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

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3 **Identifying optimal frameworks to implement or evaluate digital health interventions: A**
4 **scoping review protocol**
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Keywords: scoping review, digital health interventions, evaluation frameworks, implementation frameworks,

Word count: 2019 (main text), 274 (abstract)

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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.

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

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10 We will conduct a scoping review to comprehensively search the literature, ‘map’ the
11 evidence, and identify gaps in the research knowledge base.^{7 8} The study will be conducted using
12 established methods outlined by the Joanna Briggs Institute Reviewers’ Manual⁷ and reporting
13 will conform to the PRISMA Extension for Scoping Reviews (PRISMA-ScR).⁹ Our protocol is
14 registered on Open Science Framework (OSF) and is available at (<https://osf.io/8jydm/>).
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18 **Eligibility Criteria**

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

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43 An experienced information specialist developed the literature search in consultation with
44 the multidisciplinary research team. The search will be peer reviewed by a second information
45 specialist using the Peer Review of Electronic Search Strategy (PRESS) checklist to ensure the
46 search is comprehensive and maximizes appropriate search terms.¹⁰
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51 We will search MEDLINE, EMBASE, CINAHL, and PsychINFO using key words such
52 as ‘digital health’ and ‘framework’. The databases will be searched from inception to present and
53 the search strategy is presented in Appendix 1. We chose not to use the BeHEMoTh (behaviour of
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3 interest, health context, exclusions, and models or theory) approach¹¹ as specified in our OSF
4 registration. Although this approach has been successful in identifying frameworks in knowledge
5 translation,⁴ it did not prove to be a feasible approach in our scoping review as it yielded a vast
6 number of citations with limited specificity related to our objectives. We utilized a simplified
7 heuristic, which included identifying DHIs in various healthcare contexts, adding terms for
8 frameworks, and removing exclusions such as animal studies (Appendix 1).
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14 The search strategy will be supplemented by a search for grey literature using the checklist
15 suggested by the Canadian Agency for Drugs and Technologies in Health (CADTH).¹²
16 Specifically, we will search for white papers or benefit evaluation studies through Health
17 Technology Assessment Agencies such as Agency for Healthcare Research and Quality (AHRQ)
18 and National Institute for Health and Care Excellence (NICE), Canada Infoway and other relevant
19 organizations involved in providing guidance on delivery of healthcare services. We will also scan
20 reference lists of included studies and conduct a forward citation search (i.e., examine studies that
21 reference included studies) to ensure our approach is comprehensive.
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28 **Eligibility Screening Process**

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31 Citations obtained from the literature search will be uploaded to Covidence,¹³ a systematic
32 review software program which organizes citations, enables screening of citations by multiple
33 reviewers, and identifies discrepancies. We will apply a two-step process for identifying relevant
34 citations. At level 1, titles and abstracts will be assessed using the eligibility criteria (Appendix 2).
35 Studies with abstracts fulfilling criteria will be passed to level 2 where the eligibility criteria will
36 be applied to the full text articles.
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42 Prior to screening, a pilot test will be completed using a random sample of citations or full
43 text, with the expressed purpose of assessing agreement between reviewers at each level.
44 Specifically, percent agreement will be used to assess agreement among reviewers (inter-rater
45 reliability $\geq 80\%$ will be considered adequate). A third reviewer will mediate any disagreements.
46 Citations and full text articles will be screened in duplicate by two reviewers.
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51 **Data items and abstraction process**

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

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20 We will not assess the quality of included articles in the scoping review (consistent with
21 Joanna Briggs Institute Reviewer's Manual⁷) as our purpose is to gain an overview of frameworks
22 used in relation to DHIs and not to assess the quality of their application.
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26 **Ethics and Dissemination**

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28 This scoping review is focused on published reports and studies of DHI and does not
29 involve patients; as such, no formal ethics approval is required.
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32 To facilitate uptake and dissemination of findings, we will employ an integrated knowledge
33 translation strategy to ensure our findings meet the needs of various knowledge users, defined as
34 individuals who are likely to use the information from the review to make an informed health
35 decision.³ We established a panel of digital health knowledge users, *a priori*, who will provide
36 input at strategic stages of the scoping review, including study design, interpretation of results, and
37 communication of findings. Specifically, digital health knowledge users will help refine inclusion
38 and exclusion criteria, prioritize selection of data abstraction elements, assist in interpretation and
39 help develop dissemination strategies for communication of findings stemming from the review.
40 Digital health knowledge users will include senior leaders at organizations that promote or support
41 implementation of digital health solutions, and researchers focused on evaluating DHIs. Digital
42 health knowledge users will have national and international networks that will help to ensure the
43 review reflects the knowledge needs of a diverse audience, which is directly in line with the stated
44 aim of providing practical guidance on the selection and application of frameworks for DHIs.
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55 **Patient and Public Involvement**

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3 No patients are involved.
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5 **Analysis**

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8 Included studies will be summarized using qualitative description, an approach that seeks
9 to create an understanding of phenomenon through accessing the meanings ascribed by authors.¹⁴
10 Descriptions of individual frameworks will be organized by key categories, including study design,
11 report type (published vs non-published), methodological approach (i.e. how the framework is
12 intended to be applied) and application papers (i.e. how the framework has been applied in
13 practice). We will then synthesize findings by mapping core components of the frameworks and
14 examining how research objectives and type of DHI are linked to the framework. Categorization
15 will use language directly from included studies, where possible, and authors will be contacted
16 when information is not present or unclear. Digital health knowledge users will guide the synthesis
17 of findings by providing input on the level of detail abstracted from included articles and provide
18 input on categorization of frameworks, where appropriate.
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27 **Strengths and Limitations**

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30 To our knowledge, this is the first scoping review to examine the use of frameworks to
31 guide implementation or evaluation of DHIs. A clear understanding of which frameworks can be
32 used for the different phases of a research study will provide practical guidance for researchers,
33 clinicians, policymakers and developers in implementing or determining effectiveness of DHIs.
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38 Given the breadth of this scoping review, we anticipate a few key challenges. The first
39 relates to the inconsistent and often ill-defined nature of DHIs and frameworks. To be inclusive,
40 we have defined DHIs broadly as any health intervention that can be delivered through technology
41 to ensure we capture frameworks that are currently being used across healthcare settings.
42 Moreover, the term framework also create challenges, as we have defined as a tool to
43 systematically organize and link research questions or constructs, but a range of terms are often
44 used synonymously (e.g., models or processes). To account for this, we will include studies
45 reporting on 'models' and work closely with the digital health knowledge user panel to confirm
46 whether the reported framework aligns with our *a priori* definition. Relatedly, authors may not
47 provide sufficient details on the frameworks they utilize or their method of application. To mitigate
48 this, we will contact authors to obtain additional information whenever information is missing or
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3 unclear. Finally, we anticipate that some included frameworks will have a dual purpose of
4 addressing implementation and evaluation, or may contain components that lend themselves to
5 both constructs. When this occurs, we will discuss the overlap with digital health knowledge users
6 and devise the most appropriate plan for analysis.
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11 We also anticipate challenges searching the literature. DHIs are not well defined in
12 electronic databases as they are referenced using a plethora of key terms. As such, we have
13 constructed our search in an attempt to balance comprehensiveness and specificity. We have
14 worked closely with an information specialist to ensure the number of citations are focused and
15 feasible. Several iterations of the literature search were conducted using a randomized sample of
16 200 citations and the specificity and sensitivity of search terms were tested using the inclusion
17 criteria. Two reviewers screened citations, discrepancies were discussed among the internal
18 research team, and the number of included studies were examined to examine the specificity of
19 search terms. Through iterative testing, we feel confident in our current literature strategy,
20 however, additional challenges may arise when screening.
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29 Overall, identification of frameworks will serve as a guide for researchers, clinicians,
30 policymakers and developers of DHIs by providing practical guidance on which frameworks may
31 be most appropriate for which objectives (i.e., implementation or evaluation). In parallel, the
32 results will contribute to a more nuanced understanding of how to evaluate and implement DHIs,
33 including the identification and understanding of key constructs.
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3 **1 Authors' Contributions:**
4

5 2 CS, LD conceived and developed the study. CS drafted the manuscript. MC, VK, RSB, TH, SM,
6
7 3 DI, HCW, JZ, CGS, and LD reviewed and edited the manuscript.
8

9
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11

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13 6 not-for-profit sectors.
14

15 **7 Conflict of Interest:**
16

17 8 The authors have no conflicts of interest to report.
18
19

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21

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23
24 11 generating the literature search, as well as Beatrice Choremis, who helped screen a few
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26 12 preliminary citations.
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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

