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# Identifying optimal frameworks to implement or evaluate digital health interventions: A scoping review protocol



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# Identifying optimal frameworks to implement or evaluate digital health interventions: A scoping review protocol

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## Abstract

**Introduction**: Digital health interventions (DHIs) are increasingly popular in healthcare. DHIs involve complex interactions between user, technology and the healthcare team, posing challenges for implementation and evaluation. Theoretical or interpretive frameworks are crucial in providing researchers guidance and clarity on implementation and evaluation approaches; however, there is a lack of standardization on which frameworks to use in which contexts. Our goal is to conduct a scoping review to identify frameworks to guide the implementation or evaluation of DHIs.

**Methods and Analysis**: We will conduct a scoping review using methods outlined by the Joanna Briggs Institute Reviewers' Manual and will conform to the PRISMA Extension for Scoping Reviews. Studies will be included if they report on frameworks (i.e., theoretical, interpretive, developmental) that are used to guide either implementation or evaluation of DHIs. Electronic databases, including MEDLINE, EMBASE, CINAHL, and PsychINFO will be searched in addition to grey literature and reference lists of included studies. Citations and full text articles will be screened independently and in duplicate in Covidence after a reliability check among reviewers. We will use qualitative description to summarize findings, and focus on how research objectives and type of DHI are aligned with the frameworks used.

**Ethics and dissemination**: We will employ an integrated knowledge translation approach and establish a digital health knowledge user panel to provide input at strategic stages of the scoping review. 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 provide practical guidance on frameworks to guide the implementation or evaluation of DHIs.

**Strengths and Limitations**

- Frameworks are crucial in providing researchers guidance and clarity on implementation and evaluation approaches; however, there is a lack of standardization on which frameworks to use for digital health interventions.
- A comprehensive scoping review is detailed
- Findings will provide practical guidance for researchers, clinicians, policymakers and developers of digital health interventions on selecting optimal for implementation or evaluation of digital health interventions

## Introduction

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. A plethora of frameworks exist,[2 3] with over 159 created to guide implementation and evaluation of healthcare interventions.[4] This is likely due, in part, to the reality that framework often vary based on specific aspects of implementation or evaluation and are often tailored to a specific clinical area.[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.[1] 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.

Digital health interventions (DHIs) differ from traditional health interventions such as implementing a new program or evaluating drug effectiveness. DHIs include any health service or treatment delivered using technology that aims to facilitate, capture, or exchange knowledge.[5] Examples of DHIs include electronic medical records, mobile applications or wearable sensors for remote monitoring. DHIs are complex, differ both in intended functionality (e.g., self-management support versus data sharing), and intended users (e.g., patients versus providers). DHIs are not static; instead the interaction between the technology, end-user and the healthcare team and setting is by its nature dynamic and thus can vary substantially over time.[6] Given this, implementing or evaluating DHIs is challenging. Accordingly, frameworks may help guide researchers, clinicians, policymakers, and developers of DHIs in such activities; however, there is a lack of standardization in DHIs and it is unclear which frameworks should be used for implementation or evaluation.

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

1. Identify frameworks designed to guide the implementation or evaluation of DHIs.
2. Identify the proposed role of each framework, including the constructs they target.
3. Describe how each framework has been applied in primary studies, if applicable.

The results of this review will provide practical guidance to researchers, organizations, policy makers and developers interested in implementing or evaluating DHIs.

## Methods and Analysis

We will conduct a scoping review to comprehensively search the literature, 'map' the evidence, and identify gaps in the research knowledge base.[7 8] The study will be conducted using established methods outlined by the Joanna Briggs Institute Reviewers' Manual[7] and reporting will conform to the PRISMA Extension for Scoping Reviews (PRISMA-ScR).[9] Our protocol is registered on Open Science Framework (OSF) and is available at (https://osf.io/8jydm/).

## Eligibility Criteria

Studies reporting on the development or application of frameworks (i.e., theoretical or interpretive) to guide implementation or evaluation of DHIs in healthcare will be included. Implementation frameworks will be operationalized according to MRC guidance, as frameworks that aim to guide research into practice, which can include development, feasibility, and dissemination frameworks.[1] Evaluation frameworks will be defined as frameworks that focus on determining the effectiveness of DHIs, which includes measuring outcomes and understanding processes or mechanisms of action.[1] No limitations will be placed on user population, comparators, study design, publication status or geographic region. Conference abstracts/proceedings and white papers will be included. We will include studies reported in other languages and use appropriate tools (i.e., Google translate, translation services, contact author) to assess inclusion. Commentaries and studies examining mathematical or statistical frameworks will be excluded.

## Information sources

An experienced information specialist developed the literature search in consultation with the multidisciplinary research team. The search will be peer reviewed by a second information specialist using the Peer Review of Electronic Search Strategy (PRESS) checklist to ensure the search is comprehensive and maximizes appropriate search terms.[10]

We will search MEDLINE, EMBASE, CINAHL, and PsychINFO using key words such as 'digital health' and 'framework'. The databases will be searched from inception to present and the search strategy is presented in Appendix 1. We chose not to use the BeHEMoTh (behaviour of

interest, health context, exclusions, and models or theory) approach[11] as specified in our OSF registration. Although this approach has been successful in identifying frameworks in knowledge translation,[4] it did not prove to be a feasible approach in our scoping review as it yielded a vast number of citations with limited specificity related to our objectives. We utilized a simplified heuristic, which included identifying DHIs in various healthcare contexts, adding terms for frameworks, and removing exclusions such as animal studies (Appendix 1).

The search strategy will be supplemented by a search for grey literature using the checklist suggested by the Canadian Agency for Drugs and Technologies in Health (CADTH).[12] Specifically, we will search for white papers or benefit evaluation studies through Health Technology Assessment Agencies such as Agency for Healthcare Research and Quality (AHRQ) and National Institute for Health and Care Excellence (NICE), Canada Infoway and other relevant organizations involved in providing guidance on delivery of healthcare services. We will also scan reference lists of included studies and conduct a forward citation search (i.e., examine studies that reference included studies) to ensure our approach is comprehensive.

**Eligibility Screening Process**

Citations obtained from the literature search will be uploaded to Covidence,[13] a systematic review software program which organizes citations, enables screening of citations by multiple reviewers, and identifies discrepancies. We will apply a two-step process for identifying relevant citations. At level 1, titles and abstracts will be assessed using the eligibility criteria (Appendix 2). Studies with abstracts fulfilling criteria will be passed to level 2 where the eligibility criteria will be applied to the full text articles.

Prior to screening, a pilot test will be completed using a random sample of citations or full text, 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 ≥80% will be considered adequate). A third reviewer will mediate any disagreements. Citations and full text articles will be screened in duplicate by two reviewers.

**Data items and abstraction process**

Studies fulfilling the eligibility criteria will be abstracted in Excel. We will extract the following study characteristics for the identified frameworks: name, reference, theory associated

with framework (if applicable), description of its components or constructs, and its application in research (or stage of research to which it was applied, if applicable). For studies outlining the application of a framework, additional characteristics will be abstracted such as the type of DHI, healthcare setting, method of application, and nature and directionality of the results. We will abstract information such as name of the framework, the role of framework in study (i.e., development, feasibility/pilot testing, implementation, evaluation), components of the framework that were utilized, type of DHI, the objective of the study (if applicable), and healthcare setting from included studies.

