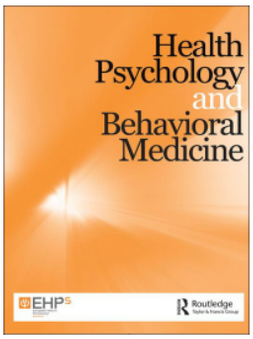

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REVIEW ARTICLE

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Has the COVID-19 pandemic changed characteristics, administration modalities, and implementation of psychological interventions for chronic headache? An updated systematic review

Annalisa De Lucia, Valeria Donisi, Michela Rimondini, Lidia Del Piccolo and Cinzia Perlini

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ABSTRACT

Background: The COVID-19 pandemic has brought increased global attention to headache disorders. Building on a pre-pandemic published systematic review covering the period from 2008 to 2018, we updated the literature on evidence-based psychological interventions for adults with chronic headaches (CH), with a specific focus on the potential impact of the pandemic. Besides exploring characteristics of the interventions, evidence, and possible factors influencing their implementation in clinical practice, we aimed to investigate whether the pandemic affected interventions' features, delivery modalities, and uptake.
Methods: We conducted a systematic search of PubMed and PsycINFO (2019–2024), checked ClinicalTrials.gov for upcoming trials, and consulted websites of clinical centers cited in the included studies. We assessed the quality of selected studies using the *Quality Assessment Tool with Diverse Designs* and carried out a narrative synthesis.
Results: We included 20 studies (10 new and 10 updates of previously reviewed studies), with migraine being the most represented disease, and 12 upcoming trials. An emphasis on cognitive-behavioral therapy, biofeedback, and relaxation training still emerged, alongside a significant rise in eHealth solutions, particularly in upcoming trials, after the pandemic.
Discussion: While the pandemic seems to have accelerated the adoption of eHealth for CH, the gap between research and clinical implementation of psychological intervention has not yet been effectively bridged.

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KEYWORDS
Chronic headache; migraine; tension-type headache; psychological interventions; COVID-19

Introduction

Chronic headache (CH) disorders (i.e. headache occurring on at least 15 days/month for at least 3 months) represent a highly prevalent health issue, affecting about 1 billion people worldwide (Murphy & Hameed, 2023), besides being heavily disabling. Given the complex nature of headache disorders and their significant impact on somatic, psychological, and social well-being, a multidisciplinary approach combining pharmacological and non-pharmacological treatments is widely recommended for more effective management (Licina et al., 2023). Previous literature reviews showed the effectiveness and feasibility of psychological interventions for CH in adults, (e.g. Dudeney et al., 2022; Lee et al., 2019; Sullivan et al., 2016; Szok et al., 2023). In this regard, a previous systematic review by our research group (Perlini et al., 2020) identified several types of interventions, such as cognitive-behavioural therapy, multi-disciplinary treatments, relaxation training, biofeedback, and others. Most of the included studies indicated such interventions to be effective, mainly in reducing the frequency of headache attacks. In this review, we also emphasised that, despite a broad number of available interventions, their actual implementation into clinical practice is limited. Indeed, only a few studies referenced the possibility of incorporating the intervention into routine clinical settings. We also highlighted the need to explore factors that may affect the accessibility and generalisability of these treatments, along with cost-effectiveness analyses, in subsequent studies (Perlini et al., 2020).

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With the rise of the COVID-19 pandemic, headache disorders have reached unprecedented significance worldwide (European Brain Council, 2022; Pöhlmann & Holle-Lee, 2024). As noted in a recent literature review (Caronna et al., 2023), the reason seems to be twofold: on the one hand, SARS-CoV-2 infection and/or SARS-CoV-2 vaccines may lead to headaches as a secondary headache disorder and, on the other hand, adversely affect primary headache disorders, already invalidating and widespread. Moreover, COVID-19 transmission and protective measures entailed dramatic changes in lifestyle habits as well as in healthcare services, with a significant reduction or complete withdrawal of scheduled medical appointments and subsequent negative impact on routine care (Chudasama et al., 2020). Given the urgent need for implementing alternative solutions to ensure continuity of healthcare in the wake of the pandemic, there has been an acceleration in the adoption of eHealth modalities in several areas, (e.g. Getachew et al., 2023; Leibar Tamayo et al., 2020; Yagiz & Goderis, 2022), including chronic disease management (Vratimos et al., 2024). Indeed, eHealth solutions—which generally refers to the '*use of information and communications technology in support of health and health-related fields*' (World Health Organization, 2019)—have shown their potential to foster greater access to healthcare services and could be effective strategies to increase treatment adherence and the implementation of the interventions even after the pandemic (Olmastroni et al., 2023).

Considering the above observations and the current relevance of the topic of interest, the overall aim of the present paper is therefore to provide an update on our previous review (Perlini et al., 2020), by exploring the impact of the COVID-19 pandemic on the psychological interventions' administration modalities and the implementation of such interventions in the clinical practice. More in detail, the main aims of the current paper are:

1) to update the literature (including the most recent protocols and ongoing trials) regarding the available evidence-based psychological interventions for CH in adults, also exploring the factors that may affect their implementation into routine clinical settings (e.g. funding, setting, healthcare providers) and the potential gaps to their implementation;
2) to evaluate how the COVID-19 pandemic has affected the interventions' characteristics, administration modalities, and implementation.

Materials and methods

To achieve our aims, we adopted a multidimensional four-step approach as follows: a) updating the published systematic review (Perlini et al., 2020) by searching for any new relevant evidence in the current scientific literature published in the years 2019–2024; b) checking for any updates (i.e. further publications of the same research group) to studies included in the previous review; c) searching for any ongoing or upcoming trials on the target subject. Finally, as an overall additional strategy (d), we have visited the websites of the clinical centres cited in the included articles (where available) to obtain additional information on the intervention implementation with respect to those described in the literature (see Figure 1).

Searching relevant literature and selection procedures

As for step (a) 'relevant evidence in the current scientific literature', the search and selection of relevant studies were performed following the standard guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Liberati et al., 2009). Electronic databases PubMed and PsycINFO were searched to retrieve results. The following three sets of keyword algorithms were used linked with the Boolean operator 'AND': 'migraine' OR 'headache'; 'chronic'; 'psychol* intervention'. The same search formula as in the prior review was used: [((migraine) OR headache)) AND chronic) AND psychol* intervention]. Filters for the English language and publication date (1 st January 2019–31st March 2024) were applied. All yielded articles were exported to Rayyan (Rayyan Systems Inc), a web-based tool created to aid the systematic review process (Ouzzani et al., 2016), and duplicates were removed. Two reviewers (ADL and CP) independently screened titles and abstracts to determine eligibility. The same two independent reviewers retrieved and reviewed the full texts of potentially eligible articles. Any

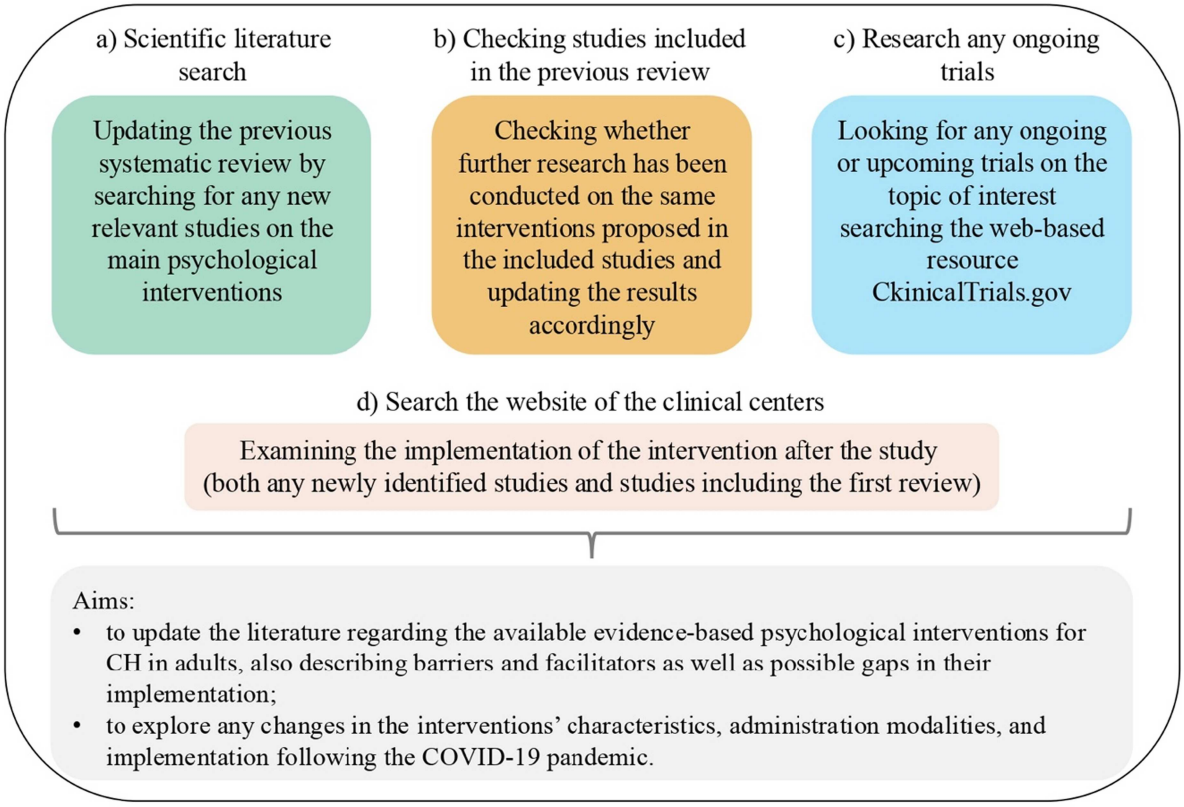

Figure 1. Multicomponent approach including four consecutive research methodologies.

uncertainties were resolved through discussion, with a third reviewer (VD) being consulted if needed. As for step (b) 'updates to studies included in the previous review', we assessed whether further studies had been conducted by the same research groups on the same interventions already detailed in Perlini et al. (2020), as well as through screening articles included in recent reviews concerning the topic of interest. Concerning step (c) 'ongoing or upcoming trials', the web-based resource Clinical.Trial.Gov was searched for identifying any ongoing or upcoming studies using the following search strategy: - condition/disease: headache OR migraine; - other terms: chronic. Filters for age (Adult: 18–64; older adult: 65+) were applied. In this case, we have not used the keywords 'psychological intervention' as it limited the number of results obtained resoundingly while potentially missing an important number of trials that met the eligibility criteria instead. In addition, we screened the yielded results considering only the trials first posted on Clinical.Trial.Gov between January 1, 2019, and March 31, 2024. Finally, for the included studies that emerged from the previous research methods, additional information and details on the included interventions have been collected by visiting the websites of the clinical centres cited in the included papers (if available).

