations, policymakers and developers in selecting the most appropriate framework for DHIs, which will support evidence-based approaches in relation to implementation and evaluation efforts.”*

p.7 (line 47) should be ‘this paper outlines the’ not ‘outlines a’.

We appreciate the grammatical catch. We have revised accordingly.

Also, on p.7 - the constructs mentioned - from what discipline/which disciplines?

We have clarified the key words in the Information Sources section.

Page 7 Paragraph 2: *“We will search MEDLINE, EMBASE, CINAHL, and PsychINFO using key words such as ‘digital health’ and ‘framework’. Additional search terms were drawn from multiple disciplines such as psychology, nursing, sociology, and medicine to ensure comprehensiveness.”*

Grey literature needs a mention on p.8, with an emphasis on multidisciplinary (and which disciplines?).

Thank you for this comment, we have addressed this on Page 7, Paragraph 3:

“We will use keywords such as ‘digital health’, ‘frameworks’, and ‘benefits evaluation’ to refine our supplementary search. In addition, we will also scan reference lists of included studies and conduct a forward citation search (i.e., examine studies that reference the included studies) in Web of Science using the cited reference search feature. This will ensure our approach is comprehensive.”

What is OSF on p.9?

We have added the following sentence to better describe OSF on Page 6, Paragraph 1:

“OSF is an open source platform where researchers can share protocols, data and contributes to transparency of research.¹⁰”

Also on p.9 there is mention of ‘Random sample’ - by % or n= or?? Please clarify.

We have revised to improve clarity.

Page 8, Paragraph 1: *“Prior to screening, a pilot test will be completed using a random sample of 10% of citations or full text articles, with the expressed purpose of assessing agreement between reviewers at each level. Specifically, percent agreement will be used to assess agreement among reviewers (inter-rater reliability $\geq 80\%$ will be considered adequate). If agreement is not reached, a second pilot will be conducted with another random sample of 10%. A third reviewer will mediate any disagreements. Citations and full text articles will be screened in duplicate by two reviewers.”*

Who are the appropriate knowledge users? Need to specify on p.10.

Thank you for your comment, we have revised select sentences throughout the manuscript to better highlighted researchers, clinicians, policymakers and developers of DHIs as the intended knowledge users.

Page 6, Paragraph 1: *“The results of this review will provide practical guidance and support for researchers, clinicians, policymakers, and developers in selecting the most appropriate framework for DHIs, which will support evidence-based approaches in relation to implementation and evaluation efforts.”*

Page 9, Paragraph 2: *“A priori, we decided to engage senior leaders and policymakers at organizations that promote or support implementation of digital health solutions, as well as researchers, clinicians, and developers evaluating DHIs in real world settings”.*

Page 11, Paragraph 2: *“Overall, identification of frameworks will serve as a guide for researchers, clinicians, policymakers, and developers of DHIs by providing practical guidance on which frameworks may be most appropriate for which objectives (i.e., implementation or evaluation).”*

Re PPI - this is dismissive. Actually, people are involved via included studies and also as stakeholders. Please address.

Thanks, we have addressed your comment, by adding our digital health knowledge users panel to the PPI section, and detailed their role, selection and contributions.

Page 9, Paragraph 1: *“We employed an integrated knowledge translation strategy to engage digital health knowledge users in the review process to ensure the scope of the project met the needs of various end-users. Knowledge users are defined as individuals who are likely to use the findings to inform health decision making.² A priori, we decided to engage senior leaders and policymakers at organizations that promote or support implementation of digital health solutions, as well as researchers, clinicians, and developers evaluating DHIs in real world settings. An advisory panel of*

digital health knowledge users was established to provide input at strategic phases of the scoping review.

