Digital Self-Help for Chronic Pain and Depression: Development and Evaluation of the Lenio/COGITO Program in a Randomized Controlled Trial

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Introduction and Scientific Background

Chronic pain is among the most common health complaints worldwide, with some studies estimating that it affects more than 30% of all adults (Cohen, Vase and Hooten, 2021). It causes not only physical suffering but is often associated with considerable psychosocial and health policy consequences for both individuals and society (Gaskin and Richard, 2012). A particularly relevant aspect is the high comorbidity with depressive disorders: estimates suggest that up to 85% of patients with chronic pain meet the criteria for at least mild depressive symptoms (Meda *et al.*, 2022). This constellation often leads to a bidirectional reinforcement of both conditions and poses a particular challenge for diagnosis and treatment (Hooten, 2016; Qiu, Ma and Huang, 2022).

Despite these findings, psychological care for people with chronic pain remains inadequate (Goldsmith *et al.*, 2023). Psychotherapeutic interventions, particularly cognitive behavioural therapy (CBT) and newer CBT-based approaches such as acceptance and commitment therapy (ACT) or mindfulness-based procedures, are considered evidence-based components of multimodal pain management (Becker *et al.*, 2018). However, in practice they are rarely implemented on a broad scale (Becker *et al.*, 2017). Goldsmith and colleagues identify barriers, especially patient-related factors such as limited mobility, low treatment expectations, motivational difficulties, or a lack of fit between personal beliefs and the therapeutic concept (Goldsmith *et al.*, 2023).

Against this backdrop, digital health applications are becoming increasingly important. Internet-based self-help programmes within the scope of so-called internet-based cognitive behavioural therapy (iCBT) offer a low-threshold, flexible, and often cost-free supplementor alternative to in-person psychotherapy (Carlbring *et al.*, 2018). They can be used regardless of location and time, making them accessible to structurally disadvantaged or less mobile target groups. They also offer a high degree of anonymity, which is therapeutically and health-policy relevant in light of the persistent stigma surrounding mental illness (Schröder *et al.*, 2016).

The COVID-19 pandemic coincided with the development and evaluation of our programme Lenio and, due to contact restrictions, social isolation, and the increased infection risk particularly for older and chronically ill individuals, significantly impeded access to conventional face-to-face therapies. As a result, the need for easily accessible,

location-independent digital services increased. Such services proved helpful and have found a lasting place in healthcare provision (Wong *et al.*, 2020).

Meta-analyses demonstrate the effectiveness of internet-based interventions for various mental disorders (Williams *et al.*, 2020; Tao *et al.*, 2023). Studies show comparable effect sizes between therapist-guided iCBT and traditional face-to-face therapy for depression, anxiety disorders, or somatic conditions such as chronic pain (Mehta *et al.*, 2022). Purely self-guided programmes, i.e. interventions without therapeutic support, generally perform worse in terms of adherence (Terpstra *et al.*, 2021).

One area that remains under-researched is the digital provision of care for individuals with both chronic pain and depressive symptoms. Most existing e-mental-health programmes focus either on affective or on somatic symptoms; a systematic integration of both aspects within a self-guided, cost-effective, and low-barrier intervention is largely absent.

The development and clinical evaluation of such a programme was the focus of the present randomised controlled trial. We developed the online programme Lenio, which combines modern CBT, ACT-based therapy, and mindfulness exercises in a programme tailored to chronic pain and comorbid depression, together with the companion app COGITO, where users could activate the "Chronic Pain" programme package.

In contrast to digital health applications (DiGA) regulated under §33a SGB V in Germany, which can be prescribed by physicians and reimbursed by health insurance, Lenio is not intended as a reimbursable medical device but as a low-threshold, prevention-oriented self-help programme. This deliberate distinction made it possible to evaluate an intervention that functions independently of medical diagnosis, prescription, or healthcare provision, and thus also reaches people outside formal healthcare systems or those who do not access such services for structural, motivational, or stigma-related reasons.

Study Objective

The aim was to examine the extent to which a newly developed digital self-help programme, in combination with a smartphone app for daily use, is feasible, accepted, and effective in simultaneously alleviating chronic pain and depressive symptoms. The primary endpoint was pain-related interference in daily life ("pain interference"), assessed using the validated German Pain Questionnaire (Deutscher Schmerzfragebogen, DSF), which captures limitations in everyday activities, leisure, and work. Calculations were based on the von Korff Disability Score. Secondary endpoints included depressive symptoms

(measured using the BDI-II and PHQ-9), pain intensity (measured using the von Korff Index), and participants' subjective evaluation of the intervention.

Methods

Study design and procedure

In a three-arm randomised controlled trial (RCT), participants completed online surveys at three time points: at baseline (t0), after 8 weeks (post, t1), and after 16 weeks (follow-up, t2). The study compared the effects of the internet-based self-help intervention Lenio/COGITO (intervention group, IG), an active control group (ACG) with access to a predecessor version of the COGITO app without pain-specific content (MCT & More), and a waitlist control group (WCG) receiving treatment-as-usual. Participation was pseudonymised, and all data were processed in accordance with data protection regulations.

Participant recruitment and criteria

Participants were recruited via clinics, self-help groups, and social media (e.g., Facebook, Google Ads). Data collection took place exclusively online. Inclusion criteria were: the presence of depressive symptoms (BDI-II $\geq$ 14 or PHQ-9 $\geq$ 10), chronic pain (DSF $\geq$ 4), age between 18 and 75 years, sufficient German language skills, internet access, and access to suitable hardware. Exclusion criteria included schizophrenia, bipolar disorder, substance use disorder, or acute suicidality. The final sample consisted of 263 participants.

Intervention and data collection

During the 8-week intervention phase, the IG had access to the internet-based self-help programme Lenio as well as the accompanying self-help app COGITO. The ACG used the app MCT & More, an earlier version of COGITO originally designed for people with depressive symptoms and without pain-specific content. The WCG received treatment-as-usual. Outcomes measured included pain interference (primary endpoint), depressive symptoms, and pain intensity (secondary endpoints), as well as participants' subjective evaluations of the intervention. Data were collected using Qualtrics®.

Instruments

The main instrument was the DSF (German Pain Questionnaire) to assess pain-related interference in daily life. Additional questionnaires measured depressive symptoms (BDI-II, PHQ-9), pain intensity, catastrophising, avoidance, self-efficacy, perceived injustice,

and quality of life (including PCS, FABQ, WHOQOL-BREF). Satisfaction with the intervention was assessed using the ZUF-8.

Results

A total of 263 individuals participated in the randomised controlled trial and were assigned in a 1:1:1 ratio to one of three groups: the IG (n = 97), which used Lenio together with the companion app COGITO; the ACG (n = 94), which had access to the app MCT & More without pain-specific content; and the WCG (n = 72), which received treatment-as-usual. The mean age of participants was 43.7 years (SD = 13.7). The sample was predominantly female (approximately 80%). There were no significant differences in demographic or psychometric baseline variables between the groups, indicating successful randomisation. Participation rates in the online assessments were 73% at post-assessment and 68% at follow-up.

Average use of Lenio/COGITO fell short of recommendations: on average, only 1.95 of the 10 available modules were completed (SD = 2.85). Usage intensity averaged 3.3 on a scale from 1 (“used only once”) to 7 (“used daily”), corresponding to less than once per week. This reflects known challenges for internet-based self-help programmes with regard to adherence. Although various measures to encourage programme use were implemented (e.g., reminder emails, app notifications, gamification elements in COGITO), the recommended frequency of at least two modules per week was achieved only by a minority of participants.

Primary and secondary endpoints

In the intention-to-treat (ITT) analyses, the primary endpoint of pain-related interference (von Korff score) showed a significant group difference with a small effect size (η^2 = 0.023) in favour of the ACG compared with the IG (p = .022) — however, this difference was not maintained at follow-up. For depressive symptoms (BDI-II), in contrast, the IG showed a significant advantage over the WCG at both post-assessment (p = .011, η^2 = 0.039) and follow-up (p = .025, η^2 = 0.028). The effect was particularly pronounced for the somatic-affective subscale of the BDI-II (η^2 = 0.035).

Compared with similar studies, Lenio/COGITO falls within the lower to mid-range of effectiveness. For example, in a review of internet-based pain management programmes,

Buhrman and colleagues found an average pain reduction with a small to medium effect size (Hedges' g = –0.33) (Buhrman, Gordh and Andersson, 2016)

Within-group changes

Significant improvements in depressive symptoms (BDI-II and PHQ-9) and quality of life (WHOQOL-BREF) were observed in all three groups (IG, WCG, ACG). In the IG, a significant reduction in pain interference was observed only at follow-up.

Subjective evaluation

Overall, subjective evaluations of the programme were positive. According to the ZUF-8, more than 90% of respondents reported high satisfaction with Lenio, and about two-thirds found the programme helpful. Nearly 75% stated that they would use Lenio again or recommend it to others. Nevertheless, more than half of participants reported having difficulties motivating themselves to use the application. The majority rated the content as understandable, useful, and applicable to everyday life.