Study selection criteria

The following inclusion criteria were used for the inclusion of papers for the search strategy a, b, c: i) adult population (age > 18 years); ii) diagnosis of chronic primary headache (migraine, TTH, mixed headache); iii) the study has to focus on the administration of psychological interventions for chronic primary headache (i.e. the term 'chronic' is specified in the title) with or without medication overuse headache (MoH), or severe headache (presence of MoH; without MoH but with high triptan or analgesic intake frequency; Migraine Disability Assessment-MIDAS score > 5; no maximum number of days or attacks specified); iv) psychological interventions which have shown to be evidence-based such as cognitive-behavioural therapy (CBT), mindfulness and acceptance and commitment therapy

(ACT), biofeedback, relaxation training; v) peer-reviewed research articles; vi) observational studies, retrospective or prospective cohort studies, randomised trials, qualitative and mixed methods studies; study protocols; vii) English language; viii) publication date between 1 st January 2019 and 31 March 2024 (the study period in the present review begins from the date on which the previous research ended (i.e. 12/31/2018).

The inclusion of different study designs, including qualitative studies and study protocols, reflects the aim of updating the literature on psychological interventions for CH, with a specific focus on intervention characteristics, administration modalities, and factors potentially influencing their implementation into routine clinical practice, rather than restricting the review to effectiveness outcomes only.

Exclusion criteria were: i) review papers, conference abstracts or posters, books or book chapters, and case reports; ii) papers not focusing on psychological interventions; iii) papers in which the maximum number of headache days were specified in the inclusion criteria was lower than expected for a diagnosis of CH (i.e. 'Headache attack frequency had to be between one and six attacks per month'); iv) papers explicitly excluding chronic condition (i.e. 'subjects with more than 14 headache days/month were not enroled'); v) studies on general chronic pain where it was not possible to distinguish the diagnosis of CH or studies on general chronic pain where it is possible to identify the sub-sample with CH but the percentage of participants with CH was less than 50% (in order to be sure that psychological interventions were focused on samples made up by the majority of the patients affected by CH).

Data extraction

Data were extracted from the included articles by two independent reviewers (ADL and CP) using a data charting table in Microsoft Excel. Any disagreements were discussed and resolved involving a third reviewer (VD). Data extracted from each study included: first author, year of publication, country, setting, hospital/clinical centre involved in recruitment and/or intervention (if mentioned in the study), website of the hospital/clinical centre, study design, pathology declared in the article, number of participants included in the study, recruitment, type of psychological intervention, intervention provider, duration and format (individual and/or group) of the intervention, type of delivery mode (in-person; fully remotely; blended), type of eHealth tool used to deliver the intervention (if applicable), percentage of adherence to the intervention, main results, funding, implementation into clinical context at the end of research [as specified in the paper and/or by visiting website, see (d)], conducting a cost-benefit analysis.

Assessment of methodological quality

Two independent reviewers (ADL and VD) assessed all eligible studies using the Quality Assessment Tool for Studies with Diverse Designs (QATSDD) (Sirriyeh et al., 2012). Any potential disagreements were addressed through discussions that involved a third rater (CP) making a final decision. The tool demonstrated strong reliability and validity (Sirriyeh et al., 2012), allowing for the evaluation of research papers' quality on a scale from 0 (not at all) to 3 (complete) across 16 different criteria. These criteria apply to studies utilising various methodologies, including qualitative, quantitative, and mixed methods. For qualitative or quantitative research, the highest possible score is 42, while for mixed methods studies, it is 48. Each included article received a score for each criterion, as well as an overall quality score, which is calculated by summing the individual scores for all items. Additionally, to determine which items had the highest and lowest scores, the mean and standard deviation for each item were calculated, along with the average quality score for all studies.

Ethics statement

Ethical review and approval were waived for this study, as it is a literature review that analysed only previously published and publicly available data.

Results

We retrieved 686 studies from electronic databases and 15 from reviews and reference lists of studies included in the original review (Perlini et al., 2020). After removing duplicates and implementing eligibility criteria, 20 articles were finally included in this review, of which 10 were novel studies (Arina et al., 2022; Bottiroli et al., 2022; Crawford et al., 2020; Cuneo et al., 2023; Haggiag & Speciali, 2020; Khazraee et al., 2023; Majore-Dusele et al., 2021; Short, 2019; Underwood et al., 2023; Zambrano-Camiña et al., 2024) and 10 were updated to studies included in the previous review (i.e. further studies by the same research groups on the same interventions) (Donath et al., 2022; Grazzi et al., 2019, 2022, 2023; Martin et al., 2021; McLean et al., 2020; Minen et al., 2019a, 2020, 2021; Seng et al., 2019) (see Figure 2 for details).

Of these 20 studies, 10 (50%) were experimental, of which 8 were RCTs (80%) (Cuneo et al., 2023; Grazzi et al., 2023; Khazraee et al., 2023; Majore-Dusele et al., 2021; Martin et al., 2021; Minen et al., 2020; Seng et al., 2019; Underwood et al., 2023), 1 (10%) was a multiple baseline design study (Crawford et al., 2020), and 1 (10%) was a cross-over sham-controlled study (Arina et al., 2022). 4 (50%) out of the 8 RCTs were defined as 'pilot RCTs' by authors (Cuneo et al., 2023; Majore-Dusele et al., 2021; Minen et al., 2020; Seng et al., 2019). 2 (10%) articles were protocols for an RCT (Bottiroli et al., 2022) and a longitudinal study (Zambrano-Camiña et al., 2024). The remaining papers (8/20; 40%) were observational studies (Donath et al., 2022; Grazzi et al., 2019, 2022; Haggiag & Speciali, 2020; McLean et al., 2020; Minen et al., 2019a; Minen et al., 2021; Short, 2019). The following paragraphs summarise the variables of interest in the included articles (the characteristics of the included new and updated studies are described in tabular format in the Supplementary File 1).

Country of the study

Among the 20 studies, 9 (45%) were carried out in Europe (of which 4 in Italy (Bottiroli et al., 2022; Grazzi et al., 2019, 2022, 2023), 1 in Spain (Zambrano-Camiña et al., 2024), 1 in Germany (Donath et al., 2022),

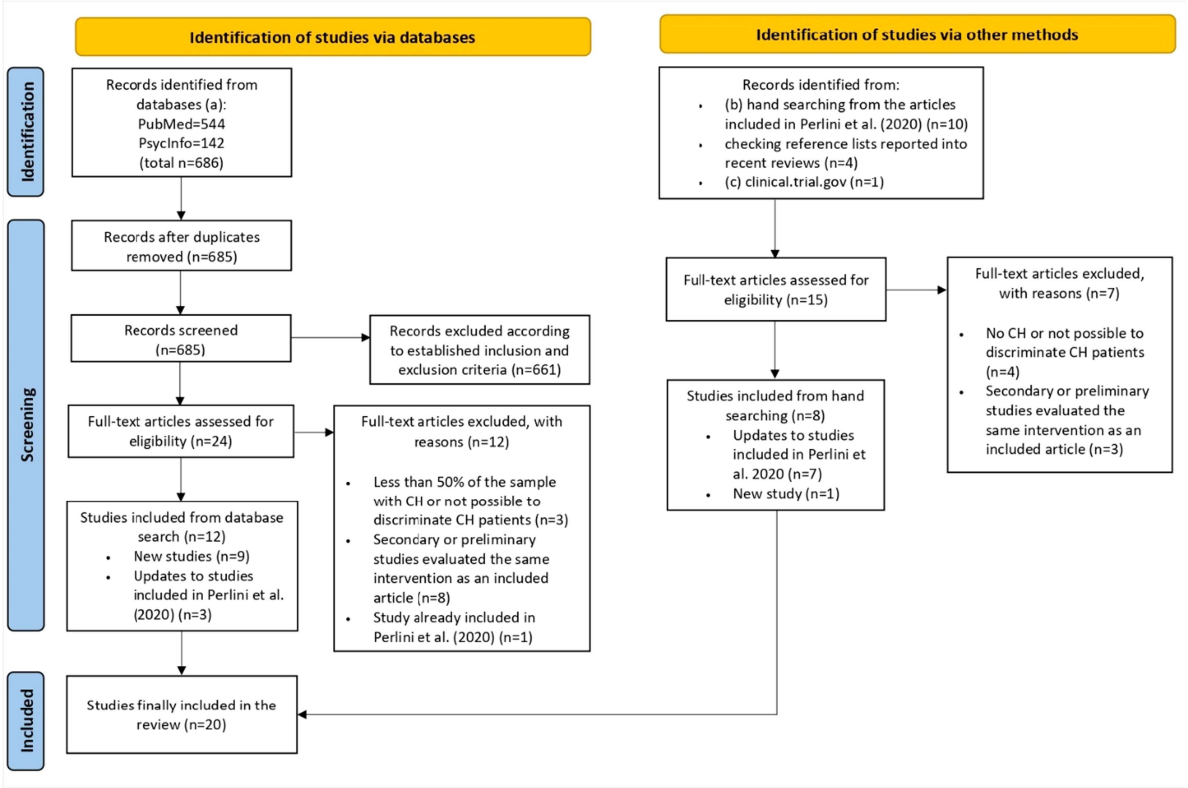

Figure 2. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of the study selection.

