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Protocol

Effect of biopsychosocial comprehensive chronic pain management physiotherapy practice protocol in patients with chronic musculoskeletal pain-a randomised control trial

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ABSTRACT

Background: Chronic musculoskeletal pain (CMP) is a common condition treated by physiotherapists. Many existing treatments focus mainly on biomedical aspects, which have limited effectiveness and do not align with clinical practice guidelines that advocate for a biopsychosocial (BPS) approach. To address this issue, a new physiotherapy protocol has been developed that incorporates pain neurophysiological education, cognitive behaviour modification, and self-management strategies. This protocol will undergo clinical trial evaluation and has the potential to transform physiotherapy practices in line with these guidelines.
Methods: A randomised, single-centre clinical trial will be carried out to compare the effect of a comprehensive CMP management (CCPM) which consists of 16 sessions weekly twice for 8 weeks neuroscience education program (4 sessions, 4 hrs) cognitive behaviour modification program (6 sessions, 6 hrs), self-management strategies (4 sessions, 4 hrs) and revision of the program (2 sessions, 2 hrs) along with usual care physiotherapy treatment for thrice weekly for 8 weeks, with standardised physiotherapy thrice weekly for 8 weeks as control group. The study aims to evaluate the effect of CCPM intervention on central sensitisation, as well as on fear avoidance, pain, disability, and pain self-efficacy The outcome variables will be measured at the beginning of the intervention and after 8 weeks.
Discussions: The Physiotherapy practice must adopt a multi-dimensional pathway of treatment that considers all the bio-psychosocial factors during treatment sessions, rather than just following a bio-model pathway of management.
Trial registration: CTRI/2023/05/053340 [Registered on: 31/05/2023]

Keywords: Chronic musculoskeletal pain, Pain neuroscience education, Cognitive behaviour modification, Self-management strategies treatment protocol, Physiotherapy care

INTRODUCTION

Musculoskeletal pain affects a significant portion of the population, regardless of their demographic. Proper management of this condition is crucial to maintain a good quality of life. Over 20% of individuals experience persistent pain known as CMP that requires professional attention. Recent evidence suggests that multidisciplinary approaches are necessary to manage this type of pain condition effectively. Guidelines now recommend implementing preventative strategies and physical tools as a first-line defence to minimise medication use. It is imperative to prioritize comprehensive (medical and probable bio-psychosocial) and proactive approaches to ensure optimal outcomes for those suffering with CMP.[1-3] There are several risk factors associated with CMP, including age, gender, smoking, low education, low physical activity, deconditioning, poor social interaction, low family income, depression, anxiety, and sleep disorders.[4,5] The impact of psychological factors on

common musculoskeletal disorders has significant implications for patient treatment.[6,7] Central sensitization (CS) is characterized by general hypersensitivity and increased temporal summation of nociception, which contributes to the chronicity of musculoskeletal pathology and is believed to be associated with psychosocial and cognitive-behavioural factors.[8-15] Chronic musculoskeletal conditions can cause allodynia and hyperalgesia, limiting an individual's physical, mental, and functional abilities. This is due to increased sensitivity of the central nervous system and decreased functioning of the nervous system to regulate pain inhibition.[16,17] Pain-related fear avoidance is a common issue among patients with painful medical conditions. There is a significant interest in the relationship between FA and disability.[18]

The BPS model is not only a philosophy of clinical care but a practical clinical guide which insists on a bio-psychosocial-oriented clinical practice which focuses on self-awareness, active cultivation of trust, empathy, self-calibration, educating the emotions, using informed intuition and communicating clinical evidence to foster dialogue, not just the mechanical application of the protocol.[19] Research has found that a multidisciplinary approach to treating chronic pain can reduce its intensity and disability. However, structured interdisciplinary programs can be expensive. Interventions should be incorporated into a comprehensive treatment plan for chronic pain. However, more research is needed to confirm the effectiveness of many combination treatments.[5,20] Current research suggests that treating CMP through various approaches yields superior outcomes. However, accessing these treatments may prove challenging due to prevailing healthcare practices. In light of this, physiotherapy should adopt a multidimensional approach CCPM wherein biological, psychological, and social factors are considered during every session, rather than relying solely on biological management (Usual standard physiotherapy).[21] Therefore, the primary objectives of the study are to find out the effect of BPS CCPM physiotherapy practice protocol on clinical outcomes (central sensitization, fear avoidance pain, self-efficacy and pain disability) in patients with CMP.

