Received: 16 October 2023 | Revised: 28 February 2024 | Accepted: 29 February 2024

DOI: 10.1002/ejp.2262

EJP European Journal of Pain

REVIEW ARTICLE

# Implementation frameworks guiding digital self-management intervention in chronic pain: A scoping review

**R. de la Vega**[1,2] | **S. L. Bartels**[3,4] | **R. W. Wicksell**[3,5]

[1]Faculty of Psychology, University of Málaga, Málaga, Spain

[2]Biomedical Research Institute of Málaga (IBIMA), Málaga, Spain

[3]Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

[4]Department of Psychiatry and Neuropsychology, Maastricht University, Maastricht, the Netherlands

[5]Pain Clinic, Capio St. Göran Hospital, Stockholm, Sweden

**Correspondence**
R. de la Vega, Facultad de Psicología y Logopedia, Universidad de Málaga, C/ Doctor Ortíz Ramos 12, 29190 Málaga, Spain.
Email: rocio.delavega@uma.es

## Abstract

**Background and Objective:** The development, evaluation and implementation of digital self-management interventions for chronic pain have increased exponentially. While intervention outcomes appear promising to improve well-being and functioning in target populations, it is unclear how the development and evaluation processes were structured and how implementation was planned and executed. The aim of this systematic review is to provide a comprehensive overview of implementation frameworks used to guide and evaluate scientific innovation in chronic pain.

**Databases and Data Treatment:** Four bibliography databases (Medline, Web of Science, PsycInfo, CINAHL) and two registries (PubMed Central, MedaRxiv) were systematically searched. Hits ($n = 6830$) and full texts ($n = 351$) were screened and read by two independent reviewers. Peer-reviewed articles that met the inclusion criteria were included in the narrative synthesis.

**Results:** In total, 10 studies were identified that report on seven distinct interventions. Five implementation frameworks were utilized across these studies: Behavioural Interventions using Technology (BIT); Consolidated Framework for Implementation Research (CFIR); mHealth Agile and User-Centered Research and Development Lifecycle; Medical Research Council (MRC); Reach, Effectiveness, Adoption Implementation, and Maintenance (RE-AIM). Frameworks were operationalized using qualitative and quantitative methods, evaluating the innovation on various levels (e.g., individual vs. organizational) and applying a variety of study designs (e.g., single-arm or large trials).

**Conclusions:** By utilizing implementation frameworks, access to evidence-based chronic pain care may be increased. Although the evidence on the utility of implementation frameworks to guide and evaluate digital self-management interventions is still limited, the body of literature is increasing. Future studies

R. de la Vega and S. L. Bartels contributed equally to this work.

are urged to operationalize, communicate and discuss the innovation process, to promote transparency and replicability.

**Significance:** The use of implementation frameworks to guide and evaluate digital self-management interventions for chronic pain is a recent development in the field. Several promising examples exist and are presented in this review. Currently, the evidence is still limited, and prospective studies need to transparently operationalize, communicate and discuss their efforts. By utilizing an implementation framework, promising interventions can be made available to end-users, closing the research-to-clinical practice gap and increasing access to evidence-based care to people with chronic pain.

## 1 | INTRODUCTION

The prevalence of chronic pain is high, globally and across the lifespan (de la Vega et al., 2018; Murray et al., 2022; Todd et al., 2019; Yong et al., 2022). Due to the burden for patients and families (Breivik et al., 2006; Lapane et al., 2015) as well as the financial implications for society (Gaskin & Richard, 2012; Groenewald et al., 2014), improving access to effective pain treatment is a key objective. Access to adequate pain treatment is recognized as a human right (Lohman et al., 2010), but remains insufficient with considerable disparities related to geographical location and socioeconomic status.

Digital health interventions (i.e., treatments delivered remotely, using the internet or smartphone applications to support self-management) may be a cost-effective solution to improve access to evidence-based care and reduce waiting times. Over the last years, the number of digital interventions for chronic pain has increased exponentially (Valentijn et al., 2022) and a growing body of research (Hedman-Lagerlöf et al., 2023; Terpstra et al., 2022) supports the efficacy of this delivery format. However, improved access to these interventions in regular health care requires a successful development, evaluation and implementation process.

The World Health Organization (WHO) in its 71st Assembly report urged its member states to 'prioritize, as appropriate, the development, evaluation, implementation, scale-up, and greater utilization of digital technologies, as a means of promoting equitable, affordable and universal access to health for all (p. 2)' (World Health Organization, 2018). In line with WHO, the 'Societal Impact of Pain' (SIP) platform, a multi-stakeholder partnership led by the European Pain Federation (EFIC) and Pain Alliance Europe (PAE), recommends to 'Support the development and implementation of patient and clinician-friendly, interoperable, and validated digital technologies for pain assessment (p. 1)' (Societal Impact of Pain [SIP], 2022). Although implementing digital interventions (i.e., making treatment sustainably available to end users) is listed as an important step of the process, there is a lack of implementation standards to guide these efforts.

Several implementation frameworks, of which some are specific for digital interventions, are available (de la Vega et al., 2020). These frameworks can provide a structure for the innovation process, from conception to implementation. Broad adoption of such frameworks can enhance the quality of research and innovation, facilitate implementation of evidence-based interventions and shape the future landscape of digital interventions for pain.

To date, it is unclear if and how implementation frameworks are used in pain research. This study therefore aims to provide a comprehensive overview of implementation frameworks currently used to guide and evaluate scientific innovations of digital self-management interventions for people with chronic pain. In addition, strengths and weaknesses of the frameworks are presented, and recommendations for future digital health innovation provided.

## 2 | LITERATURE SEARCH METHODS

### 2.1 | Search strategy

The systematic literature search was conducted in four bibliographic databases (Medline, Web of Science Core Collection, PsycInfo and CINAHL) and two registries (PubMed Central and medaRxiv) to identify digital self-management interventions for chronic pain. The search was first performed in September 2021, and updated twice (June and November 2022) using established methods (Bramer & Bain, 2017). The outcome of the original search was also used in another systematic review with a different aim: the use of Personas in the development of digital interventions for chronic pain (Bartels et al., 2023).

The search strategy was developed in Medline (Ovid) in collaboration with research librarians at the Karolinska

Institutet University Library. For each search concept, Medical Subject Headings (MeSH terms) and free text terms were identified. The search was then translated into the other databases. The following terms were included: (i) digital, eHealth or internet, (ii) intervention or programme and (iii) chronic, persistent or long-term pain. The term 'framework' was not included in the main search, as it was expected to occur in the full text rather than in the title or abstract. Language was restricted to only include English. Studies had to be published in peer-reviewed journals. Articles older than 2007 were not reviewed as that is when the first smartphones were released, thus marking a new era of technology, which is in line with previous reviews (Bartels et al., 2019; Christie et al., 2018). Duplicates of hits were removed, in line with previous research (Bramer et al., 2016). Also, reference lists from included articles were searched for other relevant papers.

Next, a list of articles citing the primary article of the identified frameworks was retrieved from Web of Science, to identify any articles that were potentially missed in the initial search (i.e., searches were made within the list of articles that cited the frameworks for those meeting the inclusion criteria of being digital interventions for pain). The search strategy and purpose of the review were registered in the Open Science Framework platform (https://osf.io) before selecting the included articles (accessible at: https://doi.org/10.17605/OSF.IO/XDPS9/; de la Vega et al., 2022). The search strategy is presented in Supplemental Material 1.

## 2.2 | Study selection

Once the search was finished, abstracts and full-text articles were read by two reviewers independently. SLB performed the complete search together with RV, or with another researcher (SP; AST, see Acknowledgements). Differences between reviewers in decisions to include or exclude articles were resolved by consensus.

## 2.3 | Inclusion and exclusion criteria

Studies had to meet the following criteria to be included in the synthesis: (i) An implementation framework, defined as a theoretical and pragmatic structure to guide research efforts (Damschroder et al., 2022), was used to assess both the effectiveness and implementation of programmes (de la Vega et al., 2020). (ii) Implementation frameworks had to be used in the context of eHealth, defined as 'treatment, typically behaviorally based, that is operationalized for delivery via the internet' (p. 1; Ritterband et al., 2006). (iii) Interventions were developed for people with chronic pain, with chronic pain defined as 'pain that persists or recurs for longer than three months' (Treede et al., 2019). Notably, studies targeting all types of pain such as primary, cancer, neuropathic, headache, orofacial, visceral and musculoskeletal pain were therefore included. (iv) Studies had to use the implementation framework in multiple phases or stages of the innovation process.

Studies were excluded if the intervention only provided support for physical health (e.g., exercising, physiotherapy, medication monitoring only) as the focus of this review lies on self-management, which typically includes psychological and/or social aspects. Notably, telephone-, virtual reality-, video-only, CD-ROM and assistive technology (e.g., sensors) were not included as they did not fit the eHealth definition. The design (e.g., pilot study) or status of the study (e.g., protocol) was not an exclusion criterion as frameworks were expected to be used at any stage.