**Methodological appraisal**

We will not assess the quality of included articles in the scoping review (consistent with Joanna Briggs Institute Reviewer's Manual[7]) as our purpose is to gain an overview of frameworks used in relation to DHIs and not to assess the quality of their application.

**Ethics and Dissemination**

This scoping review is focused on published reports and studies of DHI and does not involve patients; as such, no formal ethics approval is required.

To facilitate uptake and dissemination of findings, we will employ an integrated knowledge translation strategy to ensure our findings meet the needs of various knowledge users, defined as individuals who are likely to use the information from the review to make an informed health decision.[3] We established a panel of digital health knowledge users, *a priori*, who will provide input at strategic stages of the scoping review, including study design, interpretation of results, and communication of findings. Specifically, digital health knowledge users will help refine inclusion and exclusion criteria, prioritize selection of data abstraction elements, assist in interpretation and help develop dissemination strategies for communication of findings stemming from the review. Digital health knowledge users will include senior leaders at organizations that promote or support implementation of digital health solutions, and researchers focused on evaluating DHIs. Digital health knowledge users will have national and international networks that will help to ensure 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.

**Patient and Public Involvement**

No patients are involved.

**Analysis**

Included studies will be summarized using qualitative description, an approach that seeks to create an understanding of phenomenon through accessing the meanings ascribed by authors.[14] 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). We will then synthesize findings by mapping core components of the frameworks and examining how research objectives and type of DHI are linked to the framework. Categorization will use language directly from included studies, where possible, and authors will be contacted when information is not present or unclear. Digital health knowledge users will guide the synthesis of findings by providing input on the level of detail abstracted from included articles and provide input on categorization of frameworks, where appropriate.

**Strengths and Limitations**

To our knowledge, this is the first scoping review to examine the use of frameworks to guide implementation or evaluation of DHIs. A clear understanding of which frameworks can be used for the different phases of a research study will provide practical guidance for researchers, clinicians, policymakers and developers in implementing or determining effectiveness of DHIs.

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 through technology to ensure we capture frameworks that are currently being used across healthcare settings. Moreover, the term framework also create challenges, as we have defined 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, we will include studies reporting on 'models' and work closely with the digital health knowledge user panel to confirm whether the reported framework aligns with our *a priori* definition. Relatedly, authors may not provide sufficient details on the frameworks they utilize or their method of application. 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. When this occurs, we will discuss the overlap with digital health knowledge users and devise the most appropriate plan for analysis.

We also anticipate challenges searching the literature. DHIs are not well defined in electronic databases as they are referenced using a plethora of key terms. As such, we have constructed our search in an attempt to balance comprehensiveness and specificity. We have worked closely with an information specialist to ensure the number of citations are focused and feasible. Several iterations of the literature search were conducted using a randomized sample of 200 citations and the specificity and sensitivity of search terms were tested 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 examine the specificity of search terms. Through iterative testing, we feel confident in our current literature strategy, however, additional challenges may arise when screening.

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). In parallel, the results will contribute to a more nuanced understanding of how to evaluate and implement DHIs, including the identification and understanding of key constructs.

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**Authors' Contributions:**

CS, LD conceived and developed the study. CS drafted the manuscript. MC, VK, RSB, TH, SM, Dl, HCW, JZ, CGS, and LD reviewed and edited the manuscript.

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**Conflict of Interest:**

The authors have no conflicts of interest to report.

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## Appendix 1. Primary Literature Search in Medline

Database: Ovid MEDLINE: Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE® <1946-Present>
Search Strategy:
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1 exp Telemedicine/ (25845)
2 (telemed* or tele-med* or telecare or tele-care or teleconsult* or tele-consult* or telehealth* or tele-health* or telemonitor* or tele-monitor* or telerehab* or tele-rehab*).tw,kf. (17416)
3 (ehealth* or e-health* or mhealth* or m-health* or emental health* or e-mental health* or epsychiatr* or e-psychiatr* or epsychol* or e-psychol* or etherap* or e-therap*).tw,kf. (10073)
4 (emedicine or e-medicine*).tw,kf. (78)
5 (mobile health* or mobile care or mobile medicine).tw,kf. (3793)
6 (digital* adj3 (medic* or care or health* or healthcare or health-care)).tw,kf. (3065)
7 (digital* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or surger* or surgic* or therap* or treatment?)).tw,kf. (5936)
8 (remote* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or surger* or surgic* or therap* or treatment?)).tw,kf. (6643)
9 Monitoring, Ambulatory/ (7806)
10 ((outpatient* or out-patient* or ambulator* or home? or homebased or home-based) adj3 (manag* or monitor*)).tw,kf. (24341)
11 exp Biomedical Technology/ (13203)
12 ((biomedic* or bio-medic* or health* or healthcare or health care or medical) adj technolog*).tw,kf. (13535)
13 Medical Informatics/ or Medical Informatics Applications/ (13622)
14 ((health* or medical) adj informatic*).tw,kf. (5056)
15 exp Therapy, Computer-Assisted/ (59720)
16 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 care).tw,kf. (8049)
17 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 health*).tw,kf. (27319)
18 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (healthcare or health care)).tw,kf. (6410)
19 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (medicine or medical)).tw,kf. (19800)
20 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile

phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 consult*).tw,kf. (1299)
21 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 diagnos*).tw,kf. (13043)
22 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 intervention?).tw,kf. (9139)
23 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 manag*).tw,kf. (7259)
24 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 monitor*).tw,kf. (8457)
25 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 palliat*).tw,kf. (133)
26 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 rehab*).tw,kf. (1264)
27 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (surger* or surgic*)).tw,kf. (7354)
28 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 therap*).tw,kf. (6817)
29 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 treatment?).tw,kf. (10336)
30 Wearable Electronic Devices/ (1321)
31 wearable?.tw,kf. (10007)
32 or/1-31 (253918)
33 exp *Delivery of Health Care/ (619520)
34 exp Computers/ (76307)
35 Electronic Mail/ (2573)
36 Internet/ (69753)
37 Telecommunications/ (4741)

38 (internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver*).tw,kf. (995758)
39 33 and (34 or 35 or 36 or 37 or 38) (50511)
40 32 or 39 [DIGITAL HEALTH APPLICATIONS] (282776)
41 (evaluat* adj3 (design* or frame or frames or framework? or guid* or model or models or schem* or strateg* or theor*)).tw,kf. (105535)
42 (apprais* adj3 (frame or frames or framework? or model or models or theor*)).tw,kf. (927)
43 (apprais* adj3 (design* or guid* or schem* or strateg*)).ti,kf. (313)
44 (assess* adj3 (frame or frames or framework? or model or models or theor*)).tw,kf. (47798)
45 (assess* adj3 (design* or guid* or schem* or strateg*)).ti,kf. (3366)
46 (implement* adj3 (design* or frame or frames or framework? or guid* or model or models or schem* or strateg* or theor*)).tw,kf. (57152)
47 (evidence-based adj (frame or frames or framework? or model or models or theor*)).tw,kf. (769)
48 (evidence-based adj (design* or guid* or schem* or strateg*)).ti,kf. (1559)
49 (service adj (frame or frames or framework? or model or models or theor*)).tw,kf. (2165)
50 (service adj (design* or guid* or schem* or strateg*)).ti,kf. (201)
51 or/41-50 [EVALUATION/IMPLEMENTATION FRAMEWORKS] (212588)
52 40 and 51 [DIGITAL HEALTH - EVALUATION/IMPLEMENTATION FRAMEWORKS] (8974)
53 exp Animals/ not Humans/ (4614915)
54 52 not 53 [ANIMAL-ONLY REMOVED] (8859)

**********

## Appendix 2. Eligibility Criteria

**Question 1: Does this study include humans?**

a. If yes, **INCLUDE**
b. **EXCLUDE** animal studies/models, non-humans or vertebrae 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: ehealth, 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 exclude: 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 discuss checklists, theoretical mathematical models or statistical models.