METHODS

This clinical trial has been registered (Clinical trials registry India http://ctri.nic.in/CTRI/2023/05/053340 [Registered on: 31/05/2023]-trial registered prospectively) and has received approval from the PP Savani ethical review committee on 11/05/2023. This study protocol describes the design of a single centre (SPINEX Surat), assessor-blinded, randomised, controlled, clinical trial (RCT) of parallel groups (ratio 1:1). The study protocol complies with the standard protocol items: recommendations for interventional trials (SPIRIT). This RCT complies with the consolidated standards of reporting trials (CONSORT) reporting guidelines.[22-24]

Participants

All the participants of this study will be the ones who were examined and referred to the study centre Spinex by specialist practitioners. They then will take part in an initial screening interview to give an overview of the study. Informed written consent will be obtained from all participants before the baseline examination. Potential risks and benefits will be mentioned in the written informed consent. Information provided by participants through their study involvement is well protected and will be used only for the study purpose. Belmont report principle will be strictly followed to uphold privacy and avoid injustice to participants.[25]

After completing the baseline examinations, individuals who agreed to participate in the study will be assigned to either the experimental or control.

Inclusion criteria

Patients having musculoskeletal pain experienced daily over the 3 months, non-specific back pain of at least three months (The presence of pain in other regions, in addition to back, will not be grounds for exclusion), patients of both sexes between age 18 and 65 years, agree to participate in the study and sign informed consent were included.

Exclusion criteria

Patients having cancer-related pain, non-neuromusculoskeletal pain (surgery/fracture), upper motor lesions, pregnancy, Cauda equina syndrome, patients presenting other clinical conditions that may aggravate chronic spinal pain (chronic fatigue syndrome, fibromyalgia and complex regional pain syndrome), myopathies, neurological diseases, patient receiving other alternate therapies, people will be excluded if they present with rheumatoid arthritis, infective arthritis, or metastases; unable to understand and read Gujarati, or unwilling to provide signed consent were excluded.

Recruitment method

At first, patients arriving at the centre will complete a screening form during their first visit. Those meeting the inclusion criteria and not meeting the exclusion criteria will be invited to participate in the RCT. Physiotherapists managing the recruitment process will undergo a clinical session to ensure adherence to proper recruitment procedures.

Informed written consent will be obtained from interested patients following a verbal explanation and provision of a written patient information sheet.

Randomisation and blinding

Following consent, participants will undergo an initial evaluation and will then be randomly assigned to either the experimental (CCPM) group or the control (standard physiotherapy) group. The responsible person for participant assignments is committed to maintaining the confidentiality of the assignment status of the participants, an impartial analyst, who is unaware of the participant's allocation, will oversee and evaluate the collected study data. We will use a simple random sampling method to select and allocate participants to the experimental and control groups. After the initial evaluation and screening, each eligible patient will be assigned to either the experimental or control group using a centralized, computer-generated coding system. The random codes will be written in opaque, sealed envelopes numbered sequentially from 1 to 80, thus ensuring the confidential allocation of research participants to study groups. It will not be possible to blind the intervention performed or the physiotherapists who perform it, but physiotherapists who perform the intervention do not participate in the patient evaluation process. An independent biostatistician will conduct the statistical analysis of the data.

Outcomes variables

All the outcome variables will be measured before the intervention and after 8 weeks. The CONSORT flowchart of the study and SPIRIT recommendations can be seen in Figure 2 and Table 2.

Primary outcome measures

CSI (Gujarati version): Central sensitization inventory (CSI): The central sensitization inventory includes 25 statements assessing current health symptoms, measured on a 5-point Likert scale will be used. The cumulative score ranges from 0 to 100, and scores equal to or greater than 40 indicate the presence of central sensitization. Randy et al described five categories of CSI severity based on the scores, ranging from subclinical (0-29) to mild (30-39), moderate (40-49), severe (50-59), and extreme (60-100).[26]

FACS (Gujarati version): The fear-avoidance components scale (FACS) is a newly developed patient-reported tool that comprises 20 different statements that are rated on a scale of 0 ("completely disagree") to 5 ("completely agree"), with a possible total score of 100 will be used. The FACS provides five severity levels-subclinical (0-20), mild (21-40), moderate (41-60), severe (61-80), and extreme (81-100)-which can be used for clinical interpretation.[27]

Secondary outcome measures

Numerical pain rating scale (NPRS): A 0-10 scale will rate the patient's pain over the last 24 hours.[28,29]

Pain disability index (PDI): It is a brief instrument that was developed to assess pain-related disability will be used.[30,31]