1 in the U.K. (Underwood et al., 2023), 1 in Latvia (Majore-Dusele et al., 2021), and 1 in Russia (Arina et al., 2022)), 9 (45%) in America (of which 7 in the US (Crawford et al., 2020; Cuneo et al., 2023; Minen et al., 2019a, 2020, 2021; Seng et al., 2019; Short, 2019)), 1 in Canada (McLean et al., 2020), and 1 in Brazil (Haggiag & Speciali, 2020), 1 (5%) in Australia (Martin et al., 2021), and 1 (5%) in Asia (Iran) (Khazraee et al., 2023).

Healthcare setting of the intervention

Most of the studies (16/20; 80%) were performed in clinical contexts, with participants recruited from patients referring to various facilities, namely outpatient rehabilitation clinics (Majore-Dusele et al., 2021; Short, 2019), medical centres attached to universities (Crawford et al., 2020), specialised pain/headache centres that are part of hospitals or universities—3 of them were classified as tertiary headache centres (Bottiroli et al., 2022; Cuneo et al., 2023; Donath et al., 2022; Grazzi et al., 2019, 2022, 2023), a tertiary care neurology practice (Minen et al., 2020), a neurology department of a university hospital (Zambrano-Camiña et al., 2024), health services facilities (McLean et al., 2020), a private dentist office (Haggiag & Speciali, 2020), a hospital-based clinical psychology clinic with participants referred by neurologists (Khazraee et al., 2023), a primary care practice (Minen et al., 2019a), and an emergency department (Minen et al., 2021) belonging to the same hospital. 2 (10%) studies were conducted in academic settings—University—(Martin et al., 2021; Seng et al., 2019), with participants mainly enroled among the general and/or university student population through local and online advertisements, the media, or medical practice/neurology office referral. 1 (5%) study was carried out with the collaboration between university and general practices from which most participants were recruited (Underwood et al., 2023). In 1 (5%) study, the setting was not specified (Arina et al., 2022).

Characteristics of the disease declared in the study

Most studies (14 out of 20; 70%) included patients with migraine (Bottiroli et al., 2022; Crawford et al., 2020; Cuneo et al., 2023; Grazzi et al., 2019, 2022, 2023; Haggiag & Speciali, 2020; Khazraee et al., 2023; Minen et al., 2019a, 2020, 2021; Seng et al., 2019; Short, 2019; Zambrano-Camiña et al., 2024), 3 (15%) focused on migraine and tension-type headache (TTH) (Majore-Dusele et al., 2021; Martin et al., 2021; Underwood et al., 2023), 2 (10%) on primary and secondary headache diagnoses (Donath et al., 2022; McLean et al., 2020), and 1 (5%) on TTH only (Arina et al., 2022). Among them, 8 out of 20 (40%) studies included patients with MoH (Bottiroli et al., 2022; Cuneo et al., 2023; Donath et al., 2022; Grazzi et al., 2019, 2022, 2023; McLean et al., 2020; Underwood et al., 2023), while 2 (11.8%) studies excluded these patients (Khazraee et al., 2023; Martin et al., 2021) and 10 (50%) studies did not specify this aspect either in the inclusion/exclusion criteria or among the sample characteristics (Arina et al., 2022; Crawford et al., 2020; Haggiag & Speciali, 2020, Majore-Dusele et al., 2021; Minen et al., 2019a, 2020, 2021; Seng et al., 2019; Short, 2019; Zambrano-Camiña et al., 2024). 3 out of the 8 studies focused specifically on the treatment of patients with CM and MoH (i.e. after withdrawing) (Grazzi et al., 2019, 2022, 2023). As for the comorbidities, 2 studies involved patients with a diagnosis of CM and awake bruxism (Haggiag & Speciali, 2020) and CM plus insomnia (Crawford et al., 2020).

Characteristics of the psychological interventions and evidence on headache-related outcomes

The characteristics of psychological interventions and the main results regarding their effectiveness are described below in 2 distinct paragraphs: one about 'new' interventions and the other addressing updated interventions (see Tables 1 and 2).

New interventions published after 2018

Among the 10 new interventions that were included in the new search after 2018, 4 (40%) focused on strategies within the CBT approaches (i.e. CBT for insomnia, mindfulness-based training, programme integrating both CBT and third-wave CBT's principles) (Crawford et al., 2020; Khazraee et al., 2023; Majore-Dusele et al., 2021; Zambrano-Camiña et al., 2024); 2 (20%) described education and self-management programmes (Short, 2019;

Table 1. Characteristics of the interventions included in the 'new studies' emerged in the years 2019-2024.

New study	Main aims	Main contents	Details	Duration Format (group/ individual); Delivery mode (in-person; fully remotely; blended)	eHealth modality	Intervention provider	Adherence to intervention	Follow-up	Implementation into clinical context at the end of research (as specified in the paper and/or website)	Cost-effectiveness analysis
Short (2019)	To decrease migraine disability and enhance self-efficacy	Evidence-based self-management programme with multimodal formats designed to provide a toolkit of education and lifestyle behaviour recommendations for patients with CM[a]	The programme also includes the use of self-care strategies and a headache diary	8 weeks; individual; blended	Website + (phone calls)	Nurse Practitioner	100%	No	NS[b]	No
Haggiag and Speciali (2020)	To manage and control awake bruxism and to reduce pain	Biofeedback treatment using a partial interocclusal device that monitors the interocclusal space in real time, helping patients recognise unconscious teeth clenching and relax the jaw muscles.	//	3 months; individual; blended	Intraoral device (biofeedback)	Dentist	100%	7, 30, 90, 180 days, and 1 years	Yes	No
Crawford et al. (2020)	To improve insomnia symptoms and migraines	Digital CBT[c] including behavioural, cognitive, and relaxation strategies as well as advice on lifestyle and bedroom factors (sleep hygiene)	Participants could complete sessions at their own pace within 12 weeks	6 weeks; individual; fully remotely	Website	Animated virtual therpist	PP (Per protocol analysis) = 89,7%. ITT (intention-to-treat analysis) = 83,3%.	No	Yes (for sleep problems)	No
Majore-Dusele et al. (2021)	To reduce pain intensity and interference and improve psychological variables	EG[d]: Mindful-Based Dance Movement Therapy (MBDMT) +TAU[e] (pharmacological treatment) VS CG[f]: TAU only	10 90-minute sessions (twice a week) with a similar structure: check-in and physical warm-up; body-scan; work with themes; closure and homework	5 weeks; group; in-person	NA[g]	Dance movement therapist in training (already licensed as a psychotherapist)	75.9%	4 months	No	No
Arina et al. (2022)	To reduce TTH[h] frequency	10 sessions of infra-low frequency electroencephalographic neurofeedback and 10 sessions of sham-	The study also included a psychoeducational session before the main study phases, emotional support	10 weeks; individual; blended	Neurofeedback device	Clinician	100%	No	Yes	No

(*Continued*)

Table 1. (*Continued*)

New study	Main aims	Main contents	Details	Duration Format (group/ individual); Delivery mode (in-person; fully remotely; blended)	eHealth modality	Intervention provider	Adherence to intervention	Follow-up	Implementation into clinical context at the end of research (as specified in the paper and/or website)	Cost-effectiveness analysis
		neurofeedback, with the order of treatments being randomised	throughout the study period, and use of relaxation audio recordings for home practice							
Bottiroli et al. (2022)	To promote pain relief and improve the perception of own's body image	EG: exposure to the enfacement illusion of a happy face through an immersive VR[i] system VS CG: exposure to a pleasant immersive virtual environment	Both groups will be exposed to 3 20-minute VR sessions	1 week; individual; blended	VR	Psychologist	NA	No	NS	No
Underwood et al. (2023)	To promote behaviour change, healthy living, understanding CH[j], and learning strategies to manage life despite headache	EG: education and self-management intervention (CHESS) VS CG: standard care + relaxation	The CHESS intervention consisted of 2 one-day group sessions 1 week apart, followed by a one-to-one nurse interview and telephone support. CG was given a compact disc for relaxation	2-days sessions 1 week apart; group; blended	Phone calls	Sessions were co-led by a nurse and another registered allied health professional and just once by research assistant	81%	8 and 12 months	NS	Yes
Cuneo et al. (2023)	To improve several headache-related outcomes	EG: frequent use of a heart rate variability (HRV) biofeedback-VR device + TAU (i.e. evidence-based acute and preventive medications, dietary supplements, neuromodulation devices, and lifestyle modifications) VS CG: TAU only	EG' participants wore a heart rate monitor; identified optimal respiratory rate; listened to calming music synced to breathing cues via a biofeedback-VR device; wore a headset; selected a VR environment; initiated cued breathing; viewed real-time HRV tracing	12 weeks; individual; blended	A mobile VR headset + a heart rate monitor	NS	72%	No	NS	No

Table 1. (*Continued*)

New study	Main aims	Main contents	Details	Duration Format (group/ individual); Delivery mode (in-person; fully remotely; blended)	eHealth modality	Intervention provider	Adherence to intervention	Follow-up	Implementation into clinical context at the end of research (as specified in the paper and/or website)	Cost-effectiveness analysis
			on screen; aimed for sine wave-like curves; and explored the VR environment for engagement and relaxation							
Khazraee et al. (2023)	To reduce headache disability and intensity and to improve psychological inflexibility and pain acceptance	EG: Mindful Hypnotherapy, that incorporates elements of both mindfulness and hypnosis. + TAU (medical treatment) VS CG: TAU only	EG received 9 weekly 1-hour sessions of mindful hypnotherapy + daily practice through audio recordings	9 weeks; individual; in-person	NA	Clinical psychologist	94,7%	No	NS	No
Zambrano-Camiña et al. (2024)	To improve physical and psychological well-being in adults with difficult-to-treat CM	EG: psychological intervention (MIDITRA) providing psychoeducational information, and practice of emotional self-regulation, cognitive, and social skills VS CG: waiting list	EG received 10 weekly sessions (lasting 90–120 minutes)	10 weeks; group; in-person	NA	NS	NA	4 weeks	No	NS

[a] CM: chronic migraine
[b] NS: not specified
[c] CBT: cognitive-behavioural therapy
[d] EG: experimental group
[e] TAU: treatment-as-usual
[f] CG: control group
[g] NA: not applicable
[h] TTH: tension-type headache
[i] VR: virtual reality
[j] CH: chronic headache

Table 2. Characteristics of the interventions included in the 'updated studies' regarding interventions included in the previous review.