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3 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
4 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 consult*).tw,kf. (1299)
5 21 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
6 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
7 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
8 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 diagnos*).tw,kf. (13043)
9 22 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
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12 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 intervention?).tw,kf. (9139)
13 23 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
14 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
15 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
16 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 manag*).tw,kf. (7259)
17 24 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
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19 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
20 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 monitor*).tw,kf. (8457)
21 25 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
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25 26 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
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28 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 rehab*).tw,kf. (1264)
29 27 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
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31 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
32 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 (surger* or surgic*).tw,kf.
33 (7354)
34 28 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
35 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
36 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
37 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 therap*).tw,kf. (6817)
38 29 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
39 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
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41 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 treatment?).tw,kf. (10336)
42 30 Wearable Electronic Devices/ (1321)
43 31 wearable?.tw,kf. (10007)
44 32 or/1-31 (253918)
45 33 exp *Delivery of Health Care/ (619520)
46 34 exp Computers/ (76307)
47 35 Electronic Mail/ (2573)
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5 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
6 webbased or web-based or webdeliver* or web-deliver*).tw,kf. (995758)
7
8 39 33 and (34 or 35 or 36 or 37 or 38) (50511)
9 40 32 or 39 [DIGITAL HEALTH APPLICATIONS] (282776)
10 41 (evaluat* adj3 (design* or frame or frames or framework? or guid* or model or models or schem*
11 or strateg* or theor*)).tw,kf. (105535)
12 42 (apprais* adj3 (frame or frames or framework? or model or models or theor*)).tw,kf. (927)
13 43 (apprais* adj3 (design* or guid* or schem* or strateg*)).ti,kf. (313)
14 44 (assess* adj3 (frame or frames or framework? or model or models or theor*)).tw,kf. (47798)
15 45 (assess* adj3 (design* or guid* or schem* or strateg*)).ti,kf. (3366)
16 46 (implement* adj3 (design* or frame or frames or framework? or guid* or model or models or
17 schem* or strateg* or theor*)).tw,kf. (57152)
18
19 47 (evidence-based adj (frame or frames or framework? or model or models or theor*)).tw,kf. (769)
20 48 (evidence-based adj (design* or guid* or schem* or strateg*)).ti,kf. (1559)
21 49 (service adj (frame or frames or framework? or model or models or theor*)).tw,kf. (2165)
22 50 (service adj (design* or guid* or schem* or strateg*)).ti,kf. (201)
23 51 or/41-50 [EVALUATION/IMPLEMENTATION FRAMEWORKS] (212588)
24 52 40 and 51 [DIGITAL HEALTH - EVALUATION/IMPLEMENTATION FRAMEWORKS] (8974)
25 53 exp Animals/ not Humans/ (4614915)
26 54 52 not 53 [ANIMAL-ONLY REMOVED] (8859)
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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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3 **Identifying optimal frameworks to implement or evaluate digital health interventions: A**
4 **scoping review protocol**
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For peer review only

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.

1 Introduction

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

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

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

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

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

29 The results of this review will provide practical guidance and support for researchers, clinicians,
30 policymakers, and developers in selecting the most appropriate framework for DHIs, which will
31 support evidence-based approaches in relation to implementation and evaluation efforts.

32 **Methods and Analysis**

33 We will conduct a scoping review to comprehensively search the literature, ‘map’ the
34 evidence, and identify gaps in the research knowledge base.^{7 8} The study will be conducted using
35 established methods outlined by the Joanna Briggs Institute Reviewers’ Manual⁷ and reporting
36 will conform to the PRISMA Extension for Scoping Reviews (PRISMA-ScR).⁹ Our protocol is
37 registered on Open Science Framework (OSF) and is available at (<https://osf.io/8jydm/>). OSF is
38 an open source platform where researchers can share protocols, data and contributes to
39 transparency of research.¹⁰

40 **Eligibility Criteria**

41 Studies reporting on the development or application of frameworks (i.e., theoretical or
42 interpretive) to guide implementation or evaluation of DHIs in healthcare will be included. We
43 will use the WHO definition of healthcare which encompasses physical, mental and social well-
44 being and spans across multiple disciplines such as psychology, sociology or medical sciences.¹¹
45 DHI was defined as any health service or treatment delivered using technology that aims to
46 facilitate, capture, or exchange knowledge (formally or informally).⁵ DHI definition was generated
47 from a search of the literature and consultations with digital health knowledge users, including
48 policymakers, researchers, clinicians and developers. Implementation frameworks will be
49 operationalized according to MRC guidance, as frameworks that aim to guide research into
50 practice, which can include development, feasibility, and dissemination frameworks.³ Evaluation
51 frameworks will be defined as frameworks that focus on determining the effectiveness of DHIs,
52 which includes measuring outcomes and understanding processes or mechanisms of action.³ No
53 limitations will be placed on user population, comparators, study design, publication status or
54 geographic region. Conference abstracts/proceedings and white papers will be included. We will
55 include studies reported in other languages and use appropriate tools (i.e., Google translate,
56 translation services, contact author) to assess inclusion. Commentaries and studies examining
57 mathematical or statistical frameworks will be excluded.

58 **Information sources**

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

63 We will search MEDLINE, EMBASE, CINAHL, and PsychINFO using key words such
64 as ‘digital health’ and ‘framework’. Additional search terms were drawn from multiple disciplines
65 such as psychology, nursing, sociology, and medicine to ensure comprehensiveness. The databases
66 will be searched from inception to present and the search strategy is presented in Appendix 1. We
67 chose not to use the BeHEMOTH (behaviour of interest, health context, exclusions, and models or
68 theory) approach¹³ as specified in our OSF registration. Although this approach has been
69 successful in identifying frameworks in knowledge translation,⁴ it did not prove to be a feasible
70 approach in our scoping review as it yielded a vast number of citations with limited specificity
71 related to our objectives. We utilized a simplified heuristic, which included identifying DHIs in
72 various healthcare contexts, adding terms for frameworks, and removing exclusions such as animal
73 studies (Appendix 1).

74 The search strategy will be supplemented by a search for grey literature using the checklist
75 suggested by the Canadian Agency for Drugs and Technologies in Health (CADTH).¹⁴
76 Specifically, we will search for white papers or benefit evaluation studies through Health
77 Technology Assessment Agencies such as Agency for Healthcare Research and Quality (AHRQ)
78 and National Institute for Health and Care Excellence (NICE), Canada Infoway and other relevant
79 organizations involved in providing guidance on delivery of healthcare services. We will use
80 keywords such as ‘digital health’, ‘frameworks’, and ‘benefits evaluation’ to refine our
81 supplementary search. In addition, we will also scan reference lists of included studies and conduct
82 a forward citation search (i.e., examine studies that reference the included studies) in Web of
83 Science using the cited reference search feature. This will ensure our approach is comprehensive.

84 **Eligibility Screening Process**

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

1
2
3 87 reviewers, and identifies discrepancies. We will apply a two-step process for identifying relevant
4
5 88 citations. At level 1, titles and abstracts will be assessed using the eligibility criteria (Appendix 2).
6
7 89 Studies with abstracts fulfilling criteria will be passed to level 2 where the eligibility criteria will
8
9 90 be applied to the full text articles.

10
11 91 Prior to screening, a pilot test will be completed using a random sample of 10% of citations
12
13 92 or full text articles, with the expressed purpose of assessing agreement between reviewers at each
14
15 93 level. Specifically, percent agreement will be used to assess agreement among reviewers (inter-
16
17 94 rater reliability $\geq 80\%$ will be considered adequate). If agreement is not reached, a second pilot will
18
19 95 be conducted with another random sample of 10%. A third reviewer will mediate any
20
21 96 disagreements. Citations and full text articles will be screened in duplicate by two reviewers.

22 97 **Data items and abstraction process**

23
24 98 Studies fulfilling the eligibility criteria will be abstracted in Excel. We will extract the
25
26 99 following study characteristics for the identified frameworks: name, reference, theory associated
27
28 100 with framework (if applicable), description of its components or constructs, and its application in
29
30 101 research (or stage of research to which it was applied, if applicable). For studies outlining the
31
32 102 application of a framework, additional characteristics will be abstracted such as the type of DHI,
33
34 103 healthcare setting, method of application, and nature and directionality of the results. We will
35
36 104 abstract information such as name of the framework, the role of framework in study (i.e.,
37
38 105 development, feasibility/pilot testing, implementation, evaluation), components of the framework
39
40 106 that were utilized, type of DHI, the objective of the study (if applicable), and healthcare setting
41
42 107 from included studies.

43 108 **Methodological appraisal**

44
45 109 We will not assess the quality of included articles in the scoping review (consistent with
46
47 110 Joanna Briggs Institute Reviewer's Manual⁷) as our purpose is to gain an overview of frameworks
48
49 111 used in relation to DHIs and not to assess the quality of their application.

50 112 **Ethics and Dissemination**

51
52
53 113 This scoping review is focused on published reports and studies of DHI and does not
54
55 114 involve patients or primary data collection; as such, no formal ethics approval is required.

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3 115 The dissemination plan will be tailored to end-users and will include passive and interactive
4
5 116 strategies such as peer reviewed publications, conference events and other network events with
6
7 117 digital health knowledge users. To ensure broader reach, we will also disseminate our findings
8
9 118 through social media platforms, and public-facing communications such as one-page briefs
10
11 119 released on the Women's College Institute for Health Innovation website at Women's College
12
13 120 hospital.