Pain self-efficacy questionnaire (PSEQ-2): A 2-item measure will assess confidence in managing daily activities despite pain.[32]

Patient health questionnaire (PHQ): PHQ is a self-administered tool that measures depression severity using DSM criteria on a scale of "0" (not at all) to "3" (nearly every day) will be used.[33]

WHO-BREF QoL: quality of life and general health will be measured using a 26-item instrument with four domains: physical health (7 items), psychological health (6 items), social relationships (3 items), and environmental health (8 items).[34]

Subjective units of distress scale (SUDS): A scale measuring subjective distress on a range of 0-10 will be used.[35]

Neuro physiological pain questionnaire (NPQ): The neurophysiology of pain education questionnaire will be used to assess how an individual conceptualizes the biological mechanisms that underpin one's pain.[36]

Psychological distress scale: A reliable and valid 10-item tool will be used to screen and assess psychological symptoms.[37]

Global rate of change (GROC): A patient-rated outcome measure will be used to evaluate treatment efficacy.[38]

Short assessment of patient satisfaction (SAPS:) A patient satisfaction scale will be utilized to assess satisfaction with healthcare services, providing valuable insights into the quality of care and empathy.[39]

Implementation measures for adaptability, acceptability and feasibility: Implementation outcome measures such as the acceptability of intervention measure (AIM), intervention appropriateness measure (IAM), and feasibility of the intervention measure (FIM) will be used.[40]

Study group interventions

The control group received a standardized physiotherapy protocol, consisting of three sessions per week for eight weeks, with each session lasting 45 minutes to 1 hour (a total of 24 hours).

The experimental group received the same physiotherapy, supplemented with psychosocial approaches, including psychoeducation and cognitive-behavioural strategies, with five sessions per week over eight weeks (a total of 40 hours).

Experimental group intervention

Comprehensive chronic pain management physiotherapy practice protocol (BPS approach-CCPM) includes the regular standard physiotherapy protocol along with sessions of neuro-physiological education (NPE) cognitive behaviour modification AND self-management strategies**.** The CCPM intervention protocol consists of 16 sessions. Sessions 1-4 focus on pain mechanisms, NPE, and the BPS model, emphasising neuroplasticity and sensitisation. Session 5 introduces SMART goal setting, while sessions 6-7 cover pacing principles, relaxation techniques, and breathing exercises. Sessions 8-10 explore pleasant activities, cognitive-behavioural therapy (CBT) for unhelpful thoughts, and action plans. Session 11 addresses distress management and coping skills, followed by sleep hygiene (session 12) and lifestyle/self-management strategies (sessions 13-14). The final sessions (15-16) are interactive revisions and feedback on earlier content (Table 3).

Control group intervention

The control group will receive the standard care treatment (Biomedical approach) carried out in physiotherapy that is supported by the current physiotherapy protocols and guidelines. The treatment consists of 24 sessions of thermotherapy or analgesic electrotherapy modalities in the area of pain, and specific exercises recommended.[41]

The procedure of physiotherapist training and treatment credibility

The professional physiotherapists delivering the intervention will undergo a rigorous 12-16 hours of specific training program, through workshops. The training involved interactive lectures, and learning sessions with a psychological expert. And each will receive a therapist manual and a CCPM intervention workbook which were detailed during training sessions. Post training the therapist had a pre-study experience of assessing and treating patients in front of the expert.

The physiotherapists who conducted treatment in the control group had good expertise in musculoskeletal treatment. The physiotherapists documented the therapy content for each participant, session by session. To ensure the proper implementation of both therapies, the physiotherapists received regular monitoring and feedback throughout the trial. At every session, physiotherapists gave information on their training and demographics.

Senior physiotherapists observed portions of both intervention groups' sessions to conduct a qualitative evaluation. In addition to assessing pre- and post-intervention outcomes, we will rigorously measure the feedback of the intervention and its effects on patient satisfaction, distress, and quality of life during the therapy sessions (Figure 1).[24]

