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Evaluation of emotion-centric psychological interventions for chronic pain: Protocol for a systematic review and meta-analysis

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Abstract

Introduction

Chronic pain, defined as pain persisting longer than 3 months, is more than an unpleasant sensory experience. Persistent negative emotions and emotional comorbidities, such as depression and anxiety, plague people with chronic pain leading to worsening pain intensity and increasing disability. While cognitive behavioural therapy (CBT) is the gold standard psychological treatment, recent evidence highlights that CBT lacks efficacy for the physical and emotional aspects of chronic pain. Increasingly, researchers are investigating emotion-centric psychological therapies. While treatment modalities vary, these interventions frequently target understanding emotions, and train individuals for an emotionally adaptive response. The aim of this systematic review and meta-analysis is to quantify the efficacy of emotion-centric interventions for the physical and emotional characteristics of chronic pain.

Methods/Analysis

Electronic databases (EMBASE, PubMed, PsychINFO, CENTRAL, CINAHL and Web of Science), will be systematically searched for randomised controlled trials. Studies that compare an emotion-centric intervention with another form of treatment or placebo/control for adults (≥18 years old) with chronic pain will be included. All treatment modes (e.g., online or in-person), any duration, and group-based or individual treatments will be included. Studies that do not investigate at least one emotion-centric treatment will be excluded. The primary outcome is pain intensity. Secondary outcomes include emotion dysregulation, depression, anxiety, safety, and intervention compliance. A quantitative synthesis using a random-effects meta-analysis will be adopted. Risk of bias will be evaluated using Cochrane RoB 2.0 with the certainty of evidence assessed according to GRADE. Data permitting, subgroup analysis will be conducted for intervention type and pain condition.

Ethics and dissemination

Ethical approval is not required for this systematic review. Results may inform an efficacy study examining a new emotion-centric intervention for chronic pain. Dissemination will be through peer-reviewed publications and in conference presentations.

PROSPERO Registration number

CRD42021266815

Strengths and limitations of this study

- This systematic review will follow recommendations for conduct and reporting of systematic reviews including independent study selection, data extraction, risk of bias assessments by two researchers according to Cochrane RoB 2.0, quality of evidence assessed according to GRADE recommendations, and reporting according to PRISMA guidelines.
- To the best of our knowledge, this is the first systemic review and meta-analysis to examine interventions that focus on changing the negative emotional experiences associated with chronic pain.
- A meta-analysis may not be possible if there are a lack of comparable studies or interventions, in which case a narrative synthesis is planned.
- Findings may be limited by heterogeneity arising from the inclusion of different psychological interventions and different pain conditions or a lack of data.

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Background

Chronic pain, defined as pain persisting longer than 3 months[1], is a substantial and costly source of suffering. Twenty percent of people live with chronic pain[2], and annual economic costs to the healthcare system are estimated to exceed that of heart disease, cancer, and diabetes combined[3]. Chronic pain is commonly regarded as being both a sensory and an emotional experience. The International Association for the Study of Pain, explains that without emotion, the understanding of chronic pain is incomplete[4]. Research supports this perspective, with fear, anger, worry and low mood frequently reported by people with chronic pain[5-8]. Beyond negative emotional states, anxiety, and depression present in up to 80 percent of individuals[9-12]. Emotional comorbidities are related to greater suffering, including increased pain intensity and disability[13 14], and are a factor regardless of chronic pain type[15]. Despite the wide acceptance that emotions are key components of chronic pain, the most effective approach to modulate the distressing emotional experience of chronic pain is not yet fully understood.

One mechanism related to negative emotions experienced by people with chronic pain is emotion dysregulation, defined as a heightened sensitivity to emotional stimuli, impeding the ability to identify emotions and to moderate emotional states and expression in line with an adaptive response[16]. Long considered a factor in emotional disorders such as major depression, generalised and social anxiety disorders[17], emotion dysregulation is now thought to be a crucial factor in the development and the maintenance of chronic pain[18-20]. One cause of emotion dysregulation may be the debilitating and distressing aspect of chronic pain and the experience of missing out (e.g., on career, education, and social activities), which perpetuates negative emotional appraisal of situations, that over time fatigues emotion regulation capabilities[21-23]. Emotion dysregulation may also be antecedent to chronic pain, whereby some individuals have a trait-like propensity for emotion dysregulation meaning they are at greater risk of developing chronic pain[24 25]. Attempts to manage overwhelming emotions have been found to lead to maladaptive emotion regulation strategies (e.g., expressive suppression, experiential avoidance, and rumination) which are largely counterproductive and led to a cycle of increasingly intense emotions and worsening chronic pain[26].

In the treatment of chronic pain, analgesic medication is commonly prescribed to manage painful symptoms[27]. However, there is no single medication that is consistently effective for all individuals[28], and some, such as opioids carry an increased risk of experiencing adverse events including dependence and even death[29 30]. Moreover, evidence shows that pain-relieving medications have little effect on emotional problems associated

with chronic pain[10 31]. Cognitive-behavioural therapy (CBT), is considered the gold standard in psychological treatment for chronic pain[32]. CBT focuses on modifying thoughts, physical sensations and maladaptive behaviours[33], and in some studies demonstrates improvement in pain severity[34], and related distress[35]. However, a recent Cochrane review concludes that overall, CBT has minimal effect on pain severity and no effect on mood in people with chronic pain[33]. Thus, some researchers are enhancing existing psychological treatment modalities and developing new interventions to treat chronic pain by managing its emotional components. Examples include interventions which incorporate emotion regulation skills adjunct to CBT[36], those that focus on emotion awareness and expression[37], and those such as dialectical behavioural therapy, a behavioural therapy for emotion dysregulation[38]. While the theory underpinning these interventions vary, the primary focus is on understanding emotions and training skills for an adaptive emotional response.

Previous systematic reviews have explored the effects of psychological therapies for chronic pain. The focus of these reviews has predominantly been on exploring cognitive and behavioural treatments[33 39 40], acceptance and mindfulness-based interventions[33 40-43], and psychodynamic therapies[44]. The results of these reviews fail to demonstrate an intervention that consistently reduces chronic pain, highlighting the need for further exploration of alternative psychological interventions. While a narrative synthesis of studies exploring the effects of varying treatments on the emotional experience of chronic pain demonstrates promising findings[21], a more rigorous evaluation is required of studies that specifically target emotions as a feature of chronic pain. Additionally, a meta-analytic synthesis of the data across studies exploring emotion-centric interventions is necessary to determine effect estimates to guide psychotherapeutic plans. These insights are important for psychologists and clinicians, including physiotherapists working with chronic pain patients[45]. The results may also be insightful to identify gaps in the literature to provide direction for future studies.

Objectives

The present systematic review will analyse the evidence from studies that investigate the efficacy of emotion-centric interventions to treat the unpleasant sensory and emotional aspects of chronic pain. We will compare emotion-centric psychological interventions to other types of psychological treatment, treatment as usual and control/waitlist. The primary objective is to evaluate the evidence to reduce pain intensity for people with chronic pain. The secondary objective is to evaluate the evidence to improve other factors associated with chronic pain, specifically, emotion dysregulation, depression, and anxiety. An additional objective of this review is to narratively report on safety and intervention compliance.

Methods and Analysis

Study Design

This protocol was written in accordance with the PRISMA extension for developing review protocols (PRISMA-P)[46] (Appendix 1). The systematic review protocol has been registered with the International Prospective Register of Systematic Reviews (PROSPERO): CRD42021266815.

Eligibility criteria

Types of studies

We will include randomised controlled trials (RCTs) that have evaluated the efficacy of emotion-centric interventions delivered online or in-person for any chronic pain condition. This will include emotion-centric interventions compared with treatment as usual (standard care waitlist/no-treatment conditions), and active psychological therapies (e.g., cognitive-behavioural therapy, acceptance-commitment therapy, and mindfulness-based stress reduction). Observational studies, non-randomised trials, research letters, thesis, and conferences abstracts will be excluded. Completed unpublished studies registered in clinical trial registries (e.g., ClinicalTrials.gov, EU Clinical Trials Register, ANZ Clinical Trial Registry, WHO International Clinical Trial Registry Platform) will be included.