14 121 **Patient and Public Involvement**

15
16 122 We employed an integrated knowledge translation strategy to engage digital health
17
18 123 knowledge users in the review process to ensure the scope of the project met the needs of various
19
20 124 end-users. Knowledge users are defined as individuals who are likely to use the findings to inform
21
22 125 health decision making.² A priori, we decided to engage senior leaders and policymakers at
23
24 126 organizations that promote or support implementation of digital health solutions, as well as
25
26 127 researchers, clinicians, and developers evaluating DHIs in real world settings. An advisory panel
27
28 128 of digital health knowledge users was established to provide input at strategic phases of the scoping
29
30 129 review.

31 130 Potential panelists were identified through organizational networks and were invited to participate
32
33 131 via email. Six members agreed to participate (CSG, TS, HCW, JZ, SM, DL) on the advisory panel.
34
35 132 Panelists and the research team convened a meeting and discussed the strategic steps and
36
37 133 opportunities for involvement and input in the review. Specifically, the advisory panel will support
38
39 134 refinement of inclusion criteria, prioritization of data abstraction elements, assist in interpretation
40
41 135 of findings and develop dissemination strategies. Panelists have national and international
42
43 136 networks that will ensure the scope of the review reflects the knowledge needs of a diverse
44
45 138 selection and application of frameworks for DHIs. As the intended audience of this paper does not
46
47 139 include patients and members of the general public, they were not included as part of the advisory
48
49 140 panel. The perspectives of patients and the general public will be incorporated through their
50
51 141 participation and involvement in the respective studies included as part of this review.

52 142 **Analysis**

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2
3 143 Included studies will be summarized using qualitative description, an approach that seeks
4
5 144 to create an understanding of phenomenon through accessing the meanings ascribed by authors.¹⁶
6
7 145 Descriptions of individual frameworks will be organized by key categories, including study design,
8
9 146 report type (published vs non-published), methodological approach (i.e. how the framework is
10
11 147 intended to be applied) and application papers (i.e. how the framework has been applied in
12
13 148 practice). We will then synthesize findings by mapping core components of the frameworks and
14
15 149 examining how research objectives and type of DHIs are linked to the framework. Categorization
16
17 150 will use language directly from included studies, where possible, and authors will be contacted
18
19 151 when information is not present or unclear. The advisory panel will guide the synthesis of findings
20
21 152 by providing input on the level of detail abstracted from included articles and provide input on
22
23 153 categorization of frameworks, where appropriate.

24 25 154 **Strengths and Limitations**

26
27 155 To our knowledge, this is the first scoping review to examine the use of frameworks to
28
29 156 guide implementation or evaluation of DHIs on a broad scale. A clear understanding of which
30
31 157 frameworks can be used for development, feasibility, implementation and evaluation of DHIs will
32
33 158 facilitate decision making by making evidence-based approaches available to policymakers,
34
35 159 researchers, clinicians and developers.

36
37 160 Given the breadth of this scoping review, we anticipate a few key challenges. The first
38
39 161 relates to the inconsistent and often ill-defined nature of DHIs and frameworks. To be inclusive,
40
41 162 we have defined DHIs broadly as any health intervention that can be delivered through technology
42
43 163 to ensure we capture frameworks that are currently being used across healthcare settings.
44
45 164 Moreover, the term framework also creates challenges, as we have defined as a tool to
46
47 165 systematically organize and link research questions or constructs, but a range of terms are often
48
49 166 used synonymously (e.g., models or processes). To account for this, we will include studies
50
51 167 reporting on 'models' and work closely with the advisory panel to confirm whether the reported
52
53 168 framework aligns with our *a priori* definition. Relatedly, authors may not provide sufficient details
54
55 169 on the frameworks they utilize or their method of application. To mitigate this, we will contact
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57 170 authors to obtain additional information whenever information is missing or unclear. Finally, we
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59 171 anticipate that some included frameworks will have a dual purpose of addressing implementation
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172 and evaluation or may contain components that lend themselves to both constructs. When this

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3 173 occurs, we will discuss the overlap with digital health knowledge users and devise the most
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5 174 appropriate plan for analysis.
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7 175 We also anticipate challenges searching the literature. DHIs are not well defined in
8
9 176 electronic databases as they are referenced using a plethora of key terms. As such, we have
10
11 177 constructed our search to balance comprehensiveness and specificity. We have worked closely
12
13 178 with an information specialist to ensure the number of citations are focused and feasible. Several
14
15 179 iterations of the literature search were conducted using a randomized sample of 200 citations and
16
17 180 the specificity and sensitivity of search terms were tested using the inclusion criteria. Two
18
19 181 reviewers screened citations, discrepancies were discussed among the internal research team, and
20
21 182 the number of included studies were examined to explore the specificity of search terms. Through
22
23 183 iterative testing, we feel confident in our current literature strategy, however, additional challenges
24
25 184 may arise when screening.

26 185 Overall, identification of frameworks will serve as a guide for researchers, clinicians,
27
28 186 policymakers, and developers of DHIs by providing practical guidance on which frameworks may
29
30 187 be most appropriate for which objectives (i.e., implementation or evaluation). In parallel, the
31
32 188 results will contribute to a more nuanced understanding of how to evaluate and implement DHIs,
33
34 189 including the identification and understanding of key constructs.
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3 **233 Authors' Contributions:**
4

5 234 CS, LD conceived and developed the study. CS drafted the manuscript. MC, VK, RSB, TS, SM,
6
7 235 DL, HCW, JZ, CGS, and LD reviewed and edited the manuscript.
8

9
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11
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13 238 not-for-profit sectors.
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16
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18
19

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23
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25
26 244 preliminary citations.
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For peer review only

1 Appendix 1. Primary Literature Search in Medline

2 Database: Ovid MEDLINE: Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid
3 MEDLINE® Daily and Ovid MEDLINE® <1946-Present>

4 Search Strategy:

5 -----

6 1 exp Telemedicine/ (25845)

7 2 (telemed* or tele-med* or telecare or tele-care or teleconsult* or tele-consult* or telehealth* or
8 tele-health* or telemonitor* or tele-monitor* or telerehab* or tele-rehab*).tw,kf. (17416)

9 3 (ehealth* or e-health* or mhealth* or m-health* or emental health* or e-mental health* or
10 epsychiatr* or e-psychiatr* or epsychol* or e-psychol* or etherap* or e-therap*).tw,kf. (10073)

11 4 (emedicine or e-medicine*).tw,kf. (78)

12 5 (mobile health* or mobile care or mobile medicine).tw,kf. (3793)

13 6 (digital* adj3 (medic* or care or health* or healthcare or health-care)).tw,kf. (3065)

14 7 (digital* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or
15 surger* or surgic* or therap* or treatment?)).tw,kf. (5936)

16 8 (remote* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or
17 surger* or surgic* or therap* or treatment?)).tw,kf. (6643)

18 9 Monitoring, Ambulatory/ (7806)

19 10 ((outpatient* or out-patient* or ambulator* or home? or homebased or home-based) adj3
20 (manag* or monitor*)).tw,kf. (24341)

21 11 exp Biomedical Technology/ (13203)

22 12 ((biomedic* or bio-medic* or health* or healthcare or health care or medical) adj
23 technolog*).tw,kf. (13535)

24 13 Medical Informatics/ or Medical Informatics Applications/ (13622)

25 14 ((health* or medical) adj informatic*).tw,kf. (5056)

26 15 exp Therapy, Computer-Assisted/ (59720)

27 16 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
28 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
29 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
30 webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 care).tw,kf. (8049)

31 17 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
32 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
33 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
34 webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 health*).tw,kf. (27319)

35 18 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
36 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
37 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
38 webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (healthcare or health
39 care)).tw,kf. (6410)

40 19 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
41 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
42 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
43 webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (medicine or medical)).tw,kf.
44 (19800)

45 20 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
46 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile

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2
3 47 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
4 48 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 consult*).tw,kf. (1299)
5 49 21 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
6 50 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
7 51 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
8 52 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 diagnos*).tw,kf. (13043)
9 53 22 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
10 54 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
11 55 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
12 56 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 intervention?).tw,kf. (9139)
13 57 23 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
14 58 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
15 59 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
16 60 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 manag*).tw,kf. (7259)
17 61 24 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
18 62 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
19 63 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
20 64 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 monitor*).tw,kf. (8457)
21 65 25 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
22 66 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
23 67 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
24 68 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 palliat*).tw,kf. (133)
25 69 26 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
26 70 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
27 71 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
28 72 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 rehab*).tw,kf. (1264)
29 73 27 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
30 74 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
31 75 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
32 76 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 (surger* or surgic*).tw,kf.
33 77 (7354)
34 78 28 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
35 79 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
36 80 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
37 81 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 therap*).tw,kf. (6817)
38 82 29 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
39 83 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
40 84 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
41 85 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 treatment?).tw,kf. (10336)
42 86 30 Wearable Electronic Devices/ (1321)
43 87 31 wearable?.tw,kf. (10007)
44 88 32 or/1-31 (253918)
45 89 33 exp *Delivery of Health Care/ (619520)
46 90 34 exp Computers/ (76307)
47 91 35 Electronic Mail/ (2573)
48 92 36 Internet/ (69753)
49 93 37 Telecommunications/ (4741)