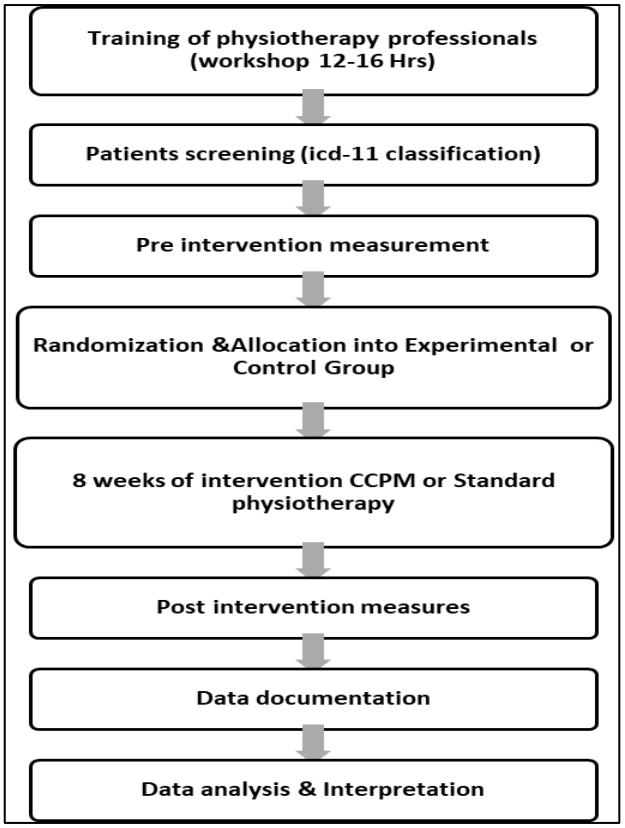

Figure 1: Execution plan of the trial.

Sample size calculation

The sample size will be calculated based on assumptions of medium to large effect sizes in the previous research literature, with a power of 0.9 and type I error α=0.05, considering CSI as a primary outcome measure. Including a 15% dropout estimation, the total sample size is calculated to be 80 individuals. Calculation has been done using G*Power 3.1.9.2 (Düsseldorf, Germany).[42,43]

Statistical analysis

The categorical variables will be presented in percentages and numerical variables in terms of mean and standard deviations for the demographic and clinical outcomes. After checking the Normality of collected data using the Shapiro-Wilk test of normality, parametric, non-parametric and 2×2 factorial ANOVA analyses will be used to determine the time effect, group effect, and time × group interaction effect for the interpretation of the data. For testing the association between qualitative variables, Chi-squared statistics will be used. The effect size of the numerical outcomes for exposure will be presented as Cohen's d. using the pooled SD of baseline scores, where 0.2 was considered a small effect, 0.5 a moderate effect, and 0.8 a large effect. All the analyses will be done using IBM SPSS statistics for Windows, version 20.0. Armonk, NY: IBM Corp. Statistical significance will be set at "$p<0.05$" for all statistical analyses.

