What Content Should Be Integrated into a Digital Therapeutic App for Fibromyalgia? A Review of Evidence-Based Self-Management Strategies

Thomas Lebeau Foustoukos, Marc Blanchard, Thomas Hügle

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Abstract

Background: Fibromyalgia is a prevalent musculoskeletal condition that incurs significant personal, social, and societal costs. Self-management, particularly in the areas of lifestyle, physical activity and in the cognitive and mental areas, plays an important role in fibromyalgia as pharmacological treatments often not effective. Digital health applications are increasingly recognized as point-of-care to deliver and coordinate self-management programs to patients. However, the therapeutic content they offer is often inconsistent, lacks transparency, and may not be evidence-based.

Objective: To elaborate an online self-management program for fibromyalgia patients based on current evidence and to explore optimization strategies.

Methods: PubMed and Cochrane databases were searched for guidelines and systematic reviews of randomized controlled trials on self-management interventions for adults diagnosed with fibromyalgia or other nociplastic pain conditions. The AGREE II – GRS or the AMSTAR 2 tools were used to assess the selected studies. Self-management interventions considered had to be adaptable to a mobile application.

Results: Thirty systematic reviews and eight guidelines were included in the analysis. Three categories of self-management interventions for fibromyalgia emerged: 1. Physical activity 2. Psycho-education and 3. Mind-Body exercises. While flexibility exercises did not demonstrate significant benefits, aerobic and resistance exercises showed potential in reducing fibromyalgia symptoms. Psycho-educative interventions, such as cognitive-behavioural therapies and educational intervention, are also considered to improve fibromyalgia symptoms. Mind-body therapies had mixed effects, with meditative movement therapies like Qi Gong, Tai Chi, and Yoga showing benefits, while meditation, hypnosis, and relaxation did not exhibit significant efficacy. Psycho-educative therapies in form of cognitive behaviour therapy (CBT) followed by physical exercise instructions were considered as the most suitable evidence-based content to be integrated in mobile health applications.

Conclusions: Effective mHealth self-management programs for fibromyalgia patients should consist of tailored multicomponent interventions with proven evidence. Psycho-educative and physical activity interventions appear to be most adaptable for the integration in mobile health applications.

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ABSTRACT

Background: Fibromyalgia is a prevalent musculoskeletal condition that incurs significant personal, social, and societal costs. Self-management, particularly in the areas of lifestyle, physical activity and in the cognitive and mental areas, plays an important role in fibromyalgia as pharmacological treatments often are not effective. Digital health applications are increasingly recognized as point-of-care to deliver and coordinate self-management programs to patients.

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Conclusion: Effective mHealth self-management programs for fibromyalgia patients should consist of tailored multicomponent interventions with proven evidence. Psycho-educative and physical activity interventions appear to be most adaptable for the integration in mobile health applications.

Keywords: Fibromyalgia; Chronic Pain; Self-management; eHealth; Mobile Application; Physical Exercises; Psycho-educative; Mind-Body Therapies.

Key Summary Points

- Fibromyalgia is among the most prevalent musculoskeletal conditions leading to notable personal et societal burden
- Treating fibromyalgia and comorbidities is complex and requires a multimodal approach with non-pharmacological therapies
- Self-management is a key part of the strategy with mobile applications which emerge as accurate tools
- The aim of the study was to provide evidence-based recommendations to develop a mHealth self-management program for patients with fibromyalgia
- Effective mHealth self-management programs for fibromyalgia patients should consist of tailored multicomponent of physical activities (aerobic and resistance exercises), psycho-educative (CBT) and mind-body therapies (relaxation, meditation and mind-body movements)
- The mHealth programs development should employ evidence-based theories, engage stakeholders, take into account socio-economic factors and adopt a multidisciplinary approach

1.   INTRODUCTION

1.1.   Fibromyalgia disease characteristics

Fibromyalgia is defined as a syndrome characterized by moderate-to-severe symptoms, including widespread pain, point tenderness, fatigue, sleep disturbance, cognitive complaints, and an increase in somatic complaints [1]. Despite these efforts to clarify the definition of fibromyalgia, it remains challenging to accurately assess its diagnosis, prevalence, management, and the personal and societal impacts it has [2].

Fibromyalgia ranks among the most prevalent musculoskeletal conditions, following lumbar pain and osteoarthritis. It affects 1-2% of the general population, with a higher prevalence in women (8-9 women for one man) aged between 20 and 55 years, and its prevalence tends to increase with age [3]. The physical and psychological health status of individuals with fibromyalgia is considerably lower compared to the general population or those with other specific pain conditions [4]. Fibromyalgia is often accompanied by psychiatric, rheumatological, or gastrointestinal comorbidities which further complicate the management and contribute to its overall personal and societal burden [5].

Proposing a clear treatment strategy for fibromyalgia remains arduous due to disparities among recommendations. The focus lies on non-pharmacological therapies, particularly physical interventions, psychological therapies, and mind-body approaches and should promote self-management. Patient education plays a crucial role in enhancing their understanding of the disease and fostering their active participation in its management. Pharmacological treatments have shown limited benefits compared to their potential adverse effects [6–10]. Multimodal treatment programs are recommended for treatment-resistant fibromyalgia patients as they combine different treatment modalities and offer group effects. However, such programmes require significant resources that are not necessarily considered cost-effective.