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3 94 38 (internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
4 95 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
5 96 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
6 97 webbased or web-based or webdeliver* or web-deliver*).tw,kf. (995758)
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8 98 39 33 and (34 or 35 or 36 or 37 or 38) (50511)
9 99 40 32 or 39 [DIGITAL HEALTH APPLICATIONS] (282776)
10 100 41 (evaluat* adj3 (design* or frame or frames or framework? or guid* or model or models or schem*
11 101 or strateg* or theor*).tw,kf. (105535)
12 102 42 (apprais* adj3 (frame or frames or framework? or model or models or theor*).tw,kf. (927)
13 103 43 (apprais* adj3 (design* or guid* or schem* or strateg*).ti,kf. (313)
14 104 44 (assess* adj3 (frame or frames or framework? or model or models or theor*).tw,kf. (47798)
15 105 45 (assess* adj3 (design* or guid* or schem* or strateg*).ti,kf. (3366)
16 106 46 (implement* adj3 (design* or frame or frames or framework? or guid* or model or models or
17 107 schem* or strateg* or theor*).tw,kf. (57152)
18 108 47 (evidence-based adj (frame or frames or framework? or model or models or theor*).tw,kf. (769)
19 109 48 (evidence-based adj (design* or guid* or schem* or strateg*).ti,kf. (1559)
20 110 49 (service adj (frame or frames or framework? or model or models or theor*).tw,kf. (2165)
21 111 50 (service adj (design* or guid* or schem* or strateg*).ti,kf. (201)
22 112 51 or/41-50 [EVALUATION/IMPLEMENTATION FRAMEWORKS] (212588)
23 113 52 40 and 51 [DIGITAL HEALTH - EVALUATION/IMPLEMENTATION FRAMEWORKS] (8974)
24 114 53 exp Animals/ not Humans/ (4614915)
25 115 54 52 not 53 [ANIMAL-ONLY REMOVED] (8859)
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1 Appendix 2. Eligibility Criteria

Question 1: Does this study include humans?

- 2 a. If yes, **INCLUDE**
- 3 b. **EXCLUDE** animal studies/models, non-humans or vertebrae studies

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

- 4 a. **INCLUDE** studies focusing on digital health interventions as their primary component of
5 the study. A digital health intervention is any health intervention that is being delivered
6 by technology and can include the following items: ehealth, virtual healthcare,
7 smartphone apps aimed at healthcare issue, wearable technologies, telemedicine or health
8 education interventions delivered digitally.
- 9 b. **EXCLUDE** interventions that are focused on creating scales, checklists or other metrics
10 that are not a digital health intervention.
 - 11 • Example of an exclude: a cross-sectional study to create a checklist for
12 conducting health technology assessments.

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

- 13 a. **INCLUDE** studies that focus on frameworks. Frameworks can help guide evaluation
14 questions by systematically organizing and linking research questions when evaluating a
15 digital intervention.
- 16 b. **EXCLUDE** studies that discuss checklists, theoretical mathematical models or statistical
17 models.

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

- 19 a. **INCLUDE** any study design (i.e., randomized controlled trials, observational studies,
20 cross-sectional studies, qualitative studies, systematic review)
- 21 b. **EXCLUDE** studies if it's an editorial (without any primary data), letter to the editor or
22 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.	
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.	
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.	
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.	
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.	
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.	
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.	
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	
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.	
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	
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).	
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	



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.	
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	
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.	
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	
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.	
Limitations	20	Discuss the limitations of the scoping review process.	
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.	
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.	

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 (PRISMA-ScR): 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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1
2
3 **Identifying optimal frameworks to implement or evaluate digital health interventions: A**
4 **scoping review protocol**
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6
7
8

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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. 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.

1 Introduction

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

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

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

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

- 26 1. To describe the attributes of existing frameworks that have been used to guide the
27 implementation or evaluation of DHIs.
- 28 2. Identify the proposed role of each framework, including the constructs and mechanisms
29 they target.

30 3. Describe how each framework has been applied in primary studies, if applicable.

31 The results of this review will provide practical guidance and support for researchers, clinicians,
32 policymakers, and developers in selecting the most appropriate framework for DHIs, which will
33 support evidence-based approaches in relation to implementation and evaluation efforts.

34 **Methods and Analysis**

35 We will conduct a scoping review to comprehensively search the literature, ‘map’ the
36 evidence, and identify gaps in the research knowledge base.^{7 8} The study will be conducted using
37 established methods outlined by the Joanna Briggs Institute Reviewers’ Manual⁷ and reporting
38 will conform to the PRISMA Extension for Scoping Reviews (PRISMA-ScR).⁹ This protocol is
39 registered on Open Science Framework (OSF) and is available at <https://osf.io/8jydm/>. OSF is an
40 open source platform where researchers can share protocols, data and contributes to transparency
41 of research.¹⁰

42 **Eligibility Criteria**

43 Studies reporting on the development or application of frameworks (i.e., theoretical or
44 interpretive) to guide implementation or evaluation of DHIs in healthcare will be included. We
45 will use the WHO definition of health which encompasses physical, mental and social well-being
46 and spans across multiple disciplines such as psychology, sociology or medical sciences.¹¹ DHI
47 was defined as any health service or treatment delivered using technology that aims to facilitate,
48 capture, or exchange knowledge (formally or informally).⁵ DHI definition was generated from a
49 search of the literature and consultations with digital health knowledge users, including
50 policymakers, researchers, clinicians and developers. Implementation frameworks will be
51 operationalized according to MRC guidance, as frameworks that aim to guide research into
52 practice, which can include development, feasibility, and dissemination frameworks.³ Evaluation
53 frameworks will be defined as frameworks that focus on determining the effectiveness of DHIs,
54 which includes measuring outcomes and understanding processes or mechanisms of action.³ No
55 limitations will be placed on user population, comparators, study design, publication status or
56 geographic region to enhance the comprehensiveness of our results and avoid unintended
57 exclusion of relevant studies. Conference abstracts/proceedings and white papers will be included.
58 We will include studies reported in other languages and use appropriate tools (i.e., Google

1
2
3 59 translate, translation services, contact author) to assess inclusion. Commentaries and studies
4
5 60 examining mathematical or statistical frameworks will be excluded.
6

7 61 **Information sources**

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9
10 62 An experienced information specialist developed the literature search in consultation with
11
12 63 the multidisciplinary research team. The search will be peer reviewed by a second information
13
14 64 specialist using the Peer Review of Electronic Search Strategy (PRESS) checklist to ensure the
15
16 65 search is comprehensive and maximizes appropriate search terms.¹²

17
18 66 We will search MEDLINE, EMBASE, CINAHL, and PsychINFO using key words such
19
20 67 as ‘digital health’ and ‘framework’. Additional search terms were drawn from multiple disciplines
21
22 68 such as psychology, nursing, sociology, and medicine to ensure comprehensiveness. The databases
23
24 69 will be searched from inception to present and the search strategy is presented in Appendix 1. We
25
26 70 chose not to use the BeHEMoTh (behaviour of interest, health context, exclusions, and models or
27
28 71 theory) approach¹³ as specified in our OSF registration. Although this approach has been
29
30 72 successful in identifying frameworks in knowledge translation,⁴ it did not prove to be a feasible
31
32 73 approach in our scoping review as it yielded a vast number of citations with limited specificity
33
34 74 related to our objectives. We utilized a simplified heuristic, which included identifying DHIs in
35
36 75 various healthcare contexts, adding terms for frameworks, and removing exclusions such as animal
37
38 76 studies (Appendix 1).

39
40 77 The search strategy will be supplemented by a search for grey literature using the checklist
41
42 78 suggested by the Canadian Agency for Drugs and Technologies in Health (CADTH).¹⁴
43
44 79 Specifically, we will search for white papers or benefit evaluation studies through Health
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46 80 Technology Assessment Agencies such as Agency for Healthcare Research and Quality (AHRQ)
47
48 81 and National Institute for Health and Care Excellence (NICE), Canada Infoway and other relevant
49
50 82 organizations involved in providing guidance on delivery of healthcare services. We will use
51
52 83 keywords such as ‘digital health’, ‘frameworks’, and ‘benefits evaluation’ to refine our
53
54 84 supplementary search. In addition, we will also scan reference lists of included studies and conduct
55
56 85 a forward citation search (i.e., examine studies that reference the included studies) in Web of
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58 86 Science using the cited reference search feature. This will ensure our approach is comprehensive.