Types of participants

We will include studies with adults (≥18 years old) with chronic pain, defined as persistent or recurring pain for a minimum of three months[47]. All types of chronic pain conditions will be included, because emotions are part of the experience regardless of the chronic pain condition[15]. Chronic pain conditions may include but will not be limited to, rheumatoid arthritis, arthralgia, temporomandibular joint syndrome, myofascial pain, neck pain, back pain, neuralgia, myalgia, myodynia, chronic compartment syndrome, rheumatic polymyalgia, migraine, and fibromyalgia. Studies that enrolled children or adolescents aged <18 years and studies enrolling individuals who have been experiencing pain for less than three months will be excluded.

Types of interventions

We will include emotion-centric psychological intervention regardless of the study mode (e.g., internet-delivered, telehealth, or face-to-face) and regardless of whether it is group-based or individual. We define emotion-centric interventions as those that help participants understand emotions and teach strategies for an adaptive emotional response. Dialectical-behavioural therapy (DBT) is one such intervention that incorporates

understanding emotions and teaches emotion regulation skills, thus studies administering DBT to participants with chronic pain will be included if they also meet the other inclusion criteria.

Studies using psychological interventions that do not focus on helping individuals understand emotions and do not deliver emotional strategies or techniques for effective emotion expression will be excluded. Specifically, mindfulness-based stress reduction (MBSR), cognitive-behavioural therapy (CBT), and acceptance-commitment therapy (ACT), when delivered in their standard formats do not purposefully seek to identify emotional reactions and do not typically administer strategies for emotional expression or regulation, so will be excluded[18 48 49]. However, studies which administer MBSR, CBT, ACT or another psychological treatment, adjunct to an emotion-centric intervention or emotional targeted strategies will be considered for inclusion. In case of doubt, we will contact corresponding authors to obtain more details on the psychological intervention. Eligible interventions may be delivered by a licenced health professional (e.g., registered psychologist or physiotherapist), or by a skills trainer in an emotion-centric treatment modality (e.g., dialectical-behavioural therapy skills trainer). If it is unclear, study eligibility will be determined by consensus among reviewers.

Types of settings

There will be no restriction placed on setting of intervention delivery. For example, studies where the intervention was delivered in primary care, secondary care, university-based clinics, homes, residential care homes and community settings, including those online will all be included.

Types of outcome measures

The primary outcome (pain intensity) will be measured with validated self-rating instruments (e.g., 0–10 Numerical Rating Scale; NRS, or a 0–10/0–100 visual analogue scale; VAS)[50]. Studies that use other scales to measure pain intensity will not be excluded, providing they demonstrate psychometric properties for reliability and validity.

Secondary outcomes of interest are, emotion dysregulation (e.g., Difficulties in Emotion Regulation Scale), depression (e.g., Beck Depression Inventory), and anxiety (e.g., State-Trait Anxiety Inventory). Studies that use other scales will not be excluded providing they demonstrate psychometric properties for reliability and validity.

We will consider two outcome assessment timepoints: short term follow-up, outcome data assessed immediately following the treatment; and long-term follow-up, outcome data

assessed at least three months, but not longer than 12 months, after the end of treatment. If multiple follow-up data is available for a single timepoint, we will select the last time point.

Further secondary outcomes are safety and intervention compliance. Safety is defined as the proportion of participants who experience at least one adverse event during the intervention period. Adverse events are broadly defined as any 'adverse event', 'serious adverse event', 'side effect, or 'complication' resulting in discontinuation of treatment associated with the treatment under investigation (emotion-centric or comparison). Intervention compliance is reflected by the proportion of participants who completed the modules in each study-specific treatment (emotion-centric or comparison) during the intervention period.

Search strategy

The following databases will be searched for eligible studies: EMBASE (Ovid), Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, SCOPUS, PubMed and CINAHL (EBSCO) (Appendix 2). Search concepts will include language and keywords for: randomised controlled trial, chronic pain, and terms relating to emotion centric psychological interventions, according to the eligibility criteria defined earlier in the protocol. A search for ongoing trials will be conducted on ClinicalTrials.gov, EU Clinical Trials Register, ANZ Clinical Trial Registry, WHO International Clinical Trial Registry Platform. We will manually search the reference lists of included studies and previous reviews to identify additionally eligible studies. No limitations will be placed on year of publication. Studies written in English, French, German, or Persian will be included. While the review is in progress, citation searching for forward citation of recent studies and citation alerts (e.g., on Google Scholar) on included studies will be used to identify new studies as they appear. The searches will be rerun prior to the final analysis and further retrieved studies will be included.

Study Selection

Studies retrieved using the search strategy and those from additional sources will be imported to Covidence[51], where an automatic deduplication function will be applied to remove duplicate records. Two reviewers (NN-N and NH-S) will independently screen titles and abstracts to determine eligibility and then will conduct full paper reviews. If consensus cannot be reached on eligibility, a third author (YQ) will be contacted to resolve through discussion or arbitration. Excluded studies and the reasons for exclusion will be recorded and documented. The search process will be summarised using an adapted PRISMA flow diagram[52].

Data Management and Extraction

Two reviewers (NN-N and NH-S) will independently extract data from the included studies using a customised data extraction spreadsheet in Microsoft Excel. The form will be pilot tested on two articles. Disagreements will be resolved by consensus or through discussion with a third reviewer (YQ).

Study Characteristics

Data about the study characteristics will be extracted, including study design, sample size, country, setting, pain condition(s) investigated, and duration of the follow-up(s).

Participant Characteristics

Data will be extracted about the study sample including, age, sex, education, ethnicity, socioeconomic status, duration of pain, comorbidities, and baseline mean and variability for the primary and secondary outcomes.

Interventions and Comparators

Data about the intervention and the comparators will be extracted:

- Key components of the psychological intervention, including:
  - Specific details of the psychological approach (e.g., CBT plus emotion regulation strategies).
  - Number of sessions.
  - Whether the sessions are group-based or individual.
  - Emotional strategies delivered.
  - Qualifications of personnel delivering the intervention.
- Mode of delivery (e.g., online or in-person).
- Intervention frequency and duration.

Outcomes

Data about the definition for the primary and secondary outcomes investigated will be extracted. Data about the type, dimensions and anchors the measurement tools used to assess the primary and secondary outcomes will also be extracted.

Results

We will extract data on study results including details of the number of participants randomised to each condition (e.g., emotion-centric intervention or comparison). Data will be extracted for the primary outcome of pain intensity, and the secondary outcomes of emotion

dysregulation, depression, anxiety, safety, and intervention compliance (including the study specific definitions of safety and intervention compliance).

The outcomes of safety and intervention compliance will be summarised at a descriptive level because it is expected that these aspects will not be reported in all identified studies and compliance is likely only to be observed in the intervention groups. For all other outcomes we will preferentially extract the outcome score and measure of variance at the end of treatment (or closest time point) for each group and at follow-up, followed by the change from baseline and measure of variance. Follow-up means the assessment timepoint which is at least three months after the end of treatment but not longer than 12 months. If data are not available for each trial arm, we will extract the between-group statistics at the end of treatment.

If a study reports more than one measure for pain, we will prioritise the extraction as follows: 100-mm VAS, 10-cm VAS, 11-point NRS, rating on a pain intensity scale for a composite measure (e.g., McGill Pain Questionnaire), and then rating on an ordinal scale. For all other outcomes, if a given outcome is measured by several measurement tools the hierarchy for analysis will be decided by consensus from the reviewers. Whenever possible, we will use results from an intention-to-treat (ITT) analysis[53].