1.2.   Self-management

Self-management programs play a crucial role in supporting individuals with chronic conditions [11], and are recommended by management fibromyalgia guidelines [6–9]. Although interpretation may differ from the definition given by Miles et al. in 2011 [12], the fundamental concept of self-management emphasizes the active involvement of patients [11,13]. Self-management takes into account the multidimensional nature of the illness and combines multiple interventions. Self-management offers a relevant approach to address the challenges in fibromyalgia management and showed its efficiency to improve fibromyalgia patients' well-being [14,15], such as the limited efficacy of pharmacological therapies and the tendency of patients to seek repeated consultations with healthcare professionals. Currently, there are numerous research studies focusing on self-management programs for patients with chronic pain or fibromyalgia. While these programs have shown promise in improving pain intensity, functionality, cognitive behaviour, emotions, and quality of life, several limitations exist, reducing the quality of the studies and complicating their practical application. Many programs lack detail and clarity, raising questions about their reliability [16–20]. When programs are detailed, their references are often unclear, relying on peer opinions or interviews [21–27] or they may offer only one component, such as psychoeducation or exercises [28–31].

1.3.   E-Health technology

Technological advancements are continuously shaping the healthcare landscape, and the field of health technology, often referred to as "eHealth," encompasses various digital innovations such as the internet, digital gaming, virtual reality, and robotics, which are utilized for health promotion, prevention, treatment, and maintenance [32]. Within the realm of eHealth, a specific subgroup known as "mHealth" focuses on mobile and wireless applications. The World Health Organization (WHO) actively supports the advancement of

mHealth which highlights the easy worldwide accessibility of mHealth technologies [33]. In a clinical context, mHealth have demonstrated several key functionalities, including diagnostics and clinical decision-making, behaviour change interventions, digital therapeutics, and the delivery of disease-related education and communication support. The latter three functionalities are particularly relevant for delivering self-management interventions, empowering patients to monitor and manage their own health conditions, and providing an additional avenue for healthcare professionals to support their patients' well-being [34]. In 2019, the law was passed in Germany that DIGAs (Digital Health Application) are reimbursable by health insurance companies under certain conditions. Currently eight DIGAs for musculoskeletal indications are registered, two of those for chronic pain syndromes including fibromyalgia [35]. There was a second acceleration of e-health during the COVID-19 pandemic, notably concerning telemonitoring and video-consultations. In the meantime, eHealth interventions have been shown to enhance patients' quality of life and treatment experiences [36,37]. A notable limitation is that these web-based or native applications currently offer minimal personalization features. This is also due to the fact that the apps are approved on clinical results in a certain study protocol and cannot be changed dynamically. Another technical limitation is the lack of interoperability with electronic medical records or between apps. In addition, not all functions such as smartwatches or other mobile accessories, can be accessed in native apps.

1.4.   Fibromyalgia mHealth Apps

Mobile applications have demonstrated promising benefits for individuals with chronic pain or musculoskeletal conditions [37,38]. The use of mHealth technologies offers an accessible, cost-effective, and available 24/7 solution without geographical constraints, empowering patients to become more self-reliant in managing their chronic conditions [39,40]. With the rapid development and increasing accessibility of mobile applications, integrating them into the self-management approach seems like a logical future.

Although mobile applications exist, the quality of evidence from studies evaluating them is generally low [41,42], and in some cases, relevant studies are absent [43]. The Fibrowalk program appears to be the most comprehensive online program available, but it is based on unclear references and presented in Spanish, limiting its practicability to other countries [44–46]. The existing guidelines for the development of mHealth clearly emphasize the importance of basing the process on evidence-based material and provide strategies to optimize its effectiveness [47–49]. A recent systematic review assessed online pain management programs for chronic musculoskeletal conditions, analyzing 18 trials [50]. It found modest improvements in pain intensity, quality of life, and depression, but effects were small. Guided programs outperformed self-guided ones.

1.5.   Objectives

Therefore, the objective of this current study was to provide evidence-based recommendations to develop a mHealth self-management program for patients with fibromyalgia. A comprehensive literature review was conducted to evaluate the effectiveness of self-management interventions on symptoms in patients with fibromyalgia. Where applicable, relevant practical characteristics of the interventions were also reported. The discussion focused on optimizing the identified self-management interventions and exploring the potential development of a mobile application program.

2.   METHODS

2.1.   Eligibility criteria

To establish the eligibility criteria, the PICOS (Population, Intervention, Comparison, Outcomes, and Study design) framework was employed. It remains the most used tool within the databases such as PubMed and Cochrane and enables to increase the research specificity [51]. The study was approved by the University of Edinburgh Medical School Ethics Committee. The eligible population consisted of patients diagnosed with fibromyalgia as recommended by Wolfe et al. [1]. They were adults aged 18 or over, representing the

majority of the fibromyalgia patients in the general population [3]. The research excluded individuals younger than 18 years of age due to their comorbidities, psychosocial impacts, behavioural consequences, and prognostic variances [52]. However, studies recruiting individuals under 18 years old in addition to adults or diagnosed with other forms of chronic nociplastic pain, such as non-specific chronic low back pain, could also be included in the research. The research focused on evaluating self-management interventions, as described by Miles et al., as interventions that include a taught or self-taught element with the goal of enhancing participants' skills and knowledge, enabling them to apply these skills in various aspects of their lives beyond the intervention [12]. The delivery of these interventions could potentially be facilitated through mHealth technologies. However, it should be noted that certain interventions, such as biofeedback interventions that require complex measuring devices, may not be feasible to administer remotely. The interventions under investigation were compared to various other approaches, including another self-management intervention, alternative forms of treatment (e.g. pharmacological treatment), usual care, or a waiting list. The studies included in the evaluation assessed pain as a minimum outcome measure. Additionally, other outcomes such as quality of life (QoL), disability, mood (including depression, anxiety, and fatigue), sleep, and physical function were considered. It is worth noting that a single outcome could be assessed using multiple instruments, and conversely, a single instrument could measure several outcomes as long as its validity has been established. For the study, guidelines and systematic reviews (SR) that were based on randomized controlled trials (RCT) were selected. The eligible SR could be either associated or not associated with a MA.