## 2.4 | Data extraction

General information of the study was extracted, including author, year, country, study design, aim, target population (i.e., age range and type of pain) and intervention description. Furthermore, data extraction focused on the use of the framework: (i) when (at what stages of the project) the framework is used, (ii) how the framework is operationalized, (iii) what strengths and/or weaknesses are reported by the authors using the framework. Additionally, as a measure of the respective frameworks impact, the total number of citations in Web of Science is reported, as well as how many of those citations that are specifically related to pain.

## 2.5 | Data synthesis

The main objective of this study is to provide an overview of the use of implementation frameworks in the scientific literature, that is not evaluate the effectiveness of digital interventions itself. Therefore, a narrative synthesis was seen as most suitable, and with such textual approach, information from different studies can be summarized and descriptively elaborated (Popay et al., 2006).

## 2.6 | Study quality

Study quality was assessed using a modified version of the US National Institutes of Health Study Quality Assessment tool (US National Institutes of Health, 2014) in line with previous reviews (Murphy et al., 2021; Murray et al., 2022).

# 3 | RESULTS

## 3.1 | Review process

A total of $n = 6830$ hits (titles and abstracts) were screened, and $n = 377$ articles were included in the full-text review. Of these, 10 articles could not be accessed or retrieved and an additional 16 were not peer-reviewed reports, resulting in 351 articles that were reviewed in full. In total, 10 articles were included in the synthesis, consisting of 7 distinct interventions and 5 different implementation frameworks. The systematic review process is illustrated in Figure 1.

## 3.2 | General study characteristics

The 10 included studies were published between 2018 and 2022 and conducted in USA ($n = 6$), Sweden ($n = 3$) or Norway ($n = 1$). Four were study protocols that presented research plans (Bartels et al., 2022; Burgess et al., 2020; Harrison et al., 2022; Palermo et al., 2018), four interventions were evaluated in a feasibility study (Gentili et al., 2020; Phillips et al., 2021; Rognsvåg et al., 2021) and/or effectiveness trial (Gentili et al., 2021; Palermo et al., 2020). Moreover, the implementation of one intervention was studied (de la Vega et al., 2020). Interventions targeted adults with chronic pain (Bartels et al., 2022; Gentili et al., 2020), paediatric chronic pain (de la Vega et al., 2020; Harrison et al., 2022; Palermo et al., 2020), a specific pain condition (i.e., Sickle cell disease; Phillips et al., 2021), a certain care context (i.e., military health service; Burgess et al., 2020), and people at risk for chronic pain (following total knee arthroplasty; Rognsvåg et al., 2021). All interventions used an internet-based format (i.e., web- and/or smartphone-delivered). More details from the included studies are presented in Table 1.

## 3.3 | Identified implementation frameworks and their citations in the field of pain

In total, five implementation frameworks meeting the study criteria were identified: (i) Behavioural Interventions using Technology (BIT) (Hermes et al., 2019); (ii) Reach, Effectiveness, Adoption Implementation, and Maintenance (RE-AIM) (Glasgow et al., 2019); (iii) Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2022); (iv) Framework commissioned by the Medical Research Council and National Institute for Health Research (MRC/NHIR framework) (Skivington et al., 2021); and (v) the mHealth Agile Development and Evaluation Lifecycle (Wilson et al., 2018).

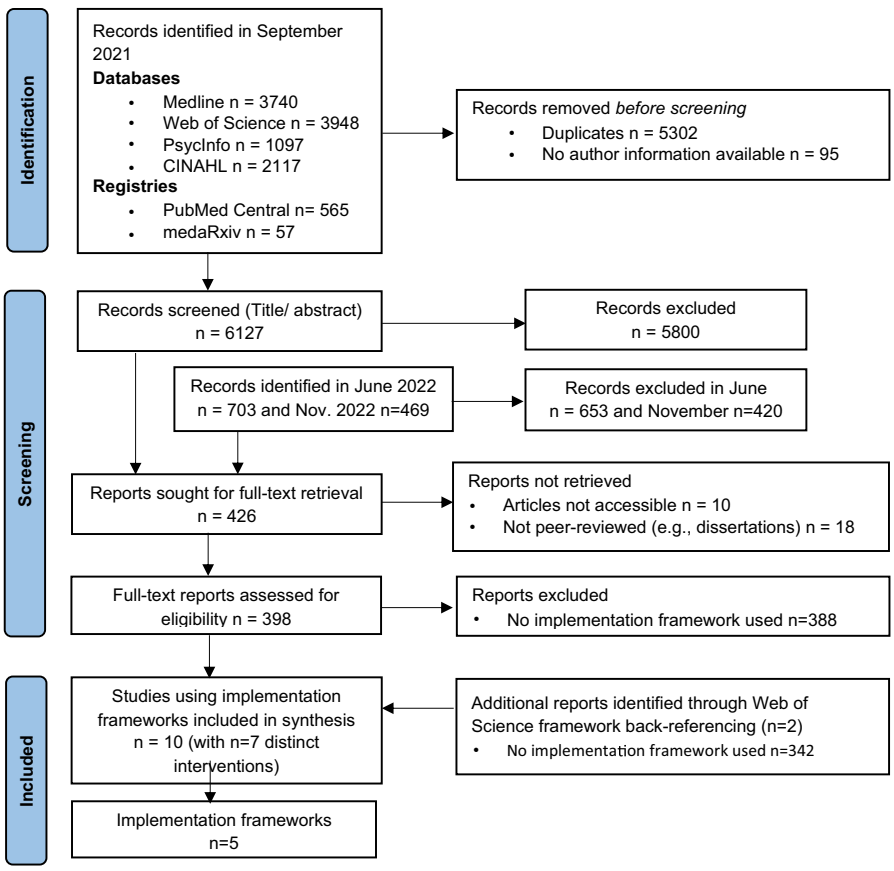


**FIGURE 1** PRISMA flowchart of the review process from reference identification to inclusion for narrative synthesis.

**TABLE 1** Characteristics of included studies.

| # | Author (year), country | Design/stage of the project (i.e., protocol, evaluation, implementation) | Study aim | Target population | Intervention technology, language, theory/aim | Framework |
|---|---|---|---|---|---|---|
| 1 | Bartels et al. (2022), Sweden | Multi-phase project (i.e., development, optimization, clinical trial evaluation, post-market surveillance); protocol | To develop, evaluate and implement an intervention to improve well-being | Individuals with chronic pain | DAHLIA treatment: 6-week web-based behavioural (i.e., exposure−/ACT-based), self-guided intervention with micro-sessions, blended with HCP (i.e., therapist/psychologist) contact | mHealth agile research lifecycle; CFIR; (MRC) |
| 2 | Burgess et al. (2020), USA | Pragmatic randomized clinical trial; protocol | To test two approaches to delivering an intervention to improve chronic pain and mental health comorbidities | Veterans with chronic pain | LAMP treatment: Two adaptions of standard mindfulness-based stress reduction (i.e., Mobile + Group LAMP with online training modules delivered by mindfulness instructor and group discussion, and Mobile LAMP, self-guided without group discussion) | RE-AIM |
| 3 | Gentili et al. (2020, 2021), Sweden | Multi-phase project (i.e., development and evaluation); evaluation | To document the development process (alpha/beta testing), and to evaluate (i.e., feasibility, acceptability, usability) and optimize the intervention | Adults with chronic pain | ACTsmart treatment: 8-week smartphone-delivered ACT-based intervention, supported by chat messages from HCP (i.e., therapist) | mHealth agile research lifecycle |
| 4 | Harrison et al. (2022), USA | Multi-phase project (i.e., development, evaluation); protocol | To develop and refine a prototype, and to evaluate the intervention (i.e., feasibility, preliminary efficacy) | Youth with chronic pain | iGET living treatment: 6-week digital exposure intervention accessible through mobile devices, mainly self-guided, with daily engagement, supported by HCPs (i.e., therapist) | mHealth research lifecycle |
| 5.1 | Palermo et al. (2018, 2020) | Hybrid effectiveness implementation stepped-wedge cluster randomized trial; protocol, evaluation, implementation | To determine the effectiveness of a smartphone-delivered self-management programme for improving pain-related outcomes and to evaluate an implementation strategy to maximize the public health impact | Youth with chronic pain | Web-MAP Mobile treatment: 6- to 8-week, app-based, interactive, self-guided intervention with six core treatment modules and 2 extra modules for participants with depression and/or insomnia symptoms. Programme based on cognitive-behavioural, social learning and family system frameworks | RE-AIM |
| 5.2 | de la Vega et al. (2020), USA | Implementation | To compare the RE-AIM; and BIT with data collected in a real-world trial | Youth with chronic pain | Same as 5.1 | RE-AIM, BIT |
| 6 | Phillips et al. (2021), USA | Feasibility trial; evaluation | To assess the feasibility of an intervention | | Voices Crisis Alert V2 treatment: 12-week, app-delivered mHealth self-management intervention (i.e., education, symptom tracking and monitoring, mechanism for communication between child and caregiver and provider) | RE-AIM |
| 7 | Rognsvåg et al. (2021), Norway | Multi-phase project (i.e., development and feasibility trial); evaluation | To develop and test/customize an intervention | Individuals at increased risk for chronic pain following total knee arthroplasty | Internet-delivered CBT (iCBT) programme combined with exercise therapy and education | MRC |

*Note*: Gentili et al. (2020, 2021), as well as Palermo et al. (2018, 2020) report on both the protocol and the outcome of the same intervention. de la Vega et al. (2020) reports on Palermo's intervention with different aims and different frameworks.