Dealing with Missing Data

In the case of missing data, the study authors will be contacted where necessary a maximum of three times, after which point it will be considered that the data/information is irretrievable. If data for the primary or secondary outcomes are not presented in an appropriate form for meta-analysis (e.g., median, minimum and maximum values are reported instead of mean and standard deviation), established methods will be considered to impute these values[54].

Assessment of Risk of Bias

The risk of bias of the included randomised trials will be assessed by two reviewers (NH-S and NN-N) using the Cochrane Risk of Bias (RoB 2.0) tool for RCTs[55]. According to RoB 2.0, five domains are evaluated: (a) bias arising from the randomization process; (b) bias due to deviations from intended interventions; (c) bias due to missing outcome data; (d) bias in measurement of the outcome; and (e) bias in selection of the reported results. Risk of bias judgement for each domain and an overall judgement can be made in terms of low risk of bias, high risk of bias, or some concerns. Reviewers will judge items at the study level, which prioritises information regarding the primary outcome (pain intensity). In case of disagreement, a third reviewer will be consulted (YQ).

Assessment of Heterogeneity

To assess the extent that the investigated studies are similar, such as they deliver the same emotion-centric intervention, we will assess for heterogeneity using a standard Chi^2 test and will estimate the percentage of the variability that is due to heterogeneity using the I^2 statistic. Heterogeneity will be considered significant when $p < .1$ and $I^2 \geq 50\%$[55].

Data Synthesis

If possible, outcome data extracted from the RCTs will be quantitatively synthesised using a random effects meta-analysis in R (RStudio v1.2.5033). If a meta-analysis is not possible (due to lack of comparable studies or interventions), a narrative synthesis of the findings will be used to report outcomes according to SWiM (Synthesis without meta-analysis) guidelines[56].

We plan to conduct two classes of comparisons depending on the comparators used in the studies. Firstly, we will compare emotion-centric intervention to active comparator including other therapies (Active). Secondly, we will compare emotion-centric intervention to treatment-as-usual including, sham, no treatment, and waitlist (TAU). The treatment will be compared at two time points, immediately post-treatment (T1), defined as the assessment timepoint occurring at the end of treatment and at follow-up (T2), defined as the assessment timepoint which is at least three months after the end of treatment but not longer than 12 months, and the longer follow-up if there were more than one follow-up assessment. Therefore, the four separate comparisons are planned as:

1. Emotion-centric versus Active at T1
2. Emotion-centric versus Active at T2
3. Emotion-centric versus TAU at T1
4. Emotion-centric versus TAU at T2

For each comparison the primary outcome data (pain intensity) will be converted to a common 0-100 point scales (mean and standard deviation)[57]. For numerical and continuous scales, the score value will be divided by the range of scale, and then multiplied by 100. For example, for a 0 to 20 scale, the score value will be divided by 20 and multiplied by 100. We plan to use a weighted mean difference (WMD) with 95% confidence intervals (CI).

For the secondary outcome data (emotion dysregulation, depression, and anxiety) standardised mean differences (SMD), with 95% CI, will be computed to obtain a summary measure of effect size across the studies to quantify the impact of treatment relative to

Active or TAU for each comparison. By utilising a SMD for the secondary outcomes we will be able to synthesise across data measuring the same outcomes (e.g., depression) but with different scales[55].

Binary outcome data based on clinical improvement are rare [33], but if they exist (e.g., for pain intensity) we will calculate relative risk with 95% CI for binary outcomes.

We will classify the magnitude of the effect as small/slight, moderate or large/substantial in accordance with definitions provided by the American Pain Society[58] for the primary outcome (pain intensity), and according to Cohen[59], for the secondary outcomes (emotion dysregulation, depression, and anxiety) (Table 1).

Table 1. Definitions for Magnitude of the Effects, Based on Mean Between-Group Differences[58-60]

Slight/Small	Moderate	Large/Substantial
Pain Intensity		
5 – 10 points on a 0- to 100-point VAS or equivalent	>10-20 points on a 0- to 100-point VAS or equivalent	>20 points on a 0- 100-point VAS or equivalent
0.5-1.0 points on a 0-to 10-point NRS or equivalent	>1-2 points on a 0- to10-point NRS or equivalent	>2 points on a 0- to 10-point NRS or equivalent
Function*		
0.2-0.5 SMD	>0.5-0.8 SMD	>0.8 SMD

VAS = visual analogue scale; NRS = numeric rating scale; SMD = standard mean difference

* Function includes the secondary outcomes of emotion dysregulation, depression, and anxiety.

Certainty of Evidence

Two reviewers (NH-S and NN-N) will assess the evidence for each of the outcomes based on the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) approach[61]. For each GRADE domain the evidence will be rated according to the level of certainty of an intervention effect: High, we are very certain that the true effect of the intervention is close to the estimate of the effect; Moderate, we are moderately certain that the estimate of the effect is close to the true effect; Low, we have limited certainty that the estimate of the effect represents the true effect; Very low, we have very little certainty in the effect estimate and the true effect is likely to be substantially different.

We limit the inclusion of studies to RCTs which according to GRADE are classified as high. Evidence of an effect will be downgraded using the following criteria:

Risk of Bias. The rating will be downgraded by one level if more than 25% (but less than 50%) of participants are from studies with a high risk of bias , and will be downgraded by two levels if more than 50% of participants are from studies with high risk of bas.[62]

Inconsistency. The rating will be downgraded by one level if significant heterogeneity is identified ($p < .1$) and variability is substantial ($I^2 \geq 50\%$)[63].

Imprecision. The rating will be downgraded by one level if the optimal information size is not met (> 400). If the optimal information size is met, the rating will be downgraded by one level if confidence intervals are wide. For example, for continuous outcomes there is a 20 point difference to the point estimate; i.e. twice the minimal clinically important difference of 10 points on a 100-point scale, and for dichotomous measures if the lower or upper limits of the 95% confidence interval include appreciable benefit or harm (i.e. 95% CI under 0.75 or over 1.25) level[64].

Publication Bias. The rating will be downgraded by one level if the funnel plot suggests the presence of publication bias[65].

The GRADE domain of indirectness will not be assessed because the inclusion criteria will help determine sufficient similarity of participants, interventions and comparators across studies [66].

Subgroup and Sensitivity Analysis

If significant heterogeneity is present (*p <. 1)*, by treatment type (e.g., emotion-centric intervention), and pain condition (e.g., low back pain, facial pain) a subgroup analysis will be performed.

A sensitivity analysis will also be conducted excluding studies with a high risk of bias.

Patient and Public Involvement

No patient involved.

Discussion

Evidence widely supports the presence of pervasive and distressing emotions as a key feature of chronic pain[4 5-7]. These emotional problems lead to heightened suffering and disability[13 14]. While pharmacological medications are commonly prescribed for people with chronic pain symptoms, there is little effect on emotional problems[10 31]. Moreover, recent evidence indicates that CBT, the gold standard in psychological treatment for chronic pain, has limited efficacy for both the physical and emotional aspects[33]. Increasingly, researchers are developing and testing new and adjunct emotion-centric psychological treatments[21 36-38]. While findings are promising, a firm conclusion cannot yet be determined about the extent that emotion-centric interventions are effective for chronic pain symptoms. Results from this systematic review and meta-analysis will be a step towards closing this knowledge gap.

Findings may be insightful for psychologists and clinicians, including physiotherapists working with people with chronic pain.

Authors' contributions

NN-N, and SMG conceptualised this protocol; NN-N, NH-S, AC, and MW defined the concepts, search items, data extraction process, and methodological appraisal of the studies; NN-N drafted the manuscript; and all authors critically reviewed the manuscript. All authors have approved the final manuscript.

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Competing interests' statement

Chelsey R. Wilks receives consulting fees from Mindstrong Health, Behavioral Tech, and Lyra Health.

