CHRONIC – A Digital Multimodal Pain Intervention: Study Protocol for a Randomized Controlled Trial

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Abstract

Background: Chronic pain affects approximately 12 million individuals in Germany and significantly impairs quality of life. Although multimodal treatment approaches—combining physical, psychological, and behavioral strategies—are considered the gold standard, long waiting times for psychotherapy limit timely access to care. Digital health interventions, particularly those grounded in established therapeutic models, offer a promising solution to bridge this treatment gap. The German Digital Health Care Act (DVG) has opened pathways for reimbursable digital applications such as CHRONIC, which uniquely integrates cognitive behavioral therapy (CBT), Acceptance and Commitment Therapy (ACT), mindfulness, and physiotherapy into a structured web-based program.

Objective: This study protocol outlines a randomized controlled trial aimed at evaluating the effectiveness of CHRONIC, a 12-week web-based, multimodal self-help program for individuals with chronic pain, with a focus on reducing pain-related interference and improving quality of life.

Methods: This is a monocentric, three-arm randomized controlled trial (RCT) with pre-, post-, and three-month follow-up assessments. A total of N = 200 participants with chronic non-malignant pain will be randomized into one of three groups: (1) intervention with individualized psychological feedback (EGpsych), (2) intervention with standardized computer-generated feedback (EGcomp), and (3) treatment-as-usual waitlist control (TAU). Weekly modules in the intervention arms include psychotherapeutic video sessions, interactive ACT- and CBT-based exercises, mindfulness practices, and physiotherapeutic movement training. Outcomes will be assessed via validated self-report instruments: the WHYMPI for pain intensity and interference, AQoL-8D for quality of life, CPAQ-D for pain acceptance, PHQ-9 for depression, and GAD-7 for anxiety. Data will be analyzed using repeated measures ANOVAs with intention-to-treat and per-protocol approaches. Missing data will be addressed using multiple imputation.

Results: Recruitment not yet started; no results available. Primary outcomes include reductions in pain-related interference and improvements in quality of life from pre- to post-intervention and follow-up. Secondary outcomes include increases in pain acceptance and reductions in depressive and anxiety symptoms. Differences between the two feedback formats will be explored to assess the added value of individualized therapist feedback over computer-generated feedback.

Conclusions: This study protocol describes a randomized controlled trial designed to evaluate the clinical utility of CHRONIC as a scalable, low-threshold intervention for chronic pain. By combining psychotherapeutic, physiotherapeutic, and mindfulness-based strategies in a digital format, CHRONIC is expected to address the multifactorial nature of chronic pain more comprehensively than existing unimodal tools. The findings aim to inform future digital health developments and contribute to the implementation of biopsychosocial care models in routine practice. Clinical Trial: German Clinical Trials Register (DRKS), ID: DRKS00036901. Registered on July 17, 2024.

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Conclusions: This study protocol describes a randomized controlled trial designed to evaluate the clinical utility of CHRONIC as a scalable, low-threshold intervention for chronic pain. By combining psychotherapeutic, physiotherapeutic, and mindfulness-based strategies in a digital format, CHRONIC is expected to address the multifactorial nature of chronic pain more comprehensively than existing unimodal tools. The findings aim to inform future digital health developments and contribute to the implementation of biopsychosocial care models in routine practice.

Trial Registration: German Clinical Trials Register (DRKS), ID: DRKS00036901. Registered on July 17, 2024.

Keywords: chronic pain; telemedicine; cognitive behavioral therapy; acceptance and commitment therapy; mindfulness; self-help program; digital health application; DiGA