Primary study	Update study	Main aims	Main contents	Details	Duration Format (group/ individual); Delivery mode (in-person; fully remotely; blended)	eHealth modality	Intervention provider	Adherence to intervention	Follow-up	Implementation into clinical context at the end of research (as specified in the paper and/or website)	Cost-effectiveness analysis
Grazzi et al. (2017)	Grazzi et al. (2019)	To explore any changes in plasma levels of catecholamines and elusive amines	5-day structured withdrawal programme followed by: EG1: Pharmacological prophylaxis EG2: Mindfulness training	EG2 received 6 45-minute weekly sessions + regular home self-practice (7-10 minutes/day). Both EGs were encouraged to engage in healthy lifestyle habits	6 weeks; group (+homework); in-person	NA	Experienced neurologist trained in mindfulness practice	65.9%	12 months	Yes	NS
	Grazzi et al. (2022)	To reinforce patients' clinical improvement and to develop pain management strategies without the use of medications	Pharmacological prophylaxis + internet-based mindfulness programme	Besides the weekly live sessions, brief (10-12 minutes) recorded home exercise for daily practice	12 months; group (+homework); fully remotely	Video calls + recorded videos (smartphone)	'	73.7%	12 months	NS	NS
	Grazzi et al. (2023)	To improve several physical and psychological migraine-related outcomes	EG: Mindfulness-based intervention (MIND) + TAU (i.e. overused drugs withdrawal; education on proper medication use, and prescription of tailored prophylaxis) CG: TAU	EG received 6 90-minute weekly sessions + audio files to practice for 7-10 minutes or longer during the 12 months' follow-up	6 weeks; group (+homework); in-person	NA	'	87%	6 and 12 months	Yes	Yes
Sauro and Becker (2008)	McLean et al. (2020)	To provide patients with evidence-based medical and behavioural headache information/ resources, and to orient them to the	Education session consisting of a medical lecture and a behavioural headache management overview	Following the education session patients participate in CHAMP's behavioural components	2-hour interactive lecture; group; in-person	NA	Neurologist and occupational therapist or nurse	48.7% (response rate)	No	Yes	NS

Table 2. (*Continued*)

Primary study	Update study	Main aims	Main contents	Details	Duration Format (group/ individual); Delivery mode (in-person; fully remotely; blended)	eHealth modality	Intervention provider	Adherence to intervention	Follow-up	Implementation into clinical context at the end of research (as specified in the paper and/or website)	Cost-effectiveness analysis
		Calgary Headache Assessment And Management Programme (CHAMP)									
Minen et al. (2019b)	Minen et al. (2019a)	To reduce headache days and examine potential predictors of app and/or PMR use	Smartphone-based PMR intervention (RELAXaHEAD): completing a headache diary and performing app-assisted PMR for 20 minutes/day	The app records the amount of time spent playing the PMR intervention audio and provides reminders to complete the PMR programme and diary	3 months; individual; fully remotely	Smartphone app	NA	82.4%	No	NS	NS
	Minen et al. (2020)	To reduce headache-related disability and headache days	EG: as above (but performing app-assisted PMR for 15 minutes/day or longer) CG: completing a headache diary using the same smartphone app without PMR	‘	‘	‘	‘	21,3%	‘	‘	‘
	Minen et al. (2021)	‘	Same as Minen et al. (2019a)	‘	‘	‘	‘	54.9%	6 months	No	‘
Martin et al. (2014)	Martin et al. (2021)	To improve headache triggers management	EG1: learning to cope with triggers (LCT) integrated into a CBT programme (LCT/CBT) EG2: avoidance of triggers integrated	Both EGs were provided with 12 60-minute sessions	12 weeks; group; in-person	NA (but self-monitoring of headaches, triggers, and medication consumption through e-diares)	Registered psycholo-gists	57.3% (percentage of participants in both EGs that provided 12-month follow-up data)	4 and 12 months	NS	No

(*Continued*)

Table 2. (*Continued*)

Primary study	Update study	Main aims	Main contents	Details	Duration Format (group/ individual); Delivery mode (in-person; fully remotely; blended)	eHealth modality	Intervention provider	Adherence to intervention	Follow-up	Implementation into clinical context at the end of research (as specified in the paper and/or website)	Cost-effectiveness analysis
			into CBT; CG: Wait-list/TAU								
Day et al. (2014)	Seng et al. (2019)	To reduce migraine attack frequency and migraine-related disability	EG: Mindfulness-Based Cognitive Therapy for Migraine (MBCT-M) CG: Wait-list/TAU	EG was provided with 8 75-minute weekly sessions, daily headache diary and mindfulness log' + 'homework'	8 weeks; individual; in-person	Phone calls (only in case of disabling attacks that prevented participants from attending in-person sessions)	Doctoral-level clinical psychology graduate students	91.7%	No	NS	No
Gunreben-Stempfle et al. (2009)	Donath et al. (2022)	To improve pain self-management and health-related behaviour	Multimodal headache-specific interdisciplinary pain therapy	The intervention involved both physical (e.g. exercise programme) and psychological (e.g. relaxation, training) activities	2 weeks for 6 to 8 h per day for a total of 5 days per week; group; in-person	NA	Physician and psychologist	95.3%	No	NS	NS

Underwood et al., 2023); 3 (30%) used biofeedback (Arina et al., 2022; Cuneo et al., 2023; Haggiag & Speciali, 2020), which in 1 case (Arina et al., 2022) was integrated with a psychoeducational component; and 1 (10%) proposed the exposure to the enfacement illusion of a happy face to promote pain relief (Bottiroli et al., 2022). The interventions were administered individually in 7 studies (70%) (Arina et al., 2022; Bottiroli et al., 2022; Crawford et al., 2020; Cuneo et al., 2023; Haggiag & Speciali, 2020; Khazraee et al., 2023; Short, 2019) and in a group setting in 3 (30%) studies (Majore-Dusele et al., 2021; Underwood et al., 2023; Zambrano-Camiña et al., 2024). The interventions were delivered in person in 3 studies (30%) (Khazraee et al., 2023; Majore-Dusele et al., 2021; Zambrano-Camiña et al., 2024), fully remotely in 1 (10%) study (Crawford et al., 2020), and through a blended modality in 6 studies (60%) (Arina et al., 2022; Bottiroli et al., 2022; Cuneo et al., 2023; Haggiag & Speciali, 2020; Short, 2019; Underwood et al., 2023). Intervention duration varied across the studies, ranging from 2 days (Underwood et al., 2023) to 3 months (Cuneo et al., 2023; Haggiag & Speciali, 2020). Treatment adherence ranged from 72% (Cuneo et al., 2023) to 100% (Arina et al., 2022; Haggiag & Speciali, 2020; Short, 2019).

7 out of the 10 included studies involved some type of eHealth modalities to deliver (totally or partially) interventions (Arina et al., 2022; Bottiroli et al., 2022; Crawford et al., 2020; Cuneo et al., 2023; Haggiag & Speciali, 2020; Short, 2019; Underwood et al., 2023). These eHealth solutions encompass the following typologies: 2 (20%) (Crawford et al., 2020; Short, 2019) studies used web-based programmes (i.e. '*a primarily self-guided intervention programme that is executed by means of a prescriptive online programme operated through a website [...] to create positive change and or improve/ enhance knowledge, awareness, and understanding via the provision of sound health-related material and use of interactive web-based components*' (Barak et al., 2009)); 2 (20%) (Bottiroli et al., 2022; Cuneo et al., 2023) studies adopted a virtual reality system (i.e. '*computer-generated simulation of a three-dimensional environment the user is able to view and manipulate or interact with*' (Kilmon et al., 2010)); 3 (30%) (Arina et al., 2022; Cuneo et al., 2023; Haggiag & Speciali, 2020) studies proposed devices based on biofeedback (i.e. '*a technique used to improve the ability to modify involuntary processes consciously*' (Malik & Dua, 2024)). Conversely, 3 (30%) (Khazraee et al., 2023; Majore-Dusele et al., 2021; Zambrano-Camiña et al., 2024) studies did not include any eHealth modality to deliver the interventions. Finally, although not strictly falling under the category of eHealth, it should be noted that, in some cases (3/10; 30%), audio recordings (e.g. relaxation techniques, mindfulness) for home practice were provided as part of a larger programme administered during in-person meetings (Cuneo et al., 2023; Khazraee et al., 2023) or as a control condition—i.e. only the CG received a relaxation compact disk (Underwood et al., 2023).