Supplementary Data

Appendix 1 – PRISMA-P checklist

Appendix 2 – Search Strategy

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Appendix 1 - PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) checklist*

Section and topic	Item No	Checklist item	Page number
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	15
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:			
Sources	5a	Indicate sources of financial or other support for the review	15
Sponsor	5b	Provide name for the review funder and/or sponsor	15
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	5-6
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	7-9
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	9
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	*Supplementary file*

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	9-10
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	9-10
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	9-11
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	10-11
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	10-11
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	11-12
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	12-13
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	12-13
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	14
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	12
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	14
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	13-14

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Appendix 2 - Search strategy through EMBASE, PubMed, PsychInfo, CENTRAL, CINAHL, and Web of Science

EMBASE

1 exp pain/

2 ((chronic* OR back musculoskel* OR intractabl* OR neuropath* OR phantom limb OR fantom limb OR neck OR myofasc* OR temporomandib* joint* OR temperomandib* joint* OR tempromandib* joint* OR central OR post*stroke OR complex OR regional OR spinal cord) adj4 pain*).tw.

3 (sciatica OR back-ache OR back*ache OR lumbago OR fibromyalg* OR (trigemin* adj2 neuralg*) OR (herp* adj2 neuralg*) OR (diabet* adj2 neuropath*) OR (reflex adj4 dystroph*) OR (sudeck* adj2 atroph*) OR causalg* OR whip-lash OR whip*lash OR whiplash OR polymyalg* OR (failed back adj4 surg*) OR (failed back adj4 syndrome*)).tw.

4 or/1-3

5 (emotion* focus* OR emotion* dysregulation OR emotion* regulation OR affect dysregulation OR affect regulation OR emotion* problems OR emotion* issues OR emotion* wellbeing OR emotion* well*being OR self*regulation OR emotion* expression).tw.

6 exp psychotherapy/

7 (psychotherap* OR therap* OR strateg* OR skills OR training OR treatment* OR intervention* OR management OR group therapy OR dialectic* OR dialectic* behavio#r* OR DBT OR dialectical behavio#r* OR DPM OR emotion* awareness and expression OR EAET OR problem adaption OR PATH OR emotion* schema OR schema OR cognitive*behavio#r* OR acceptance*commitment OR CBT OR ACT OR meditat* OR mindfulness OR mindfulness*based stress reduction OR MBSR).tw.

8 or/6-7

9 exp randomized controlled trial/

10 (randomi*ed controlled trial OR controlled clinical trial OR comparative study OR clinical trial OR randomly or placebo).tw.

11 or/9-10

12 4 AND 5 AND 8 AND 11

PubMed

#1 pain[MeSH Terms]

#2 chronic*[Title/Abstract] OR back[Title/Abstract] OR musculoskel*[Title/Abstract] OR intractabl*[Title/Abstract] OR neuropath*[Title/Abstract] OR phantom limb[Title/Abstract] OR fantom limb[Title/Abstract] OR neck[Title/Abstract] OR myofasc*[Title/Abstract] OR temporomandib* joint*[Title/Abstract] OR temperomandib* joint*[Title/Abstract] OR tempromandib* joint*[Title/Abstract] OR central[Title/Abstract] OR post stroke[Title/Abstract] OR complex[Title/Abstract] OR regional[Title/Abstract] OR spinal cord[Title/Abstract] OR chronic[Title/Abstract] n4 pain*

#3 sciatica[Title/Abstract] OR back-ache[Title/Abstract] OR back ache[Title/Abstract] OR lumbago[Title/Abstract] OR fibromyalg*[Title/Abstract] OR trigemin* n2 neuralg*[Title/Abstract] OR herpes n2 neuralg*[Title/Abstract] OR diabet* n2 neuropath* [Title/Abstract] OR reflex n2 dystroph*[Title/Abstract] OR sudeck* n2 atroph*[Title/Abstract] OR causalg*[Title/Abstract] OR whip-lash[Title/Abstract] OR whip lash[Title/Abstract] OR whiplash[Title/Abstract] OR

polymyalg*[Title/Abstract] OR failed back n2 surg*[Title/Abstract] OR failed back syndrome*[Title/Abstract]

#4 (#3) OR (#2) OR (#1)

#5 emotion* focus*[Title/Abstract] OR emotion* dysregulation[Title/Abstract] OR emotion* regulation[Title/Abstract] OR affect dysregulation[Title/Abstract] OR affect regulation[Title/Abstract] OR emotion* problems[Title/Abstract] OR emotion* issues[Title/Abstract] OR emotion* wellbeing[Title/Abstract] OR emotion* wellbeing[Title/Abstract] OR wellbeing[Title/Abstract] OR well-being[Title/Abstract] OR self-regulation[Title/Abstract] OR self regulation[Title/Abstract] OR emotion* expression[Title/Abstract]

#6 psychotherapy[MeSH Terms]

#7 psychotherap*[Title/Abstract] OR therap*[Title/Abstract] OR strateg*[Title/Abstract] OR skills[Title/Abstract] OR training[Title/Abstract] OR treatment*[Title/Abstract] OR intervention*[Title/Abstract] OR management[Title/Abstract] OR group therapy[Title/Abstract] OR dialectic*[Title/Abstract] OR dialectic* behaviour*[Title/Abstract] OR DBT[Title/Abstract] OR dialectical behavior*[Title/Abstract] OR DPM[Title/Abstract] OR emotion* awareness expression[Title/Abstract] OR EAET[Title/Abstract] OR problem adaption[Title/Abstract] OR PATH[Title/Abstract] OR emotion*[Title/Abstract] OR schema[Title/Abstract] OR cognitive*behaviour*[Title/Abstract] OR cognitive*behavior*[Title/Abstract] OR "acceptance commitment"[Title/Abstract] OR CBT[Title/Abstract] OR ACT[Title/Abstract] OR meditat*[Title/Abstract] OR mindfulness[Title/Abstract] OR "mindfulness based stress reduction"[Title/Abstract] OR MBSR[Title/Abstract]

#8 (#7) OR (#6)

#9 randomized controlled trial[MeSH Terms]

#10 "randomised control trial"[Title/Abstract] OR "randomized control trial"[Title/Abstract] OR "controlled clinical trial"[Title/Abstract] OR "comparative study"[Title/Abstract] OR "clinical trial"[Title/Abstract] OR "randomly"[Title/Abstract] OR "placebo"[Title/Abstract]

#11 (#10) AND (#9)

#12 (#11) AND (#8) AND (#5) AND (#4)

BMJ Open

Evaluation of emotion-centric psychological interventions for chronic pain: Protocol for a systematic review and meta-analysis

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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Anaesthesia
Keywords:	PAIN MANAGEMENT, MENTAL HEALTH, Depression & mood disorders < PSYCHIATRY

Evaluation of emotion-centric psychological interventions for chronic pain: Protocol for a systematic review and meta-analysis

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Abstract

Introduction

Chronic pain, defined as pain persisting longer than 3 months, is more than an unpleasant sensory experience. Persistent negative emotions and emotional comorbidities, such as depression and anxiety, plague people with chronic pain leading to worsening pain intensity and increasing disability. While cognitive behavioural therapy (CBT) is the gold standard psychological treatment, recent evidence highlights that CBT lacks efficacy for the physical and emotional aspects of chronic pain. Increasingly, researchers are investigating emotion-centric psychological therapies. While treatment modalities vary, these interventions frequently target understanding emotions, and train individuals for an emotionally adaptive response. The aim of this systematic review and meta-analysis is to quantify the efficacy of emotion-centric interventions for the physical and emotional characteristics of chronic pain.