Introduction

Approximately 12 million individuals in Germany suffer from chronic pain [1] representing around 14% of the national population. Alongside physiotherapy and medication, psychotherapeutic interventions have proven effective in treating chronic pain [2]. However, the average waiting time for psychotherapy in Germany is approximately five months, with considerable regional differences [3], highlighting the urgent need for scalable, cost-effective treatment options. To address this gap, the German government implemented the Digital Healthcare Act (Digitale-Versorgung-Gesetz, DVG) on December 9, 2019, enabling physicians and psychotherapists to prescribe reimbursable digital health applications. The web-based application “CHRONIC” is designed to address this care gap for individuals with chronic pain. Unlike comparable tools, CHRONIC combines psychotherapeutic techniques from Acceptance and Commitment Therapy (ACT) [4] and mindfulness-based therapy [5] with physiotherapeutic exercises. The goal is to offer a comprehensive educational and therapeutic program that equips users to manage their pain condition effectively. Given the multidimensional nature of chronic pain, a multimodal treatment approach—integrating biological, psychological, and social elements—is considered necessary [6]. Skelly et al. (2020) found that unimodal non-pharmacological interventions for chronic pain—such as isolated exercise or psychological therapies—often produce only modest and short-term effects [7]. Long-term benefits were rare, and methodological heterogeneity limited the strength of evidence. The authors conclude that single-modality treatments fail to address the biopsychosocial complexity of chronic pain, highlighting the need for integrated, multimodal approaches.

Identification and Treatment of Chronic Pain

Pain is defined by the International Association for the Study of Pain (IASP) as a persistent sensation following the expected healing time of an acute injury [8]. Due to variability in recovery durations depending on the nature of the injury, clinical practice commonly applies a fixed time threshold to define chronic pain. For instance, low back pain is classified as chronic when persisting beyond six months, whereas postherpetic neuralgia may be considered chronic after only three months [9].

The ICD-11 has improved the classification of chronic pain by introducing clinically relevant categories and specific diagnostic criteria [10]. Chronic pain is now divided into seven distinct categories: (1) chronic primary pain, (2) chronic cancer-related pain, (3) chronic postsurgical and posttraumatic pain, (4) chronic neuropathic pain, (5) chronic headache and orofacial pain, (6) chronic visceral pain, and (7) chronic musculoskeletal pain. All categories share the criterion of persistent or recurrent pain for a minimum duration of three months, with optional specifiers addressing psychosocial factors and severity. The latter is assessed through pain intensity, interference, and functional limitations. Each category also emphasizes the significant impairment in quality of life and the necessity to exclude other potential etiologies before diagnosis [11].

A review by Hylands-White et al. (2017) outlined the diverse range of chronic pain treatments [6]. Pharmacologic approaches such as analgesics may offer short-term relief but often show limited effectiveness in chronic non-malignant pain. Even opioids typically reduce pain by only 30%, with potential for tolerance, side effects, and reduced long-term benefit. Non-steroidal anti-inflammatory drugs (NSAIDs) are more effective in some cases but carry risks such as gastrointestinal bleeding and cardiovascular events, particularly with long-term or high-dose use. Topical analgesics offer lower systemic risk, though concerns regarding dependency persist—especially for opioid-based agents [12]. Adjuvant medications, including anxiolytics, hypnotics, antidepressants, and anticonvulsants (often used off-label), are also possible approaches. Non-pharmacological treatments include spinal cord stimulation (SCS), deep brain stimulation (DBS), repetitive transcranial magnetic

stimulation (rTMS), transcranial direct current stimulation (tDCS), counter-irritation, transcutaneous or percutaneous electrical nerve stimulation (TENS/PENS), topical capsaicin, and thermo-/cryotherapy.

However, the inherently multidimensional nature of chronic pain necessitates a biopsychosocial framework that integrates biological, psychological, and social interventions. Physiotherapy contributes by maintaining or restoring physical function, while psychotherapeutic techniques from cognitive behavioral therapy (CBT) and ACT assist patients in coping with chronic pain, implementing stress management strategies, and achieving emotional stabilization [6]. Digital interventions in chronic pain management show significant promise but require further rigorous investigation to establish their evidence base and long-term effectiveness [13,14]. Currently, in Germany, just one digital health application is officially listed and reimbursable for chronic pain treatment: “HelloBetter Chronische Schmerzen”, an interactive online program based on ACT techniques including psychoeducation, videos, and audio [15]. This program primarily addresses the psychotherapeutic dimension of chronic pain but does not include physiotherapeutic components, therefore, the inclusion of applications such as CHRONIC, which incorporate both physical activation and psychological guidance, would represent a valuable extension of current digital care offerings within a truly biopsychosocial framework.