Across the included studies, the interventions were administered by different health professionals, namely registered psychologists (Bottiroli et al., 2022; Khazraee et al., 2023; Zambrano-Camiña et al., 2024) or psychotherapists (Majore-Dusele et al., 2021) with experience in the delivered interventions and/or in the management of chronic pain conditions; dentist (Haggiag & Speciali, 2020); clinician (Arina et al., 2022); an interdisciplinary team consisting of a nurse and another registered health professional (nurse, health psychologist, physiotherapist, chiropractor or occupational therapist) and just once by a research assistant (Underwood et al., 2023). 1 study involved a blended delivery mode of the intervention, i.e. in-person sessions led by a nurse in addition to the use of a website, the content of which was sourced from published literature, online resources (provided by institutions dealing with headache-related issues), and previous studies conducted by nurse practitioners (Short, 2019). In 1 study the intervention was delivered fully remotely through online sessions led by a virtual therapist (Crawford et al., 2020). Finally, 1 study did not specify the intervention provider (Cuneo et al., 2023).

In most studies, the proposed psychological interventions have been shown to improve at least one headache-related outcome. More in detail, a reduction in headache frequency (Crawford et al., 2020; Khazraee et al., 2023; Short, 2019) and intensity (4/17; (Crawford et al., 2020; Haggiag & Speciali, 2020; Khazraee et al., 2023; Majore-Dusele et al., 2021)) is the most reported finding, followed by a reduction in pain-related disability (Crawford et al., 2020; Khazraee et al., 2023; Short, 2019) and medication intake (Cuneo et al., 2023; Short, 2019). Improvements were found in the following outcomes: depressive symptoms (Cuneo et al., 2023; Majore-Dusele et al., 2021); self-efficacy (Underwood et al., 2023), psychological inflexibility and pain acceptance (Khazraee et al., 2023), and insomnia severity and impact (Crawford et al., 2020). In 75% (3/4) of the studies comparing psychological intervention with treatment as

usual (TAU) or waiting list, the experimental intervention outperformed the control condition in at least one headache-related outcome (Cuneo et al., 2023; Khazraee et al., 2023; Majore-Dusele et al., 2021).

Despite generally positive findings, several studies reported null effects, adverse events, or feasibility issues that warrant consideration. In the large CHESS RCT (Underwood et al., 2023), no significant differences were observed between the self-management intervention and the control group for the primary outcome (i.e. quality of life) at 12 months, nor for headache frequency, duration, severity, or medication overuse. Similarly, in the study combining HRV biofeedback and VR (Cuneo et al., 2023), no statistically significant between-group differences emerged for monthly headache days, disability, perceived stress, or catastrophizing, despite improvements over time in both groups.

Null findings were also reported for specific secondary outcomes. Majore-Dusele et al. (2021) found no significant between-group differences in mindfulness levels, despite the intervention being grounded in mindfulness principles, and changes in anxiety and depression did not consistently reach statistical significance compared with controls.

Negative or adverse effects were infrequently reported but present. Underwood et al. (2023) observed a temporary increase in headache days in the intervention group at 4 months and a higher number of adverse events compared with controls, although the only serious adverse event occurred in the control group and was unrelated to the intervention. Mild technology-related side effects, such as nausea ('cybersickness'), were reported in digitally delivered interventions (Crawford et al., 2020). Additionally, nocebo effects, including headache exacerbation, were observed in sham neurofeedback conditions (Arina et al., 2022).

Finally, feasibility issues were noted in some studies, including higher dropout rates due to treatment burden or device inconvenience (Cuneo et al., 2023) and early withdrawal of participants who perceived group-based body-focused interventions as emotionally overwhelming (Majore-Dusele et al., 2021).

Interventions in the 'Update studies'

Among the 10 updated studies of the intervention already included in the previous review (Perlini et al., 2020), 5 (50%) focused on strategies within the CBT approaches (i.e. mindfulness-based training and 'learning to cope with triggers' programme (Grazzi et al., 2019, 2022, 2023; Martin et al., 2021; Seng et al., 2019); 3 (30%) were based on a relaxation training (Minen et al., 2019a, 2020, 2021); 1 (10%) proposed an interdisciplinary intervention including at least a psychological component (Donath et al., 2022); and 1 (10%) evaluated a new patient-centred education session as an entry point into a larger headache multimodal programme (McLean et al., 2020).

The interventions were administered individually in 4 studies (40%) (Minen et al., 2019a, 2020, 2021; Seng et al., 2019) and in a group setting in 6 studies (60%) (Donath et al., 2022; Grazzi et al., 2019, 2022, 2023; Martin et al., 2021; McLean et al., 2020). In 3 of the latter studies (Grazzi et al., 2019, 2022, 2023), participants were also asked to engage in daily home self-practice. The interventions were delivered in person in 6 studies (60%) (Donath et al., 2022; Grazzi et al., 2019,2023; Martin et al., 2021; McLean et al., 2020; Seng et al., 2019), and fully remotely in 4 studies (40%) (Grazzi et al., 2022; Minen et al., 2019a, 2020, 2021). Intervention duration varied across the studies, ranging from 2 hours (McLean et al., 2020) to 12 months (Grazzi et al., 2022). Treatment adherence ranged from 48.7% to 95.3%.

4 out of 10 included studies (40%) involved m-Health solutions (i.e. '*medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, Personal Digital Assistants [PDAs], and other wireless devices*' (WHO, n.d.)), to deliver interventions (Grazzi et al., 2022, 2023; Minen et al., 2019a, 2020, 2021), which in 1 case was adopted as part of a broader web-based programme (Grazzi et al., 2022). The remaining 6 studies (60%) (Donath et al., 2022; Grazzi et al., 2019, 2023; Martin et al., 2021; McLean et al., 2020; Seng et al., 2019) did not include any eHealth modality to deliver the interventions. However, in Seng et al. (2019) telephone sessions (up to 3 sessions out of 8 per participant) were arranged in case of disabling attacks that prevented participants from attending in-person meetings. In Martin et al. (2021), the adoption of e-diaries was included for self-monitoring of headaches, triggers, and medication consumption in the context of an in-person intervention. Although not strictly under the eHealth category, it should be noted that in 1 study, audio recordings (e.g. mindfulness practices) for home practice were provided as part of a larger programme administered during in-person meetings (Grazzi et al., 2023).

Across the included studies, the interventions were administered by different health professionals, namely doctoral-level clinical psychology graduate students (Seng et al., 2019); trained neurologists (Grazzi et al., 2019, 2022, 2023); an interdisciplinary team consisting of, depending on the study, at least two among nurses, occupational therapists, neurologists, physicians, psychologists (Donath et al., 2022; McLean et al., 2020). Finally, in 3 studies the interventions were delivered fully remotely by accessing a smartphone app (Minen et al., 2019a, 2020, 2021).

In most studies, the proposed psychological interventions were associated with improvements in at least one headache-related outcome. More in detail, reductions in pain-related disability (6/10; (Grazzi et al., 2019, 2022, 2023; Martin et al., 2021; Minen et al., 2021; Seng et al., 2019)) and headache frequency (6/10; (Donath et al., 2022; Grazzi et al., 2019; 2022, 2023; Martin et al., 2021; Minen et al., 2020)) were the most reported findings, although the strength of evidence varied across studies. These were followed by reductions in medication intake (4/10; (Donath et al., 2022; Grazzi et al., 2019, 2022, 2023)) and headache intensity (1/10; (Martin et al., 2021)). Improvements were found in the following outcomes: self-efficacy (Seng et al., 2019), use of psychological coping strategies to deal with pain (Donath et al., 2022), frequency of endurance (aerobic) training (Donath et al., 2022), loss of productive time (Grazzi et al., 2023), and plasma levels of catecholamines (Grazzi et al., 2019). In 60% (3/5) of the studies comparing psychological intervention with treatment as usual (TAU) or waiting list, the experimental intervention outperformed the control condition in at least one headache-related outcome (Grazzi et al., 2023; Martin et al., 2021; Seng et al., 2019).

Despite overall favourable findings, several studies reported null effects or limited efficacy on specific headache-related outcomes. In the RCT by Seng et al. (2019), Mindfulness-Based Cognitive Therapy for Migraine significantly reduced headache-related disability but did not lead to significant improvements in headache frequency or pain intensity compared with the waiting list/treatment-as-usual control condition. Similarly, in the study by Martin et al. (2021), cognitive–behavioural interventions targeting trigger management did not result in significant reductions in medication intake, nor did the learning-to-cope-with-triggers approach outperform traditional trigger avoidance on primary headache outcomes.

Null or non-significant effects were also observed in digital and primary care–based interventions. In the RCT conducted in primary care by Minen et al. (2020), the reduction in migraine-related disability associated with smartphone-delivered progressive muscle relaxation did not reach statistical significance compared with the control condition, despite a small-to-moderate effect size. Furthermore, in the telemedicine-based study conducted during the COVID-19 emergency (Grazzi et al., 2022), improvements in headache frequency were accompanied by reductions in disability and headache impact at 6 months; however, these latter benefits were not maintained at the 12-month follow-up.

Finally, behavioural changes targeted by interdisciplinary interventions were not uniformly achieved. For example, Donath et al. (2022) reported significant improvements in psychological coping strategies but did not observe a significant increase in the frequency of aerobic endurance training at long-term follow-up.

Funding and resources for the interventions

11 out of 20 studies included in the current review (55%) were acknowledged as funded. More in detail, they were granted by public (6/11; 54.5%) (Bottiroli et al., 2022; Grazzi et al., 2023; Majore-Dusele et al., 2021; Martin et al., 2021; McLean et al., 2020; Underwood et al., 2023), private (2/11; 18.2%) (Crawford et al., 2020; Zambrano-Camiña et al., 2024) or both public and private (4/11; 36.4%) (Minen et al., 2019a, 2020, 2021; Seng et al., 2019) funding. 3 studies (15%) declared no funding (Donath et al., 2022; Grazzi et al., 2019; Khazraee et al., 2023). Finally, 5 studies (25%) did not specify any funding in the acknowledgements or elsewhere (Arina et al., 2022; Cuneo et al., 2023; Grazzi et al., 2022; Haggiag & Speciali, 2020; Short, 2019).