Moderation analyses

Two significant moderator effects were identified: older participants benefited above average from Lenio compared with the WCG, and individuals with a higher comorbidity burden (measured using the Web Screening Questionnaire, WSQ) showed a greater reduction in depressive symptoms in the IG compared with the WCG.

Discussion

This study examined whether the online self-help programme Lenio, in combination with the COGITO app, can alleviate both pain and depressive symptoms in individuals with chronic pain and comorbid depression. The outcomes aligned with our hypotheses only partially. Although positive effects on pain and depressive symptoms were observed over time, these were not consistently greater than in the two control groups. Notably, the ACG achieved even better short-term results for pain intensity than Lenio/COGITO—an effect that did not persist at follow-up. However, Lenio/COGITO performed better than the WCG for depressive symptoms, particularly for the somatic-affective subscale of the BDI-II. Improvement in these symptoms could, in the long term, also contribute to pain reduction. So-called "sleeper effects" have been reported in other studies as well (Moritz *et al.*, 2014). Such developments, however, can only be captured over a longer observation period, which was beyond the scope of the present study.

The stronger short-term reduction in pain intensity in the ACG may be attributable to its intervention, the predecessor app MCT & More. It is possible that the broadly designed Lenio programme, combined with the additional daily use of the COGITO app, was overwhelming for some users and thus impaired adherence. Recent research suggests that combining multiple media and techniques may overwhelm participants, reducing adherence and symptom improvement, whereas a more focused approach, as seen in the ACG, might be more effective (Moritz, Weidinger and Schmotz, 2024). Average use was clearly below the recommended frequency, which may have diminished the overall effect of the intervention.

Given the limited impact of Lenio/COGITO on pain interference, our reflection on the programme also raised the question of the advantages and disadvantages of unguided online programmes. A 2019 meta-analysis found that internet-based interventions for chronic conditions are more effective when guided by a therapist. This is applicable particularly for depressive symptoms, where guided programmes achieved moderate effects, while self-guided programmes produced only small effects (Mehta, Peynenburg and Hadjistavropoulos, 2019). For example, evaluation of the recently developed group-based guided online programme *iSelf-help* showed that, for patients with chronic non-malignant pain, it was clinically no less effective than conventional face-to-face therapy in reducing pain-related interference and associated psychological symptoms such as anxiety, depression, and stress (Hale *et al.*, 2025).

A recent study on team-supported versus self-guided iCBT for chronic conditions found significant improvements in depression and anxiety in both groups, with no notable differences between them. (Mehta *et al.*, 2022). Surprisingly, the self-guided group even benefited more in some respects: more participants reported at least a 30% reduction in depressive symptoms compared with the guided group.

Paganini et al. (2019) also examined the cost-effectiveness of guided and unguided online programmes for reducing chronic pain. Unguided ACT programmes demonstrated good efficacy at lower cost, whereas guided programmes produced slightly higher effects but also higher costs. The overall probability of cost-effectiveness was actually greater for the self-guided version.

These findings support the assumption that low-threshold, self-guided programmes can play a central role in broad healthcare provision, particularly where resources for personal

guidance are lacking. Anonymity, flexibility, and data protection are further advantages of unguided online therapy (Karyotaki *et al.*, 2021). However, the literature repeatedly identifies poor adherence as one of the greatest challenges for unguided interventions (Kelders *et al.*, 2012). In the use of Lenio, many participants likewise reported difficulties in engaging with the intervention regularly and completing it in full, which may have reduced its effectiveness. In this context, the use of artificial intelligence (AI) is increasingly coming into focus in research.

AI-based tools such as chatbots or "conversational agents" can offer easily accessible, location-independent mental health support that is often available around the clock. Initial studies indicate that such systems can help reduce affective symptoms such as depression or anxiety, and may also be effective in treating chronic pain (Dingler *et al.*, 2021). Of particular relevance for programmes like Lenio is the ability of AI-supported systems to dynamically adapt content to individual usage patterns and the current emotional state of users. This could substantially enhance both personalisation and adherence, as well as long-term engagement (Yasukawa *et al.*, 2024).

Initial studies of the *Wysa* chatbot for individuals with chronic pain and psychological distress have shown high levels of use and adherence, as well as significant improvements in depressive and anxiety symptoms within a subsample (Meheli, Sinha and Kadaba, 2022; Sinha, Cheng and Kadaba, 2022). These findings suggest that AI-based self-help tools like *Wysa* have the potential to reduce emotional distress in patients with chronic pain and address gaps in care. Future research should particularly evaluate safety and effectiveness with respect to reducing pain interference and intensity. In this light, it may also be worth considering the implementation of a chatbot function in Lenio to enhance adherence and user retention.

However, the significant ethical and technical challenges in this area should not be underestimated. Limited empathic responsiveness (Li *et al.*, 2023), potential data protection risks (Williamson and Prybutok, 2024), and the timely detection and appropriate handling of crisis situations (Elyoseph and Levkovich, 2023) are potential limitations of using AI in digital mental healthcare.

Concluding, this study showed that the Lenio online programme, in combination with the COGITO app, can effectively reduce depressive symptoms in individuals with chronic pain. However, no significant reduction in pain interference was observed across all

groups. Surprisingly, the ACG (MCT & More) achieved better short-term pain reduction, which may indicate greater user-friendliness and lower complexity of the intervention. The findings highlight the potential benefits of low-threshold, self-guided interventions—particularly for older users, according to moderation analyses. The effect on pain may emerge only in the long term, requiring extended observation. The limited adherence of unguided programmes remains a challenge. In this context, AI-assisted programmes are gaining attention: they offer personalised, flexible support and show initial success in reducing depressive symptoms in chronic pain patients. Nevertheless, future research should specifically examine their safety and effectiveness in reducing pain interference and intensity and critically address ethical and technical issues such as data protection and crisis detection.

Limitations of this study include the relatively low usage rate of the programme, reliance solely on self-reported data, only moderate response rates, and the short follow-up period. Further research is required to better capture long-term effects and underlying mechanisms.

Outlook

The results of this study demonstrate that Lenio/COGITO is particularly effective in reducing somatic depressive symptoms, making it a potentially relevant addition to the conventional care of patients with chronic pain. As a low-threshold, anonymously accessible self-help option, Lenio could in the future serve as a bridge to regular psychotherapy—especially for individuals facing access barriers or with low treatment readiness. However, the limited use by many participants highlights the need for adjustments in terms of structure, interactivity, and individual tailoring.

Future research should place greater emphasis on investigating long-term outcomes, for example through multi-month follow-up assessments or longitudinal study designs. Moreover, developing personalised intervention elements appears promising for improving adherence and better addressing the heterogeneity of chronic pain. Possible approaches include expanding modules to address specific pain types or comorbid conditions, as well as integrating AI-supported features such as interactive chatbots, real-life reminder functions, or personalised feedback components.

Article

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Two in one: a randomized controlled trial on an internetbased intervention (Lenio) for management of both chronic pain and depressive symptoms

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The high prevalence of chronic pain and comorbid depression, along with their negative impacts on individuals and society, highlights the need for accessible and effective interventions. This study examined the feasibility, efficacy, and acceptability of Lenio, an Internet-based self-help intervention, combined with the COGITO smartphone application for managing these conditions. The randomized controlled trial involved an intervention group (IG) using Lenio and COGITO, an active control group (ACG) using a transdiagnostic app, and a wait-list control group (WCG) receiving usual treatment. Lenio incorporates cognitive behavioral therapy and third-wave techniques, supported by COGITO's gamified daily exercises to enhance adherence. Across 263 participants assessed at three intervals over 16 weeks, the IG showed significant improvement in somaticaffective depressive symptoms compared to the WCG post-intervention and both control groups at follow-up. However, the ACG outperformed the IG in managing pain at post-intervention though these effects did not persist until follow-up. The interventions were well-received and feasible, with older participants benefiting more from the Lenio/COGITO combination. Lenio and COGITO could bridge gaps to conventional therapy, potentially easing pain by enhancing psychological well-being and coping strategies. Future studies should investigate tailored interventions for chronic pain and their long-term effectiveness.

Introduction

Pain and psyche

The fact that the body and mind mutually influence each other is not a new insight but has been suspected since ancient times. In line with this, studies have found that chronic pain and comorbid depression influence each other (1). First, on a neuronal level, brain areas and neuronal pathways related to pain are often implicated in the experience of negative emotions or depression (2). Added to this, increased cognitive engagement (e.g., brooding, focus on pain), self-esteem problems, and catastrophizing are frequently seen in individuals affected by chronic pain (3). These thinking patterns become entrenched over time, thus compromising mental health and intensifying the pain experience (3). Although the interactions between chronic pain and psychological well-being have been recognized for a long time and psychotherapy is increasingly acknowledged as part of the gold-standard multimodal treatment (4), psychoeducational and psychotherapeutic interventions are still rarely utilized in conventional pain management due to significant treatment gaps (5). Consequently, many patients with chronic pain are left to manage their symptoms alone (6), resulting in up to 85% of these individuals experiencing depressive symptoms in addition to their pain (7). Studies show that chronic pain is one of the most common reasons people seek medical support, with a global prevalence of up to 24% (8). Pharmacological treatments are often used as a standalone approach for managing both chronic pain and depression. However, while medication may alleviate pain to some extent, it does not address the underlying psychological and behavioral factors contributing to the chronic nature of these conditions (9, 10).