The future study

The aim of the future study is to evaluate the effectiveness of the digital intervention CHRONIC for individuals with chronic pain. In light of the increasing availability of web-based programs targeting chronic pain, CHRONIC adopts a multimodal approach that distinguishes itself from existing interventions by integrating multiple evidence-based components rather than relying solely on a singular therapeutic framework, thus providing a truly biopsychosocial framework. To enhance compliance and user engagement, the program incorporates a video-based therapist who guides participants through interactive modules, thereby fostering a sense of therapeutic alliance. In addition, personalized feedback is provided to further support adherence and individualization of the intervention process.

Study objectives

The following research questions and objectives are to be examined in the context of evaluating the 12-week web-based self-help program CHRONIC for individuals with chronic pain:

1. **Reduction of pain intensity**: Does participation in CHRONIC lead to a reduction in experienced pain intensity compared to a treatment-as-usual group (tau) at post-intervention and follow-up?

2. **Reduction of pain-related impairment**: Does CHRONIC reduce the degree to which chronic pain interferes with daily life and functioning compared to tau at post-intervention and follow-up?

3. **Improvement in quality of life**: Does participation in CHRONIC enhance participants’ quality of life compared to tau at post-intervention and follow-up?

4. **Increase in pain acceptance**: Does CHRONIC support participants in developing a higher level of acceptance regarding their chronic pain compared to tau at post-intervention and follow-up?

5. **Comparison of feedback formats**: Does template-based, computer-generated feedback offer comparable benefits to individualized therapist feedback within a web-based self-help setting? Specifically, do participants receiving standardized feedback (experimental group *comp*) differ significantly from those receiving personalized feedback (experimental group *psych*) regarding primary outcomes?

The overall aim is to evaluate the effectiveness of CHRONIC as a low-threshold, scalable intervention for individuals with chronic pain, and to explore the potential of automated feedback systems within digital health interventions.

Methods

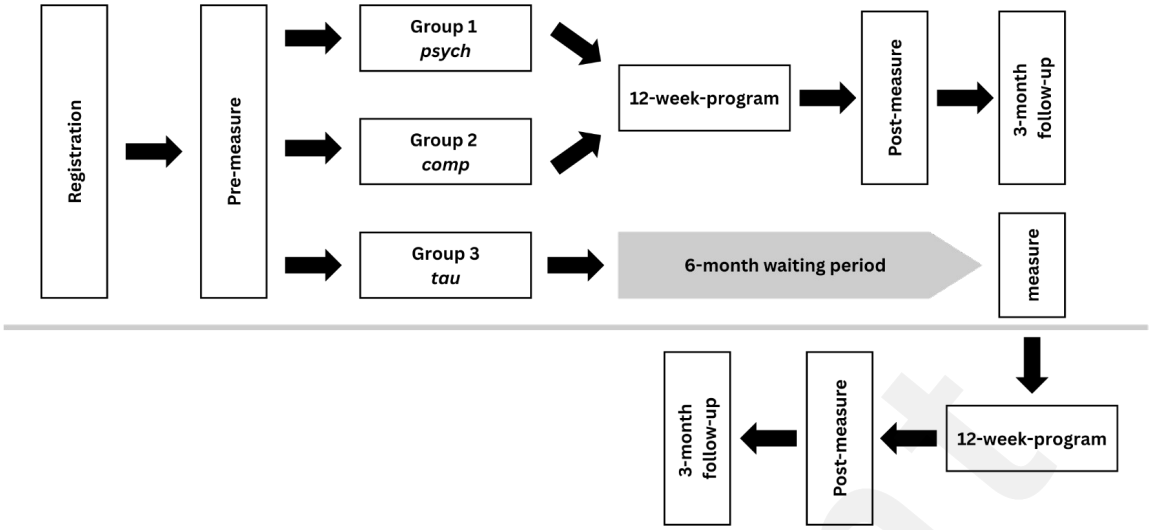
Participants

The study population consists of individuals with chronic pain. Inclusion criteria are as follows: (a) chronic pain defined as pain in one or more anatomical regions persisting for more than 3 months and associated with significant emotional distress or functional disability; (b) minimum age of 18 years; and (c) sufficient knowledge of German. Exclusion criteria include acute suicidal ideation, uncorrected hearing impairments, significant language barriers, and current participation in psychotherapy.