Abbreviations: ACT, Acceptance and Commitment Therapy; BIT, Behavioural Intervention using Technology (Framework); CBT, cognitive behavioural therapy; CFIR, Consolidated Framework for Implementation Research; HCP, healthcare professional; MRC, Medical research council (Framework); RE-AIM, Reach, Effectiveness, Adoption, Implementation, and Maintenance (Framework); LAMP, Learning to Apply Mindfulness to Pain.

**TABLE 2** Identified studies using the BIT framework.

| BIT domains | Brief description of BIT domain | Study | Measures (as operationalized in the study) |
|---|---|---|---|
| Acceptability | Perception of the treatment as useful or satisfactory | de la Vega et al. (2020) | *Individual level*: level of satisfaction with treatment (questionnaire)<br>*Organization level*: clinician satisfaction with app prescription |
| Adoption | Initiation of use of the intervention | | *Individual level*: % of participants installing the app; % using the app after first log-in; % completing at least 1 module |
| Appropriateness | Relevance of fit within a context, compatibility with practice, usability | | *Individual level*: satisfaction with appearance, navigation, theme and content (questionnaire) |
| Feasibility | Extent to which the intervention can be successfully used in a specific context | | *Individual level*: number of technical issues<br>*Organization level*: % of centres agreeing to participate; % making referrals; clinician feedback (questionnaire) |
| Fidelity | Intended use versus actual use | | *Individual level*: % of participants completing treatment; number of days tracking symptoms |
| Implementation costs | Expenses related to the intervention development or its implementation | | Actual costs compared with budgeted costs |
| Penetration | Integration of the intervention within the service or clinic | | *Individual level*: number of participants using the app after the study ended<br>*Organization level*: % of centres recommending the app after the study ended |
| Sustainability | Extent to which the practice is maintained, its ongoing use | | *Organization level*: % of centres agreeing to keep recommending the app after the study ended; % of them making 1 or more recommendations |

Abbreviation: BIT, Behavioural Intervention using Technology.

According to Web of Science (WoS) (accessed February 2023), the CFIR has the most citations ($n = 5653$), with $n = 256$ (5%) on 'pain'. Following, the original MRC framework (Craig et al., 2008) had $n = 4291$ citations, with 346 (8%) referring to pain. The updated version of the MRC framework (Skivington et al., 2021) had 328 citations and 23 (7%) regarding pain. The RE-AIM has $n = 2901$ citations, with $n = 92$ (3%) being pain-related studies. The BIT framework was cited $n = 252$ times, one of them (0.4%) was in the pain field. Finally, the mHealth Agile Development and Evaluation Lifecycle was cited the least often ($n = 27$ citations) with $n = 8$ (30%) including the term 'pain' in the full text.

## 3.4 | Frameworks used to guide scientific innovation in chronic pain

This review sought to identify how each of the frameworks was used, when (at what stages of the study), as well as strengths and weaknesses as mentioned and discussed in these studies by the researchers.

*The Behavioural Interventions using Technology Framework (BIT)*: Only one study used the BIT framework to assess implementation outcomes (de la Vega et al., 2020). This framework is technology-specific, and the identified study compared it with a well-established implementation framework, the RE-AIM, to determine whether it allowed to capture different or additional implementation domains. It was used retrospectively (once the study had finished) and included the assessment of all stages of the process (e.g., reaching out to participating centres, recruitment, adherence, sustainability of the intervention). The authors concluded that there is some overlap between the frameworks and that whereas the RE-AIM focuses more on the reach and effectiveness of the intervention, the BIT allows for assessing several items at the maintenance level and some technology-specific aspects. See Table 2 for a summary of the use of the framework domains.

*The Consolidated Framework for Implementation Research (CFIR)*: One multi-phase project reported in a study protocol paper the use of the CFIR (Bartels et al., 2022). The framework is included in two phases: (i) the development phase to prepare the implementation process through a business model and identify potential barriers and facilitators and (ii) the post-market surveillance to follow-up on the implementation process and summarize lessons learned. In these two phases, stakeholder interviews will be conducted and qualitative data will be mapped onto the CFIR domains (Table 3). The protocol was published prior to the updated

**TABLE 3** Identified studies using the CFIR framework.

| Topic | Brief description (Damschroder et al., 2009) | Bartels et al. (2022) |
|---|---|---|
| *I. Intervention characteristics* | | |
| A: Intervention source | Perception of key stakeholders about whether the intervention is externally or internally developed. | Phase 1: Development<br>Study 2: Stakeholder interviews (regional)<br>Aim: Develop a preliminary business model for the digital behavioural treatment and identify barriers and facilitators of the prospective implementation process.<br>Methods:<br>• 'To build knowledge base across the multiple studies and settings, the CIFR will be used. The CFIR has five major domains: intervention characteristics, outer setting, inner setting, characteristics of the individual involved, and the process of implementation. It will be used as part of the analysis [...]' (p. 7).<br>• Semi-structured interview guide (provided in Supplementary Material in Bartels et al., 2022) will gather information on gatekeepers, barriers and facilitators for prospective dissemination and use, with questions being tailored to the different stakeholder ($n = 8$, e.g., healthcare professionals, managers, IT developers).<br>• 'A qualitative thematic analysis will be performed with statements related to potential barriers and facilitators. An indicative approach to group the information will be applied in order to best scope the replies and map categories onto the CFIR domains' (p. 8).<br>Phase 4: Post-market surveillance<br>Study 5: Stakeholder interviews (national)<br>Aim: Follow-up of the implementation process and summarize lessons-learned<br>Methods:<br>• Semi-structured interview (in line with study 2, Supplementary Material provided in Bartels et al., 2022) with participants of study 2 and additional stakeholders identified during the process.<br>• Qualitative data: 'An inductive analysis to identify and summarize themes will be performed, and information will be mapped onto the domains of the CFIR' (p. 15). |
| B: Evidence strength and quality | Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes. | |
| C: Relative advantage | Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution. | |
| D: Adaptability | The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs. | |
| E: Trialability | The ability to test the intervention on a small scale in the organization and to be able to reverse course (undo implementation) if warranted. | |
| F: Complexity | Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality and intricacy and number of steps required to implement. | |
| G: Design quality and packaging | Perceived excellence in how the intervention is bundled, presented and assembled. | |
| H: Cost | Costs of the intervention and costs associated with implementing that intervention including investment, supply and opportunity costs. | |
| *II. Outer setting* | | |
| A: Patient needs and resources | The extent to which patient needs, as well as barriers and facilitators to meet those needs are accurately known and prioritized by the organization. | |
| B: Cosmopolitanism | The degree to which an organization is networked with other external organizations. | |
| C: Peer pressure | Mimetic or competitive pressure to implement an intervention; typically, because most or other key peer or competing organizations have already implemented or in a bid for a competitive edge. | |
| D: External policy and incentives | A broad construct that includes external strategies to spread interventions including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives and public or benchmark reporting. | |
| *III. Inner setting* | | |
| A: Structural characteristics | The social architecture, age, maturity and size of an organization. | |
| B: Networks and communication | The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization. | |
| C: Culture | Norms, values and basic assumptions of a given organization. | |
| D: Implementation climate[a] | The absorptive capacity for change, shared receptivity of involved individuals to an intervention and the extent to which use of that intervention will be rewarded, supported and expected within their organization. | |

(Continues)

**TABLE 3** (Continued)

| Topic | Brief description (Damschroder et al., 2009) | Bartels et al. (2022) |
|---|---|---|
| E: Readiness for implementation[b] | Tangible and immediate indicators of organizational commitment to its decision to implement an intervention. | |
| *IV. Characteristics of individuals* | | |
| A: Knowledge and beliefs about the intervention | Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths and principles related to the intervention. | |
| B: Self-efficacy | Individual belief in their own capabilities to execute courses of action to achieve implementation goals. | |
| C: Individual stage of change | Characterization of the phase an individual is in, as he or she progresses towards skilled, enthusiastic and sustained use of the intervention. | |
| D: Individual identification with organization | A broad construct related to how individuals perceive the organization and their relationship and degree of commitment with that organization. | |
| E: Other Personal attributes | A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity and learning style. | |
| *V. Process* | | |
| A: Planning | The degree to which a scheme or method of behaviour and tasks for implementing an intervention are developed in advance and the quality of those schemes or methods. | |
| B: Engaging[c] | Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modelling, training and other similar activities. | |
| C: Executing | Carrying out or accomplishing the implementation according to plan. | |
| D: Reflecting and evaluating | Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience. | |

Abbreviation: CFIR, Consolidated Framework for Implementation Research.