Psychotherapeutic treatment of chronic pain

Research has shown considerable improvement in chronic pain following psychotherapeutic interventions. A meta-analysis by Veehof et al. (11) revealed that acceptance- and mindfulnessbased interventions led to notable decreases in chronic pain intensity and interference compared to control groups receiving no treatment, medical treatment as usual, or educational and support interventions. Cognitive behavioral therapy (CBT) and its third wave techniques are considered the gold standard in psychotherapeutic treatment of individuals with chronic pain (12, 13). Despite this strong evidence, psychotherapeutic intervention in pain is still the exception rather than the rule (6, 14). Many people with chronic pain are themselves unaware of the connection between pain and psychological factors (15). Furthermore, affected people often struggle with low self-efficacy and depressive symptoms, which can make it difficult for them to take initiative and seek therapy (16). Immobility can also be a factor for pain patients, making it more difficult for them to access healthcare facilities, hospitals, and therapists (17, 18).

These arguments underscore the need for low-threshold, accessible, and effective treatment options that meet the needs of people with chronic pain and comorbid depression.

Internet-based self-help programs

Due to the inherent flexibility and anonymity of Internet-based interventions, compliance in studies is usually high (19, 20). Internet-based programs can be offered unguided (self-help) or guided (e.g., by a

therapist). A meta-analysis by Carlbring et al. (21) showed that guided Internet-based interventions for psychiatric and somatic disorders (e.g., OCD, anxiety, fatigue, chronic pain) have a similar effect size to conventional face-to-face therapy. If the main drawback of unaccompanied interventions—adherence to the program (22)—is addressed, they can provide an alternative to conventional therapy in the treatment of chronic pain (21, 23, 24) and are somewhat superior to guided interventions in terms of resource efficiency and anonymity (20).

Self-help programs for chronic pain

Buhrman and colleagues conducted a systematic review of Internet-based interventions aimed at addressing chronic pain and concluded that these programs have a modest impact on the reduction of pain intensity (Hedges's g = − 0.33 (25)). To the best of our knowledge, however, there is currently no freely accessible, Internet-based self-help program specifically designed for the treatment of chronic pain and comorbid depressive symptoms in Germany. This led us to research and develop such an intervention.
In a pilot study, Miegel and colleagues (26) conducted an evaluation of a guided Internet-based intervention against depression called NOVEGO in people with chronic pain. Significant reductions in depressive symptoms with small to moderate effect sizes emerged in the NOVEGO group compared to the wait-list control group (h_p^2= 0.043). However, improvements in pain intensity were only evident among a subgroup, including those experiencing pain in their upper back or hands. Thus, there is a need for an Internet-based program that specifically caters to the unique requirements of patients dealing with chronic pain and comorbid depressive symptoms. These requirements include accessibility for patients with limited mobility, flexibility to adapt treatment to the patients' schedules, and anonymity to reduce stigma or hesitation in seeking help. Furthermore, such an intervention should offer tailored psychoeducational content that addresses the interaction between chronic pain and psychological factors and offers evidence-based techniques, particularly cognitive behavioral and mindfulnessbased approaches, to improve coping strategies and self-efficacy. Our intervention, Lenio and the accompanying smartphone application COGITO, aim to address these needs by providing a low-threshold, self-paced Internet intervention designed specifically for this target group.

The objective of the present study was to evaluate the feasibility, efficacy, and acceptance of the Internet-based self-help intervention Lenio combined with COGITO in addressing the particular requirements of people with chronic pain and comorbid depressive symptoms, which include accessibility, flexibility, and tailored psychoeducational content.

Methods

Study design

In this three-armed randomized controlled trial (RCT) with three measurement time points, an online assessment was conducted at baseline (t0), followed by an 8-week online post assessment (t1) and a 16-online-based follow-up assessment (t2). The design allowed for the exploration of underlying mechanisms by comparing three different treatment approaches—an intervention group (IG) receiving Lenio/COGITO, a waitlist control group (WCG) receiving treatment as usual, and an active control group (ACG) receiving an alternative app—and their effects over time. Participants provided informed consent through the web platform during the baseline assessment. Throughout the study, no personally identifiable information was collected, and participants were asked to create a pseudonymous email address (participants were provided instructions for this) and a personal code-word. All collected data were pseudonymized and securely stored electronically on a password-protected computer. Participants had the option to request the deletion of their data by providing either their code-word or their pseudonymized email address. At the end of the post-assessment period, participants in the IG, WCG, and ACG were provided with a gift card for various online shops as an incentive and then also received access to Lenio and the COGITO app. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki. The study was registered at the German Clinical Trials Register (DRKS00026722). The local psychological ethics committee at the Center for Psychosocial Medicine, University Medical Center Hamburg-Eppendorf (Germany), approved the study project (approval number: LPEK-0078a).

Participant recruitment

Participants were recruited from inpatient and outpatient clinics in Germany. Additionally, study details and links were shared through relevant social media groups, such as groups for chronic pain. A targeted advertising campaign was implemented using Facebook/Instagram , and Google ads. Further recruitment sources included self-help groups, Internet forums, websites, newsletters of health insurance companies/associations, and various social media platforms (Instagram, Reddit, Twitter, YouTube, LinkedIn). This approach aimed to reach not only patients already in treatment but also individuals from the wider community. Participants received comprehensive information about the study's objectives, procedures, and data protection measures at the beginning of the baseline assessment. Electronic informed consent was obtained from each participant.

Participant selection criteria

To be included in the RCT, participants had to meet the following criteria: (a) presence of depressive symptoms (Beck Depression Inventory-II (BDI-II) score ≥ 14; or Patient Health Questionnaire-9 (PHQ-9) score ≥ 10), (b) presence of chronic pain symptoms (mean score pain intensity on the German Pain Questionnaire (DSF) ≥ 4), (c) age between 18 and 75 years, (d) provision of

informed consent, (e) sufficient command of the German language, (f) willingness to participate in three anonymous online surveys, (g) willingness to use the Internetbased treatment program for a minimum of 8 weeks, and (h) access to a computer/laptop and a smartphone.

The program was designed to cater to a diverse group of patients with chronic pain and co-occurring depressive symptoms. The effects of previous diagnoses and concurrent treatment programs were analyzed through moderation analyses.

Exclusion criteria included a lifetime diagnosis of schizophrenia spectrum disorder, bipolar disorder, substance abuse disorder, or acute suicidality (assessed using an item on suicidality in the Web Screening Questionnaire; WSQ). Inclusion and exclusion criteria were assessed during the baseline assessment. Excluded participants were provided with an explanation for their exclusion and received information about alternative resources for seeking help, including telephone numbers for acute crisis situations. Data collection for the study took place in Germany from November 2021 (first baseline assessment) to August 2022 (last follow-up assessment). A total of 147 participants were excluded as they did not meet the inclusion criteria. The final sample included 263 individuals (see Figure 1).

Procedure

Data were collected at each measurement point (baseline, post,
and follow-up) using the survey software Qualtrics. During the baseline assessment, participants' sociodemographic information and psychopathological data were assessed and the participants filled out questionnaires on their cognitions and beliefs about their symptoms (see Measures section for details). After baseline, participants were randomized into one of three groups: IG, ACG, or WCG. During the 8-week intervention period, the IG used the Internet-based self-help intervention with an accompanying smartphone app and the ACG used a self-help smartphone app without pain-specific content (for more detailed descriptions, see interventions). After the 8-week intervention period, all participants received an email invitation to participate in the post assessment. They were required to enter their pseudonymous email address and personal code again to ensure accurate matching of pre-intervention and post-intervention data. This process was repeated after 16 weeks for the follow-up assessment.

During the post assessment and follow-up assessment, participants completed the same psychopathological questionnaires as those used in the baseline assessment. Additionally, participants were asked how frequently they had used the intervention ("How often have you used Lenio during the past 8 weeks?"), any side effects they experienced, and their satisfaction with the self-help intervention (see Measures section for details). The study was conducted at the Hamburg-Eppendorf University Medical Center in Germany.

Randomization

Randomization was conducted using the Qualtrics survey software following the baseline assessment. The "equal distribution" option was selected to ensure a balanced distribution among the three groups. The allocation rule was set to 1:1:1; that is, participants were assigned to each group in an equal ratio.