Potential panelists were identified through organizational networks and were invited to participate via email. Six members agreed to participate (CSG, TS, HCW, JZ, SM, DL) on the advisory panel. Panelists and the research team convened a meeting and discussed the strategic steps and opportunities for involvement and input in the review. Specifically, the advisory panel will support refinement of inclusion criteria, prioritization of data abstraction elements, assist in interpretation of findings and develop dissemination strategies. Panelists have national and international networks that will ensure the scope of the review reflects the knowledge needs of a diverse audience, which is directly in line with the stated aim of providing practical guidance on the selection and application of frameworks for DHIs. As the intended audience of this paper does not include patients and members of the general public, they were not included as part of the advisory panel. The perspectives of patients and the general public will be incorporated through their participation and involvement in the respective studies included as part of this review.”

On p.11, consider adding ‘application’ as well as ‘evaluation’ of frameworks.

Thank you for your comment, we have addressed this in our analysis section.

Page 10, Paragraph 1: *“Descriptions of individual frameworks will be organized by key categories, including study design, report type (published vs non-published), methodological approach (i.e. how the framework is intended to be applied) and application papers (i.e. how the framework has been applied in practice).”*

Is this work to guide implementation or evaluation or both? Please confirm at p.11/line 32.

The work is to guide both implementation and evaluation and we acknowledge that we may find frameworks with a sole focus on either implementation or evaluation as well as frameworks that address both. We have clarified this in the main text.

Page 10, Paragraph 2: *“Finally, we anticipate that some included frameworks will have a dual purpose of addressing implementation and evaluation or may contain components that lend themselves to both constructs. When this occurs, we will discuss the overlap with advisory panel and devise the most appropriate plan for analysis.”*

On p.11/line 44/45 = creates not create.

Thank you for catching that grammatical mistake, we have revised accordingly.

The user panel must involve PPI??? This needs addressing at p.11.

Thanks we have addressed your comment, by adding our advisory panel to the PPI section and highlighting the contributions of patients and the general public.

Page 9, Paragraph 1: *“We employed an integrated knowledge translation strategy to engage digital health knowledge users in the review process to ensure the scope of the project met the needs of various end-users. Knowledge users are defined as individuals who are likely to use the findings to inform health decision making.² A priori, we decided to engage senior leaders and policymakers at organizations that promote or support implementation of digital health solutions, as well as researchers, clinicians, and developers evaluating DHIs in real world settings. An advisory panel of digital health knowledge users was established to provide input at strategic phases of the scoping review.*

Potential panelists were identified through organizational networks and were invited to participate via email. Six members agreed to participate (CSG, TS, HCW, JZ, SM, DL) on the advisory panel. Panelists and the research team convened a meeting and discussed the strategic steps and opportunities for involvement and input in the review. Specifically, the advisory panel will support refinement of inclusion criteria, prioritization of data abstraction elements, assist in interpretation of findings and develop dissemination strategies. Panelists have national and international networks that will ensure the scope of the review reflects the knowledge needs of a diverse audience, which is directly in line with the stated aim of providing practical guidance on the selection and application of frameworks for DHIs. As the intended audience of this paper does not include patients and members of the general public, they were not included as part of the advisory panel. The perspectives of patients and the general public will be incorporated through their participation and involvement in the respective studies included as part of this review.”

DHIs definition - please consider the role off PPI/user group in defining this?

Thank you for your comment, we have included additional details on how the definition of DHI was generated.

Page 6, Paragraph 2: *“DHI definition was generated from a search of the literature and consultations with digital health knowledge users, including policymakers, researchers, clinicians and developers.”*

Close work with an information specialist is great, but more with other who define DHIs needs to be incorporated throughout.

We have revised the eligibility section to expand on the definition of DHIs.

Page 6, Paragraph 2: *“We will use the WHO definition of healthcare which encompasses physical, mental and social well-being and spans across multiple disciplines such as psychology, sociology or medical sciences.¹¹ DHI was defined as any health service or treatment delivered using technology that aims to facilitate, capture, or exchange knowledge (formally or informally).⁵ DHI definition was generated from a search of the literature and consultations with digital health knowledge users, including policymakers, researchers, clinicians and developers.”*

What is this communications and dissemination plan for society???