[a]Including: Tension for change, compatibility, relative priority, organization incentives and rewards, goals and feedback, learning climate.

[b]Including: Leadership engagement, available resources, access to knowledge and information.

[c]Including: Opinion leaders, formally appointed internal implementation leaders, champions, external change agents.

CFIR (Damschroder et al., 2022) and therefore refers to the previous version of the CFIR (Damschroder et al., 2009). No findings of this study are published.

*The mHealth Agile Development and Evaluation Lifecycle*: This framework is used in three projects (Bartels et al., 2022; Gentili et al., 2020; Harrison et al., 2022). All three projects utilize the framework in Phases 0–2, including the project identification phase (Phase 0), user-experience design, development, & Alpha-testing (Phase 1), and Beta-testing (Phase 2) (see Table 4). Bartels et al. (2022) and Harrison et al. (2022) present study protocols, and Gentili et al. (2020) report results of Phase 0–2. Additionally, Bartels et al. (2022) provided an operationalization of Phase 3 (Clinical trial evaluation) and Phase 4 (Post-market surveillance).

*The Framework commissioned by the Medical Research Council and National Institute for Health Research (MRC/NHIR framework)*: Two studies refer to the MRC framework in their articles. In Rognsvåg et al. (2021), two phases (i.e., development, feasibility) of the 2013 version of the MRC framework (Craig et al., 2013) were operationalized as 'problem identification, determination of recipients' and provider's needs, examination of the current practice and context, and intervention design' (p. 11). In the development phase, evidence, theory and model underlying pathways were identified. In the feasibility phase, feedback loops were used to evaluate whether the programme was relevant, manageable and understandable for patients, and whether the manual was relevant for the physiotherapists. Prospectively, a three-armed RCT is planned to determine the effectiveness of the

**TABLE 4** Identified studies using the mHealth Agile and User-Centred Research and Development Lifecycle.

| # | Author (year), status of the project | Phases of the mHealth agile and user-centred research and development lifecycle | | | | |
|---|---|---|---|---|---|---|
| | | **Project identification** | **Phase 1: User-experience design, development and alpha-testing** | **Phase 2: Beta-testing** | **Phase 3: Clinical trial evaluation** | **Phase 4: Post-market surveillance** |
| 1 | Bartels et al. (2022); Protocol | Involvement of inter-sectorial partners and international collaborators; Acquisition of funding; consensus on theoretical frameworks and guiding principles; treatment prototype composed guided by Patient Personas. | (i.e., Development)<br>Two qualitative studies:<br>(i) Focus groups with patients and HCPs to identify needs and match the treatment content to these needs (one therapist and two patient focus groups with 6–8 participants per group)<br>(ii) Stakeholder interviews ($n=8$) to develop a preliminary business model and identify barriers and facilitators of the prospective implementation process. | (i.e., Optimization phase) Pilot testing and improving treatment in an iterative, data-driven process using small patient cohorts (4–6 iterations with $n=10$ patients and their treating HCPs); Determine feasibility, acceptability, individual change processes, and efficacy on a group-level. Mixed-methods approach. | Determine the clinical effectiveness of the treatment in a two-armed RCT enhanced with SCED providing information on the population- and individual level; Health economy evaluation; $n=180$ participants per arm (total $n=360$). Quantitative approach. | Interviews with stakeholders to follow-up on the implementation process, review implementation strategies, and summarize lessons-learned (no sample size information). Qualitative approach. |
| 3 | Gentili et al. (2020, 2021); Evaluation | (i) Innovation: Identification of challenge; Envisioning of product; User research; Identification of end-users; Identify target market.<br>(ii) Organizational: Gather expertise and resources needed; Create project organization; Identify strategies/operative goals; Secure funding and resources allocated for phase 1; Define work model. | (i.e., Development/Alpha testing) Individuals with complex chronic pain ($n=9$) were interviewed to inform Personas and workflow ideas; Treatment interface build based on Personas and repeatedly tested with alpha users (in four sprints); Involvement of therapists ($n=6$) through interviews. Mixed-methods approach. | (i.e., Beta-testing)<br>Two studies using qualitative and quantitative data:<br>(i) Feasibility: Individuals ($n=31$) with chronic pain included in a clinical feasibility trial (8 weeks), followed by in-depth UX patient interviews ($n=7$, 23%) and survey ($n=16$, 52%), and therapists ($n=4$, 100%).<br>(ii) Open-label pilot trial: Individuals with long-standing pain ($n=34$) completed 8-week treatment and outcomes were assessed pre- and post-treatment, at 3-, 6- and 12-month follow-ups and weekly during treatment. | - | - |
| 4 | Harrison et al. (2022); Protocol | Figure 1, but not further elaborated on in text: Problem identified; Solution conceived; Partners engaged; User research; Funding acquired. | (i.e., User-centred development)<br>Series of interviews with youth with lived experience of chronic pain ($n=15$) and their caregivers ($n=15$). Qualitative approach. | (i.e., Beta-testing) Examine feasibility and preliminary efficacy using SCED ($n=20$ youth and one of their caregivers ($n=20$)). Mixed-methods approach. | - | - |

Abbreviations: HCP, healthcare professional; RCT, randomized controlled trial; SCED, single case experimental design; UX, user experience.

**TABLE 5** Identified studies using the MRC framework.

| Elements | Core elements | Development | Feasibility | Evaluation | Implementation |
|---|---|---|---|---|---|
| As defined by Craig et al. (2013) | | 1: Identify the evidence base<br>2: Identify/develop theory<br>3: Model process/outcomes | 1: Test procedures<br>2: Estimate recruitment/retention<br>3: Determine sample size | 1: Assess effectiveness<br>2: Understand change process<br>3: Assess cost-effectiveness | 1: Dissemination<br>2: Surveillance/monitoring<br>3: Long-term follow-up |
| As updated by Skivington et al. (2021) | Consider context; develop, refine, and (re)test programme theory; engage stakeholders; identify key uncertainties; refine intervention; Economic considerations. | Develop intervention (i.e., Either developing a new intervention, or adapting an existing intervention for a new context, based on research evidence and theory of the problem) OR Identify intervention (i.e., Choosing an intervention that already exists (or is planned), either via policy or practice, and exploring its options for evaluation (evaluability assessment). | Assessing feasibility and acceptability of intervention and evaluation design to make decisions about progression to next stage of evaluation. | Assessing an intervention using the most appropriate method to address research questions. | Deliberate efforts to increase impact and uptake of successfully tested health innovations. |
| *Study* | | | | | |
| Rognsvåg et al. (2021) | | Development phase: Creating a first prototype of the iCBT programme; guided by a multidisciplinary intervention development advisory group ($n = 14$); 1: Literature review to ensure evidence-based content; 2: Theory: CBT-focused treatment; 3: Previous internet-based therapy programme represent template for layout of intervention; Personas used to represent prospective patients. | Feasibility phase: Condensing, ensuring relevance, and testing the iCBT programme; 1: Ensuring relevance for users through two rounds of interviews with users (i.e., patients [$n = 3$] and physiotherapists [$n = 4$]) who test the iCBT programme; Condensation of content into fewer modules/modification of content for patients. Qualitative approach. | A three-arm RCT is registered and planned to test the effectiveness of the interventions prospectively (no study protocol published). | - |
| Bartels et al. (2022) | Introduction: 'The framework commissioned by the Medical Research Council and National Institute for Health Research (MRC/NHIR framework) for developing and evaluating complex interventions will inform the processes' (p. 3).<br>Discussion: 'The DAHLIA approach [i.e., multi-phase project to develop, evaluate, and implement a digital intervention for chronic pain] is also in line with the widely used MRC/NIHR framework by considering contextual and economical aspects, building on theory, involving stake-holders, and refining the intervention' (p. 15). | | | | |

*Note*: The MRC elements as described in 2012 follow a cyclic/temporal order with a bi-directional link between development and feasibility, and feasibility and evaluation. The updated version links all four elements (i.e., development, feasibility, evaluation, implementation) bi-directional with the core elements.

Abbreviations: iCBT, internet-delivered cognitive behavioural therapy; RCT, randomized controlled trial.