Sample size

The sample size calculation for an analysis of covariance (ANCOVA) with the three groups was

conducted using G*Power. The results indicated a required sample size of 246 participants, assuming an effect size of $h_p^2 = 0.06$ (moderate effect), a significance level of a = 0.05 (two-sided), and a power of 0.95. Anticipating a dropout rate of 25%, we aimed to recruit 300 participants, with 100 participants assigned to each condition. This calculation was based on the aforementioned findings from a study (26) that examined the impact on patients dealing with chronic pain of an unguided Internet-based intervention for depression that did not include pain-related content and reported small to moderate effects.

Measures

Primary outcomes

The primary outcome measure was pain interference, which encompasses the average level of impairment experienced in daily life, leisure time, and work as evaluated by the German Pain Questionnaire (DSF). The DSF is a reliable and valid self-report questionnaire and is widely used for assessing pain symptoms (27, 28). The practicality and content validity of the questionnaire have been rigorously evaluated (29). The German Pain Society advises using the DSF initially and during pain therapy as a standardized tool for quality assurance (29). It evaluates pain across multiple dimensions, such as pain location, subjective description, onset and course of pain, pain attacks, pain intensity, duration of illness, and pain-related impairment in everyday life. The DSF also captures information on previous treatments, rehabilitation clinic stays, healthcare visits, surgeries, and comorbid illnesses. Certain items assessing well-being, anxiety, and depression were excluded from the survey as these dimensions were tapped by other questionnaires (e.g., BDI-II, PHQ-9). Pain interference was calculated based on the von Korff disability score, and pain intensity (as a secondary measure) was calculated based on the von Korff index (30).

Secondary outcomes

Secondary outcome measures included depressive symptoms and pain symptom severity. Additionally, participants filled out a subjective evaluation of the intervention.

BDI-II

The BDI-II is a self-report questionnaire consisting of 21 items assessing depressive symptoms experienced over the previous two weeks (31). Scores range from 0 to 63, with higher scores indicating greater levels of depression. The BDI-II demonstrates good internal consistency, with a Cronbach's a of 0.89 (32) and has been previously used in pain patient samples (33, 34). For this study, we divided the BDI-II into two subscales based on the findings of Huang & Chen (35): somatic-affective and cognitive. This division allows for a more nuanced understanding of depression by separately examining its emotional-physical and thoughtrelated components.

PHQ-9

The PHQ-9 is a self-report questionnaire that measures the severity of depressive symptoms over the preceding week (36, 37). It consists of nine items and demonstrates high internal consistency (Cronbach's a = 0.86–0.89). Scores on the PHQ-9 range from 0 to 27, with higher scores indicating more severe depression. The sum score of the PHQ-9 was calculated for each assessment point.

Web screening questionnaire (WSQ)

The WSQ is a brief online self-report tool designed to screen for common mental disorders, including affective disorders, anxiety disorders, posttraumatic stress disorder, and suicide risk (38). Sensitivity and specificity of the WSQ vary between 0.72 and 1.00 and 0.44 and 0.77, respectively (38). The WSQ was administered at baseline, and both the sum score and cumulative values for all subscales were calculated for analysis purposes (e.g., moderation analysis).

Injustice experience questionnaire (IEQ)

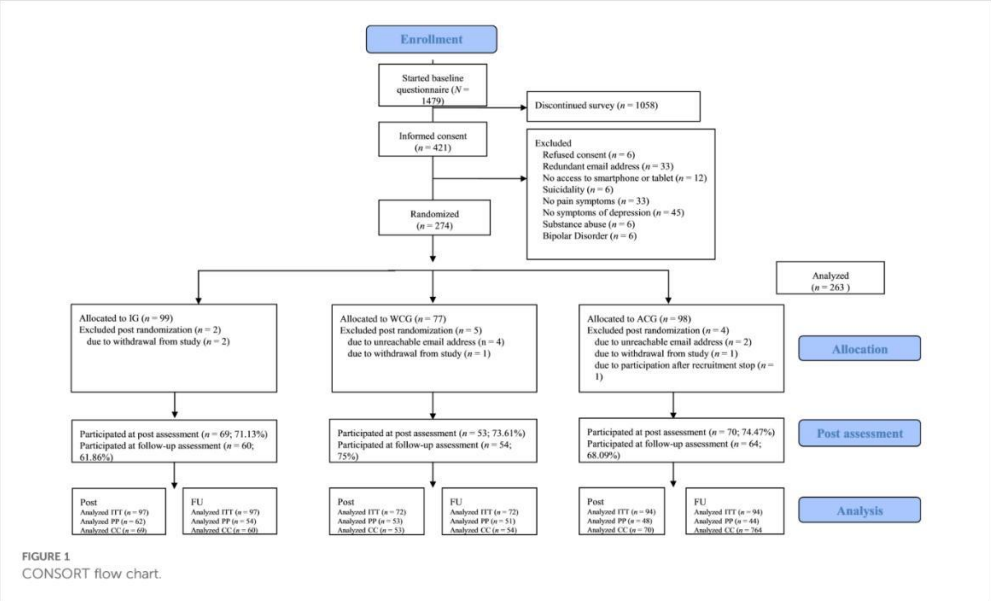

FIGURE 1
CONSORT flow chart.

The IEQ is a reliable and valid tool for assessing perceived injustice in individuals with chronic pain (3). It consists of 12 items that measure unfairness related to symptoms on a 5-point scale. The elements examined include severity of loss, blame, sense of unfairness, and irreparability of loss. A score of 30 indicates a clinically relevant level of perceived injustice. The subscales "blame/ injustice" and "severity/irreparability" and the total score were calculated at all three measuring points.

Pain catastrophizing scale (PCS)

The PCS is a reliable and valid measure of catastrophizing in patients with chronic pain. It includes 13 items assessing thoughts and feelings during pain on a 5-point scale. Quartana and colleagues found good internal consistency, with a Cronbach's a of 0.87 (39).

The PCS total score and subscores for "Rumination," "Helplessness," and "Magnification" were calculated at all three measuring points.

Fear-avoidance beliefs questionnaire (FABQ)

The FABQ was originally developed after the emergence of the biopsychosocial model for understanding low back pain by Waddell and colleagues (40). It assesses fear-avoidance beliefs about physical activity and its relation to chronic pain. It consists of 16 items rated on a 7-point Likert scale. The FABQ demonstrates excellent test-retest reliability (ICC = 0.97 (41);. For this study, the FABQ was adapted to assess general chronic pain. The sum scores for "bodily

activity" and "workload" were calculated at all three measuring points.

Pain self-efficacy questionnaire (FSS)

The Pain Self-Efficacy Questionnaire is a valid instrument for assessing self-efficacy in pain research. It measures an individual's belief in their ability to engage in activities despite pain. It has high internal consistency, with a Cronbach's a of 0.93 (42). The sum scores for the subscales "active coping" and "catastrophizing" were assessed at all three measuring points.

World health organization quality of life abbreviated version (WHOQOL-BREF)

The WHOQOL is a cross-cultural questionnaire that assesses generic quality of life. It considers an individual's perception of their life and the context of culture and value systems (e.g., personal goals). We used the global QoL item, ranging from "very poor" to "very good." The global item was assessed at all measuring points.

Subjective evaluation

The participants' subjective evaluation of Lenio and COGITO was measured using the Client Satisfaction Questionnaire (CSQ-8). Previous research indicates that the CSQ-8 has high psychometric properties, with internal consistency ranging from Cronbach's a = 0.87 to 0.93 (43). Participants rated their satisfaction on a 4-point Likert scale ("excellent", "good", "less good", "bad"), where a higher score indicated greater satisfaction. The questionnaire was modified to replace "psychotherapy" with "self-help intervention Lenio". Data on subjective appraisal of the intervention was collected through 12 questions assessing the quality, utility, and applicability of Lenio and COGITO using both open and closed response formats. The responses to the seven closed questions was assessed on a 4-point Likert scale ("not applicable" to "completely true"). The open-ended questions gathered positive and negative feedback on Lenio and requested suggestions for improvement. Additionally, participants were asked to indicate the frequency of Lenio usage during the intervention period. Subjective data were collected at post-intervention and follow-up assessments.

Interventions

During the intervention period, the IG had access to the Internet-based self-help intervention Lenio and accompanying self-help app COGITO. The ACG had access to the self-help smartphone app MCT & More, a forerunner version of COGITO intended for individuals with depressive symptoms with no specific pain-related content. The WCG received treatment as usual.

Lenio

The self-help Internet-based intervention Lenio consists of a welcome module, an introduction module, and nine modules targeting chronic pain and comorbid depressive symptoms, including dysfunctional coping. Some modules cover broader topics such as social competence and self-worth, while others focus specifically on chronic pain using techniques such as acceptance and commitment therapy (ACT), addressing specific needs, and relapse prevention.

Modules are further divided into subunits, allowing participants to prioritize topics or skip familiar ones. Users have flexibility in choosing the module order, and they can pause at any time and easily resume where they left off. Completing at least two modules per week

was recommended, with each module taking 30 to 60 minutes on average.