59 87 **Eligibility Screening Process**

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3 88 Citations obtained from the literature search will be uploaded to Covidence,¹⁵ a systematic
4
5 89 review software program which organizes citations, enables screening of citations by multiple
6
7 90 reviewers, and identifies discrepancies. We will apply a two-step process for identifying relevant
8
9 91 citations. At level 1, titles and abstracts will be assessed using the eligibility criteria (Appendix 2).
10
11 92 Studies with abstracts fulfilling criteria will be passed to level 2 where the eligibility criteria will
12
13 93 be applied to the full text articles.

14 94 Prior to screening, a pilot test will be completed using a random sample of 10% of citations
15
16 95 or full text articles, with the expressed purpose of assessing agreement between reviewers at each
17
18 96 level. Specifically, percent agreement will be used to assess agreement among reviewers (inter-
19
20 97 rater reliability $\geq 80\%$ will be considered adequate). If agreement is not reached, a second pilot will
21
22 98 be conducted with another random sample of 10%. A third reviewer will mediate any
23
24 99 disagreements. Citations and full text articles will be screened in duplicate by two reviewers.

25 100 **Data items and abstraction process**

26
27 101 Studies fulfilling the eligibility criteria will be abstracted in Excel. We will extract the
28
29 102 following study characteristics for the identified frameworks: name, reference, theory associated
30
31 103 with framework (if applicable), description of its components or constructs, and its application in
32
33 104 research (or stage of research to which it was applied, if applicable). For studies outlining the
34
35 105 application of a framework, additional characteristics will be abstracted such as the type of DHI,
36
37 106 healthcare setting, method of application, and nature and directionality of the results. We will
38
39 107 abstract information such as name of the framework, the role of framework in study (i.e.,
40
41 108 development, feasibility/pilot testing, implementation, evaluation), components of the framework
42
43 109 that were utilized, type of DHI, the objective of the study (if applicable), and healthcare setting
44
45 110 from included studies.

46 111 **Methodological appraisal**

47
48 112 We will not assess the quality of included articles in the scoping review (consistent with
49
50 113 Joanna Briggs Institute Reviewer's Manual⁷) as our purpose is to gain an overview of frameworks
51
52 114 used in relation to DHIs and not to assess the quality of their application.

53 54 115 **Ethics and Dissemination**

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3 116 This scoping review is focused on published reports and studies of DHI and does not
4
5 117 involve patients or primary data collection; as such, no formal ethics approval is required.
6

7 118 The dissemination plan will be tailored to end-users and will include passive and interactive
8
9 119 strategies such as peer reviewed publications, conference events and other network events with
10
11 120 digital health knowledge users. To ensure broader reach, we will also disseminate our findings
12
13 121 through social media platforms, and public-facing communications such as one-page briefs
14
15 122 released on the Women's College Institute for Health Innovation website at Women's College
16
17 123 hospital.

18 124 **Patient and Public Involvement**

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20
21 125 We employed an integrated knowledge translation strategy to engage digital health
22
23 126 knowledge users in the review process to ensure the scope of the project met the needs of various
24
25 127 end-users. Knowledge users are defined as individuals who are likely to use the findings to inform
26
27 128 health decision making.² A priori, we decided to engage senior leaders and policymakers at
28
29 129 organizations that promote or support implementation of digital health solutions, as well as
30
31 130 researchers, clinicians, and developers evaluating DHIs in real world settings. An advisory panel
32
33 131 of digital health knowledge users was established to provide input at strategic phases of the scoping
34
35 132 review.

36
37 133 Potential panelists were identified through organizational networks and were invited to participate
38
39 134 via email. Six members agreed to participate (CSG, TS, HCW, JZ, SM, DL) on the advisory panel.
40
41 135 Panelists and the research team convened a meeting and discussed the strategic steps and
42
43 136 opportunities for involvement and input in the review. Specifically, the advisory panel will support
44
45 137 refinement of inclusion criteria, prioritization of data abstraction elements, assist in interpretation
46
47 138 of findings and develop dissemination strategies. Panelists have national and international
48
49 139 networks that will ensure the scope of the review reflects the knowledge needs of a diverse
50
51 140 audience, which is directly in line with the stated aim of providing practical guidance on the
52
53 141 selection and application of frameworks for DHIs. As the intended audience of this paper does not
54
55 142 include patients and members of the general public, they were not included as part of the advisory
56
57 143 panel. The perspectives of patients and the general public will be incorporated through their
58
59 144 participation and involvement in the respective studies included as part of this review.
60

145 **Analysis**

146 Included studies will be summarized using qualitative description, an approach that seeks
147 to create an understanding of phenomenon through accessing the meanings ascribed by authors.¹⁶
148 Descriptions of individual frameworks will be organized by key categories, including study design,
149 report type (published vs non-published), methodological approach (i.e. how the framework is
150 intended to be applied) and application papers (i.e. how the framework has been applied in
151 practice). We will then synthesize findings by mapping core components of the frameworks and
152 examining how research objectives and type of DHIs are linked to the framework. Categorization
153 will use language directly from included studies, where possible, and authors will be contacted
154 when information is not present or unclear. The advisory panel will guide the synthesis of findings
155 by providing input on the level of detail abstracted from included articles and provide input on
156 categorization of frameworks, where appropriate.

157 **Strengths and Limitations**

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

163 Given the breadth of this scoping review, we anticipate a few key challenges. The first
164 relates to the inconsistent and often ill-defined nature of DHIs and frameworks. To be inclusive,
165 we have defined DHIs broadly as any health intervention that can be delivered utilizing technology
166 to ensure we capture frameworks that are currently being used across formal (e.g., care delivered
167 within the walls of a healthcare organization) and informal settings (e.g., direct to consumer
168 technologies). Moreover, use of the term framework itself also creates challenges. For the purposes
169 of this scoping review, we have defined a framework as a tool to systematically organize and link
170 research questions or constructs, but a range of terms are often used synonymously (e.g., models
171 or processes). To account for this variability, we will include studies reporting on ‘models’ and
172 work closely with the advisory panel to confirm whether the reported framework aligns with our
173 *a priori* definition, as well as the needs of relevant digital health knowledge user groups.

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3 174 Secondly, we also anticipate challenges searching the literature as a product of inconsistent
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5 175 terminology outlined above. We have constructed our search to balance comprehensiveness and
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7 176 specificity, working closely with an information specialist to ensure the number of citations are
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9 177 focused and feasible. Several iterations of the literature search. Specifically, we added in key words
10
11 178 and removed them in a stepwise fashion to understand the impact on specificity and sensitivity of
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13 179 our search. We used a randomized sample of 200 citations and multiple iterations of the literature
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15 180 search were screened using the inclusion criteria Two reviewers screened citations, discrepancies
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17 181 were discussed among the internal research team, and the number of included studies were
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19 182 examined to explore the specificity of search terms. Through this iterative process, we developed
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21 183 our search strategy, which was then peer reviewed using the PRESS checklist; however, we
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23 184 anticipate additional challenges when screening.

24
25 185 Thirdly, we anticipate challenges arising from poor reporting or limited description, as
26
27 186 evidenced by previous studies.^{17 18} „ Authors may not provide sufficient details on the frameworks
28
29 187 they utilize or their method of application.¹⁹ To mitigate this, we will contact authors to obtain
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31 188 additional information whenever information is missing or unclear.

32
33 189 Finally, we anticipate that some included frameworks will have a dual purpose of
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35 190 addressing implementation and evaluation or may contain components that lend themselves to both
36
37 191 constructs. We will convene with the advisory committee on a quarterly basis to discuss these
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39 192 issues as they arise and will devise the most appropriate plan for analysis through group consensus.

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41 193 Overall, identification of frameworks will serve as a guide for researchers, clinicians,
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43 194 policymakers, and developers of DHIs by providing practical guidance on which frameworks may
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45 195 be most appropriate for which objectives (i.e., implementation or evaluation). In parallel, the
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47 196 results will contribute to a more nuanced understanding of how to evaluate and implement DHIs,
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49 197 including the identification and understanding of key constructs.