We have addressed this in the ethics and dissemination section of the main text.

Page 8, last paragraph: *“This scoping review is focused on published reports and studies of DHI and does not involve patients or primary data collection; as such, no formal ethics approval is required.*

The dissemination plan will be tailored to end-users and will include passive and interactive strategies such as peer reviewed publications, conference events and other network events with digital health knowledge users. To ensure broader reach, we will also disseminate our findings through social media platforms, and public-facing communications such as one-page briefs released on the Women’s College Institute for Health Innovation website at Women’s College hospital.”

VERSION 2 – REVIEW

REVIEWER	Anastasia Mallidou University of Victoria, BC Canada
REVIEW RETURNED	15-May-2020

GENERAL COMMENTS	<p>The authors addressed most of the reviewers' previous comments. However, there are a couple of questions and areas that need clarification:</p> <ol style="list-style-type: none"> 1. One of the objectives (#1) is similar/same with the overall purpose of this scoping review. Please revise. 2. The OSF registration number is not reported (please update the PRISMA-ScR checklist as well). 3. The WHO definition refers to "health"; not to "healthcare". Also, the citation for this definition needs revision. 4. In the eligibility criteria, years considered or publication status of included studies are not described. Please provide rationale for your choice. 5. The limitations are confusing as they are described. I would suggest to group them into the following categories: a) definitions of key terms/concepts (e.g., DHIs, frameworks); b) description of frameworks (e.g., use, method of application); and c) Publication bias (?). 6. I would strongly encourage the authors to update the PRISMA-ScR checklist accordingly including page numbers. Also, in the box #8 (search), Appendix 2 is the correct response (not #1). <p>Overall, the manuscript has been much improved! Thanks for the opportunity to review this interesting and important knowledge synthesis protocol.</p>
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REVIEWER	Heather May Morgan University of Aberdeen, UK
REVIEW RETURNED	21-May-2020

GENERAL COMMENTS	Excellent responses to the reviews.
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VERSION 2 – AUTHOR RESPONSE

Reviewer 1: Comments

1. One of the objectives (#1) is similar/same with the overall purpose of this scoping review. Please revise.

Thank you for your comment, we have further clarified Objective 1 to avoid duplication.

Page 5, lines 26-27:

“This paper outlines the protocol for a scoping review to identify frameworks to guide the implementation or evaluation of DHIs. Specifically, our objectives are to:

1. *To describe the attributes of existing frameworks that have been used to guide the implementation or evaluation of DHIs.”*
2. *Identify the proposed role of each framework, including the constructs and mechanisms they target.*
3. *Describe how each framework has been applied in primary studies, if applicable.*

2. The OSF registration number is not reported (please update the PRISMA-ScR checklist as well).

We have provided a web link to our protocol and updated the PRISMA-ScR checklist.

Page 6, lines 37-38:

“This protocol is registered on Open Science Framework (OSF) and is available at <https://osf.io/8jydm/>.”

3. The WHO definition refers to "health"; not to "healthcare". Also, the citation for this definition needs revision.

We have revised the statement to align with the language used by the WHO. The reference has also been updated.

Page 6, lines 44-45:

“We will use the WHO definition of health which encompasses physical, mental and social well-being and spans across multiple disciplines such as psychology, sociology or medical sciences.¹¹”

Reference: Constitution of the World Health Organization. In: World Health Organization: Basic documents. 45th ed. Geneva: World Health Organization; 2005 [Available from: <https://apps.who.int/gb/bd/>] accessed June 8, 2020.

4. In the eligibility criteria, years considered or publication status of included studies are not described. Please provide rationale for your choice.

We have revised the statement to provide a justification of why we are not limiting inclusion based on publication status or years.

Page 6, lines 53-55:

“No limitations will be placed on user population, comparators, study design, publication status or geographic region to enhance the comprehensiveness of our results and avoid the unintended exclusion of relevant studies.”