**Question 4: Is this an experimental study, qualitative study, or review?**

a. **INCLUDE** any study design (i.e., randomized controlled trials, observational studies, cross-sectional studies, qualitative studies, systematic review)
b. **EXCLUDE** studies if it's an editorial (without any primary data), letter to the editor or commentary.

BMJ Open

# Identifying optimal frameworks to implement or evaluate digital health interventions: A scoping review protocol

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# Identifying optimal frameworks to implement or evaluate digital health interventions: A scoping review protocol

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## 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. DHIs involve complex interactions between user, technology and the healthcare team, posing challenges for implementation and evaluation. Theoretical or interpretive frameworks are crucial in providing researchers guidance and clarity on implementation or evaluation approaches; however, there is a lack of standardization on which frameworks to use in which contexts. Our goal is to conduct a scoping review to identify frameworks to guide the implementation or evaluation of DHIs.

**Methods and Analysis**: We will conduct a scoping review using methods outlined by the Joanna Briggs Institute Reviewers' Manual and will conform to the PRISMA Extension for Scoping Reviews. Studies will be included if they report on frameworks (i.e., theoretical, interpretive, developmental) that are used to guide either implementation or evaluation of DHIs. Electronic databases, including MEDLINE, EMBASE, CINAHL, and PsychINFO will be searched in addition to grey literature and reference lists of included studies. Citations and full text articles will be screened independently and in duplicate in Covidence after a reliability check among reviewers. We will use qualitative description to summarize findings and focus on how research objectives and type of DHIs are aligned with the frameworks used.

**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.

## 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.

## Introduction

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.

DHIs differ from traditional health interventions such as implementing a new program or evaluating drug effectiveness. DHIs include any health service or treatment delivered using technology that aims to facilitate, capture, or exchange knowledge.[5] Examples of DHIs include electronic medical records, mobile applications or wearable sensors for remote monitoring. DHIs are complex, differ both in intended functionality (e.g., self-management support versus data sharing), and intended users (e.g., patients versus providers). DHIs are not static; instead the interaction between the technology, end-user and the healthcare team and setting is by its nature dynamic and thus can vary substantially over time.[6] Given the unique sociotechnical aspects of DHIs, it remains unclear which frameworks can be appropriately applied in this emerging field.

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. Identify frameworks designed to guide the implementation or evaluation of DHIs.
2. Identify the proposed role of each framework, including the constructs they target.
3. Describe how each framework has been applied in primary studies, if applicable.

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.

## Methods and Analysis

We will conduct a scoping review to comprehensively search the literature, 'map' the evidence, and identify gaps in the research knowledge base.[7 8] The study will be conducted using established methods outlined by the Joanna Briggs Institute Reviewers' Manual[7] and reporting will conform to the PRISMA Extension for Scoping Reviews (PRISMA-ScR).[9] Our protocol is registered on Open Science Framework (OSF) and is available at (https://osf.io/8jydm/). OSF is an open source platform where researchers can share protocols, data and contributes to transparency of research.[10]

## Eligibility Criteria

Studies reporting on the development or application of frameworks (i.e., theoretical or interpretive) to guide implementation or evaluation of DHIs in healthcare will be included. 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. Implementation frameworks will be operationalized according to MRC guidance, as frameworks that aim to guide research into practice, which can include development, feasibility, and dissemination frameworks.[3] Evaluation frameworks will be defined as frameworks that focus on determining the effectiveness of DHIs, which includes measuring outcomes and understanding processes or mechanisms of action.[3] No limitations will be placed on user population, comparators, study design, publication status or geographic region. Conference abstracts/proceedings and white papers will be included. We will include studies reported in other languages and use appropriate tools (i.e., Google translate, translation services, contact author) to assess inclusion. Commentaries and studies examining mathematical or statistical frameworks will be excluded.

## Information sources

An experienced information specialist developed the literature search in consultation with the multidisciplinary research team. The search will be peer reviewed by a second information specialist using the Peer Review of Electronic Search Strategy (PRESS) checklist to ensure the search is comprehensive and maximizes appropriate search terms.[12]

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. The databases will be searched from inception to present and the search strategy is presented in Appendix 1. We chose not to use the BeHEMoTh (behaviour of interest, health context, exclusions, and models or theory) approach[13] as specified in our OSF registration. Although this approach has been successful in identifying frameworks in knowledge translation,[4] it did not prove to be a feasible approach in our scoping review as it yielded a vast number of citations with limited specificity related to our objectives. We utilized a simplified heuristic, which included identifying DHIs in various healthcare contexts, adding terms for frameworks, and removing exclusions such as animal studies (Appendix 1).

The search strategy will be supplemented by a search for grey literature using the checklist suggested by the Canadian Agency for Drugs and Technologies in Health (CADTH).[14] Specifically, we will search for white papers or benefit evaluation studies through Health Technology Assessment Agencies such as Agency for Healthcare Research and Quality (AHRQ) and National Institute for Health and Care Excellence (NICE), Canada Infoway and other relevant organizations involved in providing guidance on delivery of healthcare services. 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.

## Eligibility Screening Process

Citations obtained from the literature search will be uploaded to Covidence,[15] a systematic review software program which organizes citations, enables screening of citations by multiple

reviewers, and identifies discrepancies. We will apply a two-step process for identifying relevant citations. At level 1, titles and abstracts will be assessed using the eligibility criteria (Appendix 2). Studies with abstracts fulfilling criteria will be passed to level 2 where the eligibility criteria will be applied to the full text articles.

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 ≥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.

**Data items and abstraction process**

Studies fulfilling the eligibility criteria will be abstracted in Excel. We will extract the following study characteristics for the identified frameworks: name, reference, theory associated with framework (if applicable), description of its components or constructs, and its application in research (or stage of research to which it was applied, if applicable). For studies outlining the application of a framework, additional characteristics will be abstracted such as the type of DHI, healthcare setting, method of application, and nature and directionality of the results. We will abstract information such as name of the framework, the role of framework in study (i.e., development, feasibility/pilot testing, implementation, evaluation), components of the framework that were utilized, type of DHI, the objective of the study (if applicable), and healthcare setting from included studies.

**Methodological appraisal**

We will not assess the quality of included articles in the scoping review (consistent with Joanna Briggs Institute Reviewer's Manual[7]) as our purpose is to gain an overview of frameworks used in relation to DHIs and not to assess the quality of their application.

**Ethics and Dissemination**

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.

## Patient and Public Involvement

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.

## Analysis

Included studies will be summarized using qualitative description, an approach that seeks to create an understanding of phenomenon through accessing the meanings ascribed by authors.[16] 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). We will then synthesize findings by mapping core components of the frameworks and examining how research objectives and type of DHIs are linked to the framework. Categorization will use language directly from included studies, where possible, and authors will be contacted when information is not present or unclear. The advisory panel will guide the synthesis of findings by providing input on the level of detail abstracted from included articles and provide input on categorization of frameworks, where appropriate.