**TABLE 6** Identified studies using the RE-AIM framework.

| | Reach (Participation in the intervention) | Effectiveness | Adoption | Implementation (The intervention was delivered as intended) | Maintenance |
|---|---|---|---|---|---|
| Burgess et al. (2020) | Planned use of RE-AIM: 'Will conduct interviews to understand the barriers perceived by patients, staff, and health system leaders and will collect quantitative data to assess intervention application and adherence and to inform cost estimates' and 'We will create an implementation toolkit and replication manual, which will incorporate lessons learned through the RE-AIM analysis'. | | | | |
| de la Vega et al. (2020) | % of eligible participants giving consent | Change in score from baseline to post-treatment on the outcomes | % of invited centres agreeing to participate; % of centres making referrals | *Individual level*: % of participants completing at least 1 module; % completing treatment; % days tracking symptoms<br>*Organization level*: providers attitudes (questionnaire); budget increase | *Individual level*: symptoms at 3-month follow-up; number of participants using the app after the study ended<br>*Organization level*: providers attitudes; % of centres agreeing to keep recommending the app after the study ended; % of them recommending the app |
| Phillips et al. (2021), USA | Sample representativeness; Rates of recruitment; % eligible; % consented participants; % provided with baseline session | [Results provided in a different manuscript] | Adherence (length and frequency of use of intervention components); Acceptability (caregiver satisfaction reported in an interview, problems); times tracking symptoms | Number of technical issues; "Documentation of delivery of instructional sessions and follow-up questions" | "Projection of sustained use via the number of dyads who report will continue to use intervention, perceptions of intervention, and perception of provider role" |

**TABLE 7** Quality of the included studies.

| Criteria | 1 Bartels et al. (2022) | 2 Burgess et al. (2020) | 3 de la Vega et al. (2020) | 4 Gentili et al. (2020) | 5 Gentili et al. (2021) | 6 Harrison et al. (2022) | 7 Palermo et al. (2018) | 8 Palermo et al. (2020) | 9 Phillips et al. (2021) | 10 Rognsvåg et al. (2021) | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. Was the research question or objective in this paper clearly stated? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | 10/10 |
| 2. Was the study population clearly specified and defined? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | 10/10 |
| 3. Was the participation rate of eligible persons at least 50%? | NA | NA | Y | NR | Y | NA | NA | Y | Y | NR | 4/6 |
| 4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants? | Y | Y | Y | NR | Y | Y | Y | Y | Y | NR | 8/10 |
| 5. Was a sample size justification, power description, or variance and effect estimates provided? | Y | Y | NA | N | N | Y | Y | Y | Y | NA | 6/8 |
| 6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured? | Y | Y | Y | NR | Y | Y | Y | Y | Y | Y | 9/10 |
| 7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed? | Y | Y | Y | NA | Y | Y | Y | Y | Y | NA | 8/8 |
| 8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)? | Y | Y | Y | Y | Y | CD | Y | Y | Y | NR | 8/10 |

**TABLE 7** (Continued)

| Criteria | 1<br>Bartels et al. (2022) | 2<br>Burgess et al. (2020) | 3<br>de la Vega et al. (2020) | 4<br>Gentili et al. (2020) | 5<br>Gentili et al. (2021) | 6<br>Harrison et al. (2022) | 7<br>Palermo et al. (2018) | 8<br>Palermo et al. (2020) | 9<br>Phillips et al. (2021) | 10<br>Rognsvåg et al. (2021) | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 9. Were the exposure measures (independent variables) clearly defined, valid, reliable and implemented consistently across all study participants? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | 10/10 |
| 10. Was the exposure(s) assessed more than once over time? | Y | Y | Y | Y | Y | Y | Y | Y | Y | NA | 9/9 |
| 11. Were the outcome measures (dependent variables) clearly defined, valid, reliable and implemented consistently across all study participants? | Y | Y | Y | NA | Y | Y | Y | Y | NA | NA | 7/7 |
| 12. Were the outcome assessors blinded to the exposure status of participants? | NA | Y | NA | NA | NR | NA | Y | Y | NA | NA | 3/4 |
| 13. Was loss to follow-up after baseline 20% or less? | NA | NA | Y | Y | N | NA | NA | Y | N | NA | 3/5 |
| 14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)? | Y | Y | NA | NA | NR | Y | Y | Y | NA | NA | 5/6 |
| Total | 11/11 | 12/12 | 11/11 | 6/10 | 10/14 | 10/11 | 12/12 | 14/14 | 10/11 | 4/7 | |

Abbreviations: CD, cannot determine; NA, not applicable; NR, not reported; N, no; Y, yes.

treatment, which refers to the 'Evaluation' element of the MRC, while the 'Implementation' was not mentioned by the authors. The study protocol from Bartels et al. (2022) referenced both Craig et al. (2013) and the updated MRC version by Skivington et al. (2021), however, authors do not specifically refer to the MRC in their study plan (Table 5).

*The Reach, Effectiveness, Adoption Implementation, and Maintenance Framework (RE-AIM)*: Three studies used the RE-AIM framework. As mentioned above, de la Vega et al. (2020) used both RE-AIM and BIT to assess the implementation of an intervention, comparing the utility of these frameworks. Burgess et al. (2020) report planning to use RE-AIM as a guide to assess implementation barriers and facilitators and to develop an 'implementation toolkit', although not specifying how the different domains will be assessed. Finally, Phillips et al. (2021) used RE-AIM in their pilot study providing detailed metrics per domain as well as the plan to use it in a future effectiveness trial. See Table 6 for more details on the studies using RE-AIM.

### 3.5 | Strengths and weaknesses of each framework as identified by the researchers

Four protocol studies are included, and none of these present strengths or weaknesses of the frameworks, simply because they are not yet evaluated. Gentili et al. (2020) report that the mHealth Agile Development and Evaluation Lifecycle was useful as the agile process allowed for a continuous development of the technical solution as well as the intervention, until satisfying levels of acceptance and practicalities (e.g., technical feasibility) were reached. For the other included studies, a full comparison of the BIT and RE-AIM is provided in de la Vega et al. (2020), concluding that the main challenges include the costs to assess the different domains (e.g., increased app development costs to be able to track back-end information; increased human resources cost to follow-up with participants), and the suggestion to consider implementation assessment costs at the grant writing stage, to secure funding for this process. The other articles using RE-AIM (i.e., Burgess et al., 2020; Phillips et al., 2021) did not comment on its feasibility of use or on the strengths or weaknesses. Similarly, Rognsvåg et al. (2021) did not reflect on the MRC framework in detail but refers to the use of it as a general study strength.

### 3.6 | Quality of the included studies

Following the National Institutes of Health Study Quality Assessment tool (US National Institutes of Health, 2014), the quality of most of the included studies is on average very good, with five studies reporting on all applicable items of the scale (i.e., questions about recruitment, participation, or sample retention were not applicable for protocol studies) and one having only one item that was difficult to determine. One study reported on all but one item (Phillips et al., 2021), one study was missing two items (Rognsvåg et al., 2021), and two studies did not report on four items (Gentili et al., 2020, 2021). In all studies, the research questions were clearly stated, the population was defined, sufficient time to observe treatment effects was allowed, and the independent variables were clearly specified and assessed more than once. A few studies failed to conduct sample size calculations, to report on sample sizes, participation rates or the sample lost at follow-up (see Table 7).

## 4 | DISCUSSION AND CONCLUSIONS

This review provides a comprehensive overview of implementation frameworks used to guide and evaluate digital innovations in digital self-management interventions for chronic pain. Through a systematic search, 10 articles presenting seven distinct interventions were identified. In these studies, ranging in methodological quality from good to high, five frameworks were used; BIT (Hermes et al., 2019), CFIR (Damschroder et al., 2022), mHealth Agile Development and Evaluation Lifecycle (Wilson et al., 2018), MRC (Craig et al., 2013), and RE-AIM (Dzewaltowski et al., 2004). Overall, the use of implementation frameworks is a recent development in the field, as a rather small number of studies ($n=10$) was identified, which for the most ($n=9$) part were published within the past 3 years. Results also illustrate that, although the MRC and CFIR are more established frameworks (i.e., they have more citations), they are not used (proportionally) more often in the pain field than less established frameworks such as RE-AIM, BIT and mHealth Agile Development and Evaluation Lifecycle. In the articles included in this review, researchers operationalized frameworks in different ways, integrating both qualitative and quantitative methods, evaluating the innovation on various levels (e.g., individual vs. organizational; de la Vega et al., 2020) and applied different study designs, including single-arm or small cohorts as well as large-scale trials (Bartels et al., 2022; Gentili et al., 2020; Harrison et al., 2022). This heterogeneity reflects the adaptability of frameworks but makes comparisons of studies difficult. Moreover, several researchers cite or refer to frameworks without providing details on how they are applied.