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3 251 **Authors' Contributions:**
4

5 252 CS, LD conceived and developed the study. CS drafted the manuscript. MC, VK, RSB, TS, SM,
6
7 253 DL, HCW, JZ, CGS, and LD reviewed and edited the manuscript.
8

9
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11

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14

15 257 **Conflict of Interest:**
16

17 258 The authors have no conflicts of interest to report.
18
19

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21

22 260 We would like to thank Becky Skidmore, and Anne Dabrowski for their assistance with
23
24 261 generating the literature search, as well as Beatrice Choremis, who helped screen a few
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26 262 preliminary citations.
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1 Appendix 1. Primary Literature Search in Medline

2 Database: Ovid MEDLINE: Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid
 3 MEDLINE® Daily and Ovid MEDLINE® <1946-Present>
 4 Search Strategy:
 5 -----
 6 1 exp Telemedicine/ (25845)
 7 2 (telemed* or tele-med* or telecare or tele-care or teleconsult* or tele-consult* or telehealth* or
 8 tele-health* or telemonitor* or tele-monitor* or telerehab* or tele-rehab*).tw,kf. (17416)
 9 3 (ehealth* or e-health* or mhealth* or m-health* or emental health* or e-mental health* or
 10 epsychiatr* or e-psychiatr* or epsychol* or e-psychol* or etherap* or e-therap*).tw,kf. (10073)
 11 4 (emedicine or e-medicine*).tw,kf. (78)
 12 5 (mobile health* or mobile care or mobile medicine).tw,kf. (3793)
 13 6 (digital* adj3 (medic* or care or health* or healthcare or health-care)).tw,kf. (3065)
 14 7 (digital* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or
 15 surger* or surgic* or therap* or treatment?)).tw,kf. (5936)
 16 8 (remote* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or
 17 surger* or surgic* or therap* or treatment?)).tw,kf. (6643)
 18 9 Monitoring, Ambulatory/ (7806)
 19 10 ((outpatient* or out-patient* or ambulator* or home? or homebased or home-based) adj3
 20 (manag* or monitor*)).tw,kf. (24341)
 21 11 exp Biomedical Technology/ (13203)
 22 12 ((biomedic* or bio-medic* or health* or healthcare or health care or medical) adj
 23 technolog*).tw,kf. (13535)
 24 13 Medical Informatics/ or Medical Informatics Applications/ (13622)
 25 14 ((health* or medical) adj informatic*).tw,kf. (5056)
 26 15 exp Therapy, Computer-Assisted/ (59720)
 27 16 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
 28 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
 29 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
 30 webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 care).tw,kf. (8049)
 31 17 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
 32 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
 33 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
 34 webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 health*).tw,kf. (27319)
 35 18 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
 36 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
 37 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
 38 webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (healthcare or health
 39 care)).tw,kf. (6410)
 40 19 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
 41 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
 42 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
 43 webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (medicine or medical)).tw,kf.
 44 (19800)
 45 20 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
 46 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile

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4 48 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 consult*).tw,kf. (1299)
5 49 21 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
6 50 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
7 51 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
8 52 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 diagnos*).tw,kf. (13043)
9 53 22 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
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11 55 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
12 56 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 intervention?).tw,kf. (9139)
13 57 23 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
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16 60 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 manag*).tw,kf. (7259)
17 61 24 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
18 62 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
19 63 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
20 64 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 monitor*).tw,kf. (8457)
21 65 25 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
22 66 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
23 67 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
24 68 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 palliat*).tw,kf. (133)
25 69 26 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
26 70 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
27 71 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
28 72 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 rehab*).tw,kf. (1264)
29 73 27 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
30 74 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
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32 76 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 (surger* or surgic*).tw,kf.
33 77 (7354)
34 78 28 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
35 79 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
36 80 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
37 81 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 therap*).tw,kf. (6817)
38 82 29 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
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41 85 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 treatment?).tw,kf. (10336)
42 86 30 Wearable Electronic Devices/ (1321)
43 87 31 wearable?.tw,kf. (10007)
44 88 32 or/1-31 (253918)
45 89 33 exp *Delivery of Health Care/ (619520)
46 90 34 exp Computers/ (76307)
47 91 35 Electronic Mail/ (2573)
48 92 36 Internet/ (69753)
49 93 37 Telecommunications/ (4741)

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6 97 webbased or web-based or webdeliver* or web-deliver*).tw,kf. (995758)
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8 98 39 33 and (34 or 35 or 36 or 37 or 38) (50511)
9 99 40 32 or 39 [DIGITAL HEALTH APPLICATIONS] (282776)
10 100 41 (evaluat* adj3 (design* or frame or frames or framework? or guid* or model or models or schem*
11 101 or strateg* or theor*).tw,kf. (105535)
12 102 42 (apprais* adj3 (frame or frames or framework? or model or models or theor*).tw,kf. (927)
13 103 43 (apprais* adj3 (design* or guid* or schem* or strateg*).ti,kf. (313)
14 104 44 (assess* adj3 (frame or frames or framework? or model or models or theor*).tw,kf. (47798)
15 105 45 (assess* adj3 (design* or guid* or schem* or strateg*).ti,kf. (3366)
16 106 46 (implement* adj3 (design* or frame or frames or framework? or guid* or model or models or
17 107 schem* or strateg* or theor*).tw,kf. (57152)
18 108 47 (evidence-based adj (frame or frames or framework? or model or models or theor*).tw,kf. (769)
19 109 48 (evidence-based adj (design* or guid* or schem* or strateg*).ti,kf. (1559)
20 110 49 (service adj (frame or frames or framework? or model or models or theor*).tw,kf. (2165)
21 111 50 (service adj (design* or guid* or schem* or strateg*).ti,kf. (201)
22 112 51 or/41-50 [EVALUATION/IMPLEMENTATION FRAMEWORKS] (212588)
23 113 52 40 and 51 [DIGITAL HEALTH - EVALUATION/IMPLEMENTATION FRAMEWORKS] (8974)
24 114 53 exp Animals/ not Humans/ (4614915)
25 115 54 52 not 53 [ANIMAL-ONLY REMOVED] (8859)
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1 Appendix 2. Eligibility Criteria

Question 1: Does this study include humans?

- 2 a. If yes, **INCLUDE**
- 3 b. **EXCLUDE** animal studies/models, non-humans or vertebrae studies

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

- 4 a. **INCLUDE** studies focusing on digital health interventions as their primary component of
5 the study. A digital health intervention is any health intervention that is being delivered
6 by technology and can include the following items: ehealth, virtual healthcare,
7 smartphone apps aimed at healthcare issue, wearable technologies, telemedicine or health
8 education interventions delivered digitally.
- 9 b. **EXCLUDE** interventions that are focused on creating scales, checklists or other metrics
10 that are not a digital health intervention.
 - 11 • Example of an exclude: a cross-sectional study to create a checklist for
12 conducting health technology assessments.

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

- 13 a. **INCLUDE** studies that focus on frameworks. Frameworks can help guide evaluation
14 questions by systematically organizing and linking research questions when evaluating a
15 digital intervention.
- 16 b. **EXCLUDE** studies that discuss checklists, theoretical mathematical models or statistical
17 models.

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

- 19 a. **INCLUDE** any study design (i.e., randomized controlled trials, observational studies,
20 cross-sectional studies, qualitative studies, systematic review)
- 21 b. **EXCLUDE** studies if it's an editorial (without any primary data), letter to the editor or
22 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.	
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.	
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.	
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.	
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.	
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.	
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.	
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	
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.	
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	
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).	
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	



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.	
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	
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.	
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	
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.	
Limitations	20	Discuss the limitations of the scoping review process.	
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.	
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.	

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 (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med.* 2018;169:467–473. doi: [10.7326/M18-0850](https://doi.org/10.7326/M18-0850).



BMJ Open

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

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3 **Identifying optimal frameworks to implement or evaluate digital health interventions: A**
4 **scoping review protocol**
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Keywords: scoping review, digital health interventions, evaluation frameworks, implementation frameworks

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

For peer review only

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.

1 Introduction

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

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

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

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

- 26 1. To describe the attributes of existing frameworks that have been used to guide the
27 implementation or evaluation of DHIs.
- 28 2. Identify the proposed role of each framework, including the constructs and mechanisms
29 they target.

30 3. Describe how each framework has been applied in primary studies, if applicable.

31 The results of this review will provide practical guidance and support for researchers, clinicians,
32 policymakers, and developers in selecting the most appropriate framework for DHIs, which will
33 support evidence-based approaches in relation to implementation and evaluation efforts.