**Strengths and Limitations**

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 DHIs will facilitate decision making by making evidence-based approaches available to policymakers, researchers, clinicians and developers.

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 through technology to ensure we capture frameworks that are currently being used across healthcare settings. Moreover, the term framework also creates challenges, as we have defined 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, 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. Relatedly, authors may not provide sufficient details on the frameworks they utilize or their method of application. 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. When this

occurs, we will discuss the overlap with digital health knowledge users and devise the most appropriate plan for analysis.

We also anticipate challenges searching the literature. DHIs are not well defined in electronic databases as they are referenced using a plethora of key terms. As such, we have constructed our search to balance comprehensiveness and specificity. We have worked closely with an information specialist to ensure the number of citations are focused and feasible. Several iterations of the literature search were conducted using a randomized sample of 200 citations and the specificity and sensitivity of search terms were tested 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 iterative testing, we feel confident in our current literature strategy, however, additional challenges may arise when screening.

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). In parallel, the results will contribute to a more nuanced understanding of how to evaluate and implement DHIs, including the identification and understanding of key constructs.

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**Authors' Contributions:**

CS, LD conceived and developed the study. CS drafted the manuscript. MC, VK, RSB, TS, SM, DL, HCW, JZ, CGS, and LD reviewed and edited the manuscript.

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**Conflict of Interest:**

The authors have no conflicts of interest to report.

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# Appendix 1. Primary Literature Search in Medline

Database: Ovid MEDLINE: Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE® <1946-Present>
Search Strategy:
---
1 exp Telemedicine/ (25845)
2 (telemed* or tele-med* or telecare or tele-care or teleconsult* or tele-consult* or telehealth* or tele-health* or telemonitor* or tele-monitor* or telerehab* or tele-rehab*).tw,kf. (17416)
3 (ehealth* or e-health* or mhealth* or m-health* or emental health* or e-mental health* or epsychiatr* or e-psychiatr* or epsychol* or e-psychol* or etherap* or e-therap*).tw,kf. (10073)
4 (emedicine or e-medicine*).tw,kf. (78)
5 (mobile health* or mobile care or mobile medicine).tw,kf. (3793)
6 (digital* adj3 (medic* or care or health* or healthcare or health-care)).tw,kf. (3065)
7 (digital* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or surger* or surgic* or therap* or treatment?)).tw,kf. (5936)
8 (remote* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or surger* or surgic* or therap* or treatment?)).tw,kf. (6643)
9 Monitoring, Ambulatory/ (7806)
10 ((outpatient* or out-patient* or ambulator* or home? or homebased or home-based) adj3 (manag* or monitor*)).tw,kf. (24341)
11 exp Biomedical Technology/ (13203)
12 ((biomedic* or bio-medic* or health* or healthcare or health care or medical) adj technolog*).tw,kf. (13535)
13 Medical Informatics/ or Medical Informatics Applications/ (13622)
14 ((health* or medical) adj informatic*).tw,kf. (5056)
15 exp Therapy, Computer-Assisted/ (59720)
16 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 care).tw,kf. (8049)
17 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 health*).tw,kf. (27319)
18 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (healthcare or health care)).tw,kf. (6410)
19 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (medicine or medical)).tw,kf. (19800)
20 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile

phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 consult*).tw,kf. (1299)
21 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 diagnos*).tw,kf. (13043)
22 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 intervention?).tw,kf. (9139)
23 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 manag*).tw,kf. (7259)
24 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 monitor*).tw,kf. (8457)
25 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 palliat*).tw,kf. (133)
26 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 rehab*).tw,kf. (1264)
27 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (surger* or surgic*)).tw,kf. (7354)
28 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 therap*).tw,kf. (6817)
29 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 treatment?).tw,kf. (10336)
30 Wearable Electronic Devices/ (1321)
31 wearable?.tw,kf. (10007)
32 or/1-31 (253918)
33 exp *Delivery of Health Care/ (619520)
34 exp Computers/ (76307)
35 Electronic Mail/ (2573)
36 Internet/ (69753)
37 Telecommunications/ (4741)

38 (internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver*).tw,kf. (995758)
39 33 and (34 or 35 or 36 or 37 or 38) (50511)
40 32 or 39 [DIGITAL HEALTH APPLICATIONS] (282776)
41 (evaluat* adj3 (design* or frame or frames or framework? or guid* or model or models or schem* or strateg* or theor*)).tw,kf. (105535)
42 (apprais* adj3 (frame or frames or framework? or model or models or theor*)).tw,kf. (927)
43 (apprais* adj3 (design* or guid* or schem* or strateg*)).ti,kf. (313)
44 (assess* adj3 (frame or frames or framework? or model or models or theor*)).tw,kf. (47798)
45 (assess* adj3 (design* or guid* or schem* or strateg*)).ti,kf. (3366)
46 (implement* adj3 (design* or frame or frames or framework? or guid* or model or models or schem* or strateg* or theor*)).tw,kf. (57152)
47 (evidence-based adj (frame or frames or framework? or model or models or theor*)).tw,kf. (769)
48 (evidence-based adj (design* or guid* or schem* or strateg*)).ti,kf. (1559)
49 (service adj (frame or frames or framework? or model or models or theor*)).tw,kf. (2165)
50 (service adj (design* or guid* or schem* or strateg*)).ti,kf. (201)
51 or/41-50 [EVALUATION/IMPLEMENTATION FRAMEWORKS] (212588)
52 40 and 51 [DIGITAL HEALTH - EVALUATION/IMPLEMENTATION FRAMEWORKS] (8974)
53 exp Animals/ not Humans/ (4614915)
54 52 not 53 [ANIMAL-ONLY REMOVED] (8859)

**********

## Appendix 2. Eligibility Criteria

**Question 1: Does this study include humans?**

a. If yes, **INCLUDE**
b. **EXCLUDE** animal studies/models, non-humans or vertebrae 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: ehealth, 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 exclude: 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 discuss checklists, theoretical mathematical models or statistical models.

**Question 4: Is this an experimental study, qualitative study, or review?**

a. **INCLUDE** any study design (i.e., randomized controlled trials, observational studies, cross-sectional studies, qualitative studies, systematic review)
b. **EXCLUDE** studies if it's an editorial (without any primary data), letter to the editor or commentary.

## Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

| SECTION | ITEM | PRISMA-ScR CHECKLIST ITEM | REPORTED ON PAGE # |
|---|---|---|---|
| **TITLE** | | | |
| Title | 1 | Identify the report as a scoping review. | 1 |
| **ABSTRACT** | | | |
| Structured summary | 2 | Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives. | 2 |
| **INTRODUCTION** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach. | 5 |
| Objectives | 4 | Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives. | 5 |
| **METHODS** | | | |
| Protocol and registration | 5 | Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number. | 6 |
| Eligibility criteria | 6 | Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale. | 6 |
| Information sources* | 7 | Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed. | 7 |
| Search | 8 | Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated. | 7, appendix 2 |
| Selection of sources of evidence† | 9 | State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review. | 7-8 |
| Data charting process‡ | 10 | Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators. | 8 |
| Data items | 11 | List and define all variables for which data were sought and any assumptions and simplifications made. | 8-10 |
| Critical appraisal of individual sources of evidence§ | 12 | If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate). | NA |
| Synthesis of results | 13 | Describe the methods of handling and summarizing the data that were charted. | 9-10 |

| SECTION | ITEM | PRISMA-ScR CHECKLIST ITEM | REPORTED ON PAGE # |
|---|---|---|---|
| **RESULTS** | | | |
| Selection of sources of evidence | 14 | Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram. | NA |
| Characteristics of sources of evidence | 15 | For each source of evidence, present characteristics for which data were charted and provide the citations. | NA |
| Critical appraisal within sources of evidence | 16 | If done, present data on critical appraisal of included sources of evidence (see item 12). | NA |
| Results of individual sources of evidence | 17 | For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives. | NA |
| Synthesis of results | 18 | Summarize and/or present the charting results as they relate to the review questions and objectives. | NA |
| **DISCUSSION** | | | |
| Summary of evidence | 19 | Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups. | NA |
| Limitations | 20 | Discuss the limitations of the scoping review process. | 10-11 |
| Conclusions | 21 | Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps. | 11 |
| **FUNDING** | | | |
| Funding | 22 | Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review. | 13 |

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

*From:* Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

BMJ Open

# Identifying optimal frameworks to implement or evaluate digital health interventions: A scoping review protocol

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# Identifying optimal frameworks to implement or evaluate digital health interventions: A scoping review protocol

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**Keywords**: scoping review, digital health interventions, evaluation frameworks, implementation frameworks

**Word count**: 2415 (main text), 300 (abstract)

## 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. DHIs involve complex interactions between user, technology and the healthcare team, posing challenges for implementation and evaluation. Theoretical or interpretive frameworks are crucial in providing researchers guidance and clarity on implementation or evaluation approaches; however, there is a lack of standardization on which frameworks to use in which contexts. Our goal is to conduct a scoping review to identify frameworks to guide the implementation or evaluation of DHIs.

**Methods and Analysis**: A scoping review will be conducted using methods outlined by the Joanna Briggs Institute Reviewers' Manual and will conform to the PRISMA Extension for Scoping Reviews. Studies will be included if they report on frameworks (i.e., theoretical, interpretive, developmental) that are used to guide either implementation or evaluation of DHIs. Electronic databases, including MEDLINE, EMBASE, CINAHL, and PsychINFO will be searched in addition to grey literature and reference lists of included studies. Citations and full text articles will be screened independently in Covidence after a reliability check among reviewers. We will use qualitative description to summarize findings and focus on how research objectives and type of DHIs are aligned with the frameworks used.

**Ethics and dissemination**: We engaged an advisory panel of digital health knowledge users to provide input at strategic stages of the scoping review to enhance the relevance of findings and inform 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 review will support decision making when selecting appropriate frameworks to guide the implementation or evaluation of DHIs.

## 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.

## Introduction

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.

DHIs differ from traditional health interventions such as implementing a new program or evaluating drug effectiveness. DHIs include any health service or treatment delivered using technology that aims to facilitate, capture, or exchange knowledge.[5] Examples of DHIs include electronic medical records, mobile applications or wearable sensors for remote monitoring. DHIs are complex, differ both in intended functionality (e.g., self-management support versus data sharing), and intended users (e.g., patients versus providers). DHIs are not static; instead the interaction between the technology, end-user and the healthcare team and setting is by its nature dynamic and thus can vary substantially over time.[6] Given the unique sociotechnical aspects of DHIs, it remains unclear which frameworks can be appropriately applied in this emerging field.

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.

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.

## Methods and Analysis

We will conduct a scoping review to comprehensively search the literature, 'map' the evidence, and identify gaps in the research knowledge base.[7 8] The study will be conducted using established methods outlined by the Joanna Briggs Institute Reviewers' Manual[7] and reporting will conform to the PRISMA Extension for Scoping Reviews (PRISMA-ScR).[9] This protocol is registered on Open Science Framework (OSF) and is available at https://osf.io/8jydm/. OSF is an open source platform where researchers can share protocols, data and contributes to transparency of research.[10]

## Eligibility Criteria

Studies reporting on the development or application of frameworks (i.e., theoretical or interpretive) to guide implementation or evaluation of DHIs in healthcare will be included. 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] 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. Implementation frameworks will be operationalized according to MRC guidance, as frameworks that aim to guide research into practice, which can include development, feasibility, and dissemination frameworks.[3] Evaluation frameworks will be defined as frameworks that focus on determining the effectiveness of DHIs, which includes measuring outcomes and understanding processes or mechanisms of action.[3] 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 unintended exclusion of relevant studies. Conference abstracts/proceedings and white papers will be included. We will include studies reported in other languages and use appropriate tools (i.e., Google

translate, translation services, contact author) to assess inclusion. Commentaries and studies examining mathematical or statistical frameworks will be excluded.

**Information sources**

An experienced information specialist developed the literature search in consultation with the multidisciplinary research team. The search will be peer reviewed by a second information specialist using the Peer Review of Electronic Search Strategy (PRESS) checklist to ensure the search is comprehensive and maximizes appropriate search terms.[12]

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. The databases will be searched from inception to present and the search strategy is presented in Appendix 1. We chose not to use the BeHEMoTh (behaviour of interest, health context, exclusions, and models or theory) approach[13] as specified in our OSF registration. Although this approach has been successful in identifying frameworks in knowledge translation,[4] it did not prove to be a feasible approach in our scoping review as it yielded a vast number of citations with limited specificity related to our objectives. We utilized a simplified heuristic, which included identifying DHIs in various healthcare contexts, adding terms for frameworks, and removing exclusions such as animal studies (Appendix 1).

The search strategy will be supplemented by a search for grey literature using the checklist suggested by the Canadian Agency for Drugs and Technologies in Health (CADTH).[14] Specifically, we will search for white papers or benefit evaluation studies through Health Technology Assessment Agencies such as Agency for Healthcare Research and Quality (AHRQ) and National Institute for Health and Care Excellence (NICE), Canada Infoway and other relevant organizations involved in providing guidance on delivery of healthcare services. 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.

**Eligibility Screening Process**

Citations obtained from the literature search will be uploaded to Covidence,[15] a systematic review software program which organizes citations, enables screening of citations by multiple reviewers, and identifies discrepancies. We will apply a two-step process for identifying relevant citations. At level 1, titles and abstracts will be assessed using the eligibility criteria (Appendix 2). Studies with abstracts fulfilling criteria will be passed to level 2 where the eligibility criteria will be applied to the full text articles.

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 ≥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.

**Data items and abstraction process**

Studies fulfilling the eligibility criteria will be abstracted in Excel. We will extract the following study characteristics for the identified frameworks: name, reference, theory associated with framework (if applicable), description of its components or constructs, and its application in research (or stage of research to which it was applied, if applicable). For studies outlining the application of a framework, additional characteristics will be abstracted such as the type of DHI, healthcare setting, method of application, and nature and directionality of the results. We will abstract information such as name of the framework, the role of framework in study (i.e., development, feasibility/pilot testing, implementation, evaluation), components of the framework that were utilized, type of DHI, the objective of the study (if applicable), and healthcare setting from included studies.

**Methodological appraisal**

We will not assess the quality of included articles in the scoping review (consistent with Joanna Briggs Institute Reviewer's Manual[7]) as our purpose is to gain an overview of frameworks used in relation to DHIs and not to assess the quality of their application.

**Ethics and Dissemination**

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.

**Patient and Public Involvement**

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.