Visiting websites of clinical centres participating in the included studies

In 17 out of 20 articles included in the current review (85%), the involvement of a clinical centre as a recruitment and/or treatment site was reported (Bottiroli et al., 2022; Crawford et al., 2020; Cuneo et al., 2023;

Donath et al., 2022; Grazzi et al., 2019, 2022, 2023; Khazraee et al., 2023; Martin et al., 2021; McLean et al., 2020; Minen et al., 2019a, 2020, 2021; Seng et al., 2019; Short, 2019; Underwood et al., 2023; Zambrano-Camiña et al., 2024). Among them, a webpage/website was available in 16 cases (94.1%). In 2 cases, the same website is shared by the studies from the same research group (i.e. Grazzi et al., 2019; 2022, 2023; Minen et al., 2019a, 2020, 2021, respectively); therefore, only one site will be counted for each of them from here onward. 10 websites (for which an English or Italian version was available) were visited searching for specific sections describing the psychological interventions provided for headache/migraine at the clinical centre. More in detail, on 4 websites there was a description of the intervention evaluated in the relative studies (Crawford et al., 2020; McLean et al., 2020; Short, 2019; Underwood et al., 2023); 2 websites contained information about the psychological approaches offered to patients with headaches, but the treatment investigated in the studies was not mentioned (Cuneo et al., 2023; Minen et al., 2019a, 2020, 2021); one site cites the psychological approach investigated in the study among the treatments offered for headaches (Grazzi et al., 2019, 2022, 2023). However, it is unclear whether the remote delivery modality—investigated by Grazzi et al. (2022)—is being implemented today or instead has been limited to the emergency induced by the COVID-19 pandemic. Finally, 3 websites did not contain any information about psychological therapies for headaches (Bottiroli et al., 2022; Khazraee et al., 2023; Seng et al., 2019).

Ongoing or upcoming trials

We retrieved 394 trials from the web-based resource Clinical.Trial.Gov. After removing trials that had not been first posted between January 1, 2019, and March 31, 2024, 207 remained and were screened against the eligibility criteria. Initially, 13 trials were included in this review. However, 1 of them—for which the study protocol publication was available (Zambrano-Camiña et al., 2024)—has subsequently been added to the category of 'new studies'. Thus, 12 trials were finally included in the category of ongoing/upcoming studies (NCT05244889, 2022; NCT04613362, 2022; NCT04984720, 2021; NCT04859374, 2021; NCT05101837, 2023; NCT04788667, 2021; NCT05623254, 2023; NCT06342219, 2024; NCT05979337, 2023; NCT05617339, 2023; NCT05415020, 2022; NCT06170281, 2023) (see Supplementary File 2 for details about the main characteristics of the ongoing trials).

Most of them—9/12; 75% (NCT04613362, 2022; NCT05415020, 2022; NCT05244889, 2022; NCT04788667, 2021; NCT05979337, 2023; NCT06170281, 2023; NCT05617339, 2023; NCT04859374, 2021; NCT05623254, 2023) are RCTs, 1 is a protocol for a pilot RCT (NCT06342219, 2024), and 2 are observational studies (NCT04984720, 2021; NCT05101837, 2023). As for the studies' recruitment status, 5 out of 12 are currently recruiting participants (NCT05415020, 2022; NCT05244889, 2022; NCT05979337, 2023; NCT06170281, 2023; NCT04984720, 2021), 2 have not yet started recruiting (NCT06342219, 2024; NCT05617339, 2023), 2 are completed—but the results are not yet available (NCT04613362, 2022; NCT04788667, 2021), and in 3 cases the status is unknown (NCT04859374, 2021; NCT05623254, 2023; NCT05101837, 2023). 6 (50%) studies are being conducted in Europe (NCT05244889, 2022; NCT05979337, 2023; NCT05617339, 2023; NCT04984720, 2021; NCT05623254, 2023; NCT05101837, 2023), 4 in the US (NCT04613362, 2022; NCT05415020, 2022; NCT05979337, 2023; NCT0617028, 2023), 1 in Canada (NCT06342219, 2024), and 1 in Asia (India) (NCT04984720, 2021). Most of the studies (8/12; 66.7%; (NCT04613362, 2022; NCT05244889, 2022; NCT04788667, 2021; NCT05617339, 2023; NCT04859374, 2021; NCT04984720, 2021; NCT05623254, 2023; NCT05101837, 2023) are being carried out in clinical contexts with participants recruited from patients referring to various facilities, while in 4 cases the setting is not specified (NCT05415020, 2022; NCT06342219, 2024; NCT05979337, 2023; NCT0617028, 2023). Most trials (7/12; 58.3%) include patients with CM (NCT04613362, 2022; NCT05415020, 2022; NCT06342219, 2024; NCT05244889, 2022; NCT04788667, 2023; NCT05979337, 2023; NCT06170281, 2023), 2 are focused on both episodic and chronic migraines (NCT05617339, 2023; NCT04859374, 2021), 2 involve patients with diagnoses of CM and neuropathic pain (NCT05623254, 2023; NCT05101837, 2023), and 1 includes several medical conditions (NCT04984720, 2021)(Crawford, 2022; Damush & Roudebusch, 2022; Elavarasi & Srivastava, 2021; Grazzi & Mantegazza, 2021, 2023; Herrero Gallego, 2023; Mantegazza & Grazzi, 2023; Mickleborough & Golshan, 2024; Sturgeon, 2023; Tailored Digital Treatment for Migraine, 2023; Woldeamanuel, 2022; Woldeamanuel & Rajasekaran, 2023).

Among the 12 ongoing trials, 8 (66.7%; NCT04613362, 2022; NCT06342219, 2024; NCT05244889, 2022; NCT05979337, 2023; NCT05617339, 2023; NCT04859374 2021; NCT05623254, 2023; NCT05101837, 2023) focus on strategies within the CBT approaches; 4 (33.3%; NCT05415020, 2022; NCT04788667, 2023; NCT0617028, 2023; NCT04984720, 2021) describe educational and self-management programmes. Although different in several aspects (e.g. contents, delivery mode, etc.), these interventions broadly aimed at promoting better headache self-management and quality of life through health-related behaviour and lifestyle modification strategies (see Table 3). 5 (41.7%; NCT06342219, 2024; NCT05244889, 2022; NCT04788667, 2023; NCT05617339, 2023; NCT04984720, 2021) interventions are conducted in an individual setting, 3 (25%; [NCT05979337, 2023; NCT06170281, 2023; NCT04859374, 2021) interventions are executed in a group-based format, and 1 (8.3%; NCT04613362, 2022) in a group or individual modality. In the remaining cases, it was not possible to identify the delivery format (NCT05415020, 2022; NCT05623254, 2023; NCT05101837, 2023). Intervention duration varies across the studies, ranging from 2 hours to 6 months. All the ongoing trials include some type of eHealth modalities to deliver (totally or partially) interventions, namely web platforms (i.e. video-conferencing software); mHealth solutions (i.e. smartphone apps), which in 1 case is adopted as part of a broader web-based programme (NCT04859374, 2021) and in the other in association with the use of an EEG device as part of a neurofeedback-based intervention (NCT06342219, 2024). In 2 studies, although it can be inferred either from the title or eligibility criteria that an eHealth modality is employed, the specific digital solution is not detailed (NCT05415020, 2022; NCT06170281, 2023). In almost all studies (11/12; 91.7%; NCT05244889, 2022; NCT04613362, 2022; NCT04984720, 2021; NCT04859374, 2021; NCT04788667, 2021; NCT05623254, 2023; NCT06342219, 2024; NCT05979337, 2023; NCT05617339, 2023; NCT05415020, 2022; NCT06170281, 2023), interventions are delivered fully remotely and in only 1 case through a blended modality (NCT05101837, 2023). In most trials (8/12; 66.7%; NCT04613362, 2022; NCT05415020, 2022; NCT04788667, 2021; NCT05979337, 2023; NCT06170281, 2023; NCT04984720, 2021; NCT05623254, 2023; NCT05101837, 2023), the intervention provider is not specified; in 1 study the intervention is delivered by an animated virtual therapist (NCT05244889, 2022); in 1 study the web-based programme's contents were developed by a multidisciplinary team (NCT05617339, 2023); in the remaining 2 cases interventions are administered by clinical health psychologists (NCT04613362, 2022) and mindfulness experts (NCT04859374, 2021), respectively. Half of the studies (6/12; 50%; NCT04613362, 2022; NCT05415020, 2022; NCT05244889, 2022; NCT05979337, 2023; NCT06170281, 2023; NCT05617339, 2023) were acknowledged as funded. In the remaining studies, it was not possible to determine whether external funding was provided (NCT06342219, 2024; NCT04788667, 2023; NCT04859374, 2021; NCT04984720, 2021; NCT05623254, 2023; NCT05101837, 2023).

Assessment of the methodological quality of the included studies

Overall, the QATSDD score ranged between 45.2% (mean raw score = 16) (Grazzi et al., 2022) and 95.2% (mean raw score = 40) (Underwood et al., 2023) (see Supplementary File 3), with an average quality score for all studies of 77.6% (raw score: mean 32.1, SD 5.2). The differences in quality among the studies primarily centred on the following items: the evidence of sample size considered in terms of analysis, the explanation of the rationale for the choice of data collection tools, and the evidence of user involvement in design. The lowest QATSDD single-item scores were related to the statistical assessment of reliability and validity of measurement tools (item score: mean 0.8, SD 0.9) and user involvement in the study design (item score: mean 0.8, SD 1.0), with the last one considered only in 8 (44.4%; Crawford et al., 2020; Grazzi et al., 2023; McLean et al., 2020; Minen et al., 2019a, 2020, 2021; Short, 2019; Underwood et al., 2023) of the 18 studies assessed. In addition, the evidence of sample size considered in terms of analysis (item score: mean 1.4, SD 1.4) was limited in most of the studies.