Referencing a framework without detailed information on its operationalization causes ambiguity as to which extent researchers view frameworks as practical guidelines or as general inspiration, and whether

frameworks ideally include step-by-step instructions and examples to promote standardization. In the field of digital self-management interventions for chronic pain, the identified studies provide useful examples, but the existing literature is still scarce. Prospective trials may take inspiration also from other fields, for instance, Faes et al. (2010) illustrate the use of the MRC framework in geriatrics with detailed examples of methodological considerations and checklists matching each phase. Similarly, Safaeinili et al. (2020) used the CFIR in primary health care, describing a qualitative study to identify barriers and facilitators to implementation. In their study, changes to the CFIR were documented and transparently communicated, illustrating how tailoring of the framework can be conducted (Safaeinili et al., 2020). Following, pain researchers are encouraged to contribute to more transparency and reproducibility by clearly operationalizing the frameworks used and communicating methodological considerations and steps followed in more detail.

Overall, it appears that the MRC as well as mHealth Agile Development and Evaluations Lifecycle might be especially useful for the planning of multi-phase projects in which the whole process is considered (i.e., development/adaptations of the intervention, evaluation), and to warrant sustainable implementation (Bartels et al., 2022; Gentili et al., 2020, 2021; Harrison et al., 2022; Rognsvåg et al., 2021). In contrast, RE-AIM and BIT seem more adequate for evaluation and assessment of outcomes (e.g., satisfaction; reach/ success of implementation) (de la Vega et al., 2020; Phillips et al., 2021). The CFIR, especially the updated version (Damschroder et al., 2022), may be useful for both aspects of implementation (i.e., planning and evaluation). However, CFIR is by far the most complex and detailed framework, and tailoring this framework to match the conditions within research studies might be necessary (Safaeinili et al., 2020). Nevertheless, innovation research aiming at improving human health and sustainable societal impact are usually complex by nature (Petticrew, 2011), thus, embracing complexity is critical for a useful framework. For instance, the PRECIS-2 tool (Loudon et al., 2015) can help researchers make design decisions for their trials. Additionally, intervention complexity can be determined through formal assessments (e.g., iCAT_SR; Moore et al., 2017), and checklists such as TIDieR are available to promote full and accurate reporting of intervention trials (Cotterill et al., 2018).

In the present review, frameworks that guided and evaluated interventions in at least two phases were sought while single-phase or design trials were viewed as distinctly different as their aims were narrower. Design and development frameworks such as the Persuasive System Design (PSD; Torning & Oinas-Kukkonen, 2009) or Participatory Action Research (PAR; Viswanathan et al., 2004) might be complementary and have been used in pain research (Perry et al., 2022; Reuman et al., 2022). Moreover, studies using frameworks such as the MRC, Unified Theory of Acceptance and Use of Technology framework (UTAUT; Venkatesh et al., 2003), or a holistic framework proposed by van Gemert-Pijnen et al. (2011) in a single phase in the context of chronic pain were identified in our systematic search, but not included in the synthesis because they did not match the inclusion criteria (i.e., framework used in multiple phases/evaluation and implementation) (e.g., Baumeister et al., 2015; Burke et al., 2019; Cooke et al., 2021; Devan et al., 2021; Fanning et al., 2020; Fledderus et al., 2015; Hennemann et al., 2016; Lin et al., 2018; Sandhu et al., 2022; Song et al., 2021; Sweeney et al., 2021). These studies may be inspirational for prospective trials, but an in-depth analysis is outside the scope of this review. Finally, the Double-Diamond model (UK Design Council, 2004) offers a step-by-step guide to develop and implement new interventions, focusing on: research (Discover), Synthesis (Define), Ideation (Develop) and Implementation (Deliver). This model was not mentioned by the identified studies but may potentially facilitate digital interventions, as seen in other fields (Banbury et al., 2021; Ford et al., 2022).

While this review offers a timely overview of frameworks for digital self-management interventions in the field of chronic pain that can facilitate the use of frameworks in prospective research, several limitations are acknowledged. The number of studies included in this review ($n = 10$ studies reporting on $n = 7$ distinct interventions) is small, with a primary focus on planning (protocols), development and feasibility evaluations. With more evidence, researchers may want to determine if/how using implementation frameworks benefits the development and evaluation of digital interventions for chronic pain, compared to studies in which no frameworks were utilized. This question, however, lies outside the scope of this review. Also, researchers provided little or no reflections on their experiences using the frameworks, or on the respective model's strengths and/or weaknesses. To evolve the field, prospective studies should transparently document how frameworks were used and what was learned during the trial. Additionally, the focus of this review was set specifically on digital self-management interventions; it might be interesting to conduct a review with a wider lens, for instance, including virtual reality, exergaming or wearables for chronic pain as the operationalization of frameworks might be transferable to those areas.

In summary, using frameworks to guide and evaluate digital self-management interventions for chronic pain is a recent development that can advance the field. Several promising examples exist that are included in

this review. Evidence is yet limited, and prospective studies may add to the field by transparently operationalizing, communicating and reflecting on the use of the BIT, RE-AIM, MRC, mHealth Agile Development and Evaluation Lifecycle, CFIR and other implementation frameworks. In addition to protocol papers, detailed evaluation studies are helpful to evolve the field of chronic pain and digital innovations. By organizing efforts using an implementation framework, researchers increase the chances of making promising interventions available to end-users, close the research-to-clinical practice gap, and thus increase access to evidence-based care to people living with chronic pain.

## AUTHOR CONTRIBUTIONS

SB and RV jointly conceptualized the study, reviewed all full texts, synthesized results and wrote the manuscript. Additionally, SB prepared the search strategy and reviewed all title and abstract hits. RW acquired and received funding for SB's contribution and revised the manuscript. All authors discussed the results and approved the final manuscript.

## ACKNOWLEDGEMENTS

The authors would like to thank Emma-Lotta Säätelä, library support service at Karolinska Institutet, for supporting the development of the search terms and executing the search as well as Dr. Suzanne Petersson and Afra Taygar for their involvement in the review process (i.e., title and abstract screening).

## FUNDING INFORMATION

This study, especially SLB's and RWW's contribution, has been partially supported by the Swedish Research Council (2020-01744) and AFA insurance grant number dnr 190 252. RV's salary is supported by a grant from the Spanish Ministry of Science and Innovation (RYC2018-024722-I). RV's travel expenses to visit the other authors were covered by the International Collaboration Award of the Society of Pediatric Psychology (APA Division 54). Funding for open access was provided by the Universidad de Málaga/CBUA. The sponsors had no role in study design, in the collection, analysis and interpretation of data, in the writing of the report and in the decision to submit the article for publication.

## CONFLICT OF INTEREST STATEMENT

The authors have published some of the articles included in the review. The authors declare no other relationships or financial interests that might lead to a conflict of interest related to this study.

## ORCID

*R. de la Vega* https://orcid.org/0000-0002-2517-6948

## REFERENCES

Banbury, A., Pedell, S., Parkinson, L., & Byrne, L. (2021). Using the Double Diamond model to co-design a dementia caregivers telehealth peer support program. *Journal of Telemedicine and Telecare*, *27*, 667–673.

Bartels, S. L., Johnsson, S. I., Boersma, K., Flink, I., McCracken, L. M., Petersson, S., Christie, H. L., Feldman, I., Simons, L. E., Onghena, P., Vlaeyen, J. W. S., & Wicksell, R. K. (2022). Development, evaluation and implementation of a digital behavioural health treatment for chronic pain: Study protocol of the multiphase DAHLIA project. *BMJ Open*, *12*, e059152.

Bartels, S. L., Taygar, A. S., Johnsson, S. I., Petersson, S., Flink, I., Boersma, K., McCracken, L. M., & Wicksell, R. K. (2023). Using personas in the development of eHealth interventions for chronic pain: A scoping review and narrative synthesis. *Internet Interventions*, *32*, 100619.

Bartels, S. L., van Knippenberg, R. J. M., Dassen, F. C. M., Asaba, E., Patomella, A. H., Malinowsky, C., Verhey, F. R. J., & de Vugt, M. E. (2019). A narrative synthesis systematic review of digital self-monitoring interventions for middle-aged and older adults. *Internet Interventions*, *18*, 100283.

Baumeister, H., Seifferth, H., Lin, J., Nowoczin, L., Lüking, M., & Ebert, D. (2015). Impact of an acceptance facilitating intervention on patients' acceptance of internet-based pain interventions: A randomized controlled trial. *The Clinical Journal of Pain*, *31*, 528–535.

Bramer, W., & Bain, P. (2017). Updating search strategies for systematic reviews using EndNote. *Journal of the Medical Library Association*, *105*, 285.

Bramer, W. M., Giustini, D., de Jonge, G. B., Holland, L., & Bekhuis, T. (2016). De-duplication of database search results for systematic reviews in EndNote. *Journal of the Medical Library Association*, *104*, 240–243.

Breivik, H., Collett, B., Ventafridda, V., Cohen, R., & Gallacher, D. (2006). Survey of chronic pain in Europe: Prevalence, impact on daily life, and treatment. *European Journal of Pain*, *10*, 287–333.