Methods/Analysis

Electronic databases (EMBASE, PubMed, PsychINFO, CENTRAL, CINAHL and Web of Science), will be systematically searched from inception to 28 April 2022 for randomised controlled trials. Studies that compare an emotion-centric intervention with another form of treatment or placebo/control for adults (≥18 years old) with chronic pain will be included. All treatment modes (e.g., online or in-person), any duration, and group-based or individual treatments will be included. Studies that do not investigate at least one emotion-centric treatment will be excluded. The primary outcome is pain intensity. Secondary outcomes include emotion dysregulation, depression, anxiety, affect, safety, and intervention compliance. A quantitative synthesis using a random-effects meta-analysis will be adopted. Risk of bias will be evaluated using Cochrane RoB 2.0 with the certainty of evidence assessed according to GRADE. Data permitting, subgroup analysis will be conducted for intervention type and pain condition.

Ethics and dissemination

Ethical approval is not required for this systematic review. Results may inform an efficacy study examining a new emotion-centric intervention for chronic pain. Dissemination will be through peer-reviewed publications and in conference presentations.

PROSPERO Registration number

CRD42021266815

Strengths and limitations of this study

- This systematic review will follow recommendations for conduct and reporting of systematic reviews including independent study selection, data extraction, risk of bias assessments by two researchers according to Cochrane RoB 2.0, quality of evidence assessed according to GRADE recommendations, and reporting according to PRISMA guidelines.
- To the best of our knowledge, this is the first systemic review and meta-analysis to examine interventions that focus on changing the negative emotional experiences associated with chronic pain.
- A meta-analysis may not be possible if there are a lack of comparable studies or interventions, in which case a narrative synthesis is planned.
- Findings may be limited by heterogeneity arising from the inclusion of different psychological interventions and different pain conditions or a lack of data.

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Background

Chronic pain, defined as pain persisting longer than three months[1], is a substantial and costly source of suffering. Twenty percent of people live with chronic pain[2], and annual economic costs to the healthcare system are estimated to exceed that of heart disease, cancer, and diabetes combined[3]. Chronic pain is commonly regarded as being both a sensory and an emotional experience. The International Association for the Study of Pain, explains that without emotion, the understanding of chronic pain is incomplete[4]. Research supports this perspective, with fear, anger, worry and low mood frequently reported by people with chronic pain[5-8]. Beyond negative emotional states, anxiety, and depression present in up to 80 percent of individuals[9-12]. Emotional comorbidities are related to greater suffering, including increased pain intensity and disability[13 14], and are a factor regardless of chronic pain type[15]. Despite the wide acceptance that emotions are key components of chronic pain, the most effective approach to modulate the distressing emotional experience of chronic pain is not yet fully understood.

One mechanism related to negative emotions experienced by people with chronic pain is emotion dysregulation, defined as a heightened sensitivity to emotional stimuli, impeding the ability to identify emotions and to moderate emotional states and expression in line with an adaptive response[16]. Long considered a factor in emotional disorders such as major depression, generalised and social anxiety disorders[17], emotion dysregulation is now thought to be a crucial factor in the development and the maintenance of chronic pain[18-20].

The modal model of emotion regulation helps explain emotion dysregulation in the context of chronic pain[21]. According to this model, when an emotion arises due to experiencing an internal or external stimulus, this emotion is then given attention before cognitive appraisal identifies meaning, triggering physiological arousal and a behavioural response[21 22]. For people with chronic pain, the distress related to their condition impedes self-management abilities, including emotion regulation capabilities[23]. Specifically, the debilitating and distressing aspects of chronic pain, and the experience of missing out (e.g., on career, education, and social activities), perpetuates negative emotional appraisal of situations, that over time fatigues emotion regulation capabilities[22-24]. With the progression of chronic pain, negative thoughts become more frequent, contributing to increasingly catastrophic perceptions which perpetuates maladaptive (negative) emotional appraisal[22]. The behavioural result of maladaptive emotional appraisal is hyperreactivity, meaning too large an emotional response when experiencing a distressing situation, or hyporeactivity, meaning too small an emotional response, or blunted positive emotions, in an emotionally rewarding situation[25]. An absence of positive emotions is a contributing factor for the severity

of chronic pain[26], potentially because positive emotions provide resilience against distressful symptoms and stress[27].

Emotion dysregulation may also be antecedent to chronic pain, whereby some individuals have a trait-like propensity for emotion dysregulation meaning they are at greater risk of developing chronic pain[28 29]. Attempts to manage overwhelming emotions have been found to lead to maladaptive emotion regulation strategies (e.g., expressive suppression, experiential avoidance, and rumination) which are largely counterproductive and lead to a cycle of increasingly intense emotions and worsening chronic pain[30].

In the treatment of chronic pain, analgesic medication is commonly prescribed to manage painful symptoms[31]. However, there is no single medication that is consistently effective for all individuals[32], and some, such as opioids carry an increased risk of experiencing adverse events including dependence and even death[33 34]. Moreover, evidence shows that pain-relieving medications have little effect on emotional problems associated with chronic pain[10 35]. Cognitive-behavioural therapy (CBT), is considered the gold standard in psychological treatment for chronic pain[36]. CBT focuses on modifying thoughts, physical sensations and maladaptive behaviours[37], and in some studies demonstrates improvement in pain severity[38], and related distress[39]. However, a recent Cochrane review concludes that overall, CBT has minimal effect on pain severity and no effect on mood in people with chronic pain[37]. Thus, some researchers are enhancing existing psychological treatment modalities and developing new interventions to treat chronic pain by managing its emotional components.

Examples of emotion-centric interventions include those which incorporate emotion regulation skills adjunct to CBT[40], and those that focus on emotion awareness and expression[41]. Additionally, integrating and adapting methods from dialectical behavioural therapy (DBT), such as emotion regulation skills training, may also be effective for chronic pain[42]. Originally developed for people with high suicidality and emotional distress, particularly those with borderline personality disorder, DBT is modular meaning that the skills training elements (e.g., mindfulness, emotion regulation and distress tolerance skills) can be delivered without concurrent individualised therapy, and can be very effective in many situations to help with emotional difficulties[43]. While the theory underpinning these interventions vary, the primary focus is on understanding emotions and training skills for an adaptive emotional response.

Previous systematic reviews have explored the effects of psychological therapies for chronic pain. The focus of these reviews has predominantly been on exploring cognitive and behavioural treatments[37 44 45], acceptance and mindfulness-based interventions[37 45-48], and

psychodynamic therapies[49]. The results of these reviews fail to demonstrate an intervention that consistently reduces chronic pain, highlighting the need for further exploration of alternative psychological interventions. While a narrative synthesis of studies exploring the effects of varying treatments on the emotional experience of chronic pain demonstrates promising findings[23], a more rigorous evaluation is required of studies that specifically target emotions as a feature of chronic pain. Additionally, a meta-analytic synthesis of the data across studies exploring emotion-centric interventions is necessary to determine effect estimates to guide psychotherapeutic plans. Based on the potential importance of emotion-centric interventions for chronic pain, there is still a question about the efficacy to improve pain intensity, emotion regulation, anxiety, depression, and affect. These insights are important for psychologists and clinicians, including physiotherapists working with chronic pain patients[50]. The results may also be insightful to identify gaps in the literature to provide direction for future studies.

Objectives

The present systematic review will analyse the evidence from studies that investigate the efficacy of emotion-centric interventions to treat the unpleasant sensory and emotional aspects of chronic pain. We will compare emotion-centric psychological interventions to other types of psychological treatment, treatment as usual and control/waitlist. The primary objective is to evaluate the evidence to reduce pain intensity for people with chronic pain. The secondary objective is to evaluate the evidence to improve other factors associated with chronic pain, specifically, emotion dysregulation, depression, anxiety, and affect. An additional objective of this review is to narratively report on safety and intervention compliance.

Methods and Analysis

Study Design

This protocol was written in accordance with the PRISMA extension for developing review protocols (PRISMA-P)[51] (Appendix 1). The systematic review protocol has been registered with the International Prospective Register of Systematic Reviews (PROSPERO): CRD42021266815.

Eligibility criteria

Types of studies

We will include randomised controlled trials (RCTs) that have evaluated the efficacy of emotion-centric interventions delivered online or in-person for any chronic pain condition.