Study Design

This is an interventional, randomized, controlled trial with three parallel arms, including a non-blinded tau group. Assessment points include baseline measurement at registration (T0), post-intervention measurement after program completion (T1), and a three-month follow-up (T2). The two experimental groups receive access to the digital self-help program *CHRONIC*. The tau group receives access after a waiting period of 6 months. The groups differ in the type of feedback received after each module: participants in the *experimental group psych* (EGpsych) receive individualized feedback written by the study team, whereas participants in the *experimental group comp* (EGcomp) receive standardized, template-based, computer-generated feedback. The study design is illustrated in Figure 1. Ethical approval was granted by the Ethics Committee of the Hannover Medical School (approval ID: 11563_BO_S_2024), and the trial was prospectively registered in the German Clinical Trials Register (DRKS ID DRKS00036901) on July 17, 2024.

Figure 1. Study design.



Sample size

An a priori power analysis was conducted in G*Power (version 3.1.9.7) for a repeated-measures ANOVA targeting the group × time interaction with 3 groups and 3 measurements (T0, T1, T2). We assumed an effect size of f = 0.20, α = .025 and statistical power = .95. The correlation among repeated measures was set to r = .50 and the nonsphericity correction to ε = 0.75 to account for plausible deviations from perfect sphericity. Under these assumptions, G*Power yielded a minimum required sample size of N = 114. To account for dropout, a target sample size of N = 200 was prespecified. This inflation reflects the increased risk of dropout in the TAU control group due to the six-month waiting period and the typical loss to follow-up in digital health trials. The larger sample ensures robustness against assumption violations and maintains adequate power.

Procedure and Recruitment

Participants are recruited via digital platforms (e.g., online forums, patient advocacy groups) as well as through direct cooperation with healthcare providers (e.g., pain clinics, physiotherapy practices, orthopedic clinics). Interested individuals are provided with detailed study information through an online portal, including an introductory video explaining the intervention. Support is available via a dedicated project email address. Upon registration and consent, participants undergo an onboarding process to assess eligibility and complete the baseline measurement (T0).
All assessments are administered digitally through the intervention platform. Participants are pseudonymized using computer-generated codes. The link between codes and participant information is stored separately in an encrypted file accessible only to the study team. This file allows re-identification solely for data deletion upon participant request, ensuring compliance with data protection standards.

CHRONIC Web Application

“CHRONIC” is a digital web-based intervention grounded in a combination of Acceptance and Commitment Therapy [4] and CBT. The program is further enhanced by the integration of mindfulness-based strategies and physiotherapeutic components, drawing on practical experience in the treatment of patients with chronic pain. Over the course of a 12-week self-help program, users are guided to develop a deeper understanding of their pain condition and of themselves, foster pain acceptance, improve emotional regulation and stress management, and define concrete personal goals for future behavior and life planning. Core components include strengthening personal

responsibility and building internal and external resources. From a physiotherapeutic perspective, the intervention promotes physical functionality through posture training, a full-body exercise program (adaptable in intensity), and practical knowledge for maintaining safe gait and stance to support current and future mobility. Mindfulness exercises are interspersed between modules to sharpen external awareness and enhance attentional control. Table 1 provides an overview of the program modules and their respective contents. To ensure clinical relevance and theoretical coherence, the content and sequencing of the CHRONIC modules were derived from a combination of empirically supported treatment principles and clinical experience in treating individuals with chronic pain. The psychotherapeutic modules are grounded in core components of Acceptance and Commitment Therapy (ACT), whose effectiveness in digital self-help formats for chronic pain has been demonstrated, for example, in the evaluated digital health application "HelloBetter Chronischer Schmerz". Complementing this, the physiotherapeutic components were selected based on real-world clinical demands frequently observed in outpatient settings: physical deconditioning, insecure movement patterns, and fear of movement. To address these, CHRONIC includes functional exercises (adaptable in intensity), postural guidance, and educational input on safe movement execution, aiming to promote mobility confidence and bodily self-efficacy. Mindfulness-based exercises interwoven throughout the program serve to enhance interoceptive and attentional awareness, supporting both psychological flexibility and functional engagement. Overall, the selection of modules reflects a biopsychosocial rationale: each session builds on previous content and targets a distinct yet interrelated aspect of pain coping. This structure allows participants to develop adaptive cognitive, emotional, behavioral, and physical strategies in a coherent, cumulative manner over the course of the 12-week program.