Upon logging in, participants are greeted with an introductory video and then proceed to the welcome module, which utilizes motivational interviewing techniques and interactive dialogues with avatars. Throughout the program, psychoeducational content, interactive exercises, worksheets, graphics, videos, and audios are provided. A moderator is available for technical assistance, responding within three workdays, but does not offer therapeutic guidance. Lenio offers an accessible and anonymous platform for individuals seeking assistance in managing their condition. To enhance its effectiveness, we recommended that Lenio be used in conjunction with the smartphone app COGITO, combining the advantages of an Internet-based innovation with the benefits of a mobile (smartphone) app (e.g., regular dispatch of notifications to increase usage).

COGITO

COGITO is a smartphone app that can be downloaded from the Google Play Store (for Android users) and the App Store (for iOS users). Download links are also available through the Lenio desktop app. In the introduction module, participants are instructed on how to use the app. COGITO enhances usability by sending daily push notifications with short exercises (maximum reading time of 30 seconds) and incorporating gamification elements, such as collecting medals for completed exercises or action scores for total weekly usage. Participants have the flexibility to choose the time and frequency of push notifications. COGITO offers exercise packages entitled Mood and Self-Esteem, Psychosis, Gambling Problems, OCD, Sleep and Chronic Pain. Participants were explicitly encouraged to activate the Chronic Pain and Mood and Self-Esteem packages, while other packages were initially deactivated but could be individually activated by users. Similar to Lenio, COGITO exercises are based on CBT and third-wave techniques. Previous randomized controlled trials (RCTs) of an earlier version of the COGITO app without a pain program package demonstrated significant improvements in self-reported depressive symptoms and increased self-esteem among regular users compared to individuals on a wait-list (44, 45).

MCT & More

The ACG had access to the MCT & More smartphone app, which is a pilot version of the COGITO app and shares a similar design and concept. MCT & More consists of three packages focusing on mood, metacognitive training (MCT), and gambling. However, it does not include pain-specific exercises. Participants in the ACG were allowed to choose the packages from which they wanted to receive exercises.

Adherence measures

To promote adherence to the recommended pace of completing two modules of Lenio per week, we implemented several supportive measures. Participants received regular reminder emails that highlighted specific modules that might be of interest to them, encouraging continued engagement with the program. Furthermore, the accompanying smartphone application COGITO sent daily push notifications prompting participants to complete an exercise. These measures aimed to foster regular interaction with the intervention while allowing participants the flexibility to proceed at their own pace.

Adherence to the recommended schedule was voluntary throughout the study, however, and depended on individual preferences. Retrospective analysis of

module completion data provides insight into the extent of participant engagement, as reported in the results section.

Statistical analysis

IBM® Statistics 29 was utilized for conducting the statistical analysis. ANCOVAs with difference scores (pre-post and pre-followup differences) as the dependent variable were calculated. Groups represented the between-group factor. The baseline score of the dependent variable served as covariate. Paired samples t-tests were employed to analyze within-group differences. Independent samples ttests were employed to compare baseline characteristics between groups.
To assess the efficacy of Lenio and COGITO, three types of analyses were performed: intention-to-treat (ITT), per-protocol (PP), and complete-case (CC). In ITT analyses, all participants with available baseline data were included in the evaluation. Missing post values were estimated using expectation maximization. PP analyses included only those participants who used the intervention as intended (at least once a week) and completed the post assessment. CC analyses included all participants who completed the post or follow-up assessment, regardless of whether the intervention was used. The CONSORT guidelines recommend performing both ITT and PP analyses in randomized controlled trials (46, 47). ITT analyses adhere to the conservative approach of good clinical practice and are considered the gold standard for evaluating treatment effects. PP analyses provide an estimation of actual efficacy under ideal conditions.
Additionally, an exploratory moderation analysis was conducted for the PP sample using the SPSS macro PROCESS by Hayes (48). This analysis aimed to identify potential moderators (including sociodemographic data, psychometric scales, and medication that influenced differential symptom improvement as measured by the DSF (von Korff) and the BDI-II).

Results

The final sample included 263 participants who were evenly randomized (1:1:1) to the IG (n = 97), the WCG (n = 72), or the ACG (n = 94; see Figure 1 for the study flowchart).

Sample description

Demographic and psychopathological characteristics at baseline are presented in Table 1. The sample averaged 43.70 years (SD = 13.66) of age and was predominantly female (n = 209, 79.5%), with no significant differences between the three groups on any variables, confirming successful randomization.

Study completion and intervention usage

Of the 263 participants, 193 participated in the post assessment (73.35%) and 178 participated in the follow-up assessment (67.52%), with no significant differences across groups (Lenio/ COGITO 71.13% at post and 61.86% at follow-up, WCG 73.61% at post and 75% at follow-up, ACG 74.47% at post and 68.09% at follow-up). On average, participants reported having completed 1.95 modules (out of 10; SD = 2.85). Mean usage duration of Lenio and the COGITO app was M = 3.30 (on a scale from 1 = “used only once” to 7 = “daily”; 3 = less than one time per week; SD = 2.08).

Between-group differences

ITT and PP analyses

All analyses are displayed in the Appendix. ITT analyses showed a significant between-group difference in pain interference symptoms, as indexed by the von Korff disability score (primary outcome; F (2,259) = 3.05, p = 0.049, h_p^2= 0.023), from baseline to post intervention. Post-hoc analyses revealed a greater improvement in the ACG compared with the IG (p = 0.022, h_p^2= 0.028). This effect did not persist until follow-up, when no significant group differences were noted. PP analyses showed no significant between-group differences from pre to post in the overall model (F(2,159) = 2.99, p = 0.053, h_p^2= 0.036).

TABLE 1 Sociodemographic characteristics and psychopathology at baseline.

Variable	IG Lenio/COGITO (n = 97)	ACG (n = 94)	WCG (n = 72)	Statistical Analysis
Demographics				
Gender (male/female/diverse)	15 (15.5%) / 80 (82.5%) / 2 (2.1%)	17 (18.1%) / 76 (80.9%) / 1 (1.1%)	18 (25.0%) / 53 (73.6%) / 1 (1.4%)	c^2= 2.810 (4), p = .590, h_p^2 = .097
Age in years	42.08 (13.42)	44.20 (13.85)	45.25 (13.71)	F (2,260) = 1.208; p = .300, h_p^2= .009
Number of years in school	12.41 (2.07)	11.97 (1.72)	12.35 (2.49)	F (2,260) = 0.012; p = .988, h_p^2= .000
Psychopathology				
BDI-II	26.20 (19.76)	25.41 (9.83)	25.71 (9.34)	F (2,260) = 0.147; p = .864, h_p^2= .001
PHQ-9	13.84 (5.80)	13.47 (5.10)	12.82 (4.52)	F (2,260) = 0.785; p = .457, h_p^2= .006
Von Korff severity score	3.52 (2.13)	3.11 (1.06)	2.97 (1.05)	F (2,260) = 1.480; p = .230, h_p^2= .011
Current treatment				
Currently on pain medication	66 (68.0%)	58 (61.7%)	42 (58.3%)	c^2= 2.197 (2), p = .333, h_p^2 = .091
Currently in psychotherapeutic treatment	56 (57.7%)	51 (54.3%)	38 (52.8%)	c^2= 0.456 (2), p = .796, h_p^2 = .042

IG, Intervention group receiving Lenio and COGITO; WCG, Waitlist control group receiving TAU; ACG, Active control group receiving MCT & More app: BDI – II, Beck Depression InventoryII; PHQ-9, Patient Health Questionnaire-9.

The evaluation of the BDI-II showed a significant difference between groups from baseline to post assessment ($F(2,259) = 3.23$, $p = 0.011$, $h_p^2 = 0.039$) owing to the greater improvement in the IG compared to the WCG ($p = 0.011$, $h_p^2 = 0.039$). From baseline to follow-up, group differences were again significant ($F(2,259) = 3.75$, $p = 0.025$, $h_p^2 = 0.028$), with the IG improving significantly compared to the ACG ($p = 0.011$, $h_p^2 = 0.034$).

PP analyses corroborated these findings ($F(2,159) = 3.63$, $p = 0.029$, $h_p^2 = 0.044$), with the IG showing greater improvement in depressive symptoms than both the WCG and ACG However, this improvement was not significant from baseline to follow-up.

Significant group differences were found for the somaticaffective subscale of the BDI-II ($F(2,259) = 3.12$, $p = 0.046$, $h_p^2 = 0.024$) from baseline to follow-up. The IG showed significant improvement in depressive symptoms compared to the WCG ($p = 0.015$, $h_p^2 = 0.035$). The effect for group differences were significant baseline to follow-up ($F(2,259) = 3.45$, $p = 0.032$, $h_p^2 = 0.026$), with the IG showing significant improvement compared to the WCG ($p = 0.050$, $h_p^2 = 0.023$) and to the ACG ($p = 0.018$, $h_p^2 = 0.030$). For the cognitive subscale of the BDI-II, there were no significant group differences at any assessment point (all ps >.050).