2.2.   Search method

The research was conducted by searching the Medline and Cochrane Databases, encompassing English and French articles from the inception of the databases up until January 2023, with an update conducted in June 2023. To conduct the research, the MeSH tool and Boolean operators were employed according to the following methodology:

- (#1) = Fibromyalgia [MeSH Terms] OR Chronic Pain [MeSH Terms] OR Somatoform Disorders [MeSH Terms]

- (#2) = Self-management [MeSH Terms] OR Self care[MeSH Terms] OR Self rehabilitation care [MeSH Terms] OR Self efficacy [MeSH Terms] OR Exercise movement techniques[MeSH Terms] OR Exercise therapy [MeSH Terms] OR Health education [MeSH Terms] OR Behaviour therapy [MeSH Terms] OR Mind body therapy [MeSH Terms]

- (#1) AND (#2)

Next, filters to the studies based on their article type were applied, specifically focusing on guidelines, SR, and MA. The screening process began by reviewing the titles and abstracts of the identified articles, followed by a thorough examination of the full text for the selected studies.

2.3.   Data extraction

From each of the included SR, specific details regarding the identified self-management interventions were extracted. These details encompassed the efficiency results, modalities (such as frequency, duration, and format), delivery methods (such as face-to-face or internet-based, individual or group sessions), safety considerations, the authors' conclusions or recommendations, and any other relevant characteristics that were deemed significant.

Data extracted from SR to the guidelines, recommendations were confronted. Clear differentiation was made between the authors' conclusions or recommendations and the average information provided.

2.4.   Quality assessment

AMSTAR 2 and AGREE II – GRS assessment tools were applied to evaluate SR and guidelines, respectively [53,54]. For inclusion in the analysis, only SR that demonstrated a high or moderate level of confidence based on the AMSTAR 2 evaluation and guidelines with an AGREE II – GRS score higher than 18 were considered.

2.5.   Compatibility with mHealth apps

To assess the integrability of evidence-based self-management tools as mHealth apps, the structure and navigation of currently available mHealth apps for musculoskeletal diseases including fibromyalgia and chronic pain syndromes were analysed in a focus group. In particular, DIGAs were analysed [55]. The extent to which the variables and outcomes from the clinical studies can be integrated into apps was also assessed.

3.   RESULTS

The findings of the search are presented in the study flow diagram (Figure 1). A total of 38 studies were found to meet the inclusion criteria in June 2023. These included 8 guidelines and 30 SR. Out of the 75 full-text studies that underwent assessment, 37 studies were deemed ineligible and subsequently excluded.

3.1.   Population characteristics

All of the SR focused on individuals diagnosed with fibromyalgia; 13 of these SR also included RCT involving other chronic pain conditions such as whiplash-associated pain, complex regional pain syndrome, specific areas chronic pain, neuropathic pain, or migraine. The eight guideline articles exclusively focused on fibromyalgia. The RCT included in the SR predominantly recruited women, ranging from 80% to 98% of the participants. The age range of the participants reflected the middle-age group, consistent with real-world observations [3]. The majority of studies were conducted in North America and Europe, with limited representation from countries such as Australia, Brazil, or India. Only a minority of RCT considered demographic factors such as ethnicity, level of education, marital status, or purchasing power for randomization purposes. However, aspects related to culture and religion were not taken into account. Consequently, none of the included SR drew conclusions based on these demographic characteristics, as they were not consistently examined across the studies

3.2.   Interventions types

Self-management interventions were categorized into three groups: physical exercise, psycho-educative, and mind-body interventions. Additionally, a separate category called multicomponent interventions was identified, which encompassed interventions combining two or more of the previously mentioned self-management approaches. The European, American, Canadian, and Italian guidelines covered physical exercise, psycho-educative, and mind-body self-management interventions as part of the overall management of patients with fibromyalgia, alongside other treatment modalities [6,8,9,56]. However, the German guideline divided its recommendations into four separate studies: general recommendations [7], recommendations on physical interventions [57], psychological interventions [58], and other interventions such as mind-body therapies [59]. In total, eight studies focusing on

physical activities [60–67]; fourteen studies on psychoeducative interventions [28,68–79]; four studies on mind-body therapies [80–83]; one study on multicomponent interventions [14]; one study that investigated both psychoeducative and mind-body interventions [84] and two studies that examined physical activities, psychoeducative interventions, mind-body therapies, and multicomponent interventions [85,86]. An overview of the studies is shown in Figure 2. The authors of the included studies employed various types of control groups, which encompassed the following options: treatment as usual (TAU), waiting list or no treatment, alternative pharmacological or non-pharmacological interventions, active or attention control, and placebo or sham interventions. Designing a control group for complex self-management interventions presents challenges due to the inherent difficulty of blinding participants, which can introduce measurement and interpretation bias [87].