This will include emotion-centric interventions compared with treatment as usual (standard care waitlist/no-treatment conditions), and active psychological therapies (e.g., cognitive-behavioural therapy, acceptance-commitment therapy, and mindfulness-based stress reduction). Observational studies and non-randomised trials will be excluded. Additionally, grey literature searches including, research letters, thesis, and conferences abstracts will be excluded; however, completed unpublished studies registered in clinical trial registries (e.g., ClinicalTrials.gov, EU Clinical Trials Register, ANZ Clinical Trial Registry, WHO International Clinical Trial Registry Platform) will be included.

Types of participants

We will include studies with adults (≥18 years old) with chronic pain, defined as persistent or recurring pain for a minimum of three months[52]. All types of chronic pain conditions will be included, because emotions are part of the experience regardless of the chronic pain condition[15]. Chronic pain conditions may include but will not be limited to, rheumatoid arthritis, arthralgia, temporomandibular joint syndrome, myofascial pain, neck pain, back pain, neuralgia, myalgia, myodynia, chronic compartment syndrome, rheumatic polymyalgia, migraine, headache, and fibromyalgia. Studies that enrolled children or adolescents aged <18 years and studies enrolling individuals who have been experiencing pain for less than three months will be excluded.

Types of interventions

We will include emotion-centric psychological intervention regardless of the study mode (e.g., internet-delivered, telehealth, or face-to-face) and regardless of whether it is group-based or individual. We define emotion-centric interventions as those that help participants understand emotions and teach strategies for an adaptive emotional response. Incorporating emotion regulation skills training from dialectical-behavioural therapy (DBT) is one such approach that integrates understanding emotions and teaches emotion regulation skills, thus studies administering DBT skills to participants with chronic pain will be included if they also meet the other inclusion criteria.

Studies using psychological interventions that do not focus on helping individuals understand emotions and do not deliver emotional strategies or techniques for effective emotion expression will be excluded. Specifically, mindfulness-based stress reduction (MBSR), cognitive-behavioural therapy (CBT), and acceptance-commitment therapy (ACT), when delivered in their standard formats do not purposefully seek to identify emotional reactions and do not typically administer strategies for emotional expression or regulation, so will be excluded[18 53 54]. However, studies which administer MBSR, CBT, ACT or another psychological treatment, adjunct to an emotion-centric intervention or emotional targeted

strategies will be considered for inclusion. In case of doubt, we will contact corresponding authors to obtain more details on the psychological intervention. Eligible interventions may be delivered by a licenced health professional (e.g., registered psychologist or physiotherapist), or by a skills trainer in an emotion-centric treatment modality (e.g., dialectical-behavioural therapy skills trainer). If it is unclear, study eligibility will be determined by consensus among reviewers.

Types of settings

There will be no restriction placed on setting of intervention delivery. For example, studies where the intervention was delivered in primary care, secondary care, university-based clinics, homes, residential care homes and community settings, including those online will all be included.

Types of outcome measures

The primary outcome (pain intensity) will be measured with validated self-rating instruments (e.g., 0–10 Numerical Rating Scale; NRS, or a 0–10/0–100 visual analogue scale; VAS)[55]. Studies that use other scales to measure pain intensity will not be excluded, providing they demonstrate psychometric properties for reliability and validity.

Secondary outcomes of interest are, emotion dysregulation (e.g., Difficulties in Emotion Regulation Scale), depression (e.g., Beck Depression Inventory), anxiety (e.g., State-Trait Anxiety Inventory) and affect (e.g., Positive and Negative Affect Schedule). Studies that use other scales will not be excluded providing they demonstrate psychometric properties for reliability and validity.

We will consider two outcome assessment timepoints: short term follow-up, outcome data assessed immediately following the treatment; and long-term follow-up, outcome data assessed at least three months, but not longer than 12 months, after the end of treatment. If multiple follow-up data is available for a single timepoint, we will select the last time point.

Further secondary outcomes are safety and intervention compliance. Safety is defined as the proportion of participants who experience at least one adverse event during the intervention period. Adverse events are broadly defined as any ‘adverse event’, ‘serious adverse event’, ‘side effect, or ‘complication’ resulting in discontinuation of treatment associated with the treatment under investigation (emotion-centric or comparison). Intervention compliance is reflected by the proportion of participants who completed the modules in each study-specific treatment (emotion-centric or comparison) during the intervention period.

Search strategy

The following databases will be searched for eligible studies: EMBASE (Ovid), Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, SCOPUS, PubMed and CINAHL (EBSCO) (Appendix 2). Search concepts will include language and keywords for: randomised controlled trial, chronic pain, and terms relating to emotion centric psychological interventions, according to the eligibility criteria defined earlier in the protocol. A search for ongoing trials will be conducted on ClinicalTrials.gov, EU Clinical Trials Register, ANZ Clinical Trial Registry, WHO International Clinical Trial Registry Platform. We will manually search the reference lists of included studies and previous reviews to identify additionally eligible studies. No limitations will be placed on year of publication. Studies written in English, French, German, or Persian will be included. While the review is in progress, citation searching for forward citation of recent studies and citation alerts (e.g., on Google Scholar) on included studies will be used to identify new studies as they appear. The searches will be rerun prior to the final analysis and further retrieved studies will be included.

Study Selection

Studies retrieved using the search strategy and those from additional sources will be imported to Covidence[56], where an automatic deduplication function will be applied to remove duplicate records. Two reviewers (NN-N and NH-S) will independently screen titles and abstracts to determine eligibility and then will conduct full paper reviews. If consensus cannot be reached on eligibility, a third author (YQ) will be contacted to resolve through discussion or arbitration. Excluded studies and the reasons for exclusion will be recorded and documented. The search process will be summarised using an adapted PRISMA flow diagram[57].

Data Management and Extraction

Two reviewers (NN-N and NH-S) will independently extract data from the included studies using a customised data extraction spreadsheet in Microsoft Excel. The form will be pilot tested on two articles. Disagreements will be resolved by consensus or through discussion with a third reviewer (YQ).

Study Characteristics

Data about the study characteristics will be extracted, including study design, sample size, country, setting, pain condition(s) investigated, and duration of the follow-up(s).

Participant Characteristics

Data will be extracted about the study sample including, age, sex, education, ethnicity, socioeconomic status, duration of pain, comorbidities, and baseline mean and variability for the primary and secondary outcomes.

Interventions and Comparators

Data about the intervention and the comparators will be extracted:

- Key components of the psychological intervention, including:
  - Specific details of the psychological approach (e.g., CBT plus emotion regulation strategies).
  - Number of sessions.
  - Whether the sessions are group-based or individual.
  - Emotional strategies delivered.
  - Qualifications of personnel delivering the intervention.
- Mode of delivery (e.g., online or in-person).
- Intervention frequency and duration.

Outcomes

Data about the definition for the primary and secondary outcomes investigated will be extracted. Data about the type, dimensions and anchors the measurement tools used to assess the primary and secondary outcomes will also be extracted.

Results

We will extract data on study results including details of the number of participants randomised to each condition (e.g., emotion-centric intervention or comparison). Data will be extracted for the primary outcome of pain intensity, and the secondary outcomes of emotion dysregulation, depression, anxiety, affect, safety, and intervention compliance (including the study specific definitions of safety and intervention compliance).

The outcomes of safety and intervention compliance will be summarised at a descriptive level because it is expected that these aspects will not be reported in all identified studies and compliance is likely only to be observed in the intervention groups. For all other outcomes we will preferentially extract the outcome score and measure of variance at the end of treatment (or closest time point) for each group and at follow-up, followed by the change from baseline and measure of variance. Follow-up means the assessment timepoint which is at least three months after the end of treatment but not longer than 12 months. If

data are not available for each trial arm, we will extract the between-group statistics at the end of treatment.