PP analyses also showed a significant group differences for the somatic-affective subscale of the BDI-II from baseline to post assessment ($F(2,159) = 3.91$, $p = 0.022$, $h_p^2 = 0.047$). A significant decrease in somatic-affective depressive symptoms was found in the IG compared to the WCG ($p = .015$, $h_p^2 = .052$), and the ACG also improved compared to the WCG ($p = 0.022$, $h_p^2 = 0.052$). However, no significant differences were found between the groups from baseline to follow up. Similar to the ITT analyses, no group differences were found in the analysis of the cognitive subscale, neither from baseline to post nor from baseline to followup assessment.

Furthermore, the ITT analyses showed a significant improvement in pain catastrophizing as measured by the PCS ($F(2,259) = 3.94$, $p = 0.021$, $h_p^2 = 0.030$). The ACG improved relative to the WCG at post intervention ($p = 0.006$, $h_p^2 = 0.045$), however the IG failed to reach significance with the WCG ($p = 0.052$, $h_p^2 = 0.022$). Baseline to follow-up analysis showed no significant group differences for this outcome. PP analyses revealed no significant group differences on PCS scores from baseline to post or baseline to follow-up.

Within-group differences

Results of the within-group differences for complete cases are shown in Supplementary Table A in the Supplementary File 1. Significant improvements emerged for all three groups (i.e., IG, WCG, ACG) from baseline to post and baseline to follow-up for BDI-II total, BDI-II Cognitive Subscale, BDI-II Somatic-Affective Subscale, QoL, and PHQ-9. For the primary outcome, the von Korff Disability Score, dependent sample t-tests showed significant reductions from baseline to post or baseline to follow-up within the WCG or the ACG (see Appendix). However, for the IG it was only significant from baseline to follow-up ($t(59) = 2.492$, $p = 0.016$, $d = 0.322$).

Client satisfaction questionnaire-8 and subjective appraisal

CSQ-8

In total, 45 participants at post and 38 participants at follow-up completed the subjective evaluation of Lenio (CSQ-8; Table 2). Participants' subjective appraisal of COGITO was not assessed. The great majority of the

participants assessed the program's quality positively (post: 91.1%; follow-up: 79.0%) and reported experiencing relief from depressive symptoms (post: 80.0%). Approximately two out of three participants indicated that they received the help they expected (post: 66.7%; follow-up: 65.8%), that their needs were met (post: 62.2%; follow-up: 63.1%), and that they were satisfied with the assistance they received (post: 72.9%; followup: 68.4%). Lenio enabled participants to better cope with their problems (post: 66.7%; follow-up: 76.4%). Overall, approximately three out of four participants expressed satisfaction with the program (post: 75.6%; follow-up: 73.6%). They expressed willingness to use Lenio again (post: 66.7%; follow-up: 68.4%) and to recommend it to others (post: 66.7%; follow-up: 73.7%).

Subjective appraisal

The subjective appraisal of the intervention, as assessed in a questionnaire separate from the CSQ-8, is presented in Table 3. Overall, the intervention received a positive evaluation at post (n = 43) and follow-up (n = 36). More than four out of five participants (post: 86.0%; follow-up: 83.3%) regarded the program as suitable for self-application and found its contents comprehensible (post: 93.1%; follow-up: 88.5%). A majority considered the program to be useful (post: 69.8%; 73.5%). In accordance with our previous findings, participants subjectively reported a reduction in their depressive symptoms after using Lenio (post: 56.2%; follow-up: 36.4%). However, only 25.7% at post and 36.4% at follow-up reported a reduction in pain symptoms as a result of using Lenio. A substantial proportion (post: 55.8%, follow-up: 62.1%) indicated they had difficulty motivating themselves to engage with the Internet-based intervention. Mostly, people were able to integrate Lenio well into their everyday life (post: 61.9%; follow-up: 61.1%).

Moderator and prediction analyses

In the moderator and predictor analyses, data from the PP group were used. Positive beta coefficients indicated that higher values of the moderator led to increased reduction of symptoms in the IG. The different standard deviations illustrate the differences between the two groups in terms of change scores from baseline to post assessments at different levels of the moderator: low (−1 SD), average (0), or high (+1 SD) treatment effect.

TABLE 2 Subjective appraisal of participants who used Lenio (questionnaire adapted from the CSQ-8).

Item	Lenio post (n = 45)	Lenio follow-up (n = 38)
How do you rate the quality of Lenio? (not good (1), less good (2) vs. good (3), excellent (4)) (recoded)	3.04 (0.47) [91.1%]	3.00 (0.74) [79.0%]
Did you receive the type of treatment you expected to receive? (not at all (1), not really (2) vs. in general yes (3), yes absolutely (4))	2.62 (0.77) [66.7%]	2.71 (0.80) [65.8%]
To which extent did Lenio meet your needs? (it did not meet my needs (1), it met few of my needs (2) vs. it met most of my needs (3), it met all of my needs (4)) (recoded)	2.60 (0.81) [62.2%]	2.63 (0.82) [63.1%]
Would you recommend the manual to a friend with similar symptoms? (definitely not (1), probably not (2) vs. probably yes (3), absolutely (4))	3.18 (0.77) [66.7%]	3.08 (0.91) [73.7%]
How happy are you about the extent of the help you have received through using the program? (dissatisfied (1), somewhat dissatisfied (2) vs. mostly satisfied (3), very satisfied (4))	2.76 (0.71) [72.9%]	2.92 (0.94) [68.4%]
Did Lenio help you cope with your problems more successfully? (no, it did not help me at all (1), no, it did not help me that much (2) vs. yes, it helped me a little (3), yes, it absolutely helped me (4)) (recoded)	2.84 (0.71) [66.7%]	2.97 (0.68) [76.4%]
How satisfied are you with Lenio in general? (very satisfied (1), mostly satisfied (2) vs. somewhat unsatisfied (3), unsatisfied (4))	2.91 (0.70) [75.6%]	2.95 (0.90) [73.6%]
Would you use Lenio again? (definitely not (1), probably not (2) vs. probably yes (3), yes (4))	2.93 (0.03) [66.7%]	2.97 (0.92) [68.4%]
Has Lenio reduced your pain symptoms? (added item)	2.30 (0.95) [40.0%]	
Has Lenio improved your well-being? (added item)	2.90 (0.88) [80.0%]	

Mean scores and standard deviations in parentheses; percentages in square brackets include the two positive response options; Lenio post = Post scores 8 weeks after baseline; Lenio follow-up = Follow-up scores 16 weeks after baseline.

A significant moderation emerged from baseline to post for age. Older participants in the IG benefited significantly more compared to older participants in the WCG (B = 0.102, SE = 0.050, t = 2.042, p = .044, LLCI = 0.003, ULCI = 0.201). Moreover, higher WSQ scores, indicating the presence of multiple diagnoses, led to a greater reduction in depressive symptoms in the IG compared to the WCG (B = 1.41, SE = 0.677, t = 2.077, p = .040, LLCI = 0.065, ULCI = 2.747).

Discussion

Our study set out to investigate whether a newly developed online self-help program (Lenio) in combination with a self-help

TABLE 3 Subjective appraisal of participants who who used Lenio (measured with the self-developed questionnaire on the differential effectiveness of the three techniques).

Item	Lenio post (n = 43)	Lenio follow-up (n = 36)
I think Lenio is good for self-help and self-guidance.	3.35 (0.78) [86.1%]	3.11 (0.89) [83.3%]
I think Lenio is useful.	2.95 (0.92) [69.8%]	3.06 (1.04) [73.5%]
I found Lenio easy to understand.	3.48 (0.63) [93.1%]	3.34 (0.84) [88.5%]
I was able to integrate Lenio and the associated exercises well into my everyday life.	2.74 (1.01) [61.9%]	2.67 (0.90) [61.1%]
I had to force myself to use Lenio.	2.51 (1.10) [55.8%]	2.76 (1.12) [62.1%]
I feel that Lenio has reduced my pain.	1.89 (0.93) [25.7%]	2.12 (0.99) [36.4%]

I feel that Lenio has alleviated my emotional problems.	2.49 (1.04) [56.2%]	2.37 (1.00) [46.5%]

Mean scores and standard deviations in parentheses (4-point Likert scale: 1 = “not at all true,” 2 = “a little,” 3 = “mostly agree,” 4 = “absolutely”); percentages in square brackets include response options from “a little” to “absolutely”.

smartphone app (COGITO) would reduce both pain and depression in a large and heterogeneous sample of individuals. Our hypotheses were only partially confirmed. The results demonstrate that Lenio/COGITO ameliorated pain and most secondary outcomes across time. Yet, these improvements were rarely larger than in the ACG and WCG, which unexpectedly improved as well. For pain interference reduction, the ACG even outperformed Lenio/COGITO from baseline to post intervention. However, this effect did not persist until follow-up. For depressive symptoms (measured by the BDI-II), Lenio/COGITO was significantly more effective than the WCG from baseline to post intervention. Additionally, the IG showed a sustained advantage over the ACG until follow-up. This effect was particularly pronounced for the somatic-affective subscale of the BDI-II, whereas no significant group differences were found for the cognitive subscale. We plan to return to this result in the future and consider the hypothesis that Lenio/COGITO is more effective for psychosomatic symptoms than for pain, which is different than we had initially intended.