3.3. Outcomes

A wide range of variables were assessed both before and after the interventions: pain (both qualitative and quantitative measures), Quality of Life (QoL), psychological functions such as depression, anxiety, self-efficacy, acceptance, catastrophizing, and fear-avoidance, physical functions such as strength and disability, sleep quality, fatigue, healthcare utilization indicators such as visits, sick leaves, return to work, and care-seeking behaviour, as well as trial withdrawal rates and adverse effects. The Fibromyalgia Impact Questionnaire (FIQ) was frequently employed as a multidimensional measurement tool. In certain RCT, participants were followed up over a period of two to 36 months, with assessments conducted once or up to three times to track the evolution of the outcome measures.

3.3.1. Physical interventions

All of the guidelines strongly endorse the inclusion of aerobic exercises (AE) and resistance (or strength) exercises (RE) in self-management interventions for fibromyalgia [6,8,9,56,57]. On the other hand, flexibility and stretching exercises are either not recommended [8,9] or recommended with weak or insufficient evidence of benefit [56,57]. Exercise interventions were found to be superior to control groups in improving pain, FIQ scores, sleep quality, fatigue, and depression [86]. The characteristics of the exercises were extracted based on the prescription guidelines provided by the American College of Sports Medicine (ACSM), which include frequency, intensity, time, and type (FITT) of exercises [88]. Additionally, the duration of the exercises, delivery modalities, whether they were tailored or standardized, and safety considerations were also taken into account. AE had positive effects on pain, QoL, depression [62,64,65]. AE demonstrated a high effect on reducing the FIQ [54]. AE probably improve stiffness and slightly improve physical function and cardiovasculatory function [62]. According to Couto et al., RE yielded positive effects on pain and QoL, but did not show a significant effect on depression [65]. On the other hand, Albuquerque et al. found that RE demonstrated a moderate effect in reducing the FIQ scores [60]. RE has the potential to improve fatigue and sleep [68]. Although FE did not show superiority over control groups (other interventions or no intervention), the quality of evidence is insufficient to draw definitive conclusions regarding the effectiveness of FE on fibromyalgia symptoms [60,64,65,67]. However, there is some evidence suggesting that FE may help decrease muscle stiffness [67]. Interventions that combine AE, RE, and/or FE have shown greater effectiveness in improving FIQ scores compared to single-type exercise interventions [60]. However, Bidonde et al. state that no definitive conclusion can be drawn regarding the optimal proportion, synergy, or specific characteristics of each exercise type [61]. Exergames have demonstrated promising benefits in improving pain, disability, and physical function in both short and long term [85]. There is a lack of available information regarding other exercises such as Pilates and motor control exercises.

Exercices (AE, RE and FE) characteristics were gathered in Table 1.

3.3.2. Psycho-educative interventions

Consensus guidelines recommend the inclusion of psychological and educational interventions, such as cognitive-behavioural therapy (CBT) and health education [6–9,56]. These interventions can encourage self-management, enhance self-efficacy, and reduce maladaptive thoughts and behaviours [8]. It is particularly important to consider these interventions when patients have comorbid mental disorders [58]. Regarding hypnosis and guided imagery, recommendations are conflicting, and patients should be informed that their efficacy has not been proven [6,9,58]. Although other psychological interventions, such as relaxation, therapeutic writing, Roger therapy, family therapy, psychodynamic therapy, and psychoanalytic therapy, are available, they should not be proposed as standalone treatments due to the lack of evidence or limited recommendations [58]. CBT is a commonly used psychological approach in chronic pain management. It incorporates education on the physiopathology of pain, self-management skills, cognitive reappraisal, pacing activities, and problem-solving techniques to help patients modify their behaviours, thoughts, and emotions, ultimately reducing pain, improving functioning, and enhancing mood. Additional components, such as sleep hygiene, may be included to address comorbidities. Homework assignments are given to encourage the practice of skills in everyday life [79]. Acceptance and commitment therapy (ACT) and mindfulness-based therapy (MBT) are extensions of CBT. Acceptance and commitment therapy comprises two main core components: mindfulness and acceptance, as well as commitment and behaviour change. It involves various processes, including acceptance, defusion, contact with the present moment, self as context, values, and committed action [89]. Acceptance and commitment therapy interventions often incorporate CBT processes, making it difficult to distinguish between CBT and ACT [70]. Evidence suggests that CBT can reduce pain, disability, and negative mood in patients with chronic pain or fibromyalgia, both immediately after treatment and at long-term follow-up (six and 12 months), although the effect size is small or very small [68,79,84,86]. Enomoto et al. recommend offering CBT for insomnia, or at least CBT for insomnia and pain, to patients with chronic pain who also experience insomnia as a comorbidity [71]. Cognitive-behavioural therapy for insomnia has been effective in improving sleep, pain, disability, and depression. Acceptance and commitment therapy has also demonstrated benefits for patients with chronic pain, improving pain acceptance, quality of life, pain intensity, functioning, and mood [76,78]. For fibromyalgia, ACT has shown significant improvements in patient functioning in both the short and long term, based on a meta-analysis with moderate-quality evidence [70]. Acceptance and commitment therapy can be considered to enhance patients' psychological flexibility and, subsequently, their functioning in pursuing valued activities [70,78]. Education serves as both an intervention and a CBT tool [77]. Joypaul et al. defined education as providing instructions to inform participants, making it applicable to various interventions as an instructional tool [74]. Therapeutic pain neuroscience education (TPNE), also referred to as pain neuroscience education (PNE) by some authors, aims to enhance patients' knowledge and understanding of pain neurophysiology to improve their cognitive and behavioural skills related to pain [75,90]. Therapeutic pain neuroscience education has demonstrated benefits for patients with chronic pain in reducing fear of movement, pain intensity, pain disability, and pain catastrophizing [77]. Therapeutic pain neuroscience education, in the context of chronic musculoskeletal pain, improved pain intensity, pain knowledge, disability, maladaptive thoughts and behaviours, physical function, and healthcare utilization, even up to one year post-treatment [75]. Other educational content has been studied, including lifestyle components focusing on areas such as nutrition, sexuality, social coping strategies, and the regulation and adjustment of everyday life [14]. It is important to note that education should be an integral part of a multidisciplinary approach to chronic pain, alongside graded physical activities, graded exposure, and pacing for example, and not offered as a standalone treatment [73–75,77,86].
Cognitive-behavioural therapy and education characteristics were gathered in Table 1.