Burgess, D. J., Evans, R., Allen, K. D., Bangerter, A., Bronfort, G., Cross, L. J., Ferguson, J. E., Haley, A., Hagel Campbell, E. M., Mahaffey, M. R., Matthias, M. S., Meis, L. A., Polusny, M. A., Greg Serpa, J., Taylor, S. L., & Taylor, B. C. (2020). Learning to apply mindfulness to pain (LAMP): Design for a pragmatic clinical trial of two mindfulness-based interventions for chronic pain. *Pain Medicine*, *21*, S29–S36.

Burke, D., Lennon, O., Blake, C., Nolan, M., Barry, S., Smith, E., Maye, F., Lynch, J., O'Connor, L., Maume, L., Cheyne, S., Ní Ghiollain, S., & Fullen, B. M. (2019). An internet-delivered cognitive behavioural therapy pain management programme for spinal cord injury pain: A randomized controlled trial. *European Journal of Pain*, *23*, 1264–1282.

Christie, H. L., Bartels, S. L., Boots, L. M. M., Tange, H. J., Verhey, F. J. J., & de Vugt, M. E. (2018). A systematic review on the implementation of eHealth interventions for informal caregivers of people with dementia. *Internet Interventions*, *13*, 51–59.

Cooke, M., Richards, J., Tjondronegoro, D., Raj Chakraborty, P., Jauncey-Cooke, J., Andresen, E., Theodoros, J., Paterson, R., Schults, J., Raithatha, B., Wilson, S., & Alcock, M. (2021). myPainPal: Co-creation of a mHealth app for the management

of chronic pain in young people. *Informatics for Health & Social Care*, *46*, 291–305.

Cotterill, S., Knowles, S., Martindale, A.-M., Elvey, R., Howard, S., Coupe, N., Wilson, P., & Spence, M. (2018). Getting messier with TIDieR: Embracing context and complexity in intervention reporting. *BMC Medical Research Methodology*, *18*, 1–10.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2013). Developing and evaluating complex interventions: The new Medical Research Council guidance. *International Journal of Nursing Studies*, *50*, 587–592.

Craig, P., Dieppe, P., Macintyre, S., Mitchie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: The new Medical Research Council guidance. *BMJ*, *337*, 979–983.

Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implementation Science*, *4*, 1–15.

Damschroder, L. J., Reardon, C. M., Widerquist, M. A. O., & Lowery, J. (2022). The updated Consolidated Framework for Implementation Research based on user feedback. *Implementation Science*, *17*, 1–16.

de la Vega, R., Bartels, S. L., & Wicksell, R. (2022). *Implementation frameworks guiding scientific innovation in chronic pain: A systematic review of digital self-management interventions*. OSF.

de la Vega, R., Groenewald, C., Bromberg, M. H., Beals-Erickson, S. E., & Palermo, T. M. (2018). Chronic pain prevalence and associated factors in adolescents with and without physical disabilities. *Developmental Medicine and Child Neurology*, *60*, 596–601.

de la Vega, R., Ritterband, L., & Palermo, T. M. (2020). Assessing digital health implementation for a pediatric chronic pain intervention: Comparing the RE-AIM and BIT frameworks against real-world trial data and recommendations for future studies. *Journal of Medical Internet Research*, *22*, e19898.

Devan, H., Perry, M. A., Yaghoubi, M., & Hale, L. (2021). "A coalition of the willing": Experiences of co-designing an online pain management programme (iSelf-help) for people with persistent pain. *Research Involvement and Engagement*, *7*, 1–13.

Dzewaltowski, D. A., Glasgow, R. E., Klesges, L. M., Estabrooks, P. A., & Brock, E. (2004). RE-AIM: Evidence-based standards and a web resource to improve translation of research into practice. *Annals of Behavioral Medicine*, *28*, 75–80.

Faes, M. C., Reelick, M. F., Esselink, R. A., & Rikkert, M. G. O. (2010). Developing and evaluating complex healthcare interventions in geriatrics: The use of the Medical Research Council framework exemplified on a complex fall prevention intervention. *Journal of the American Geriatrics Society*, *58*, 2212–2221.

Fanning, J., Brooks, A. K., Ip, E., Nicklas, B. J., Rejeski, W. J., Nesbit, B., & Ford, S. (2020). A mobile health behavior intervention to reduce pain and improve health in older adults with obesity and chronic pain: The MORPH pilot trial. *Frontiers in Digital Health*, *2*, 598456.

Fledderus, M., Schreurs, K. M., Bohlmeijer, E. T., & Vollenbroek-Hutten, M. M. (2015). Development and pilot evaluation of an online relapse-prevention program based on acceptance and commitment therapy for chronic pain patients. *JMIR Human Factors*, *2*, e1.

Ford, K. L., West, A. B., Bucher, A., & Osborn, C. Y. (2022). Personalized digital health communications to increase COVID-19 vaccination in underserved populations: A double diamond approach to behavioral design. *Frontiers in Digital Health*, *4*, 831093.

Gaskin, D. J., & Richard, P. (2012). The economic costs of pain in the United States. *The Journal of Pain: Official Journal of the American Pain Society*, *13*, 715–724.

Gentili, C., Zetterqvist, V., Rickardsson, J., Holmström, L., Simons, L. E., & Wicksell, R. K. (2020). ACTsmart—Development and feasibility of digital acceptance and commitment therapy for adults with chronic pain. *NPJ Digital Medicine*, *3*, 20.

Gentili, C., Zetterqvist, V., Rickardsson, J., Holmström, L., Simons, L. E., & Wicksell, R. K. (2021). ACTsmart: Guided smartphone-delivered acceptance and commitment therapy for chronic pain-a pilot trial. *Pain Medicine (Malden, Mass.)*, *22*(2), 315–328. https://doi.org/10.1093/PM/PNAA360

Glasgow, R. E., Harden, S. M., Gaglio, B., Rabin, B., Smith, M. L., Porter, G. C., Ory, M. G., & Estabrooks, P. A. (2019). RE-AIM planning and evaluation framework: Adapting to new science and practice with a 20-year review. *Frontiers in Public Health*, *7*, 64.

Groenewald, C. B., Essner, B. S., Wright, D., Fesinmeyer, M. D., & Palermo, T. M. (2014). The economic costs of chronic pain among a cohort of treatment-seeking adolescents in the United States. *The Journal of Pain*, *15*, 925–933.

Harrison, L. E., Webster, S. N., van Orden, A. R., Choate, E., Jehl, N., Stinson, J., Wicksell, R. K., Darnall, B. D., & Simons, L. E. (2022). Agile development of a digital exposure treatment for youth with chronic musculoskeletal pain: Protocol of a user-centred design approach and examination of feasibility and preliminary efficacy. *BMJ Open*, *12*, e065997.

Hedman-Lagerlöf, E., Carlbring, P., Svärdman, F., Riper, H., Cuijpers, P., & Andersson, G. (2023). Therapist-supported internet-based cognitive behaviour therapy yields similar effects as face-to-face therapy for psychiatric and somatic disorders: An updated systematic review and meta-analysis. *World Psychiatry*, *22*, 305–314.

Hennemann, S., Beutel, M. E., & Zwerenz, R. (2016). Drivers and barriers to acceptance of web-based aftercare of patients in inpatient routine care: A cross-sectional survey. *Journal of Medical Internet Research*, *18*, e337.

Hermes, E. D. A., Lyon, A. R., Schueller, S. M., & Glass, J. E. (2019). Measuring the implementation of behavioral intervention technologies: Recharacterization of established outcomes. *Journal of Medical Internet Research*, *21*, e11752.

Lapane, K. L., Quilliam, B. J., Benson, C., Chow, W., & Kim, M. S. (2015). Impact of noncancer pain on health-related quality of life. *Pain Practice*, *15*, 333–342.

Lin, J., Faust, B., Ebert, D. D., Krämer, L., & Baumeister, H. (2018). A web-based acceptance-facilitating intervention for identifying patients' acceptance, uptake, and adherence of internet- and mobile-based pain interventions: Randomized controlled trial. *Journal of Medical Internet Research*, *20*, e244.

Lohman, D., Schleifer, R., & Amon, J. J. (2010). Access to pain treatment as a human right. *BMC Medicine*, *8*, 8. https://doi.org/10.1186/1741-7015-8-8

Loudon, K., Treweek, S., Sullivan, F., Donnan, P., Thorpe, K. E., & Zwarenstein, M. (2015). The PRECIS-2 tool: Designing trials that are fit for purpose. *BMJ*, *350*, h2147.

Moore, G. F., Evans, R. E., Hawkins, J., Littlecott, H. J., & Turley, R. (2017). All interventions are complex, but some are more complex than others: Using iCAT_SR to assess complexity. *Cochrane Database of Systematic Reviews*, *2017*, ED000122.