Comparison of the interventions in studies before and after the Covid-19 pandemic

Among the 20 studies included in the current review, 6 were conducted after or straddling the onset of the COVID-19 pandemic (30%; Bottiroli et al., 2022; Cuneo et al., 2023; Grazzi et al., 2022; Grazzi et al., 2023; Khazraee et al., 2023; Zambrano-Camiña et al., 2024). In one case, the period in which the study was

Table 3. Characteristics of the interventions included in the ongoing/upcoming trials.

NCT Number, study start date	Main aims	Intervention	Duration Format (group/ individual); Delivery mode (in-person; fully remotely; blended)	eHealth modality	Intervention provider	Follow-up	Cost-effective analysis
NCT04613362, 2022	To evaluate the feasibility and preliminary efficacy of a telemedicine-based CBT[a] programme (TENACITY) on headache-related outcomes and psychological symptoms	EG[b]: 6 CBT for headache sessions + education CG[c]: usual care (outpatient in-person health psychology or mindfulness sessions) + education	12 weeks; individual or group; fully remotely	Telehealth platform	Clinical health psychologists	6 months	Yes
NCT05415020, 2022	To evaluate the feasibility, acceptability, and outcomes of a lifestyle behaviour protocol in managing CM[d]	EG: Regular Lifestyle Behaviour (RLB) Protocol CG: Sham Behaviour Protocol	12 weeks; format NS[e]; fully remotely	NS	NS	NS	NS
NCT06342219, 2024	To explore the beneficial effects of neurofeedback mindfulness on several headache-related outcomes	EG1: 10 min/day practice of neurofeedback mindfulness CG1: attention task CG2: waitlist	8 weeks; individual; fully remotely	EEG headband + smartphone app	NS	NS	NS
NCT05244889, 2022	To evaluate the effectiveness of dCBT-I for improving insomnia and migraines in patients with CM	EG: 6-session dCBT-I programme CG: 6-sessions Sleep Hygiene Education programme	6 weeks; individual; fully remotely	Website	Animated virtual therpist	6 months	Yes
NCT04788667, 2023	To evaluate the effectiveness of a health education programme on several migraine-related outcomes	EG: health education programme (video-tutorials) + regular pharmacological treatment CG: general recommendation (video-tutorials) + regular pharmacological treatment	6 months; individual; fully remotely	Telehealth platform	NS	1, 3, and 6 months	NS
NCT05979337, 2023	To explore if changing behaviours can reduce migraine-related disability, symptom severity, and pain catastrophizing	EG1: a 2-hour behavioural intervention session (Empowered Relief) EG2: a 2-hour health education class EG3: Empowered Relief + health education CG: TAU[f]	2 hours; group; fully remotely	Video conferencing platform (Zoom)	NS	1, 2, 3, and 6 months	NS
NCT06170281, 2023	To assess patient preference, optimum combinations and sequences of a multicomponent behavioural intervention for migraine	1) Choice arm: allowed to choose from various migraine treatment options. 2) Random arm: randomised migraine behavioural treatment options.	12 weeks; group; fully remotely	NS	NS	No	NS

Table 3. (*Continued*)

NCT Number, study start date	Main aims	Intervention	Duration Format (group/ individual); Delivery mode (in-person; fully remotely; blended)	eHealth modality	Intervention provider	Follow-up	Cost-effective analysis
NCT05617339, 2023	To evaluate the effect of the addition of an internet-based biopsychosocial treatment in primary care on several migraine-related outcomes	EG: Learn to live with migraine (I AM—Internet Approach to Migraine) CG: TAU (medical treatment)	4–10 weeks; individual; fully remotely	Web app	The programme's contents were developed by a multidisciplinary team	6 months, 1 and 2 years	NS
NCT04984720, 2021	To explore if a digital application can lead to better information uptake and improved compliance and self-management	EG: smartphone app which tracks migraine and offers pill reminders for medication adherence and community blog and disease related educational material for migraineurs CG: clinic-based education and traditional paper-pen diary	4 weeks; individual; fully remotely	Smartphone app	NS	No	NS
NCT04859374, 2021	To evaluate the effectiveness of a mindfulness protocol added to pharmacological treatment on several pain-related outcomes	EG: 6 1-hour weekly video-sessions of mindfulness practice + daily standardised 12-minute mindfulness sessions + TAU (traditional pharmacological therapy) CG: TAU	8 weeks; group ('homework'); fully remotely	Web platform (STARLEAF) + video recordings (smartphone)	Mindfulness expert	Every 3 months for 12 months	NS
NCT05623254, 2023	To evaluate the feasibility and preliminary effectiveness of a mindfulness programme in promoting patients' adaptation to and better disease management while enhancing caregivers' resilience in delivering support	Weekly sessions of mindfulness practice + TAU	Duration and format NS; fully remotely	Web platform	NS	NS	NS
NCT05101837, 2023	To evaluate the feasibility and preliminary effectiveness of a mindfulness programme on headache-related and psychological outcomes	Mindfulness sessions delivered through a specific app for daily practice, added to a regular mindfulness guided face-to-face programme	Duration and format NS; blended	Smartphone app	NS	No	NS

[a] CBT: cognitive-behavioural therapy
[b] EG: experimental group
[c] CG: control group
[d] CM: chronic migraine
[e] NS: not specified
[f] TAU: treatment-as-usual

conducted could not be identified since it is not specified in the paper (Arina et al., 2022). Among these 6 studies - of which 2 are study protocols (Bottiroli et al., 2022; Zambrano-Camiña et al., 2024) - 4 focused on strategies within the CBT approaches (66.7%: Grazzi et al., 2022, 2023; Khazraee et al., 2023; Zambrano-Camiña et al., 2024), 1 used biofeedback (16.7%; Cuneo et al., 2023), and 1 proposed the enfacement illusion of a happy face as a strategy for pain relief (16.7%; Bottiroli et al., 2022). The interventions were administered individually in 3 studies (50%; Bottiroli et al., 2022; Cuneo et al., 2023; Khazraee et al., 2023) and a group setting in the remaining 3 studies (Grazzi et al., 2022, 2023; Zambrano-Camiña et al., 2024). The interventions were delivered in person in 3 studies (50%; Khazraee et al., 2023; Majore-Dusele et al., 2021; Zambrano-Camiña et al., 2024), fully remotely in 1 study (16,7%; Crawford et al., 2020), and through a blended modality in 2 studies (33.3%; Arina et al., 2022; Bottiroli et al., 2022; Cuneo et al., 2023; Haggiag & Speciali, 2020; Short, 2019; Underwood et al., 2023). 3 studies involved some type of eHealth modalities to deliver (totally or partially) interventions (50%; Bottiroli et al., 2022; Cuneo et al., 2023; Grazzi et al., 2022), encompassing virtual reality systems, which in 1 case was used in association with a biofeedback device (Cuneo et al., 2023), and a m-Health solution (Grazzi et al., 2022). It is worth noting that among these 6 studies, only 3 (Cuneo et al., 2023; Grazzi et al., 2022, 2023) explicitly referred to the public health emergency in terms of its impact on several research-related aspects. Overall, the possibility for biased results due to compromised adherence was highlighted, as patients experienced unprecedented disruptions in their daily lives. Only the research carried out by Grazzi et al. (2022) preliminarily examined the feasibility of a mindfulness intervention—originally delivered in-person at their clinical centre - that has been shifted to a web-based modality to address the pandemic-related restrictions and ensure continuity of treatment for patients.

As for the 13 studies conducted before the pandemic outbreak (Crawford et al., 2020; Donath et al., 2022; Grazzi et al., 2019; Haggiag & Speciali, 2020; Majore-Dusele et al., 2021; Martin et al., 2021, McLean et al., 2020; Minen et al., 2019a, 2020, 2021; Seng et al., 2019; Short, 2019; Underwood et al., 2023), 5 (38.5%) focused on strategies within the CBT approaches (Grazzi et al., 2019, 2022, 2023; Martin et al., 2021; Seng et al., 2019); 3 (23.1%) were based on a relaxation training (Minen et al., 2019a, 2020, 2021); 2 (15.4%) described education and self-management programmes (Short, 2019; Underwood et al., 2023); 1 (7.7%) proposed an interdisciplinary intervention including at least a psychological component (Donath et al., 2022); 1 (7.7%) used biofeedback (Haggiag & Speciali, 2020); 1 (7.7%) evaluated a new patient-centred education session as an entry point into a larger headache multimodal programme (McLean et al., 2020). The interventions were administered individually in 7 studies (53.9%; Crawford et al., 2020; Haggiag & Speciali, 2020, Minen et al., 2019a, 2020, 2021; Seng et al., 2019; Short, 2019) and in a group setting in 6 studies (46.2%; Grazzi et al., 2019; Majore-Dusele et al., 2021; Underwood et al., 2023; McLean et al. 2020; Donath et al., 2022; Martin et al., 2021). The interventions were delivered in person in 6 studies (46.2%; Donath et al., 2022; Grazzi et al., 2019; Majore-Dusele et al., 2021; Martin et al., 2021; McLean et al., 2020; Seng et al., 2019), fully remotely in 4 studies (30.8%; Crawford et al., 2020; Minen et al., 2019a, 2020, 2021), and through a blended modality in 3 studies (23.1%; Haggiag & Speciali, 2020; Short et al., 2019; Underwood et al., 2023). 6 studies involved some type of eHealth modalities to deliver (totally or partially) interventions, including web-based programmes (Crawford et al., 2020; Short, 2019), a biofeedback device (Haggiag & Speciali, 2020), mHealth solutions (Minen et al., 2019a, 2020, 2021). Furthermore, in 1 study conducted before the pandemic onset, the follow-up measurement took place 2 weeks after the beginning of the COVID-19 pandemic, highlighting that both the collection and interpretation of data may have been influenced by the pandemic (Majore-Dusele et al., 2021).