3.3.3. Mind-body interventions

The classification of mind-body interventions was based on the Mesh terms of the National Library of Medicine. They encompass various modalities such as meditative movement

therapies (MMTs), respiration exercises, hypnosis and autogenic training, meditation, and relaxation [91]. They focus on exploring the interconnectedness between the brain, body, mind, and behaviour, and how emotional, mental, social, spiritual, experiential, and behavioural factors can directly impact health [92]. Guidelines recommend the use of MMTs with confidence [6,9,59]. However, hypnosis, guided imagery, relaxation, or meditation are not recommended, and it is advised not to propose them as standalone interventions [9,59]. The Canadian guideline suggests not discontinuing these interventions but informing the patient about their lack of evidence and potential side effects [8]. Therapies such as Qi Gong, Tai Chi, and Yoga as examples of MMTs were included [82]. Meditative movement therapies have shown improvements in outcomes such as physical functioning, pain, and mood for patients with fibromyalgia [84]. Specifically, Tai Chi has been found to significantly reduce FIQ scores, pain intensity, sleep disturbance, fatigue, and depression, while increasing QoL for individuals with fibromyalgia [80]. Tai Chi and Yoga are weakly recommended, whereas the evidence did not allow for a recommendation regarding Qi Gong for chronic pain management [82]. Lee et al. did not provide a recommendation for meditation as a treatment for chronic pain due to the limited evidence available [83]. However, they noted that meditation was a safe intervention and may offer small benefits. While no specific recommendation was provided in the systematic review, Lee et al. suggested that mindfulness-based interventions could potentially offer benefits for chronic pain management [83]. Due to the lack of evidence regarding their safety and the limited quality of available evidence, Lee et al. did not make a specific recommendation for hypnosis or guided imagery in the management of chronic pain [83].
Relaxation, meditation and MTT characteristics were gathered in Table 1.

3.3.4.   Multicomponent interventions

Multicomponent interventions were defined as combinations of at least two components, including psychological, physical activity, medical education, and mind-body therapies, based on the self-management program developed by Miles et al. [12] and further refined by Geraghty et al. [14]. All guidelines recommend not implementing interventions in isolation, but rather combining them with other approaches. Multicomponent intervention should include physical and psychoeducational interventions at a minimum [6–9,50]. Multicomponent interventions have demonstrated effectiveness in improving various aspects such as FIQ, pain, sleep, and depression, with greater effects compared to exercise alone, education alone, or psychological interventions alone [80,81]. The positive effects of multicomponent interventions typically last for an average of 14 weeks, and it is recommended to conduct follow-up assessments every three months to review and reinforce the treatment strategy [81]. Considering the variations across studies, multicomponent interventions have shown improvements in physical function, pain, FIQ, fatigue, mood, and quality of life in both the short and long term [14].

3.4.   Integration in mHealth Apps
Web and native apps are both viable platforms for integrating self-management tools for fibromyalgia. Native apps, in particular, are adept at incorporating wearable data directly from mobile phones. A comprehensive mHealth app can evaluate various aspects of fibromyalgia studies, including pain, QoL, depression, anxiety, self-efficacy, acceptance, catastrophizing, fear-avoidance, physical functions (such as strength and disability), sleep quality, fatigue, and healthcare utilization indicators like clinic visits, sick leaves, and return-to-work patterns. Additionally, these apps can include the Fibromyalgia Impact Questionnaire (FIQ). For a decentralized trial of a new fibromyalgia mHealth app, accurate diagnosis and inclusion criteria are essential. The app can incorporate either the FIRST criteria or the revised ACR2010 criteria for fibromyalgia classification into its assessment form. These criteria might be presented during the initial onboard process or within the Patient-Reported Outcomes (PRO) section, which is accessible through the main navigation bar or via weekly push notifications. Content-wise, fibromyalgia mHealth apps should ideally function as

multicomponent platforms, encompassing three main areas: psycho-education, mind-body techniques, and physical exercise guidance. The app can offer educational and psycho-educational materials in text or animated video formats. Cognitive behavioral therapy should be a primary focus, with ACT and Mindfulness-Based Therapy as supplemental options. Aerobic exercises and resistance exercises can be demonstrated through animated or real-life videos. The use of generative AI can be explored to enhance the creation of educational content and imagery. However, unless proven otherwise, relaxation and hypnosis tools should be excluded from the app due to the lack of supporting evidence.