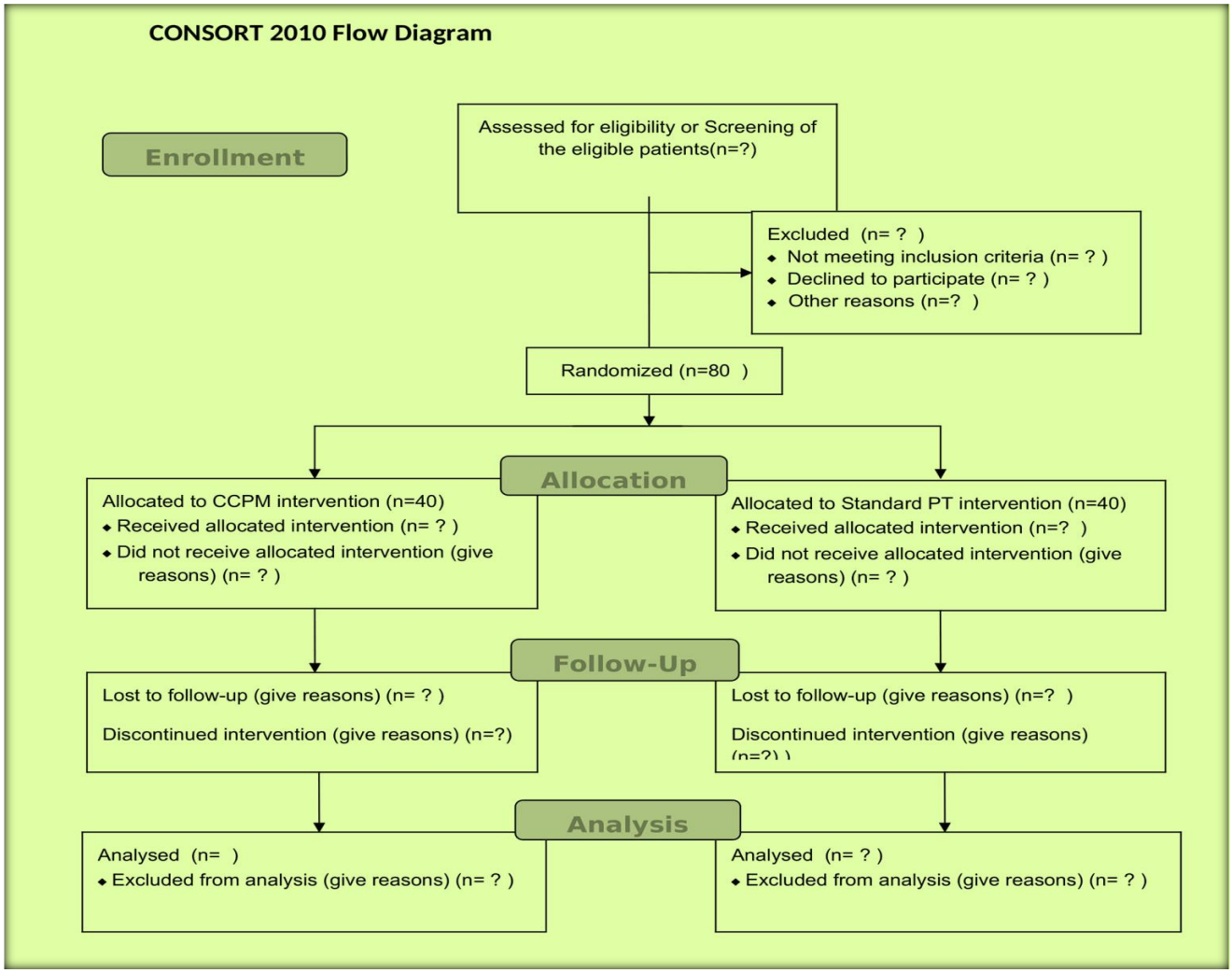

Figure 2: The CONSORT flowchart of the study.

Table 1: Brief description of trial arms.

Group	Interventions	Duration of treatment (8 weeks)	Duration of the session
Control group	Standardised physiotherapy protocol (as per standard guidelines recommended modalities and exercises)	Weekly thrice/8 weeks	45 min-1 hr/session (24 hrs).
Experimental group	Standardised physiotherapy protocol+ psychosocial approaches [CCPM] [psycho-education, cognitive behavioural approaches/self-management strategies]	Weekly thrice/8 weeks + weekly twice/8 weeks	45 min -1 hr/session (24 hrs)+ 45 min -1 hr/ session (16 hrs).

Table 2: SPIRIT statement for the clinical trial.

Study period	Enrolment	Allocation	Post-allocation		Close-out
Timepoint**	**$-t_1$**	**0**	**$t_{1\ baseline}$**	**$t_{2\ 8\ weeks}$**	**t_x**
Enrolment					
Eligibility screen	X				
Informed consent	X				
Randomization	X				
Allocation to CCPM or standard physiotherapy		X			
Interventions					
CCPM			◆——	——◆	
Standard physiotherapy			◆——	——◆	

Continued.

Study period	Enrolment	Allocation	Post-allocation		Close-out
Timepoint**	**-t_1**	**0**	**t_1 baseline**	**t_2 8 weeks**	**t_x**
Assessments					
Background data	X	X			
CSI, FACS, NPRS, PDI and PSEQ		X			X
PHQ, SUDS, NPQ, QoL and distress scale			X	X	
GROC, SAPS and implementation measures				X	

Table 3: CCPM intervention protocol.