## Analysis

Included studies will be summarized using qualitative description, an approach that seeks to create an understanding of phenomenon through accessing the meanings ascribed by authors.[16] 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). We will then synthesize findings by mapping core components of the frameworks and examining how research objectives and type of DHIs are linked to the framework. Categorization will use language directly from included studies, where possible, and authors will be contacted when information is not present or unclear. The advisory panel will guide the synthesis of findings by providing input on the level of detail abstracted from included articles and provide input on categorization of frameworks, where appropriate.

## Strengths and Limitations

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 DHIs will facilitate decision making by making evidence-based approaches available to policymakers, researchers, clinicians and developers.

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.

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. Specifically, we added in 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 the PRESS checklist; however, we anticipate additional challenges when screening.

Thirdly, 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.

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). In parallel, the results will contribute to a more nuanced understanding of how to evaluate and implement DHIs, including the identification and understanding of key constructs.

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CS, LD conceived and developed the study. CS drafted the manuscript. MC, VK, RSB, TS, SM, DL, HCW, JZ, CGS, and LD reviewed and edited the manuscript.

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**Conflict of Interest:**

The authors have no conflicts of interest to report.

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# Appendix 1. Primary Literature Search in Medline

Database: Ovid MEDLINE: Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE® <1946-Present>
Search Strategy:
---
1 exp Telemedicine/ (25845)
2 (telemed* or tele-med* or telecare or tele-care or teleconsult* or tele-consult* or telehealth* or tele-health* or telemonitor* or tele-monitor* or telerehab* or tele-rehab*).tw,kf. (17416)
3 (ehealth* or e-health* or mhealth* or m-health* or emental health* or e-mental health* or epsychiatr* or e-psychiatr* or epsychol* or e-psychol* or etherap* or e-therap*).tw,kf. (10073)
4 (emedicine or e-medicine*).tw,kf. (78)
5 (mobile health* or mobile care or mobile medicine).tw,kf. (3793)
6 (digital* adj3 (medic* or care or health* or healthcare or health-care)).tw,kf. (3065)
7 (digital* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or surger* or surgic* or therap* or treatment?)).tw,kf. (5936)
8 (remote* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or surger* or surgic* or therap* or treatment?)).tw,kf. (6643)
9 Monitoring, Ambulatory/ (7806)
10 ((outpatient* or out-patient* or ambulator* or home? or homebased or home-based) adj3 (manag* or monitor*)).tw,kf. (24341)
11 exp Biomedical Technology/ (13203)
12 ((biomedic* or bio-medic* or health* or healthcare or health care or medical) adj technolog*).tw,kf. (13535)
13 Medical Informatics/ or Medical Informatics Applications/ (13622)
14 ((health* or medical) adj informatic*).tw,kf. (5056)
15 exp Therapy, Computer-Assisted/ (59720)
16 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 care).tw,kf. (8049)
17 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 health*).tw,kf. (27319)
18 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (healthcare or health care)).tw,kf. (6410)
19 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (medicine or medical)).tw,kf. (19800)
20 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile

phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 consult*).tw,kf. (1299)
21 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 diagnos*).tw,kf. (13043)
22 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 intervention?).tw,kf. (9139)
23 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 manag*).tw,kf. (7259)
24 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 monitor*).tw,kf. (8457)
25 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 palliat*).tw,kf. (133)
26 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 rehab*).tw,kf. (1264)
27 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (surger* or surgic*)).tw,kf. (7354)
28 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 therap*).tw,kf. (6817)
29 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 treatment?).tw,kf. (10336)
30 Wearable Electronic Devices/ (1321)
31 wearable?.tw,kf. (10007)
32 or/1-31 (253918)
33 exp *Delivery of Health Care/ (619520)
34 exp Computers/ (76307)
35 Electronic Mail/ (2573)
36 Internet/ (69753)
37 Telecommunications/ (4741)

38 (internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver*).tw,kf. (995758)
39 33 and (34 or 35 or 36 or 37 or 38) (50511)
40 32 or 39 [DIGITAL HEALTH APPLICATIONS] (282776)
41 (evaluat* adj3 (design* or frame or frames or framework? or guid* or model or models or schem* or strateg* or theor*)).tw,kf. (105535)
42 (apprais* adj3 (frame or frames or framework? or model or models or theor*)).tw,kf. (927)
43 (apprais* adj3 (design* or guid* or schem* or strateg*)).ti,kf. (313)
44 (assess* adj3 (frame or frames or framework? or model or models or theor*)).tw,kf. (47798)
45 (assess* adj3 (design* or guid* or schem* or strateg*)).ti,kf. (3366)
46 (implement* adj3 (design* or frame or frames or framework? or guid* or model or models or schem* or strateg* or theor*)).tw,kf. (57152)
47 (evidence-based adj (frame or frames or framework? or model or models or theor*)).tw,kf. (769)
48 (evidence-based adj (design* or guid* or schem* or strateg*)).ti,kf. (1559)
49 (service adj (frame or frames or framework? or model or models or theor*)).tw,kf. (2165)
50 (service adj (design* or guid* or schem* or strateg*)).ti,kf. (201)
51 or/41-50 [EVALUATION/IMPLEMENTATION FRAMEWORKS] (212588)
52 40 and 51 [DIGITAL HEALTH - EVALUATION/IMPLEMENTATION FRAMEWORKS] (8974)
53 exp Animals/ not Humans/ (4614915)
54 52 not 53 [ANIMAL-ONLY REMOVED] (8859)

**********

## Appendix 2. Eligibility Criteria

**Question 1: Does this study include humans?**

a. If yes, **INCLUDE**
b. **EXCLUDE** animal studies/models, non-humans or vertebrae 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: ehealth, 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 exclude: 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 discuss checklists, theoretical mathematical models or statistical models.

**Question 4: Is this an experimental study, qualitative study, or review?**

a. **INCLUDE** any study design (i.e., randomized controlled trials, observational studies, cross-sectional studies, qualitative studies, systematic review)
b. **EXCLUDE** studies if it's an editorial (without any primary data), letter to the editor or commentary.

## Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

| SECTION | ITEM | PRISMA-ScR CHECKLIST ITEM | REPORTED ON PAGE # |
|---|---|---|---|
| **TITLE** | | | |
| Title | 1 | Identify the report as a scoping review. | 1 |
| **ABSTRACT** | | | |
| Structured summary | 2 | Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives. | 2 |
| **INTRODUCTION** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach. | 5 |
| Objectives | 4 | Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives. | 5 |
| **METHODS** | | | |
| Protocol and registration | 5 | Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number. | 6 |
| Eligibility criteria | 6 | Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale. | 6 |
| Information sources* | 7 | Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed. | 7 |
| Search | 8 | Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated. | 7, appendix 2 |
| Selection of sources of evidence† | 9 | State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review. | 7-8 |
| Data charting process‡ | 10 | Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators. | 8 |
| Data items | 11 | List and define all variables for which data were sought and any assumptions and simplifications made. | 8-10 |
| Critical appraisal of individual sources of evidence§ | 12 | If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate). | NA |
| Synthesis of results | 13 | Describe the methods of handling and summarizing the data that were charted. | 9-10 |

| SECTION | ITEM | PRISMA-ScR CHECKLIST ITEM | REPORTED ON PAGE # |
|---|---|---|---|
| **RESULTS** | | | |
| Selection of sources of evidence | 14 | Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram. | NA |
| Characteristics of sources of evidence | 15 | For each source of evidence, present characteristics for which data were charted and provide the citations. | NA |
| Critical appraisal within sources of evidence | 16 | If done, present data on critical appraisal of included sources of evidence (see item 12). | NA |
| Results of individual sources of evidence | 17 | For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives. | NA |
| Synthesis of results | 18 | Summarize and/or present the charting results as they relate to the review questions and objectives. | NA |
| **DISCUSSION** | | | |
| Summary of evidence | 19 | Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups. | NA |
| Limitations | 20 | Discuss the limitations of the scoping review process. | 10-11 |
| Conclusions | 21 | Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps. | 11 |
| **FUNDING** | | | |
| Funding | 22 | Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review. | 13 |