4.   DISCUSSION

This literature review identifies evidence-based elements for fibromyalgia self-management that should be considered in mHealth applications. Our primary findings dissect self-management of fibromyalgia in three main categories of interventions: psychoeducational interventions, mind-body therapies and physical activities. All three are included in current fibromyalgia mHealth applications on the market, several of those with proven efficacy, the underlying therapeutic content is not openly accessible [50]. Apart from CBT interventions, psychoeducation and physical exercise, they focus on pain coping skills, mindfulness, lifestyle modification, and pain neuroscience education. The recommendations regarding mind-body therapies such as MMT, meditation, relaxation, or hypnosis were conflicting. However, these therapies were generally considered relatively safe and could be offered as complementary treatments if the benefits outweighed the risks. Due to the limited amount of research and the lack of high-quality evidence, detailed prescription guidelines for these therapies could not be provided.

Regarding CBT, the heterogeneity and low quality of the studies made it challenging to define, evaluate, and describe this intervention. CBT encompassed a wide range of interventions, such as mindfulness stress reduction, breathing and relaxation exercises, and utilized various tools, including education, behavioural change techniques, cognitive restructuring, etc. The boundaries between CBT and other interventions were not always clear. For example, ACT was sometimes considered an extension of CBT, while other times it was not. Similarly, meditation could be incorporated within a CBT session or proposed as a separate intervention. Furthermore, CBT could be vaguely described, covering a wide range of topics or specifically targeting certain issues like pain or insomnia. Nevertheless, CBT remained strongly recommended to assist patients with fibromyalgia in managing their pain, comorbidities, and lifestyle [68]. Mind-body therapies presented mixed results, with meditative movement therapies showing promise. Physical exercise, notably a combined treatment by aerobic, resistance and/or flexibility exercises has the highest effect size on fibromyalgia. There are instructions for physical exercise for fibromyalgia. However, newer techniques for physical exercise guidance in the form of wearables and computer vision are only available for osteoarthritis or post-operative online rehabilitation programmes. We see here an opportunity for new techniques to offer physical exercise even better for patients with chronic musculoskeletal pain syndromes.

This review acknowledges several limitations. The variability in the definitions of key terms like "self-management" and the overlapping boundaries of CBT and mind-body therapies may have influenced the results. The inclusion criteria, encompassing studies on various chronic pain conditions beyond fibromyalgia, could have affected the specificity of the conclusions. Additionally, the reliance on only two databases (PubMed and Cochrane) might have introduced selection bias. Furthermore, the exclusion of newly evaluated interventions and reliance solely on systematic reviews and guidelines may have omitted emerging but promising self-management approaches. Another main limitation is clearly to assess whether a conventional evidence-based therapy is also effective in an app. This has not been investigated for the individual therapy applications, but only for the entire therapy program. It

is possible that the user experience plays an overriding role in apps and influences their effectiveness. Above all, adherence plays a very important role. Online programmes without a coach sometimes have very low adherence [50]. The psychiatric comorbidity affects patients with fibromyalgia particularly severely as they suffer from concentration problems and fatigue. This psychiatric component certainly also plays a role here. These are very heterogeneous in fibromyalgia, for example in the presence of depression or psychological trauma, which is often associated with fibromyalgia. To this end, it remains to be clarified if fibromyalgia apps should be coach-assisted or via stand-alone apps. As another limitation, the review excluded interventions involving additional devices, such as tools to measure heartbeat, blood pressure, or respiration rhythm, as patients may not have easy access to these devices. However, with advancements in technology and the availability of devices like smartwatches or pedometers, biofeedback interventions could be considered as part of self-management interventions. Nevertheless, these devices are often expensive and may not meet the criteria of accessibility, equity, or cost effectiveness.

There are several strategies to optimize fibromyalgia online self-management programs. The potential of integrating biofeedback interventions using wearable technologies warrants exploration, considering the challenges of accessibility and cost. Engaging stakeholders, considering socio-economic factors, and employing evidence-based theories will be essential in the iterative development process of these programs.

As fibromyalgia is a heterogeneous disorder, personalization or hyperpersonalization should be considered in mHealth programs. This can be performed according the individual symptom scores or via fibromyalgia phenotypes and personas that can be identified by machine learning [93]. Involving stakeholders such as patients and healthcare professionals, identifying necessary skills and competencies like behaviour change techniques (BCT), recognizing contextual and demographic factors (such as age, culture, ethnicity, gender, and socioeconomic status) that could influence outcomes, and

Currently, there has been a shift in the literature regarding the development of interventions for pain management, including fibromyalgia. The prevailing approach involves proposing interventions to be studied first and then exploring the BCT employed [94–96]. In the study of Pearson et al. in 2020, BCT were identified in a self-management program for fibromyalgia patients, with active involvement of patients and therapists for feedback [96]. It was observed that goal setting and planning techniques were widely represented and beneficial, feedback and monitoring techniques helped identify negative behaviours, shaping knowledge techniques provided useful tips, comparison behaviour techniques had positive effects but were time-consuming, and reward and threat techniques were appreciated by the patients. Other techniques received less representation or commentary. On the other hand, Keogh et al. in 2015 classified the BCT employed in the literature on self-management interventions for chronic low back pain and arthritis, ranking them from most to least represented [94]. Interestingly, the "goal and planning" technique ranked eighth and was employed by only eight out of 25 studies.