34 **Methods and Analysis**

35 We will conduct a scoping review to comprehensively search the literature, ‘map’ the
36 evidence, and identify gaps in the research knowledge base.^{7 8} The study will be conducted using
37 established methods outlined by the Joanna Briggs Institute Reviewers’ Manual⁷ and reporting
38 will conform to the PRISMA Extension for Scoping Reviews (PRISMA-ScR).⁹ This protocol is
39 registered on Open Science Framework (OSF) and is available at <https://osf.io/8jydm/>. OSF is an
40 open source platform where researchers can share protocols, data and contributes to transparency
41 of research.¹⁰

42 **Eligibility Criteria**

43 Studies reporting on the development or application of frameworks (i.e., theoretical or
44 interpretive) to guide implementation or evaluation of DHIs in healthcare will be included. We
45 will use the WHO definition of health which encompasses physical, mental and social well-being
46 and spans across multiple disciplines such as psychology, sociology or medical sciences.¹¹ DHI
47 was defined as any health service or treatment delivered using technology that aims to facilitate,
48 capture, or exchange knowledge (formally or informally).⁵ DHI definition was generated from a
49 search of the literature and consultations with digital health knowledge users, including
50 policymakers, researchers, clinicians and developers. Implementation frameworks will be
51 operationalized according to MRC guidance, as frameworks that aim to guide research into
52 practice, which can include development, feasibility, and dissemination frameworks.³ Evaluation
53 frameworks will be defined as frameworks that focus on determining the effectiveness of DHIs,
54 which includes measuring outcomes and understanding processes or mechanisms of action.³ No
55 limitations will be placed on user population, comparators, study design, publication status or
56 geographic region to enhance the comprehensiveness of our results and avoid unintended
57 exclusion of relevant studies. Conference abstracts/proceedings and white papers will be included.
58 We will include studies reported in other languages and use appropriate tools (i.e., Google

1
2
3 59 translate, translation services, contact author) to assess inclusion. Commentaries and studies
4
5 60 examining mathematical or statistical frameworks will be excluded.
6

7 61 **Information sources**

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10 62 An experienced information specialist developed the literature search in consultation with
11
12 63 the multidisciplinary research team. The search will be peer reviewed by a second information
13
14 64 specialist using the Peer Review of Electronic Search Strategy (PRESS) checklist to ensure the
15
16 65 search is comprehensive and maximizes appropriate search terms.¹²

17
18 66 We will search MEDLINE, EMBASE, CINAHL, and PsychINFO using key words such
19
20 67 as ‘digital health’ and ‘framework’. Additional search terms were drawn from multiple disciplines
21
22 68 such as psychology, nursing, sociology, and medicine to ensure comprehensiveness. The databases
23
24 69 will be searched from inception to present and the search strategy is presented in Appendix 1. We
25
26 70 chose not to use the BeHEMoTh (behaviour of interest, health context, exclusions, and models or
27
28 71 theory) approach¹³ as specified in our OSF registration. Although this approach has been
29
30 72 successful in identifying frameworks in knowledge translation,⁴ it did not prove to be a feasible
31
32 73 approach in our scoping review as it yielded a vast number of citations with limited specificity
33
34 74 related to our objectives. We utilized a simplified heuristic, which included identifying DHIs in
35
36 75 various healthcare contexts, adding terms for frameworks, and removing exclusions such as animal
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38 76 studies (Appendix 1).

39
40 77 The search strategy will be supplemented by a search for grey literature using the checklist
41
42 78 suggested by the Canadian Agency for Drugs and Technologies in Health (CADTH).¹⁴
43
44 79 Specifically, we will search for white papers or benefit evaluation studies through Health
45
46 80 Technology Assessment Agencies such as Agency for Healthcare Research and Quality (AHRQ)
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48 81 and National Institute for Health and Care Excellence (NICE), Canada Infoway and other relevant
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50 82 organizations involved in providing guidance on delivery of healthcare services. We will use
51
52 83 keywords such as ‘digital health’, ‘frameworks’, and ‘benefits evaluation’ to refine our
53
54 84 supplementary search. In addition, we will also scan reference lists of included studies and conduct
55
56 85 a forward citation search (i.e., examine studies that reference the included studies) in Web of
57
58 86 Science using the cited reference search feature. This will ensure our approach is comprehensive.

59 87 **Eligibility Screening Process**

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2
3 88 Citations obtained from the literature search will be uploaded to Covidence,¹⁵ a systematic
4
5 89 review software program which organizes citations, enables screening of citations by multiple
6
7 90 reviewers, and identifies discrepancies. We will apply a two-step process for identifying relevant
8
9 91 citations. At level 1, titles and abstracts will be assessed using the eligibility criteria (Appendix 2).
10
11 92 Studies with abstracts fulfilling criteria will be passed to level 2 where the eligibility criteria will
12
13 93 be applied to the full text articles.

14 94 Prior to screening, a pilot test will be completed using a random sample of 10% of citations
15
16 95 or full text articles, with the expressed purpose of assessing agreement between reviewers at each
17
18 96 level. Specifically, percent agreement will be used to assess agreement among reviewers (inter-
19
20 97 rater reliability $\geq 80\%$ will be considered adequate). If agreement is not reached, a second pilot will
21
22 98 be conducted with another random sample of 10%. A third reviewer will mediate any
23
24 99 disagreements. Citations and full text articles will be screened in duplicate by two reviewers.

25 100 **Data items and abstraction process**

26
27 101 Studies fulfilling the eligibility criteria will be abstracted in Excel. We will extract the
28
29 102 following study characteristics for the identified frameworks: name, reference, theory associated
30
31 103 with framework (if applicable), description of its components or constructs, and its application in
32
33 104 research (or stage of research to which it was applied, if applicable). For studies outlining the
34
35 105 application of a framework, additional characteristics will be abstracted such as the type of DHI,
36
37 106 healthcare setting, method of application, and nature and directionality of the results. We will
38
39 107 abstract information such as name of the framework, the role of framework in study (i.e.,
40
41 108 development, feasibility/pilot testing, implementation, evaluation), components of the framework
42
43 109 that were utilized, type of DHI, the objective of the study (if applicable), and healthcare setting
44
45 110 from included studies.

46 111 **Methodological appraisal**

47
48 112 We will not assess the quality of included articles in the scoping review (consistent with
49
50 113 Joanna Briggs Institute Reviewer's Manual⁷) as our purpose is to gain an overview of frameworks
51
52 114 used in relation to DHIs and not to assess the quality of their application.

53 54 115 **Ethics and Dissemination**

1
2
3 116 This scoping review is focused on published reports and studies of DHI and does not
4
5 117 involve patients or primary data collection; as such, no formal ethics approval is required.
6

7 118 The dissemination plan will be tailored to end-users and will include passive and interactive
8
9 119 strategies such as peer reviewed publications, conference events and other network events with
10
11 120 digital health knowledge users. To ensure broader reach, we will also disseminate our findings
12
13 121 through social media platforms, and public-facing communications such as one-page briefs
14
15 122 released on the Women's College Institute for Health Innovation website at Women's College
16
17 123 hospital.

18 124 **Patient and Public Involvement**

19
20
21 125 We employed an integrated knowledge translation strategy to engage digital health
22
23 126 knowledge users in the review process to ensure the scope of the project met the needs of various
24
25 127 end-users. Knowledge users are defined as individuals who are likely to use the findings to inform
26
27 128 health decision making.² A priori, we decided to engage senior leaders and policymakers at
28
29 129 organizations that promote or support implementation of digital health solutions, as well as
30
31 130 researchers, clinicians, and developers evaluating DHIs in real world settings. An advisory panel
32
33 131 of digital health knowledge users was established to provide input at strategic phases of the scoping
34
35 132 review.

36
37 133 Potential panelists were identified through organizational networks and were invited to
38
39 134 participate via email. Six members agreed to participate (CSG, TS, HCW, JZ, SM, DL) on the
40
41 135 advisory panel. Panelists and the research team convened a meeting and discussed the strategic
42
43 136 steps and opportunities for involvement and input in the review. Specifically, the advisory panel
44
45 137 will support refinement of inclusion criteria, prioritization of data abstraction elements, assist in
46
47 138 interpretation of findings and develop dissemination strategies. Panelists have national and
48
49 139 international networks that will ensure the scope of the review reflects the knowledge needs of a
50
51 140 diverse audience, which is directly in line with the stated aim of providing practical guidance on
52
53 141 the selection and application of frameworks for DHIs. As the intended audience of this paper does
54
55 142 not include patients and members of the general public, they were not included as part of the
56
57 143 advisory panel. The perspectives of patients and the general public will be incorporated through
58
59 144 their participation and involvement in the respective studies included as part of this review.
60

145 **Analysis**

146 Included studies will be summarized using qualitative description, an approach that seeks
147 to create an understanding of phenomenon through accessing the meanings ascribed by authors.¹⁶
148 Descriptions of individual frameworks will be organized by key categories, including study design,
149 report type (published vs non-published), methodological approach (i.e. how the framework is
150 intended to be applied) and application papers (i.e. how the framework has been applied in
151 practice). We will then synthesize findings by mapping core components of the frameworks and
152 examining how research objectives and type of DHIs are linked to the framework. Categorization
153 will use language directly from included studies, where possible, and authors will be contacted
154 when information is not present or unclear. The advisory panel will guide the synthesis of findings
155 by providing input on the level of detail abstracted from included articles and provide input on
156 categorization of frameworks, where appropriate.