Somatic components of depression and chronic pain

Between-group differences for depression in favor of Lenio/COGITO were especially marked for the somatic-affective component of depression, decreasing significantly from baseline to post intervention and until follow-up in comparison to the WCG. Moreover, somatic-affective depression decreased in the IG significantly from baseline to follow-up in comparison to the ACG. The reduction of somatic-affective depression symptoms, such as fatigue, disruptions in sleep patterns, and a sense of exhaustion (49), in patients with chronic pain could have significant implications for the long-term management of pain intensity and pain interference. Alleviating somatic-affective symptoms through targeted interventions such as Lenio/COGITO might break the vicious circle of pain and depression reinforcement.

Active control group

Individuals who received access to the smartphone app MCT & More (ACG condition) achieved a significantly stronger reduction in pain symptoms compared to the Lenio/COGITO group to post intervention, even though this intervention was not aimed at reducing chronic pain and contained only a subset of exercises conveyed by Lenio/COGITO. Thus, MCT & More did not contain any contents beyond those conveyed by the experimental condition. Importantly, the IG used the MCT & More app more frequently than Lenio/COGITO. The main reason for this could be that it is easier to integrate into everyday life. As discussed in the introduction, low-threshold interventions are becoming increasingly popular in the field of mental health. Smartphones in particular, which are regularly used in daily life, are outperforming Internet-based programs such as Lenio. Recent research (50) tentatively suggests that the combination of different media and conveying multiple techniques, in our case the combination of an

Internet-based platform and a smartphone app, may overwhelm and confuse many participants leading to decreased adherence and less reduction in symptoms. A more focused approach, as in the ACG of the current study, may thus be advantageous ("less is more"). Still, the greater reduction of pain symptoms in the ACG points to the need for a revision of the Lenio/COGITO program, possibly by providing patients with more focused guidance.

Wait-list control group

While previous research suggests that waitlist control groups typically inflate effect sizes in favor of the experimental intervention (51, 52), this unlikely applies to our study, as the WCG also demonstrated notable improvements. Several factors could explain this unexpected result. First, natural symptom fluctuations or regression to the mean may have contributed to improvements in the WCG. However, Sean and colleagues (53) argue that symptom improvements in untreated chronic pain populations cannot be entirely attributed to regression to the mean alone. Their study suggests an 'Effect of Care,' where participants benefit simply from study participation, potentially due to increased self-reflection, structured symptom tracking, and interactions with study staff. Second, participants might have sought alternative treatments or coping strategies while waiting for the intervention, influencing their symptom trajectories. Future research should further explore the conditions under which WCGs improve and refine study designs to account for such influences.

Long-term effects of cognitive behavioral therapy on chronic pain via a reduction in depression

According to prior research (54), reducing depressive symptoms in patients with chronic pain promises a long-term reduction in pain symptoms. Pain in turn impacts depression (55), speaking for a bidirectional relationship between the two conditions. Although Lenio/COGITO did not lead to significant reductions in pain interference and severity compared to the ACG and WCG in a period of 16 weeks, considering the significant reduction in depressive symptoms in the IG compared to the other groups through follow-up, longer observation intervals of the Lenio/COGITO intervention might reveal an improvement in overall pain symptoms due to enhanced mental health and coping mechanisms. Also, considering that in the subjective evaluation of the program the perceived pain reduction significantly increased from the post to the follow-up evaluation, one might hypothesize that the observation period was too short to accurately capture any improvement in pain interference (see Table 3). This can be viewed as mere speculation due to a lack of further long-term assessments in our study, but there is some evidence in favor of this hypothesis. Samwel et al. (56) found a reduction in pain after 12 months following CBT that included stress management, problem solving, and relaxation. Likewise, Zanini and colleagues (57) assume that effects in pain reduction only manifest after months. Such "sleeper effects" are well known for other disorders, too (58). To illustrate, Moritz and colleagues examined the effects of metacognitive training (MCT) in patients with schizophrenia and found significant

improvements on some outcomes, but only when measured three years after initial assessment (58). These findings further stress the need for long-term investigation of Lenio/ COGITO. However, these findings also raise the question of whether pain-specific psychotherapy is needed or whether treatment of depressive symptoms alone may also lead to "sleeper effects" on pain symptoms.

Age-related differences

Moderation analyses indicate that Lenio/COGITO resulted in a stronger reduction in depressive symptoms among older participants during the pre-to-post interval compared to the WCG. This is in line with existing research showing higher adherence to Internet-based self-help programs with higher age (59). This may have to do with less experience with such programs in this age group, leading to higher treatment expectations and enthusiasm than in younger patients, who are more Internet-savvy and perhaps find the design and presentation less appealing. In line with this, many young individuals do not complete Internet-based programs, and their adherence (e.g., frequency of usage) to such programs is often low (60). Achilles et al. (61) discuss limited time, technical difficulties, repetitive content, concerns about privacy and anonymity, and other factors as challenges that lead to reduced involvement and participation in Internet-based interventions by young people. While their results were collected in a sample younger than ours (12–25 years), we expect that further program personalization, gamification elements, participatory design, and use supported by a therapist could contribute to enhancing young people's compliance with programs such as Lenio/COGITO. To conclude, recognizing the interplay of age-related preferences, technological familiarity, and intricacies in program design can help in developing tailored strategies to boost involvement among diverse age groups in Internet-based self-help programs such as Lenio.

The biopsychosocial model and heterogeneity in pain

The biopsychosocial model of chronic pain acknowledges the complex interplay between psychological, physical, and social factors in pain management (62). For example, individuals with pain arising from accidents or from lifelong chronic conditions (e.g., rheumatoid arthritis) may have very different treatment needs, ranging from strictly medical to psychological interventions (63, 64). In developing Lenio/COGITO, we did not differentiate between the various causes of pain; we aimed instead for a broadly applicable program. This approach has both advantages and disadvantages. It might be beneficial to introduce additional program packages for other causes of pain not yet mentioned, such as cancer, spinal problems, operations and injuries, or rheumatoid arthritis (65), to create a more customizable approach.

Outlook

Acknowledging the effects on somatic components of depression and in line with our moderation analysis, Lenio in combination with COGITO could be especially useful in the treatment of somatic depression, particularly in older patients. Considering that the subjective feedback on the Lenio program was generally positive, the integration of Lenio into existing rehabilitation approaches for pain should be

considered when the program is revised as outlined above (more focus and guidance). Lenio could serve to bridge waiting times, providing affected individuals with initial self-help tools and psychoeducation. It is yet to be tested whether utilizing Lenio in a preventive fashion could ward off the onset of depression and perhaps also pain and whether the positive impact of using Lenio in combination with COGITO, especially in reducing depressive symptoms, could be leveraged to protect individuals from the emergence of depressive symptoms through regular participation in interactive exercises such as those available in the COGITO app.

Limitations

Strengths of this study include the large sample size and the inclusion of an ACG as well as a WCG. Several limitations should be acknowledged. First, the study's reliance on self-reported assessments, necessitated by data protection constraints, led to some uncertainty regarding the precision and dependability of the gathered data. Another key limitation is the participants' relatively low (self-reported) engagement with the program.

Moreover, the observed improvements in the WCG may reflect factors such as increased self-monitoring due to study participation, anticipation effects from awaiting the intervention, or natural symptom fluctuations. These effects, while beyond the scope of the current study, highlight the potential influence of external variables in interpreting control group results and underscore the need for careful consideration in future research.

Additionally, the study faced challenges with moderate reassessment rates, which could potentially impact the broader applicability of the findings. Moreover, the comparatively brief duration of the follow-up period restricts our ability to assess long-term effects, underscoring the need for further research. Our hypothesis that a reduction in depression may reduce pain at a later point in time also should be tested.

Conclusion

In conclusion, this study found that pain interference and pain intensity were reduced using the Internet-based intervention Lenio and its accompanying self-help app COGITO, but not significantly larger in comparison to the ACG and WCG. However, Lenio/ COGITO was especially successful for the treatment of somatic symptoms of depression, and this may be considered as the primary outcome in future studies. Lenio/COGITO might serve as a valuable bridge to conventional psychotherapy, psychoeducation, and overall improvement of well-being. Future research should focus on long-term effects of psychological self-help tools to measure gradual changes and consider the addition of specialized program packages to increase usage and accommodate the heterogeneity of chronic pain.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Local Ethical Committee of the University Hospital Hamburg-Eppendorf. The studies were conducted in

accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

SB: Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Writing – original draft, Writing – review & editing. A-SW: Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Writing – original draft, Writing – review & editing. SM: Data curation, Formal analysis, Funding acquisition, Resources, Supervision, Writing – review & editing. JG: Formal analysis, Funding acquisition, Methodology, Project administration, Writing – review & editing.