Furthermore, Meade et al. in 2019 found that BCT domains such as social support, goal setting and planning, shaping knowledge, comparison of behaviour, and repetition could be more effective in promoting adherence to prescribed exercise in patients with chronic musculoskeletal pain [95].

Based on the findings of the literature review, studies have consistently demonstrated that guided interventions for CBT are more effective compared to unguided interventions [28,72,97]. In this context, guided interventions refer to tailored interventions that are accompanied by instructions provided to the patient, while unguided interventions refer to accessible content provided to the patient without instructions, following the definition by Moman et al. in 2019 [98].

In order to enhance user engagement with mobile applications, Wei et al. in 2020 created an evidence-based checklist outlining essential features for the development of a user-friendly application [99]. Therefore, to optimize user engagement, the application should possess aesthetically pleasing designs incorporating attractive colour schemes, easy-to-use navigation tools, personalized preferences, graphical representations of data and

interventions, reinforcement mechanisms like reminders and rewards, communication features facilitating interaction with other users and healthcare professionals, well-structured message presentation, and provision of credible information [99]. These identified features intersect with some of the BCT, thus emphasizing the importance of considering both factors in conjunction.

5.   CONCLUSION

The comprehensive literature review presented in this study provides strong evidence-based support for providing recommendations for a self-management program for patients with fibromyalgia and its adaptation to mHealth development. To optimize the effectiveness of the program, it is crucial to employ evidence-based theories, engage the stakeholders such as the patients, multidisciplinary healthcare professionals, and technology experts, and take into account socio-economic factors, gender, age, culture, religion, and ethnicity throughout the development process. Moreover, it is crucial to embrace an iterative approach that encompasses ongoing evaluation and revision of the program. This iterative process should take into account the assessment of the application's effectiveness, acceptability, feasibility, equity, safety, and cost-effectiveness. By continuously evaluating and revising the program, it becomes possible to address any potential issues or areas for improvement, ensuring that the mHealth application meets the desired outcomes and remains aligned with the needs of the users and healthcare providers. The recommendations were summarized in Table 2 and Table 3.

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CONFLICTS OF INTERESTS

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TABLES AND FIGURES

ABBREVIATIONS

- WHO: world health organization

- eHealth: electronic health

- mHealth: mobile health

- QoL: quality of life

- SR: systematic reviews

- RCT: randomized controlled trials

- MA: meta-analysis

- ACSM: American College of Sports Medicine

- FITT: frequency, intensity, time, and type

- CBT: cognitive-behavioural therapy

- ACT: acceptance and commitment therapy

- MBT: mindfulness-based therapy

- TPNE: therapeutic pain neuroscience education

- PNE : pain neuroscience education

- MMT : meditative movement therapies

- FIQ : fibromyalgia impact questionnaire

- BCW: behaviour change wheel

- APEASE: acceptability, practicability, effectiveness, affordability, spill-over effects, and equity