If a study reports more than one measure for pain, we will prioritise the extraction as follows: 100-mm VAS, 10-cm VAS, 11-point NRS, rating on a pain intensity scale for a composite measure (e.g., McGill Pain Questionnaire), and then rating on an ordinal scale. For all other outcomes, if a given outcome is measured by several measurement tools the hierarchy for analysis will be decided by consensus from the reviewers. Whenever possible, we will use results from an intention-to-treat (ITT) analysis[58].

Dealing with Missing Data

In the case of missing data, the study authors will be contacted where necessary a maximum of three times, after which point it will be considered that the data/information is irretrievable. If data for the primary or secondary outcomes are not presented in an appropriate form for meta-analysis (e.g., median, minimum and maximum values are reported instead of mean and standard deviation), established methods will be considered to impute these values[59].

Assessment of Risk of Bias

The risk of bias of the included randomised trials will be assessed by two reviewers (NH-S and NN-N) using the Cochrane Risk of Bias (RoB 2.0) tool for RCTs[60]. According to RoB 2.0, five domains are evaluated: (a) bias arising from the randomization process; (b) bias due to deviations from intended interventions; (c) bias due to missing outcome data; (d) bias in measurement of the outcome; and (e) bias in selection of the reported results. Risk of bias judgement for each domain and an overall judgement can be made in terms of low risk of bias, high risk of bias, or some concerns. Reviewers will judge items at the study level, which prioritises information regarding the primary outcome (pain intensity). In case of disagreement, a third reviewer will be consulted (YQ).

Assessment of Heterogeneity

To assess the extent that the investigated studies are similar, such as they deliver the same emotion-centric intervention, we will assess for heterogeneity using a standard Chi^2 test and will estimate the percentage of the variability that is due to heterogeneity using the I^2 statistic. Heterogeneity will be considered significant when $p < .1$ and $I^2 \geq 50\%$[60].

Data Synthesis

If possible, outcome data extracted from the RCTs will be quantitatively synthesised using a random effects meta-analysis in R (RStudio v1.2.5033). If a meta-analysis is not

possible (due to lack of comparable studies or interventions), a narrative synthesis of the findings will be used to report outcomes according to SWiM (Synthesis without meta-analysis) guidelines[61].

We plan to conduct two classes of comparisons depending on the comparators used in the studies. Firstly, we will compare emotion-centric intervention to active comparator including other therapies (Active). Secondly, we will compare emotion-centric intervention to treatment-as-usual including, sham, no treatment, and waitlist (TAU). The treatment will be compared at two time points, immediately post-treatment (T1), defined as the assessment timepoint occurring at the end of treatment and at follow-up (T2), defined as the assessment timepoint which is at least three months after the end of treatment but not longer than 12 months, and the longer follow-up if there were more than one follow-up assessment. Therefore, the four separate comparisons are planned as:

1. Emotion-centric versus Active at T1
2. Emotion-centric versus Active at T2
3. Emotion-centric versus TAU at T1
4. Emotion-centric versus TAU at T2

For each comparison the primary outcome data (pain intensity) will be converted to a common 0-100 point scales (mean and standard deviation)[62]. For numerical and continuous scales, the score value will be divided by the range of scale, and then multiplied by 100. For example, for a 0 to 20 scale, the score value will be divided by 20 and multiplied by 100. We plan to use a weighted mean difference (WMD) with 95% confidence intervals (CI).

For the secondary outcome data (emotion dysregulation, depression, anxiety, and affect) standardised mean differences (SMD), with 95% CI, will be computed to obtain a summary measure of effect size across the studies to quantify the impact of treatment relative to Active or TAU for each comparison. By utilising a SMD for the secondary outcomes we will be able to synthesise across data measuring the same outcomes (e.g., depression) but with different scales[60].

Binary outcome data based on clinical improvement are rare [37], but if they exist (e.g., for pain intensity) we will calculate relative risk with 95% CI for binary outcomes.

We will classify the magnitude of the effect as small/slight, moderate or large/substantial in accordance with definitions provided by the American Pain Society[63] for the primary outcome (pain intensity), and according to Cohen[64], for the secondary outcomes (emotion dysregulation, depression, anxiety and affect) (Table 1).

Table 1. Definitions for Magnitude of the Effects, Based on Mean Between-Group Differences[63-65]

Slight/Small	Moderate	Large/Substantial
Pain Intensity		
5 – 10 points on a 0- to 100-point VAS or equivalent	>10-20 points on a 0- to 100-point VAS or equivalent	>20 points on a 0- 100-point VAS or equivalent
0.5-1.0 points on a 0-to 10-point NRS or equivalent	>1-2 points on a 0- to10-point NRS or equivalent	>2 points on a 0- to 10-point NRS or equivalent
Function*		
0.2-0.5 SMD	>0.5-0.8 SMD	>0.8 SMD

VAS = visual analogue scale; NRS = numeric rating scale; SMD = standard mean difference

* Function includes the secondary outcomes of emotion dysregulation, depression, and anxiety.

Certainty of Evidence

Two reviewers (NH-S and NN-N) will assess the evidence for each of the outcomes based on the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) approach[66]. For each GRADE domain the evidence will be rated according to the level of certainty of an intervention effect: High, we are very certain that the true effect of the intervention is close to the estimate of the effect; Moderate, we are moderately certain that the estimate of the effect is close to the true effect; Low, we have limited certainty that the estimate of the effect represents the true effect; Very low, we have very little certainty in the effect estimate and the true effect is likely to be substantially different.

We limit the inclusion of studies to RCTs which according to GRADE are classified as high. Evidence of an effect will be downgraded using the following criteria:

Risk of Bias. The rating will be downgraded by one level if more than 25% (but less than 50%) of participants are from studies with a high risk of bias, and will be downgraded by two levels if more than 50% of participants are from studies with high risk of bas.[67]

Inconsistency. The rating will be downgraded by one level if significant heterogeneity is identified ($p < .1$) and variability is substantial ($I^2 \geq 50\%$)[68].

Imprecision. The rating will be downgraded by one level if the optimal information size is not met (> 400). If the optimal information size is met, the rating will be downgraded by one level if confidence intervals are wide. For example, for continuous outcomes there is a 20 point difference to the point estimate; i.e. twice the minimal clinically important difference of 10 points on a 100-point scale, and for dichotomous measures if the lower or upper limits of the 95% confidence interval include appreciable benefit or harm (i.e. 95% CI under 0.75 or over 1.25) level[69].

Publication Bias. Publication bias will be evaluated using conventional funnel plots to examine publication asymmetry, potentially indicative of publication bias[70], and contour-enhanced funnel plots to judge whether the results of studies cluster around nominal thresholds for statistical significance, potentially indicative of data dredging/p-hacking[71]. Where > 10 studies are available in a funnel plot, we will also conduct Egger's regression test for statistical assessment of publication asymmetry (with $\alpha < 0.10$ indicating the presence of asymmetry)[72]. The rating will be downgraded by one level if the funnel plot suggests the presence of publication bias[73].

The GRADE domain of indirectness will not be assessed because the inclusion criteria will help determine sufficient similarity of participants, interventions and comparators across studies [74].

Subgroup and Sensitivity Analysis

If significant heterogeneity is present (*p <. 1)*, by treatment type (e.g., emotion-centric intervention), and pain condition (e.g., low back pain, facial pain) a subgroup analysis will be performed.

A sensitivity analysis will also be conducted excluding studies with a high risk of bias.

Patient and Public Involvement

No patient involved.