The program is structured so that participants complete one psychotherapeutic unit per week, followed directly by either a physiotherapy or mindfulness-based unit. Each weekly session is designed to take approximately 50 minutes, with the intention that users apply the learned content between sessions in their everyday lives. Users can revisit all materials as often as they wish during the 12-week access period. The psychotherapeutic sessions are delivered via video recordings of a licensed psychological psychotherapist, who explains the core content of each session and poses interactive questions during the modules. Videos pause automatically when user input is required, and corresponding exercises are displayed on screen. Upon completion of an exercise, marked by the user, the video continues. At the end of each session, users can download their completed exercises or obtain blank worksheets for printing and future reuse. Between sessions, users complete brief self-assessments on pain-related impairment, mood, and activity level. These data are visualized in real-time on the user's personal dashboard to support self-monitoring. After each module, participants in the EGs receive motivational feedback – either individualized or computer-generated, depending on group assignment – delivered via the app and email shortly after session completion.

Table 1. Overview of the CHRONIC program modules.

Module	Description of content
1. Pain - and Now?	Psychoeducation on the topic of chronic pain, including an overview of the program and introduction of the assigned therapist.
2. Becoming Fully Awake.	Participants are introduced to the concept of mindfulness, which involves observing the present moment without judgment. This session focuses on cultivating the ability to consciously direct attention to the here and now.
3. Understanding Pain.	Accepting the current state of one’s condition is often perceived as counterintuitive or even unimaginable. This session explores why acceptance can nonetheless lead to long-term improvement in symptoms and overall functioning.

4. Do You Feel That Too?	Emotions are a constant part of human experience. While some are perceived as pleasant and others as distressing, this session addresses strategies for managing the full range of emotional experiences in an adaptive manner.
5. Don’t Stress Me Out.	Stress is a common experience, yet in the context of chronic pain, it can become particularly overwhelming. This session provides techniques for more effective stress regulation.
6. Bird’s-Eye View.	Defusion refers to a mental state in which thoughts and emotions are observed without becoming entangled in them. Participants learn how to develop a more distanced and less reactive stance toward internal experiences.
7. What Matters to Me.	Personal beliefs significantly influence both cognition and behavior. Conversely, engaging in actions aligned with one’s core values can help reinforce a meaningful and coherent sense of self. This session explores this bidirectional relationship.
8. Commitment of the Self.	Living a meaningful life requires ongoing commitment. This session introduces the concept of value-based goal setting and encourages participants to formulate personal commitments that support long-term well-being.
9. In the Here and Now.	People often dwell on the past or worry about the future. This session highlights the benefits of present-focused awareness and offers practical guidance for anchoring attention in the here and now.
10. The Creature of Habit.	Changing entrenched behavior patterns is inherently difficult. In this session, participants reflect on habitual behaviors and explore strategies for initiating and maintaining adaptive behavioral change.
11. Reinforcement from Within.	This session centers on personal resources – both internal and external – that contribute to resilience and psychological flexibility. Participants are encouraged to identify, sustain, and further develop these resources.
12. …and Last but Not Least.	The final session acknowledges the participants' engagement throughout the program and emphasizes the importance of continuing to invest in one’s health and well-being beyond the structured intervention.

Measurements

To measure the study objectives, the following outcomes will be captured: (a) *pain intensity*, (b) *pain impairment*, (c) *quality of life*, (d) *physical and emotional functionality*, (e) *pain acceptance*, (f) *anxiety and depressive symptoms*. A list of measurement instruments is presented in Table 2.

Table 2. Measurement instruments.

Questionnaire	Pre	Post	Follow-up
Basic data			
Demographics (age, sex, education, etc.)	x		
Primary outcomes			

Pain intensity & pain impairment (WHYMPI)	x	x	x
Quality of life (AQoL-8D)	x	x	x
Secondary outcomes			
Physical functionality (WHYMPI subscales)	x	x	x
Emotional functionality (WHYMPI subscales)	x	x	x
Pain acceptance (CPAQ-D)	x	x	x
Anxiety (GAD-7)	x	x	x
Depression (PHQ-9)	x	x	x

Notes WHYMPI = West Haven-Yale Multidimensional Pain Inventory [16]; AQoL-8D = Assessment of Quality of Life [17]; CPAQ-D = Chronic Pain Acceptance Questionnaire, German version [18]; GAD-7 = Generalized Anxiety Disorder Scale [19]; PHQ-9 = Patient Health Questionnaire-9, German version [20].