157 **Strengths and Limitations**

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

167 Given the breadth of this scoping review, we anticipate a few key challenges. The first
168 relates to the inconsistent and often ill-defined nature of DHIs and frameworks. To be inclusive,
169 we have defined DHIs broadly as any health intervention that can be delivered utilizing technology
170 to ensure we capture frameworks that are currently being used across formal (e.g., care delivered
171 within the walls of a healthcare organization) and informal settings (e.g., direct to consumer
172 technologies). Moreover, use of the term framework itself also creates challenges. For the purposes
173 of this scoping review, we have defined a framework as a tool to systematically organize and link
174 research questions or constructs, but a range of terms are often used synonymously (e.g., models

1
2
3 175 or processes). To account for this variability, we will include studies reporting on ‘models’ and
4
5 176 work closely with the advisory panel to confirm whether the reported framework aligns with our
6
7 177 *a priori* definition, as well as the needs of relevant digital health knowledge user groups.
8

9 178 Secondly, we also anticipate challenges searching the literature as a product of inconsistent
10
11 179 terminology outlined above. We have constructed our search to balance comprehensiveness and
12
13 180 specificity, working closely with an information specialist to ensure the number of citations are
14
15 181 focused and feasible. Several iterations of the literature search were conducted, specifically, we
16
17 182 added in key words and removed them in a stepwise fashion to understand the impact on specificity
18
19 183 and sensitivity of our search. Through this iterative process, we developed our search strategy,
20
21 184 which was then peer reviewed using the PRESS checklist; however, we anticipate additional
22
23 185 challenges when screening.

24 186 Thirdly, we anticipate challenges arising from poor reporting or limited description, as
25
26 187 evidenced by previous studies.^{17, 18} Authors may not provide sufficient details on the frameworks
27
28 188 they utilize or their method of application.¹⁹ To mitigate this, we will contact authors to obtain
29
30 189 additional information whenever information is missing or unclear.

31 190 Finally, we anticipate that some included frameworks will have a dual purpose of
32
33 191 addressing implementation and evaluation or may contain components that lend themselves to both
34
35 192 constructs. We will convene with the advisory committee on a quarterly basis to discuss these
36
37 193 issues as they arise and will devise the most appropriate plan for analysis through group consensus.

38
39 194 Overall, identification of frameworks will serve as a guide for researchers, clinicians,
40
41 195 policymakers, and developers of DHIs by providing practical guidance on which frameworks may
42
43 196 be most appropriate for which objectives (i.e., implementation or evaluation). In parallel, the
44
45 197 results will contribute to a more nuanced understanding of how to evaluate and implement DHIs,
46
47 198 including the identification and understanding of key constructs.

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50 200

201 **References:**

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For peer review only

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2
3 252 **Authors' Contributions:**
4

5 253 CS, LD conceived and developed the study. CS drafted the manuscript. MC, VK, RSB, TS, SM,
6
7 254 DL, HCW, JZ, CSG, and LD reviewed and edited the manuscript.
8

9
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11

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13 257 not-for-profit sectors.
14

15 258 **Conflict of Interest:**
16

17 259 The authors have no conflicts of interest to report.
18
19

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21

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23
24 262 generating the literature search, as well as Beatrice Choremis, who helped screen a few
25
26 263 preliminary citations.
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1 Appendix 1. Primary Literature Search in Medline

2 Database: Ovid MEDLINE: Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid
3 MEDLINE® Daily and Ovid MEDLINE® <1946-Present>

4 Search Strategy:

5 -----

6 1 exp Telemedicine/ (25845)

7 2 (telemed* or tele-med* or telecare or tele-care or teleconsult* or tele-consult* or telehealth* or
8 tele-health* or telemonitor* or tele-monitor* or telerehab* or tele-rehab*).tw,kf. (17416)

9 3 (ehealth* or e-health* or mhealth* or m-health* or emental health* or e-mental health* or
10 epsychiatr* or e-psychiatr* or epsychol* or e-psychol* or etherap* or e-therap*).tw,kf. (10073)

11 4 (emedicine or e-medicine*).tw,kf. (78)

12 5 (mobile health* or mobile care or mobile medicine).tw,kf. (3793)

13 6 (digital* adj3 (medic* or care or health* or healthcare or health-care)).tw,kf. (3065)

14 7 (digital* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or
15 surger* or surgic* or therap* or treatment?)).tw,kf. (5936)

16 8 (remote* adj3 (consult* or diagnos* or intervention? or manag* or monitor* or palliat* or rehab* or
17 surger* or surgic* or therap* or treatment?)).tw,kf. (6643)

18 9 Monitoring, Ambulatory/ (7806)

19 10 ((outpatient* or out-patient* or ambulator* or home? or homebased or home-based) adj3
20 (manag* or monitor*)).tw,kf. (24341)

21 11 exp Biomedical Technology/ (13203)

22 12 ((biomedic* or bio-medic* or health* or healthcare or health care or medical) adj
23 technolog*).tw,kf. (13535)

24 13 Medical Informatics/ or Medical Informatics Applications/ (13622)

25 14 ((health* or medical) adj informatic*).tw,kf. (5056)

26 15 exp Therapy, Computer-Assisted/ (59720)

27 16 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
28 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
29 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
30 webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 care).tw,kf. (8049)

31 17 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
32 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
33 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
34 webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 health*).tw,kf. (27319)

35 18 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
36 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
37 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
38 webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (healthcare or health
39 care)).tw,kf. (6410)

40 19 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
41 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
42 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
43 webbased or web-based or webdeliver* or web-deliver* or "web 2.0") adj3 (medicine or medical)).tw,kf.
44 (19800)

45 20 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
46 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile

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3 47 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
4 48 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 consult*).tw,kf. (1299)
5 49 21 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
6 50 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
7 51 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
8 52 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 diagnos*).tw,kf. (13043)
9 53 22 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
10 54 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
11 55 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
12 56 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 intervention?).tw,kf. (9139)
13 57 23 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
14 58 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
15 59 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
16 60 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 manag*).tw,kf. (7259)
17 61 24 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
18 62 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
19 63 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
20 64 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 monitor*).tw,kf. (8457)
21 65 25 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
22 66 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
23 67 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
24 68 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 palliat*).tw,kf. (133)
25 69 26 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
26 70 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
27 71 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
28 72 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 rehab*).tw,kf. (1264)
29 73 27 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
30 74 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
31 75 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
32 76 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 (surger* or surgic*).tw,kf.
33 77 (7354)
34 78 28 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
35 79 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
36 80 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
37 81 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 therap*).tw,kf. (6817)
38 82 29 ((internet* or app or apps or computer* or cyber* or digital* or e-application? or e-mail* or email*
39 83 or electronic mail* or iphone? or i-phone? or (mobile adj2 application?) or mobile-based or mobile
40 84 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
41 85 webbased or web-based or webdeliver* or web-deliver* or "web 2.0" adj3 treatment?).tw,kf. (10336)
42 86 30 Wearable Electronic Devices/ (1321)
43 87 31 wearable?.tw,kf. (10007)
44 88 32 or/1-31 (253918)
45 89 33 exp *Delivery of Health Care/ (619520)
46 90 34 exp Computers/ (76307)
47 91 35 Electronic Mail/ (2573)
48 92 36 Internet/ (69753)
49 93 37 Telecommunications/ (4741)

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5 96 phone? or online or smarthome* or smart-home* or smartphone* or smart phone* or technolog* or
6 97 webbased or web-based or webdeliver* or web-deliver*).tw,kf. (995758)
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8 98 39 33 and (34 or 35 or 36 or 37 or 38) (50511)
9 99 40 32 or 39 [DIGITAL HEALTH APPLICATIONS] (282776)
10 100 41 (evaluat* adj3 (design* or frame or frames or framework? or guid* or model or models or schem*
11 101 or strateg* or theor*).tw,kf. (105535)
12 102 42 (apprais* adj3 (frame or frames or framework? or model or models or theor*).tw,kf. (927)
13 103 43 (apprais* adj3 (design* or guid* or schem* or strateg*).ti,kf. (313)
14 104 44 (assess* adj3 (frame or frames or framework? or model or models or theor*).tw,kf. (47798)
15 105 45 (assess* adj3 (design* or guid* or schem* or strateg*).ti,kf. (3366)
16 106 46 (implement* adj3 (design* or frame or frames or framework? or guid* or model or models or
17 107 schem* or strateg* or theor*).tw,kf. (57152)
18 108 47 (evidence-based adj (frame or frames or framework? or model or models or theor*).tw,kf. (769)
19 109 48 (evidence-based adj (design* or guid* or schem* or strateg*).ti,kf. (1559)
20 110 49 (service adj (frame or frames or framework? or model or models or theor*).tw,kf. (2165)
21 111 50 (service adj (design* or guid* or schem* or strateg*).ti,kf. (201)
22 112 51 or/41-50 [EVALUATION/IMPLEMENTATION FRAMEWORKS] (212588)
23 113 52 40 and 51 [DIGITAL HEALTH - EVALUATION/IMPLEMENTATION FRAMEWORKS] (8974)
24 114 53 exp Animals/ not Humans/ (4614915)
25 115 54 52 not 53 [ANIMAL-ONLY REMOVED] (8859)
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Appendix 2. Eligibility Criteria

Question 1: Does this study include humans?

- a. If yes, include
- b. Exclude animal studies/models, non-human or vertebrate 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.	
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.	
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.	
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.	
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.	
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.	
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.	
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	
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.	
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	
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).	
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	



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.	
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	
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.	
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	
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.	
Limitations	20	Discuss the limitations of the scoping review process.	
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.	
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.	

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).

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