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Conflict of interest

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Generative AI statement

The author(s) declare that no Generative AI was used in the creation of this manuscript.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2025.1528128/full#supplementary-material

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Summary

Die randomisiert-kontrollierte Studie *„Two in one: a randomized controlled trial on an internet-based intervention (*Lenio*) for management of both chronic pain and depressive symptoms“* (Frontiers in Psychiatry, 2025) untersuchte ein neu entwickeltes internetbasiertes Selbsthilfeprogramm (Lenio) in Kombination mit der Smartphone-App COGITO zur gleichzeitigen Linderung chronischer Schmerzen und depressiver Symptome. Vor dem Hintergrund der häufigen Komorbidität beider Krankheitsbilder und eingeschränkter Zugänglichkeit psychologischer Versorgung zielt Lenio auf eine niedrigschwellige, unbegleitete Unterstützung durch evidenzbasierte KVT-, ACT- und Achtsamkeitselemente ab. Die Studie umfasste 263 Teilnehmende, die einer Interventionsgruppe (IG; Lenio + App COGITO), einer Aktivkontrollgruppe (AKG; MKT & Mehr) oder einer Warteliste (WKG) zugeteilt wurden. Primärer Endpunkt war die schmerzbedingte Alltagsbeeinträchtigung, sekundäre Endpunkte waren depressive Symptome und Schmerzintensität. Die Ergebnisse zeigten signifikante Verbesserungen depressiver Symptome in der IG im Vergleich zur WKG, insbesondere im somatisch-affektiven Bereich, während eine signifikante Reduktion der Schmerzbeeinträchtigung erst im Follow-up deutlich wurde. Die Nutzung des Programms blieb insgesamt gering. Moderationsanalysen wiesen auf besonders hohe Effekte bei älteren Teilnehmenden und Personen mit höherer Komorbidität hin. Die Ergebnisse verdeutlichen das Potenzial digitaler Selbsthilfeangebote, zeigen aber zugleich die Herausforderung mangelnder Adhärenz. Vor diesem Hintergrund könnte die zukünftige Integration KI-gestützter Chatbot-Elemente erwogen werden, um Nutzerbindung und Wirksamkeit zu steigern. Die Autorin war maßgeblich an der Entwicklung der Lenio-Inhalte, der Studienplanung, Datenerhebung und -analyse sowie an der Manuskripterstellung beteiligt.

The randomized controlled trial *“Two in one: a randomized controlled trial on an internet-based intervention (*Lenio*) for management of both chronic pain and depressive symptoms”* (Frontiers in Psychiatry, 2025) evaluated the effectiveness of a newly developed internet-based self-help program (Lenio) targeting both chronic pain and depressive symptoms in combination with the mobile smartphone-application COGITO. Given the high comorbidity between both conditions and limited access to psychological care, Lenio offers a low-threshold, unguided intervention based on CBT, ACT, and mindfulness techniques. 263 participants were randomly assigned to one of three groups:

Lenio + COGITO app (IG), MCT & More (ACG), or a waitlist (WCG). Primary outcome was pain-related disability; secondary outcomes included depressive symptoms and pain intensity. The intervention group showed significant improvements in depressive symptoms compared to the wait list, particularly in the somatic-affective subscale, while reductions in pain-related interference emerged only at follow-up. Overall program usage was low. Moderation analyses suggested stronger effects among older individuals and those with high comorbidity. These findings highlight the potential of digital self-help but also the challenge of low adherence. Incorporating AI-supported elements such as chatbots may improve engagement and outcomes. The author was centrally involved in content development, study design, data analysis, and manuscript creation.

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Abbreviations

ACG – Active Control Group

ACT – Acceptance and Commitment Therapy

AI – Artificial Intelligence

BDI-II – Beck Depression Inventory-II

CBT – Cognitive Behavioural Therapy

COGITO – Smartphone app supporting the Lenio intervention

COVID-19 – Coronavirus Disease 2019

DSF – German Pain Questionnaire

FABQ – Fear-Avoidance Beliefs Questionnaire

iCBT – Internet-based Cognitive Behavioural Therapy

IG – Intervention Group

ITT – Intention-to-Treat

Lenio – Internet-based self-help program for chronic pain and depression

MCT & More – Smartphone app, predecessor version of COGITO

PCS – Pain Catastrophizing Scale

PHQ-9 – Patient Health Questionnaire-9

RCT – Randomized Controlled Trial

SD – Standard Deviation

SGB V – German Social Code, Book V

von Korff Disability Score – Measure of pain-related interference in daily life

WCG – Waitlist Control Group

WHOQOL-BREF – World Health Organization Quality of Life – Brief Version

WSQ – Web Screening Questionnaire

ZUF-8 – Satisfaction with Treatment – 8 Items

Statement of Author's Contribution

I was substantially involved, both intellectually and organisationally, in all stages of the present study. My specific contributions included the conceptual co-development of the digital self-help programme Lenio, the planning and implementation of the study, the statistical analysis, and the preparation of the manuscript.

The development of the Lenio portal began in 2021. Together with an interdisciplinary team and under the professional guidance of a licensed cognitive behavioural therapist, I worked on the content and didactic design of the modules. My responsibilities included planning the overall content structure, selecting and integrating cognitive behavioural as well as mindfulness-based and acceptance and commitment therapy (ACT) approaches,

and drafting psychoeducational texts. I was also involved in selecting suitable exercises and creating interactive elements. In close collaboration with the team, I developed texts, exercises, and illustrations, and contributed to the selection and design of characters and avatars intended to enhance user motivation and identification within the portal.

As part of the study preparation, I undertook organisational and coordination tasks. These included developing participant recruitment strategies, such as creating and distributing flyers and running targeted social media campaigns. During the active study phase, I was responsible for the formal management of participants, including administering and providing technical support for pseudonymised accounts, as well as handling general administrative tasks related to the study's operations.

A central focus of my work was the statistical analysis of the collected data using IBM SPSS Statistics®, in collaboration with my supervisor Dr Borsutzky and under the close supervision of my doctoral advisor Prof Dr Moritz. This included conducting intention-to-treat (ITT), per-protocol (PP), and complete-case (CC) analyses. In addition, we performed moderation analyses using the PROCESS macro to identify potential interaction effects and influencing factors. The interpretation of results was carried out with reference to the study's primary and secondary endpoints.

I was also deeply involved in preparing the scientific manuscript. In addition to co-authoring the initial drafts, I was particularly responsible for writing and revising the Introduction, Results, and Discussion sections. In close coordination with my co-authors, I participated in the editorial process, revised text passages to ensure content precision and clarity, and contributed to the structural and stylistic finalisation of the article.

Furthermore, I was involved in selecting suitable academic journals for publication and actively participated in managing the entire peer-review process. This included addressing reviewer feedback, drafting structured response letters to the reviewers, and revising specific manuscript sections according to the reviewers' comments. I also contributed to the formal formatting of the article in line with the chosen journal's guidelines. The work was successfully published in *Frontiers in Psychiatry* in March of 2025.

Eidesstattliche Versicherung

Ich versichere ausdrücklich, dass ich die Arbeit selbständig und ohne fremde Hilfe, insbesondere ohne entgeltliche Hilfe von Vermittlungs- und Beratungsdiensten, verfasst,

andere als die von mir angegebenen Quellen und Hilfsmittel nicht benutzt und die aus den benutzten Werken wörtlich oder inhaltlich entnommenen Stellen einzeln nach Ausgabe (Auflage und Jahr des Erscheinens), Band und Seite des benutzten Werkes kenntlich gemacht habe. Das gilt insbesondere auch für alle Informationen aus Internetquellen.

Soweit beim Verfassen der Dissertation KI-basierte Tools („Chatbots“) verwendet wurden, versichere ich ausdrücklich, den daraus generierten Anteil deutlich kenntlich gemacht zu haben. Die „Stellungnahme des Präsidiums der Deutschen Forschungsgemeinschaft (DFG) zum Einfluss generativer Modelle für die Text- und Bilderstellung auf die Wissenschaften und das Förderhandeln der DFG“ aus September 2023 wurde dabei beachtet.

Ferner versichere ich, dass ich die Dissertation bisher nicht einem Fachvertreter an einer anderen Hochschule zur Überprüfung vorgelegt oder mich anderweitig um Zulassung zur Promotion beworben habe.

Ich erkläre mich damit einverstanden, dass meine Dissertation vom Dekanat der Medizinischen Fakultät mit einer gängigen Software zur Erkennung von Plagiaten überprüft werden kann.

Hamburg, 13.08.2025

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