Primary Outcomes

Primary outcomes include pain intensity, pain-related impairment, and health-related quality of life. To assess pain intensity and impairment, the German version of the West Haven-Yale Multidimensional Pain Inventory (WHYMPI/MPI) will be used [16]. The WHYMPI is a comprehensive 52-item questionnaire comprising 12 subscales that assess the multidimensional impact of chronic pain on patients' daily lives. It includes scales for pain severity, pain-related interference, perceived life control, and affective distress. The inventory also evaluates patients' perceptions of significant others' responses to their pain (e.g., solicitous or negative behaviors) and the frequency of engagement in everyday activities, including a general activity level score. Responses are recorded on a 7-point Likert scale.

Health-related quality of life will be measured using the German version of the Assessment of Quality of Life – 8 Dimension (AQoL-8D) instrument [17]. The AQoL-8D is a validated multi-attribute utility measure consisting of 35 items that cover eight key dimensions of quality of life: independent living, happiness, mental health, coping, relationships, self-worth, pain, and senses. Response options vary between 4-point and 6-point scales depending on the domain. The AQoL-8D yields a psychometric score that reflects overall health-related quality of life.

Secondary Outcomes

Secondary outcomes include physical and emotional functioning, patients' global improvement, pain acceptance, anxiety, and depressive symptoms.
To assess pain acceptance, the German version of the Chronic Pain Acceptance Questionnaire (CPAQ-D) will be used [18]. The CPAQ-D contains 20 items across two subscales: "Activity Engagement" and "Pain Willingness". Responses are given on a 7-point scale, with higher scores indicating greater acceptance of chronic pain. Depressive Symptoms will be assessed using the Patient Health Questionnaire-9 (PHQ-9) [20] and the Generalized Anxiety Disorder 7 (GAD-7) for anxiety symptoms [19]. The PHQ-9 includes 9 items that correspond to the DSM-IV criteria for depression and are rated on a 4-point scale (0 = not at all to 3 = nearly every day). Severity is

categorized based on the total score (0–4 = minimal, 5–9 = mild, 10–14 = moderate, 15–19 = moderately severe, ≥20 = severe depression). The GAD-7 comprises 7 items rated on a 4-point scale and assesses the frequency of anxiety symptoms over the past two weeks. Severity categories include minimal, mild, moderate, and severe anxiety. Patients' subjective global improvement and perceived functionality are additionally derived from specific subscales of the WHYMPI, including general activity level and affective distress, as indicators of change in physical and emotional functioning over the course of the intervention.

Statistical analysis

All statistical analyses will be conducted using the statistical software R (version 4.5.0). First, all primary and secondary outcomes as well as participant demographics and baseline characteristics will be analyzed descriptively (means, standard deviations, frequencies), both for the total sample and stratified by study group (EG*psych*, EG*comp*, and TAU). To examine intervention effects, repeated measures analyses of variance (rmANOVAs) will be conducted with time (T0 = pre, T1 = post, T2 = follow-up) as a within-subject factor and group (psych vs. comp vs. control) as a between-subject factor. When a significant main or interaction effect is detected, Holm-corrected post-hoc tests will be applied to determine the specific time points and group differences, while controlling for the family-wise error rate. In case assumptions for ANOVA are violated, appropriate non-parametric alternatives or robust methods will be considered.

All analyses will be conducted both according to the intention-to-treat (ITT) and per-protocol (PP) principles. The ITT approach includes all randomized participants in the groups to which they were assigned, regardless of adherence to the intervention, thereby maintaining the benefits of randomization and reflecting real-world applicability. In contrast, PP analyses include only those participants who fully adhered to the intervention protocol, offering insights into the intervention's efficacy under ideal conditions. Comparing both approaches helps assess the robustness and generalizability of findings. Subgroup analyses may be conducted to explore whether intervention effects differ across specific participant characteristics, such as baseline pain severity, age, or gender. These analyses can help identify moderators of treatment effects and thereby contribute to a more personalized understanding of intervention efficacy. Moderator analyses will be exploratory in nature and interpreted with caution due to limited power. Missing data will be handled using multiple imputation, which estimates missing values based on the observed data and includes random variation across imputations. This approach reduces bias and increases the statistical power compared to complete case analyses, as it uses all available data while accounting for uncertainty introduced by the missingness [21].