5. The limitations are confusing as they are described. I would suggest to group them into the following categories: a) definitions of key terms/concepts (e.g., DHIs, frameworks); b) description of frameworks (e.g., use, method of application); and c) Publication bias (?).

Thank you for this excellent suggestion. We have revised the discussion as outlined below.

Page 10-11, lines: 162-192:

“Given the breadth of this scoping review, we anticipate a few key challenges. The first relates to the inconsistent and often ill-defined nature of DHIs and frameworks. To be inclusive, we have defined DHIs broadly as any health intervention that can be delivered utilizing technology to ensure we capture frameworks that are currently being used across formal (e.g., care delivered within the walls of a healthcare organization) and informal settings (e.g., direct to consumer technologies). Moreover, use of the term framework itself also creates challenges. For the purposes of this scoping review, we have defined a framework as a tool to systematically organize and link research questions or constructs, but a range of terms are often used synonymously (e.g., models or processes). To account for this variability, we will include studies reporting on ‘models’ and work closely with the advisory panel to confirm

whether the reported framework aligns with our a priori definition as well as the needs of relevant digital health knowledge user groups.

Second, we anticipate challenges searching the literature as a product of inconsistent terminology outlined above. We have constructed our search to balance comprehensiveness and specificity, working closely with an information specialist to ensure the number of citations are focused and feasible. Several iterations of the literature search were conducted. Specifically, we added key words and removed them in a stepwise fashion to understand the impact on specificity and sensitivity of our search. We used a randomized sample of 200 citations and multiple iterations of the literature search were screened using the inclusion criteria. Two reviewers screened citations, discrepancies were discussed among the internal research team, and the number of included studies were examined to explore the specificity of search terms. Through this iterative process we developed our search strategy, which was then peer reviewed using PRESS checklist; however, we anticipate additional challenges when screening.

Third, we anticipate challenges arising from poor reporting or limited description, as evidenced by previous studies.^{17, 18} Authors may not provide sufficient details on the frameworks they utilize or their method of application.¹⁹ To mitigate this, we will contact authors to obtain additional information whenever information is missing or unclear.

Finally, we anticipate that some included frameworks will have a dual purpose of addressing implementation and evaluation or may contain components that lend themselves to both constructs. We will convene with the advisory committee on a quarterly basis to discuss these issues as they arise and will devise the most appropriate plan for analysis through group consensus.”

6. I would strongly encourage the authors to update the PRISMA-ScR checklist accordingly including page numbers. Also, in the box #8 (search), Appendix 2 is the correct response (not #1).

We have revised the PRISMA-ScR checklist. Our search strategy is listed in appendix 1, and the criteria for inclusion is detailed in appendix 2.

VERSION 3 – REVIEW

REVIEWER	Anastasia Mallidou University of Victoria, Canada
REVIEW RETURNED	21-Jun-2020

GENERAL COMMENTS	<p>This revised manuscript has improved. However, there are some areas that need more attention. Specifically,</p> <ol style="list-style-type: none"> 1. In Abstract, grey literature is included in the searches; however, in Appendix 2 (eligibility criteria), only studies are included. By the way, the group of experimental studies are not include cross-sectional studies. 2. In Strengths and Limitations (p. 5), the second bullet does not make sense. Please revise. Also, the third bullet about quality assessment of the included studies is not a limitation, since scoping reviews do not require any. 3. In Strength and Limitations (p. 11-12), only "challenges" are described; but not any strengths. Finally, the last paragraph of the second challenge (about screening process), it may fit better in the Methods section. It is definitely not a strength of the review!
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Overall, the manuscript is interesting, innovative and timely.
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VERSION 3 – AUTHOR RESPONSE

Reviewer 1: Comments

1. In Abstract, grey literature is included in the searches; however, in Appendix 2 (eligibility criteria), only studies are included. By the way, the group of experimental studies are not include cross-sectional studies.

Thank you for your comment, we have revised Appendix 2 to reflect the inclusion of grey literature and cross-sectional studies.

Appendix 2:

“Question 1: Does this study include humans?”