- TDF: theoretical domains framework

- SMART: specific, measurable, assignable, realistic, and time-related

- HAS : haute autorité de santé

- AE: aerobic exercices

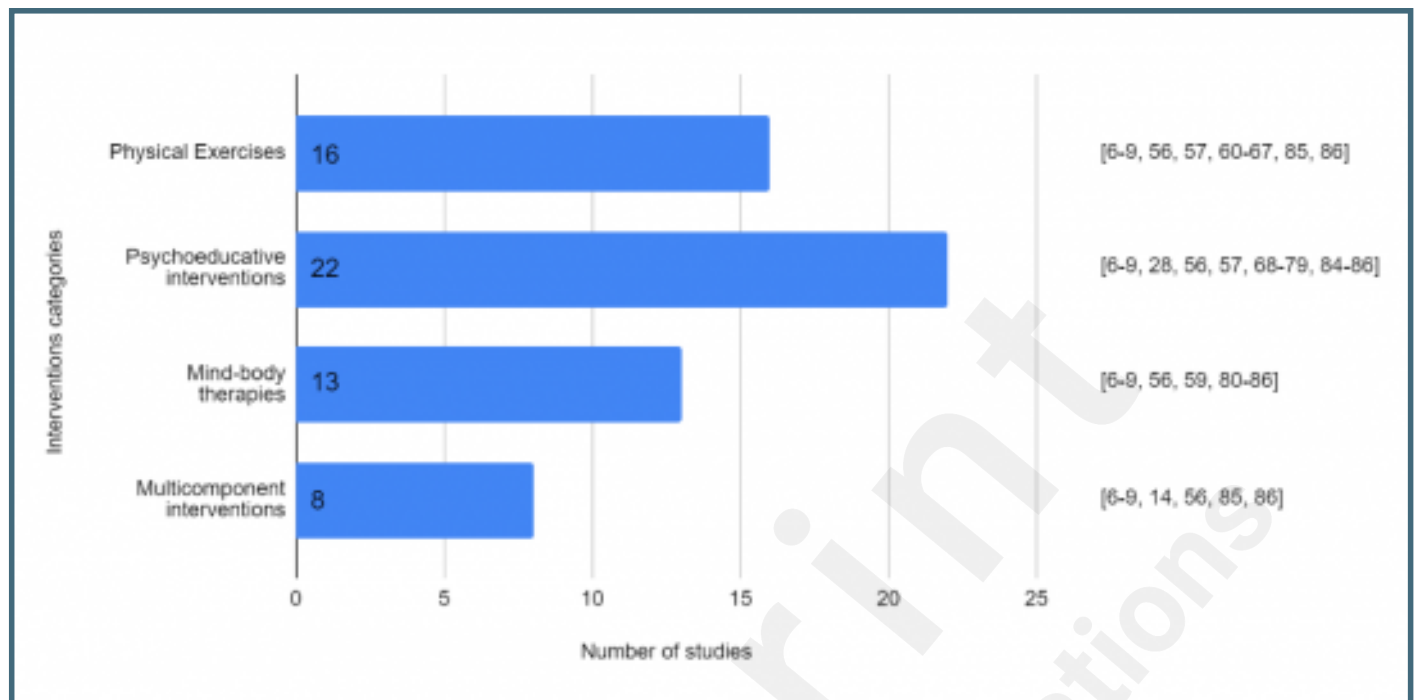- RE: resistance exercises

- FE: flexibility exercises

Supplementary Files

Figures

Flowchart.
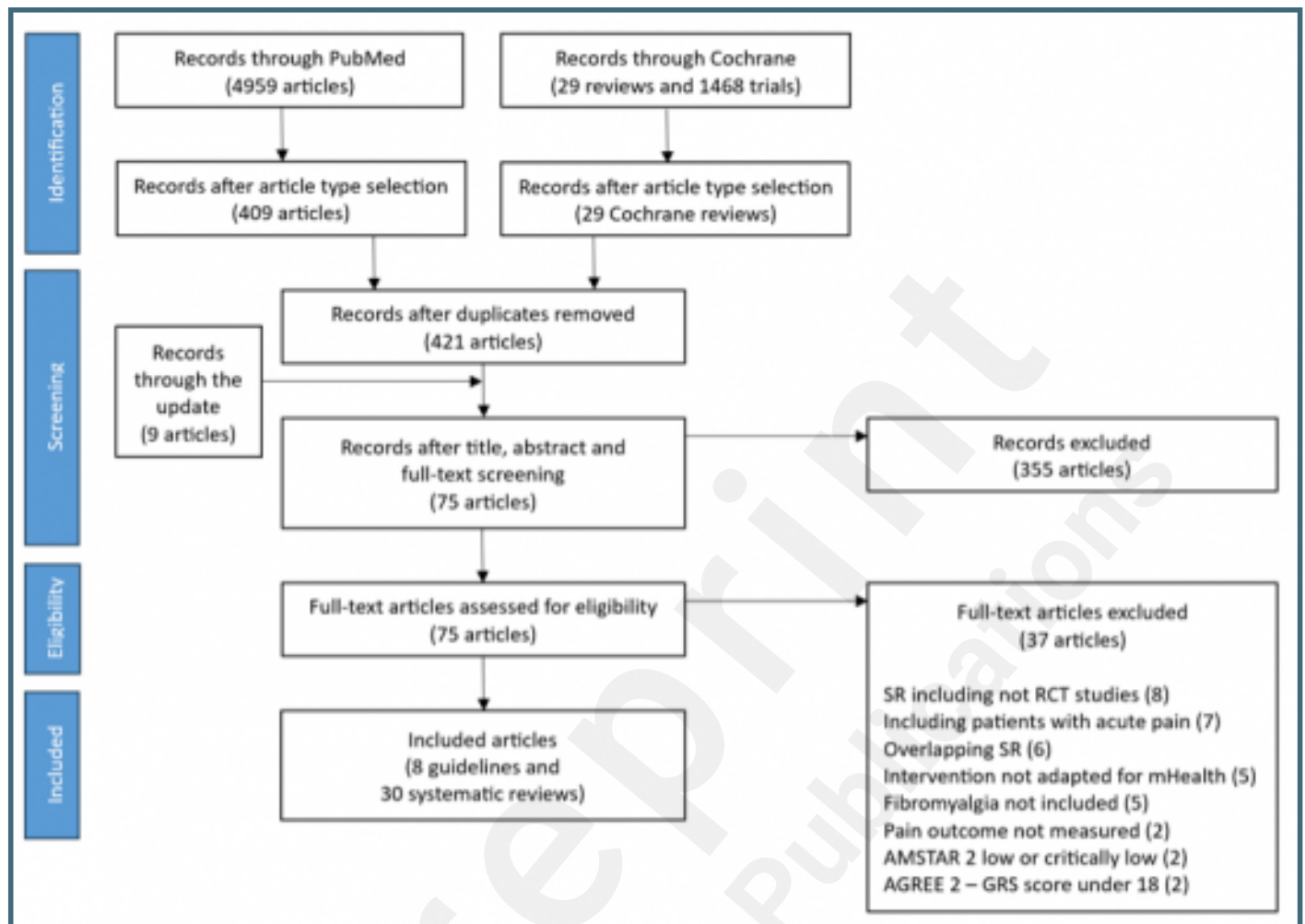
Overview of the guidelines and studies according to the interventions categories.

Multimedia Appendixes

Interventions characteristics.
URL: http://asset.jmir.pub/assets/658927a9de2523457982637e0bbaf550.docx

Recommendations for the self-management program.
URL: http://asset.jmir.pub/assets/0b5e761a1fc973135599fc1e2ccd5a14.docx

Recommendations for the mHealth self-management program development.
URL: http://asset.jmir.pub/assets/20f4ddb3e9b550fa730c63f18f545545.docx