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

*From:* Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

BMJ Open

# Identifying optimal frameworks to implement or evaluate digital health interventions: A scoping review protocol

| | |
|---|---|
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| Primary Subject Heading: | Health services research |
| Secondary Subject Heading: | Research methods, Evidence based practice |
| Keywords: | Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, STATISTICS & RESEARCH METHODS |
| | |

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# Identifying optimal frameworks to implement or evaluate digital health interventions: A scoping review protocol

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**Keywords**: scoping review, digital health interventions, evaluation frameworks, implementation frameworks

**Word count**: 2415 (main text), 300 (abstract)

## 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. DHIs involve complex interactions between user, technology and the healthcare team, posing challenges for implementation and evaluation. Theoretical or interpretive frameworks are crucial in providing researchers guidance and clarity on implementation or evaluation approaches; however, there is a lack of standardization on which frameworks to use in which contexts. Our goal is to conduct a scoping review to identify frameworks to guide the implementation or evaluation of DHIs.

**Methods and Analysis**: A scoping review will be conducted using methods outlined by the Joanna Briggs Institute Reviewers' Manual and will conform to the PRISMA Extension for Scoping Reviews. Studies will be included if they report on frameworks (i.e., theoretical, interpretive, developmental) that are used to guide either implementation or evaluation of DHIs. Electronic databases, including MEDLINE, EMBASE, CINAHL, and PsychINFO will be searched in addition to grey literature and reference lists of included studies. Citations and full text articles will be screened independently in Covidence after a reliability check among reviewers. We will use qualitative description to summarize findings and focus on how research objectives and type of DHIs are aligned with the frameworks used.

**Ethics and dissemination**: We engaged an advisory panel of digital health knowledge users to provide input at strategic stages of the scoping review to enhance the relevance of findings and inform 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 review will support decision making when selecting appropriate frameworks to guide the implementation or evaluation of DHIs.

## Strengths and Limitations

- 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 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 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.

## Introduction

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.

DHIs differ from traditional health interventions such as implementing a new program or evaluating drug effectiveness. DHIs include any health service or treatment delivered using technology that aims to facilitate, capture, or exchange knowledge.[5] Examples of DHIs include electronic medical records, mobile applications or wearable sensors for remote monitoring. DHIs are complex, differ both in intended functionality (e.g., self-management support versus data sharing), and intended users (e.g., patients versus providers). DHIs are not static; instead the interaction between the technology, end-user and the healthcare team and setting is by its nature dynamic and thus can vary substantially over time.[6] Given the unique sociotechnical aspects of DHIs, it remains unclear which frameworks can be appropriately applied in this emerging field.

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.

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.

## Methods and Analysis

We will conduct a scoping review to comprehensively search the literature, 'map' the evidence, and identify gaps in the research knowledge base.[7 8] The study will be conducted using established methods outlined by the Joanna Briggs Institute Reviewers' Manual[7] and reporting will conform to the PRISMA Extension for Scoping Reviews (PRISMA-ScR).[9] This protocol is registered on Open Science Framework (OSF) and is available at https://osf.io/8jydm/. OSF is an open source platform where researchers can share protocols, data and contributes to transparency of research.[10]

## Eligibility Criteria

Studies reporting on the development or application of frameworks (i.e., theoretical or interpretive) to guide implementation or evaluation of DHIs in healthcare will be included. 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] 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. Implementation frameworks will be operationalized according to MRC guidance, as frameworks that aim to guide research into practice, which can include development, feasibility, and dissemination frameworks.[3] Evaluation frameworks will be defined as frameworks that focus on determining the effectiveness of DHIs, which includes measuring outcomes and understanding processes or mechanisms of action.[3] 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 unintended exclusion of relevant studies. Conference abstracts/proceedings and white papers will be included. We will include studies reported in other languages and use appropriate tools (i.e., Google

translate, translation services, contact author) to assess inclusion. Commentaries and studies examining mathematical or statistical frameworks will be excluded.

**Information sources**

An experienced information specialist developed the literature search in consultation with the multidisciplinary research team. The search will be peer reviewed by a second information specialist using the Peer Review of Electronic Search Strategy (PRESS) checklist to ensure the search is comprehensive and maximizes appropriate search terms.[12]

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. The databases will be searched from inception to present and the search strategy is presented in Appendix 1. We chose not to use the BeHEMoTh (behaviour of interest, health context, exclusions, and models or theory) approach[13] as specified in our OSF registration. Although this approach has been successful in identifying frameworks in knowledge translation,[4] it did not prove to be a feasible approach in our scoping review as it yielded a vast number of citations with limited specificity related to our objectives. We utilized a simplified heuristic, which included identifying DHIs in various healthcare contexts, adding terms for frameworks, and removing exclusions such as animal studies (Appendix 1).

The search strategy will be supplemented by a search for grey literature using the checklist suggested by the Canadian Agency for Drugs and Technologies in Health (CADTH).[14] Specifically, we will search for white papers or benefit evaluation studies through Health Technology Assessment Agencies such as Agency for Healthcare Research and Quality (AHRQ) and National Institute for Health and Care Excellence (NICE), Canada Infoway and other relevant organizations involved in providing guidance on delivery of healthcare services. 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.

**Eligibility Screening Process**

Citations obtained from the literature search will be uploaded to Covidence,[15] a systematic review software program which organizes citations, enables screening of citations by multiple reviewers, and identifies discrepancies. We will apply a two-step process for identifying relevant citations. At level 1, titles and abstracts will be assessed using the eligibility criteria (Appendix 2). Studies with abstracts fulfilling criteria will be passed to level 2 where the eligibility criteria will be applied to the full text articles.

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 ≥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.

**Data items and abstraction process**

Studies fulfilling the eligibility criteria will be abstracted in Excel. We will extract the following study characteristics for the identified frameworks: name, reference, theory associated with framework (if applicable), description of its components or constructs, and its application in research (or stage of research to which it was applied, if applicable). For studies outlining the application of a framework, additional characteristics will be abstracted such as the type of DHI, healthcare setting, method of application, and nature and directionality of the results. We will abstract information such as name of the framework, the role of framework in study (i.e., development, feasibility/pilot testing, implementation, evaluation), components of the framework that were utilized, type of DHI, the objective of the study (if applicable), and healthcare setting from included studies.

**Methodological appraisal**

We will not assess the quality of included articles in the scoping review (consistent with Joanna Briggs Institute Reviewer's Manual[7]) as our purpose is to gain an overview of frameworks used in relation to DHIs and not to assess the quality of their application.

**Ethics and Dissemination**

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.

**Patient and Public Involvement**

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.