- a. *If yes, include*
- b. *Exclude animal studies/models, non-human or vertebra studies*

Question 2: Does this study examine the use of a digital health intervention?

- a. *Include studies focusing on digital health interventions as their primary component of the study. A digital health intervention is any health intervention that is being delivered by technology and can include the following items: e-health, virtual healthcare, smartphone apps aimed at healthcare issue, wearable technologies, telemedicine or health education interventions delivered digitally.*
- b. *Exclude interventions that are focused on creating scales, checklists or other metrics that are not a digital health intervention. Example of an excluded study: a cross-sectional study to create a checklist for conducting health technology assessments.*

Question 3: Does this study use a framework to implement or evaluate the digital intervention?

- a. *Include studies that focus on frameworks. Frameworks can help guide evaluation questions by systematically organizing and linking research questions when evaluating a digital intervention.*
- b. *Exclude studies that focus on theoretical mathematical models or statistical models or simulations.*

Question 4: Is this an empirical study, qualitative study, a review, or grey literature?

- a. *Include any study design (i.e., randomized controlled trials, observational studies, cross sectional studies, qualitative studies, systematic reviews), regardless of publication status. Note we will also be including grey literature such as reports, working papers, government documents, and white papers (when applicable).*
- b. *Exclude studies if an editorial, letter to the editor (without primary data) or commentaries.”*

2. In Strengths and Limitations (p. 5), the second bullet does not make sense. Please revise. Also, the third bullet about quality assessment of the included studies is not a limitation, since scoping reviews do not require any.

Thank you for your comment, we have changed the wording to highlight the respective strengths of our review protocol.

Page 4:

- *To our knowledge, this is the first scoping review to identify frameworks to implement or evaluate digital health interventions on a broad scale.*
- *The study protocol was informed by rigorous and established methods as suggested by the Joanna Briggs Institute for scoping reviews and adheres to the PRISMA Extension for Scoping Reviews (PRISMA-ScR)*
- *Digital health knowledge users, such as policymakers, researchers, clinicians, and developers have been engaged in the design and development of the review since its inception to ensure relevance and scope of project.*
- *This scoping review will not examine the usability of the frameworks, as such our findings will be limited to descriptive syntheses.*
- *Findings stemming from this review will provide practical guidance for digital health knowledge users and enable them to use evidence informed approaches to select optimal frameworks to implement or evaluate digital health interventions.*

3. In Strength and Limitations (p. 11-12), only "challenges" are described; but not any strengths. Finally, the last paragraph of the second challenge (about screening process), it may fit better in the Methods section. It is definitely not a strength of the review! Overall, the manuscript is interesting, innovative and timely.

We have revised the strengths and limitations section accordingly. To clarify, the last paragraph of the second challenge refers to the generation of the literature search and our process. The screening process is described in the methods section (Page 7-8, lines 87-99).

Page 10-11 Lines 158-162: *"To our knowledge, this is the first scoping review to examine the use of frameworks to guide implementation or evaluation of DHIs on a broad scale. The protocol was generated using established methods for the conduct of scoping reviews and informed by input from digital health knowledge users to define scope and ensure the relevance of the project. A clear understanding of which frameworks can be used for development, feasibility, implementation, and evaluation of DHIs will facilitate decision making by making evidence-based approaches available to policymakers, clinicians, and developers. Additionally, this guidance will support researchers in identifying appropriate frameworks with the goal of establishing consistency across studies, minimizing duplication, and accelerating scientific progress."*

Page 11 Lines 174-184: *"Secondly, we also anticipate challenges searching the literature as a product of inconsistent terminology outlined above. We have constructed our search to balance comprehensiveness and specificity, working closely with an information specialist to ensure the number of citations are focused and feasible. Several iterations of the literature search were conducted, specifically, we added in key words and removed them in a stepwise fashion to understand the impact on specificity and sensitivity of our search. Through this iterative process, we developed our search strategy, which was then peer reviewed using the PRESS checklist; however, we anticipate additional challenges when screening."*