Session	Program	Assessment measures used	Content of the session	Purpose
1	Introduction to CCPM intervention protocol	SUDS, NPQ scoring, clinical interview form	Mechanism of pain and its effects	Introduce patients to the CCPM protocol and educate them on pain mechanisms and their impact.
2	NPE	PHQ	BPS model, chronic pain cycle	Explain the BPS model and how chronic pain develops and persists.
3	NPE	WHO-BREF QoL	Neuroplasticity, peripheral and central sensitization	Educate on neuroplasticity and sensitization in chronic pain.
4	NPE	SUDS, NPQ scoring, NPRS	Summarize NPE, feedback, discussion	Reinforce NPE concepts and address patient questions.
5	Goal setting	Feedback from assessments	SMART goal setting	Help patients set specific, measurable, achievable, relevant, and time-bound (SMART) goals.
6	Pacing principles for exercise/body	SUDS, Walking log	Chronic pain cycle (overactivity/underacti-vity), hurt vs harm	Teach patients pacing techniques to balance physical activity without worsening pain.
7	Relaxation	Relaxation practice log	Breathing exercises, progressive muscle relaxation	Introduce relaxation techniques to help manage stress and pain.
8	Pleasant activities scheduling	Pleasant activities list, schedule	Guided imagery	Encourage patients to engage in pleasant activities to improve mood and reduce pain perception.
9	Unhelpful thought modification/action plans (mind)	Identification of automatic thoughts	CBT modeling for chronic pain, negative thought identification	Identify and address unhelpful automatic thoughts related to chronic pain.
10	Unhelpful thought modification/action plans (mind)	SUDS, NPRS	Challenging automatic negative thoughts, coping strategies	Teach strategies to challenge, and modify unhelpful thoughts for better coping
11	Distress management/ coping skills (emotion)	Distress scale	Distress tolerance session	Equip patients with coping skills to manage emotional distress linked to chronic pain.
12	Sleep	Sleep diary, NPRS	Sleep hygiene instruction printouts	Educate on healthy sleep practices to improve sleep quality and reduce pain
13	Lifestyle/self-management	Lifestyle blog, weekly activities schedule	Lifestyle instruction printouts	Encourage lifestyle changes that support self-management of chronic pain.
14	Self-management	SUDS, pain self-management strategies wheel	Self-management instructions	Reinforce self-management techniques for long-term pain control.
15	Revision 1/feedback (sessions 1-7)	GROC, PHQ, WHO-BREF QoL	Interactive sessions with patients	Review and assess progress from the first seven sessions, offering feedback and adjustments.
16	Revision 2/feedback (sessions 8-14)	SAPS, distress scale, implementation outcome measures	Interactive sessions with patients	Final review of progress, offering feedback on the last set of sessions and evaluating outcomes.

There is the requested content presented in table form. [@Patient interactive sessions/demonstrations/PowerPoint point presentations will be used as the mode of delivery of the CCPM intervention].

DISCUSSION

This study is a significant step towards enhancing the management of chronic musculoskeletal pain through a BPS comprehensive pain management physiotherapy protocol. Chronic musculoskeletal pain is a widespread issue globally and particularly prevalent in India, where it poses a substantial burden on healthcare systems and individuals. This research has the potential to significantly contribute to the evidence-based practice of physiotherapy in India and improve the quality of life for countless patients suffering from chronic musculoskeletal pain. Central sensitization is a key component of chronic pain conditions. Research by Woolf et al and subsequent studies have shown that chronic musculoskeletal pain is often associated with central sensitization, where the central nervous system becomes hypersensitive to pain signals.[44] Our study aims to evaluate the impact of the comprehensive physiotherapy protocol on central sensitization. Chronic musculoskeletal pain often leads to fear avoidance behaviours, where individuals avoid physical activities due to the fear of pain. A study highlights the role of fear-avoidance in chronic pain and disability. Our research demonstrating a reduction in fear avoidance through the protocol would signify its potential to restore patients' confidence in physical activities and improve their quality of life. Self-efficacy, or an individual's belief in their ability to manage their pain, is crucial for effective pain management. Research, including Bandura's work on self-efficacy theory, has shown that higher self-efficacy is associated with better pain outcomes. An increase in self-efficacy in the study results can be a positive outcome for adherence to treatment plans and improved overall well-being.

The impact of chronic musculoskeletal pain on a person's daily life and functional abilities is substantial. Our study can provide valuable insights into how the comprehensive pain management protocol affects patients' ability to perform daily activities and their overall disability levels. The sample size used in the study is significant enough to draw solid conclusions about the effectiveness of the proposed treatment. Patients with chronic musculoskeletal pain may benefit from changes in therapeutic management when study results show an effect size greater than 0.8 (Cohen's d) in measured variables at the first level of care.

This level of effect size is considered large and would imply a clinically meaningful improvement in patient outcomes. Our decision to opt for individual treatment sessions aligns with the common expectation of care in the Indian healthcare setup. It is essential to consider the cultural and practical aspects of healthcare delivery. While individual sessions may be more resource-intensive, they can cater to the unique needs and preferences of patients, potentially enhancing treatment adherence and effectiveness.[44-47]

CONCLUSION

In conclusion, our study holds great promise in advancing the field of physiotherapy in India and improving the lives of individuals suffering from chronic musculoskeletal pain. By focusing on central sensitization, fear avoidance, self-efficacy, and disability, and by ensuring a robust research design with a substantial sample size, our research has the potential to contribute significantly to evidence-based pain management practices in India and beyond.

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