## Analysis

Included studies will be summarized using qualitative description, an approach that seeks to create an understanding of phenomenon through accessing the meanings ascribed by authors.[16] 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). We will then synthesize findings by mapping core components of the frameworks and examining how research objectives and type of DHIs are linked to the framework. Categorization will use language directly from included studies, where possible, and authors will be contacted when information is not present or unclear. The advisory panel will guide the synthesis of findings by providing input on the level of detail abstracted from included articles and provide input on categorization of frameworks, where appropriate.

## Strengths and Limitations

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.

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.

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.

Thirdly, 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.

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). In parallel, the results will contribute to a more nuanced understanding of how to evaluate and implement DHIs, including the identification and understanding of key constructs.

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**Authors' Contributions:**

CS, LD conceived and developed the study. CS drafted the manuscript. MC, VK, RSB, TS, SM, DL, HCW, JZ, CSG, and LD reviewed and edited the manuscript.

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**Conflict of Interest:**

The authors have no conflicts of interest to report.

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# Appendix 1. Primary Literature Search in Medline

Database: Ovid MEDLINE: Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE® <1946-Present>
Search Strategy:
---
1 exp Telemedicine/ (25845)
2 (telemed* or tele-med* or telecare or tele-care or teleconsult* or tele-consult* or telehealth* or tele-health* or telemonitor* or tele-monitor* or telerehab* or tele-rehab*).tw,kf. (17416)
3 (ehealth* or e-health* or mhealth* or m-health* or emental health* or e-mental health* or epsychiatr* or e-psychiatr* or epsychol* or e-psychol* or etherap* or e-therap*).tw,kf. (10073)
4 (emedicine or e-medicine*).tw,kf. (78)
5 (mobile health* or mobile care or mobile medicine).tw,kf. (3793)
6 (digital* adj3 (medic* or care or health* or healthcare or health-care)).tw,kf. (3065)
7 (digital* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or surger* or surgic* or therap* or treatment?)).tw,kf. (5936)
8 (remote* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or surger* or surgic* or therap* or treatment?)).tw,kf. (6643)
9 Monitoring, Ambulatory/ (7806)
10 ((outpatient* or out-patient* or ambulator* or home? or homebased or home-based) adj3 (manag* or monitor*)).tw,kf. (24341)
11 exp Biomedical Technology/ (13203)
12 ((biomedic* or bio-medic* or health* or healthcare or health care or medical) adj technolog*).tw,kf. (13535)
13 Medical Informatics/ or Medical Informatics Applications/ (13622)
14 ((health* or medical) adj informatic*).tw,kf. (5056)
15 exp Therapy, Computer-Assisted/ (59720)
16 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 care).tw,kf. (8049)
17 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 health*).tw,kf. (27319)
18 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (healthcare or health care)).tw,kf. (6410)
19 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (medicine or medical)).tw,kf. (19800)
20 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile

phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 consult*).tw,kf. (1299)
21 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 diagnos*).tw,kf. (13043)
22 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 intervention?).tw,kf. (9139)
23 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 manag*).tw,kf. (7259)
24 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 monitor*).tw,kf. (8457)
25 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 palliat*).tw,kf. (133)
26 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 rehab*).tw,kf. (1264)
27 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (surger* or surgic*)).tw,kf. (7354)
28 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 therap*).tw,kf. (6817)
29 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 treatment?).tw,kf. (10336)
30 Wearable Electronic Devices/ (1321)
31 wearable?.tw,kf. (10007)
32 or/1-31 (253918)
33 exp *Delivery of Health Care/ (619520)
34 exp Computers/ (76307)
35 Electronic Mail/ (2573)
36 Internet/ (69753)
37 Telecommunications/ (4741)

38 (internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email* or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or webbased or web-based or webdeliver* or web-deliver*).tw,kf. (995758)
39 33 and (34 or 35 or 36 or 37 or 38) (50511)
40 32 or 39 [DIGITAL HEALTH APPLICATIONS] (282776)
41 (evaluat* adj3 (design* or frame or frames or framework? or guid* or model or models or schem* or strateg* or theor*)).tw,kf. (105535)
42 (apprais* adj3 (frame or frames or framework? or model or models or theor*)).tw,kf. (927)
43 (apprais* adj3 (design* or guid* or schem* or strateg*)).ti,kf. (313)
44 (assess* adj3 (frame or frames or framework? or model or models or theor*)).tw,kf. (47798)
45 (assess* adj3 (design* or guid* or schem* or strateg*)).ti,kf. (3366)
46 (implement* adj3 (design* or frame or frames or framework? or guid* or model or models or schem* or strateg* or theor*)).tw,kf. (57152)
47 (evidence-based adj (frame or frames or framework? or model or models or theor*)).tw,kf. (769)
48 (evidence-based adj (design* or guid* or schem* or strateg*)).ti,kf. (1559)
49 (service adj (frame or frames or framework? or model or models or theor*)).tw,kf. (2165)
50 (service adj (design* or guid* or schem* or strateg*)).ti,kf. (201)
51 or/41-50 [EVALUATION/IMPLEMENTATION FRAMEWORKS] (212588)
52 40 and 51 [DIGITAL HEALTH - EVALUATION/IMPLEMENTATION FRAMEWORKS] (8974)
53 exp Animals/ not Humans/ (4614915)
54 52 not 53 [ANIMAL-ONLY REMOVED] (8859)

**********

**Appendix 2. Eligibility Criteria**

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.

## Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

| SECTION | ITEM | PRISMA-ScR CHECKLIST ITEM | REPORTED ON PAGE # |
|---|---|---|---|
| **TITLE** | | | |
| Title | 1 | Identify the report as a scoping review. | 1 |
| **ABSTRACT** | | | |
| Structured summary | 2 | Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives. | 2 |
| **INTRODUCTION** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach. | 5 |
| Objectives | 4 | Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives. | 5 |
| **METHODS** | | | |
| Protocol and registration | 5 | Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number. | 6 |
| Eligibility criteria | 6 | Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale. | 6 |
| Information sources* | 7 | Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed. | 7 |
| Search | 8 | Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated. | 7, appendix 2 |
| Selection of sources of evidence† | 9 | State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review. | 7-8 |
| Data charting process‡ | 10 | Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators. | 8 |
| Data items | 11 | List and define all variables for which data were sought and any assumptions and simplifications made. | 8-10 |
| Critical appraisal of individual sources of evidence§ | 12 | If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate). | NA |
| Synthesis of results | 13 | Describe the methods of handling and summarizing the data that were charted. | 9-10 |

| SECTION | ITEM | PRISMA-ScR CHECKLIST ITEM | REPORTED ON PAGE # |
|---|---|---|---|
| **RESULTS** | | | |
| Selection of sources of evidence | 14 | Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram. | NA |
| Characteristics of sources of evidence | 15 | For each source of evidence, present characteristics for which data were charted and provide the citations. | NA |
| Critical appraisal within sources of evidence | 16 | If done, present data on critical appraisal of included sources of evidence (see item 12). | NA |
| Results of individual sources of evidence | 17 | For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives. | NA |
| Synthesis of results | 18 | Summarize and/or present the charting results as they relate to the review questions and objectives. | NA |
| **DISCUSSION** | | | |
| Summary of evidence | 19 | Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups. | NA |
| Limitations | 20 | Discuss the limitations of the scoping review process. | 10-11 |
| Conclusions | 21 | Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps. | 11 |
| **FUNDING** | | | |
| Funding | 22 | Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review. | 13 |

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

*From:* Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.