With respect to the interventions' implementation into clinical practice, no substantial differences were observed between the studies conducted before and after the COVID-19 pandemic.

Discussion

The aim of the current article was twofold: (1) building upon the findings of our previous review (Perlini et al., 2020), to provide an updated overview of the existing literature concerning evidence-based psychological interventions available for adults with CH while exploring potential factors (e.g. funding, setting, healthcare providers) that may influence their implementation in clinical practice; (2) to investigate whether the COVID-19 pandemic has impacted the characteristics, administration modalities, and

implementation of such interventions. To reach these objectives, a multidimensional four-step approach was adopted. 20 studies published between 2019 and 2024 (i.e. in the last five years after the previous review) were included. Of these studies, 10 were novel, and 10 were updates to studies included in Perlini et al. (2020). Additionally, 12 ongoing trials were considered in the current review.

As for the first research question, several psychological approaches were examined in the retrieved articles, which, while varying to some degree, primarily fall into three main categories: cognitive-behavioural therapy (including both standard approaches and more recent ones, such as mindfulness-based programmes), biofeedback, and relaxation training. Notably, one innovative approach will explore exposure to the enfacement illusion of a happy face to alleviate pain (Bottiroli et al., 2022). Overall, the evaluated psychological interventions were associated with improvements in at least one headache-related outcome, such as reduced headache frequency and intensity and pain-related disability. These findings concerning both the typologies of psychological interventions and their reported effects on headache-related outcomes in this specific field are consistent with previous reviews, including that of Perlini et al. (Lee et al., 2019; Perlini et al., 2020; Sturgeon et al., 2023). Regarding the clinical characteristics of the populations covered by the studies included in the current review, nearly 70% of them exclusively focused on migraine, while in Perlini et al. (2020), most studies encompassed all primary headache diagnoses (i.e. migraine, TTH, cluster, or mixed headache). In addition, the current updated review also provided insights into comorbidities, with mentions of two studies involving patients with CM alongside conditions such as awake bruxism or insomnia (Crawford et al., 2020; Haggiag & Speciali, 2020). The proposed interventions targeting the above comorbid conditions have been associated with improvements in both pain intensity and frequency. This observation is consistent with existing literature suggesting the potential value of comprehensive assessments and management strategies, including the integration of non-pharmacological approaches tailored to the unique profiles of patients (Caponnetto et al., 2021). Another noteworthy observation concerns the high use of different eHealth-based solutions to provide psychological interventions compared to Perlini et al. (2020). More in detail, 6 out of the 28 (21.4%) studies included in the previous review (Perlini et al., 2020) utilised some of these technologies to deliver the intervention either entirely through web-based tools and via a smartphone app, or in a blended format that incorporated biofeedback devices during in-person meetings. Notably, in the present review, a greater (i.e. 13 out of 20 studies; 65%) and more diversified use of eHealth tools emerged, including web-based programmes (Crawford et al., 2020; Short, 2019), biofeedback (Arina et al., 2022; Cuneo et al., 2023; Haggiag & Speciali, 2020), VR (Bottiroli et al., 2022; Cuneo et al., 2023) and mobile health applications (Grazzi et al., 2022; Minen et al., 2019a, 2020, 2021). Looking at the ongoing trials, in all of them (12/12; 100%) some kind of eHealth solution is being adopted, highlighting a potentially growing trend toward the incorporation of digital technologies in the specific area of psychological interventions targeting patients with headache disorders. Taken together, this pattern – particularly the systematic adoption of eHealth solutions across all ongoing trials—suggests a shift toward digital delivery models that may extend beyond the COVID-19 emergency and shape future developments in the field.

As for the actual implementation of the interventions in clinical practice, it appears to be rather lacking, to the extent that only in 4 cases the intervention described in the respective articles is offered to patients with headache disorders in clinical settings. In addition, 2 studies examined the feasibility and preliminary effectiveness of interventions originally designed and clinically used for the treatment of other conditions—often comorbid with headache disorders (i.e. insomnia and awake bruxism)—on pain-related outcomes in patients with headache disorders. However, it does not seem that these interventions are currently implemented for the specific treatment of headache-related disorders. In this regard, before proposing the dCBT-I intervention in the clinical pathway, Crawford and colleagues (Crawford et al., 2020) emphasise the need to conduct an RCT—that is underway (NCT05244889, 2022)—to demonstrate with a rigorous methodology of the treatment efficacy in patients with CM and insomnia. Overall, these results are in line with those found in the previous review (Perlini et al., 2020), which stressed the importance of considering the potential impact of several factors on the clinical implementation of evidence-based interventions, including the presence of scarce or fragmented funding (Dopp et al., 2020; Vincenten et al., 2019). In the present work, more than half of the studies were acknowledged as funded by both public (in most cases) and private grants (or a combination of the two), which can presumably be expected for a limited duration and, therefore, insufficient to ensure all the necessary steps

for the transition from research to clinical practice. It is also necessary to consider the availability of professionals adequately trained and skilled in the proposed interventions - whose engagement occurs in most of the included studies - which, in turn, may require additional financial incentives, such as those aimed at training purposes. Furthermore, there is evidence of a dearth of specialty-trained mental health providers, especially outside tertiary care settings, which consequently may hinder patients' access to effective treatments (Sturgeon et al., 2023). One potential innovative approach to address the above challenges lies in the realm of eHealth, which may contribute to enhancing accessibility to healthcare services while simultaneously decreasing the associated costs of care delivery (Mumtaz et al., 2023). However, although some preliminary evidence of the effectiveness and feasibility of eHealth solutions has emerged in different contexts—e.g. in the treatment of chronic non-cancer pain in both adult and older populations (De Lucia et al., 2024; Donisi et al., 2023), it is an emerging and heterogeneous area of research that requires further investigation, also considering the widespread inhomogeneity on a regulatory perspective worldwide (Bente et al., 2024). In parallel with this rapid expansion, increasing efforts have been directed toward the conceptualisation, classification, and regulation of eHealth interventions with the aim of establishing shared definitions and standards within a highly heterogeneous field (National Institute for Health and Care Excellence, 2019). In line with this, findings from the present review indicate a growing research interest in eHealth-based psychological interventions for headache disorders. At the same time, these observations suggest that the field is still at an early developmental stage, with evidence being consolidated prior to broader implementation in routine clinical practice.

To answer the second research question, we categorised the retrieved studies into those conducted before the COVID-19 pandemic outbreak and those undertaken after or straddling it. Globally, the pandemic has put a huge strain on public health systems, causing them to reorganise and find new modalities to ensure continuity of care (Ohannessian et al., 2020). Within this framework, the adoption of eHealth solutions has accelerated rapidly, representing an important adaptation strategy to minimise the risk of virus transmission while ensuring the delivery of medical treatments in various healthcare fields, including headache disorders management (Chiang et al., 2021). However, taking into account the 6 studies included in the current review, which were conducted after the onset of the COVID-19 pandemic, the available evidence does not indicate consistent changes in how the proposed psychological interventions were implemented. Importantly, the interpretation of these findings is constrained by the timing of the included studies, which span both the acute public health emergency phase (2020–2021) and a subsequent post-emergency period, during which healthcare services largely resumed usual practices.

Indeed, 3 studies explicitly referred to the impact of the health crisis on various research-related aspects (e.g. biased outcomes due to compromised adherence), yet without reporting substantive modifications in intervention delivery modalities. Only 1 study (Grazzi et al., 2022) examined the feasibility of a mindfulness programme originally offered in person but later moved online due to pandemic-related restrictions. Nonetheless, it cannot be ruled out that future publications will reveal further experiences of changing or transitioning to eHealth modalities for delivering psychological interventions in the specific area of headache disorders. In general, there was no evidence of relevant changes in the interventions' characteristics or the extent to which they are implemented in clinical environments.

To conclude, this review offers a comprehensive overview of available evidence-based psychological interventions for headache disorders, highlighting the significant interest in this field, particularly concerning CH, which can be profoundly debilitating. Despite the progression of research in this area and the impact of the COVID-19 pandemic on health systems, a substantial lack persists in the implementation of these interventions within clinical practice, and several barriers—already recognised in Perlini et al. (2020)—seem to persist. While the adoption of eHealth solutions theoretically presents a potentially valuable option to bridge the above gap, the ongoing digital transformation has yet to effectively facilitate the transition from research to clinical applications at least in the specific context analysed.

Some limitations of the current review should be mentioned. Firstly, the inclusion criteria focused primarily on English-language studies, potentially excluding valuable research from non-English sources. Second, we based our conclusions on the implementation of interventions into clinical practice upon information retrieved from articles or websites, the latter of which may not always be updated. Finally, while this review considered ongoing trials, the rapidly evolving landscape of eHealth interventions necessitates continuous updates to capture emerging evidence effectively.

Conclusion

In conclusion, this review emphasises both the progress and challenges in implementing evidence-based psychological interventions for chronic headache disorders. While many studies showed the effectiveness of approaches like CBT, biofeedback, and relaxation training, only a few appear to have been integrated into routine clinical practice. Therefore, a gap still exists in exploring the factors that could facilitate such implementation, an area that requires further attention in future research.

Our analysis revealed that the COVID-19 pandemic, while exerting significant pressure on public health systems and accelerating the adoption of eHealth solutions across various healthcare sectors, did not appear to markedly alter the implementation of psychological interventions in this specific field, based on the currently available evidence.

Furthermore, enhancing collaboration among researchers, healthcare providers, and policymakers is important to ensure effective psychological treatments are accessible, ultimately improving the quality of care and life for individuals with chronic headaches.

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Data availability statement

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Ethical approval

(a) Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and was approved by an Institutional Review Board/Ethics committee. See details under Methods.
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