Murphy, L. K., de la Vega, R., Kohut, S. A., Kawamura, J. S., Levy, R. L., & Palermo, T. M. (2021). Systematic review: Psychosocial correlates of pain in pediatric inflammatory bowel disease. *Inflammatory Bowel Diseases*, *27*, 697–710.

Murray, C. B., de la Vega, R., Murphy, L. K., Kashikar-Zuck, S., & Palermo, T. M. (2022). The prevalence of chronic pain in young adults: A systematic review and meta-analysis. *Pain*, *163*, e972–e984.

Palermo, T. M., de la Vega, R., Dudeney, J., Murray, C., & Law, E. (2018). Mobile health intervention for self-management of adolescent chronic pain (WebMAP mobile): Protocol for a hybrid effectiveness-implementation cluster randomized controlled trial. *Contemporary Clinical Trials*, *74*, 55–60.

Palermo, T. M., de la Vega, R., Murray, C., Law, E., & Zhou, C. (2020). A digital health psychological intervention (WebMAP Mobile) for children and adolescents with chronic pain: Results of a hybrid effectiveness-implementation stepped-wedge cluster randomized trial. *Pain*, *161*, 2763–2774.

Perry, M. A., Devan, H., Davies, C., Hempel, D., Ingham, T., Jones, B., Reid, S., Saipe, B., Godfrey, H., Snaddon, N., Morris, L., Puha, N., Haines, B., Irving, A., Brenycz, M., Fa'atafa, P., Maclean, K., Bulfin, S., & Hale, L. (2022). iSelf-Help: A co-designed, culturally appropriate, online pain management programme in Aotearoa. *Research Involvement and Engagement*, *8*, 1–15.

Petticrew, M. (2011). When are complex interventions 'complex'? When are simple interventions 'simple'? *European Journal of Public Health*, *21*, 397–398.

Phillips, S., Kanter, J., Mueller, M., Gulledge, A., Ruggiero, K., Johnson, M., & Kelechi, T. J. (2021). Feasibility of an mHealth self-management intervention for children and adolescents with sickle cell disease and their families. *Translational Behavioral Medicine*, *11*, 724–732.

Popay, J., Roberts, H., Sowden, A., Petticrew, M., Arai, L., Rodgers, M., & Britten, N. (2006). *Guidance on the conduct of narrative synthesis in systematic reviews*. A Product from the ESRC Methods Programme. Version 1.

Reuman, L., Solar, C., Maclean, R. R., Halat, A. M., Rajeevan, H., Williams, D. A., Heapy, A. A., Bair, M. J., Krein, S. L., Kerns, R. D., & Higgins, D. M. (2022). If you personalize it, will they use it?: Self-reported and observed use of a tailored, internet-based pain self-management program. *Translational Behavioral Medicine*, *12*, 693–701.

Ritterband, L. M., Andersson, G., Christensen, H. M., Carlbring, P., & Cuijpers, P. (2006). Directions for the International Society for Research on Internet Interventions (ISRII). *Journal of Medical Internet Research*, *8*, e23.

Rognsvåg, T., Lindberg, M. F., Lerdal, A., Stubberud, J., Furnes, O., Holm, I., Indrekvam, K., Lau, B., Rudsengen, D., Skou, S. T., & Badawy, M. (2021). Development of an internet-delivered cognitive behavioral therapy program for use in combination with exercise therapy and education by patients at increased risk of chronic pain following total knee arthroplasty. *BMC Health Services Research*, *21*, 1151.

Safaeinili, N., Brown-Johnson, C., Shaw, J. G., Mahoney, M., & Winget, M. (2020). CFIR simplified: Pragmatic application of and adaptations to the Consolidated Framework for Implementation Research (CFIR) for evaluation of a patient-centered care transformation within a learning health system. *Learning Health Systems*, *4*, e10201.

Sandhu, H. K., Shaw, J., Carnes, D., Furlan, A. D., Tysall, C., Adjei, H., Muthiah, C., Noyes, J., Tang, N. K. Y., Taylor, S. J. C., Underwood, M., Willis, A., & Eldabe, S. (2022). Development and testing of an opioid tapering self-management intervention for chronic pain: I-WOTCH. *BMJ Open*, *12*, e053725.

Skivington, K., Matthews, L., Simpson, S. A., Craig, P., Baird, J., Blazeby, J. M., Boyd, K. A., Craig, N., French, D. P., McIntosh, E., Petticrew, M., Rycroft-Malone, J., White, M., & Moore, L. (2021). A new framework for developing and evaluating complex interventions: Update of Medical Research Council guidance. *BMJ*, *374*, n2061.

Societal Impact of Pain (SIP). (2022). *SIP position on digital health: Pain assessment and quality indicators*.

Song, T., Yu, P., Bliokas, V., Probst, Y., Peoples, G. E., Qian, S., Houston, L., Perez, P., Amirghasemi, M., Cui, T., Hitige, N. P. R., & Smith, N. A. (2021). A clinician-led, experience-based co-design approach for developing mHealth services to support the patient self-management of chronic conditions: Development study and design case. *JMIR mHealth and uHealth*, *9*, e20650.

Sweeney, L., Moss-Morris, R., Czuber-Dochan, W., & Norton, C. (2021). Pain management in inflammatory bowel disease: Feasibility of an online therapist-supported CBT-based self-management intervention. *Pilot and Feasibility Studies*, *7*, 1–15.

Terpstra, J. A., van der Vaart, R., van Beugen, S., van Eersel, R. A., Gkika, I., Erdős, D., Schmidt, J., Radstake, C., Kloppenburg, M., van Middendorp, H., & Evers, A. W. M. (2022). Guided internet-based cognitive-behavioral therapy for patients with chronic pain: A meta-analytic review. *Internet Interventions*, *30*, 100587.

Todd, A., McNamara, C. L., Balaj, M., Huijts, T., Akhter, N., Thomson, K., Kasim, A., Eikemo, T. A., & Bambra, C. (2019). The European epidemic: Pain prevalence and socioeconomic inequalities in pain across 19 European countries. *European Journal of Pain*, *23*, 1425–1436.

Torning, K., & Oinas-Kukkonen, H. (2009). Persuasive system design: State of the art and future directions. In *ACM international conference proceeding series* (Vol. 350).

Treede, R. D., Rief, W., Barke, A., Aziz, Q., Bennett, M. I., Benoliel, R., Cohen, M., Evers, S., Finnerup, N. B., First, M. B., Giamberardino, M. A., Kaasa, S., Korwisi, B., Kosek, E., Lavand'Homme, P., Nicholas, M., Perrot, S., Scholz, J., Schug, S., … Wang, S. J. (2019). Chronic pain as a symptom or a disease: the IASP Classification of Chronic Pain for the International Classification of Diseases (ICD-11). *Pain*, *160*, 19–27.

UK Design Council. (2004). *The double diamond framework for innovation*.

US National Institutes of Health. (2014). *Quality assessment tool for observational cohort and cross-sectional studies*.

Valentijn, P. P., Tymchenko, L., Jacobson, T., Kromann, J., Biermann, C. W., AlMoslemany, M. A., & Arends, R. Y. (2022). Digital health interventions for musculoskeletal pain conditions: Systematic review and meta-analysis of randomized controlled trials. *Journal of Medical Internet Research*, *24*, e37869.

van Gemert-Pijnen, J. E., Nijland, N., van Limburg, M., Ossebaard, H. C., Kelders, S. M., Eysenbach, G., & Seydel, E. R. (2011). A holistic framework to improve the uptake and impact of eHealth technologies. *Journal of Medical Internet Research*, *13*, e111.

Venkatesh, V., Morris, M. G., Davis, G. B., & Davis, F. D. (2003). User acceptance of information technology: Toward a unified view. *MIS Quarterly*, *27*, 425–478.

Viswanathan, M., Ammerman, A., Eng, E., Garlehner, G., Lohr, K., Griffith, D., Rhodes, S., Samuel-Hodge, C., Maty, S., Lux, L., Webb, L., Sutton, S., Swinson, T., Jackman, A., & Whitener, L. (2004). Community-based participatory research: Assessing the evidence: Summary.

Wilson, K., Bell, C., Wilson, L., & Witteman, H. (2018). Agile research to complement agile development: A proposal for an mHealth research lifecycle. *NPJ Digital Medicine*, *1*, 1–6.

World Health Organization. (2018). *Seventy-first World Health Assembly*.

Yong, R. J., Mullins, P. M., & Bhattacharyya, N. (2022). Prevalence of chronic pain among adults in the United States. *Pain*, *163*, e328–e332.

## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

**How to cite this article:** de la Vega, R., Bartels, S. L., & Wicksell, R. W. (2024). Implementation frameworks guiding digital self-management intervention in chronic pain: A scoping review. *European Journal of Pain*, *00*, 1–19. https://doi.org/10.1002/ejp.2262