Discussion

Digital health interventions have gained considerable attention in recent years as effective tools for managing chronic pain. These interventions offer scalable and accessible treatment options that can complement traditional face-to-face care. Recent evidence supports their potential to reduce pain intensity, enhance physical functioning, and improve psychological outcomes in individuals living with chronic pain [22].

Pfeifer et al. (2020) conducted a systematic review and meta-analysis evaluating mobile application-based interventions for chronic pain [13]. The study found significant improvements in pain intensity and physical function among users, highlighting the clinical relevance of mobile-supported self-management, especially in the long-term. Similarly, Mecklenburg et al. (2018) reported positive effects of a multimodal 12-week digital care program combining sensor-guided exercises, education,

and psychosocial support [23]. Participants experienced reductions in pain and improvements in physical function, with a decreased intent to undergo surgery. This illustrates the potential of multi-component digital programs to support effective long-term pain management. In addition to clinical efficacy, digital interventions can mitigate common barriers to accessing care. According to the International Association for the Study of Pain (IASP, 2022), digital psychosocial interventions allow for flexible, asynchronous delivery of care, which benefits individuals with limited mobility, caregiving responsibilities, or restricted access to specialized providers [24]. Given its biopsychosocial foundation and multimodal structure, CHRONIC is particularly well-suited to address the complex needs of individuals with chronic pain in a scalable and accessible format.

Despite these advantages, challenges remain. Sustained engagement, digital literacy, and the seamless integration of these tools into existing healthcare systems require further development. Future studies should address long-term effects, cost-effectiveness, and personalization strategies to maximize benefits. In summary, digital health interventions represent a promising and evidence-based approach to chronic pain management. By leveraging technology to deliver psychological and behavioral interventions, they can improve patient outcomes, extend access to care, and support sustainable healthcare delivery models. Continued innovation and rigorous evaluation will be essential to unlocking their full potential. To our knowledge, this is the first study to systematically examine a combined psycho- and physiotherapeutic digital training program for individuals with chronic pain in Germany. Unlike existing programs that focus exclusively on either psychological or physical domains, this approach addresses both dimensions of chronic pain simultaneously - reflecting current biopsychosocial treatment recommendations. In summary, the findings of this randomized controlled trial are expected to contribute to the development of integrated, scalable, and interdisciplinary care models in the digital health sector.

Limitations

This study protocol outlines the planned design and methodology of a randomized controlled trial evaluating the digital intervention CHRONIC. Several limitations should be considered in advance of implementation. First, the monocentric design may limit the generalizability of findings to broader populations or other clinical settings. Second, the digital format, while enhancing scalability and accessibility, may exclude individuals with limited internet access or low digital literacy, potentially introducing a selection bias. Third, all outcome measures rely on self-reported data, which may be affected by recall bias, social desirability, or inaccurate self-assessment. Fourth, participants are recruited via self-registration and online platforms, which may result in a self-selection bias favoring more motivated or health-literate individuals. Lastly, although the trial compares two feedback modalities and a waitlist control, it does not include a non-digital active control group, which limits the ability to draw conclusions about the relative efficacy of digital versus traditional multimodal interventions.

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LF: Methodology; Writing – review & editing.

AL: Methodology; Writing – review & editing.

TZ: Supervision; Writing – review & editing; Funding acquisition.

Conflicts of Interest

None declared.

Abbreviations

ACT: Acceptance and Commitment Therapy
AQoL-8D: Assessment of Quality of Life – 8 Dimension
CBT: Cognitive behavioral therapy
CPAQ-D: Chronic Pain Acceptance Questionnaire – German Version
DRKS: German Clinical Trials Register
EGcomp: experimental group with computer-generated feedback
EGpsych: experimental group with individualized psychological feedback
GAD-7: Generalized Anxiety Disorder 7-Item Scale
ITT: intention-to-treat
PHQ-9: Patient Health Questionnaire-9
PP: per-protocol
RCT: randomized controlled trial
TAU: treatment as usual
WHYMPI: West Haven-Yale Multidimensional Pain Inventory

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Supplementary Files

Figures

Study design.