Discussion

Evidence widely supports the presence of pervasive and distressing emotions as a key feature of chronic pain[4 5-7]. These emotional problems lead to heightened suffering and disability[13 14]. While pharmacological medications are commonly prescribed for people with chronic pain symptoms, there is little effect on emotional problems[10 35]. Moreover, recent evidence indicates that CBT, the gold standard in psychological treatment for chronic pain, has limited efficacy for both the physical and emotional aspects[37]. Increasingly, researchers are developing and testing new and adjunct emotion-centric psychological treatments[23 40-42]. While findings are promising, a firm conclusion cannot yet be determined about the extent that emotion-centric interventions are effective for chronic pain symptoms. Results from this systematic review and meta-analysis will be a step towards closing this knowledge gap. Findings may be insightful for psychologists and clinicians, including physiotherapists working with people with chronic pain. For example, if the findings are supportive of emotion-centric interventions compared to other treatment modalities then there is evidence for clinical psychologists to utilise more emotionally centric treatment strategies for their clients

with chronic pain. Similarly, this review will report the adverse events for such emotion-centric interventions which is important to understand the safety of implementation in clinical practice.

Ethics and Dissemination

Ethical approval is not required for this systematic review. Results may inform an efficacy study examining a new emotion-centric intervention for chronic pain. Dissemination will be through peer-reviewed publications and in conference presentations.

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Authors' contributions

NN-N, and SMG conceptualised this protocol; NN-N, NH-S, AC, and MW, RR, CRW, YQ, JM and SMG defined the concepts, search items, data extraction process, and methodological appraisal of the studies; NN-N drafted the manuscript; and all authors critically reviewed and revised the manuscript for important intellectual content. All authors have approved the final manuscript. All authors agree to be accountable for all aspects of the work, and to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors have approved the final manuscript for publication.

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Competing interests' statement

Chelsey R. Wilks receives consulting fees from Mindstrong Health, Behavioral Tech, and Lyra Health.

Supplementary Data

Appendix 1 – PRISMA-P checklist

Appendix 2 – Search Strategy

Appendix 1 - PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) checklist*

Section and topic	Item No	Checklist item	Page number
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	15
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:			
Sources	5a	Indicate sources of financial or other support for the review	15
Sponsor	5b	Provide name for the review funder and/or sponsor	15
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	5-6
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	7-9
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	9
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	*Supplementary file*

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	9-10
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	9-10
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	9-11
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	10-11
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	10-11
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	11-12
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	12-13
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	12-13
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	14
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	12
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	14
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	13-14

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

Appendix 2 - Search strategy through EMBASE, PubMed, PsychInfo, CENTRAL, CINAHL, and Web of Science

EMBASE

1 exp pain/

2 ((chronic* OR back musculoskel* OR intractabl* OR neuropath* OR phantom limb OR fantom limb OR neck OR myofasc* OR temporomandib* joint* OR temperomandib* joint* OR tempromandib* joint* OR central OR post*stroke OR complex OR regional OR spinal cord) adj4 pain*).tw.

3 (sciatica OR back-ache OR back*ache OR lumbago OR fibromyalg* OR (trigemin* adj2 neuralg*) OR (herp* adj2 neuralg*) OR (diabet* adj2 neuropath*) OR (reflex adj4 dystroph*) OR (sudeck* adj2 atroph*) OR causalg* OR whip-lash OR whip*lash OR whiplash OR polymyalg* OR (failed back adj4 surg*) OR (failed back adj4 syndrome*)).tw.

4 or/1-3

5 (emotion* focus* OR emotion* dysregulation OR emotion* regulation OR affect dysregulation OR affect regulation OR emotion* problems OR emotion* issues OR emotion* wellbeing OR emotion* well*being OR self*regulation OR emotion* expression).tw.

6 exp psychotherapy/

7 (psychotherap* OR therap* OR strateg* OR skills OR training OR treatment* OR intervention* OR management OR group therapy OR dialectic* OR dialectic* behavio#r* OR DBT OR dialectical behavio#r* OR DPM OR emotion* awareness and expression OR EAET OR problem adaption OR PATH OR emotion* schema OR schema OR cognitive*behavio#r* OR acceptance*commitment OR CBT OR ACT OR meditat* OR mindfulness OR mindfulness*based stress reduction OR MBSR).tw.

8 or/6-7

9 exp randomized controlled trial/

10 (randomi*ed controlled trial OR controlled clinical trial OR comparative study OR clinical trial OR randomly or placebo).tw.

11 or/9-10

12 4 AND 5 AND 8 AND 11

PubMed

#1 pain[MeSH Terms]

#2 chronic*[Title/Abstract] OR back[Title/Abstract] OR musculoskel*[Title/Abstract] OR intractabl*[Title/Abstract] OR neuropath*[Title/Abstract] OR phantom limb[Title/Abstract] OR fantom limb[Title/Abstract] OR neck[Title/Abstract] OR myofasc*[Title/Abstract] OR temporomandib* joint*[Title/Abstract] OR temperomandib* joint*[Title/Abstract] OR tempromandib* joint*[Title/Abstract] OR central[Title/Abstract] OR post stroke[Title/Abstract] OR complex[Title/Abstract] OR regional[Title/Abstract] OR spinal cord[Title/Abstract] OR chronic[Title/Abstract] n4 pain*

#3 sciatica[Title/Abstract] OR back-ache[Title/Abstract] OR back ache[Title/Abstract] OR lumbago[Title/Abstract] OR fibromyalg*[Title/Abstract] OR trigemin* n2 neuralg*[Title/Abstract] OR herpes n2 neuralg*[Title/Abstract] OR diabet* n2 neuropath* [Title/Abstract] OR reflex n2 dystroph*[Title/Abstract] OR sudeck* n2 atroph*[Title/Abstract] OR causalg*[Title/Abstract] OR whip-lash[Title/Abstract] OR whip lash[Title/Abstract] OR whiplash[Title/Abstract] OR

	polymyalg*[Title/Abstract] OR failed back n2 surg*[Title/Abstract] OR failed back syndrome*[Title/Abstract]
#4	(#3) OR (#2) OR (#1)
#5	emotion* focus*[Title/Abstract] OR emotion* dysregulation[Title/Abstract] OR emotion* regulation[Title/Abstract] OR affect dysregulation[Title/Abstract] OR affect regulation[Title/Abstract] OR emotion* problems[Title/Abstract] OR emotion* issues[Title/Abstract] OR emotion* wellbeing[Title/Abstract] OR emotion* wellbeing[Title/Abstract] OR wellbeing[Title/Abstract] OR well-being[Title/Abstract] OR self-regulation[Title/Abstract] OR self regulation[Title/Abstract] OR emotion* expression[Title/Abstract]
#6	psychotherapy[MeSH Terms]
#7	psychotherap*[Title/Abstract] OR therap*[Title/Abstract] OR strateg*[Title/Abstract] OR skills[Title/Abstract] OR training[Title/Abstract] OR treatment*[Title/Abstract] OR intervention*[Title/Abstract] OR management[Title/Abstract] OR group therapy[Title/Abstract] OR dialectic*[Title/Abstract] OR dialectic* behaviour*[Title/Abstract] OR DBT[Title/Abstract] OR dialectical behavior*[Title/Abstract] OR DPM[Title/Abstract] OR emotion* awareness expression[Title/Abstract] OR EAET[Title/Abstract] OR problem adaption[Title/Abstract] OR PATH[Title/Abstract] OR emotion*[Title/Abstract] OR schema[Title/Abstract] OR cognitive*behaviour*[Title/Abstract] OR cognitive*behavior*[Title/Abstract] OR "acceptance commitment"[Title/Abstract] OR CBT[Title/Abstract] OR ACT[Title/Abstract] OR meditat*[Title/Abstract] OR mindfulness[Title/Abstract] OR "mindfulness based stress reduction"[Title/Abstract] OR MBSR[Title/Abstract]
#8	(#7) OR (#6)
#9	randomized controlled trial[MeSH Terms]
#10	"randomised control trial"[Title/Abstract] OR "randomized control trial"[Title/Abstract] OR "controlled clinical trial"[Title/Abstract] OR "comparative study"[Title/Abstract] OR "clinical trial"[Title/Abstract] OR "randomly"[Title/Abstract] OR "placebo"[Title/Abstract]
#11	(#10) AND (#9)
#12	(#11) AND (#8) AND (#5) AND (#4)