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Psychophysiological biomarkers to assess the effectiveness of surface electromyography biofeedback as an alternative therapy to reduce chronic low back pain: protocol for a randomised controlled trial

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ABSTRACT

The prevalence of chronic low back pain (CLBP) among the Pakistani population is reported to be as high as 78%, leading towards different physiological and psychosocial alterations, with the worst cases suffering from disabilities. This study protocol will be a randomised controlled trial designed to compare the effectiveness of biofeedback surface electromyography (sEMG) for CLBP in the Pakistani population. This will be a single-centre study to be conducted on patients with CLBP randomised into two groups, namely, Group A (intervention group) and Group B (control group) to receive biofeedback sEMG therapy as an intervention or no intervention, respectively. All participants will receive treatment for 8 weeks virtually. The primary and secondary outcomes will be assessed during the study, including the pain intensity and interference (Brief Pain Inventory), anxiety and depression (State-Trait Anxiety Inventory (STAI)), disability (The Oswestry Disability Index (ODI)) and quality of life. Further, physiological parameters, including altered cortisol levels, beta-endorphins and substance P, will also be measured. All outcomes will be assessed at baseline, immediately post-intervention and 3 months follow-up.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Chronic low back pain (CLBP) is a prevalent and debilitating condition with significant physical, mental and economic impacts globally, especially in developing countries. Surface electromyography (sEMG) biofeedback therapy has shown promise as a non-invasive approach to manage CLBP.

WHAT THIS STUDY ADDS

⇒ This study provides a protocol for a randomised controlled trial to evaluate the effectiveness of sEMG biofeedback as an alternative therapy for CLBP in the Pakistani population, focusing on psychophysiological biomarkers.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study could contribute to developing non-invasive therapies for CLBP management, particularly in resource-limited settings, and inform policy on integrating biofeedback therapies into standard pain management protocols.

INTRODUCTION

Chronic low back pain (CLBP) is a multifaceted condition with a range of adversative sequelae, including mental and physical disability, social issues and increased healthcare utilisation.[1] CLBP is an intractable disorder with a variety of devastating consequences that could affect an individual's standard of living and self-esteem. CLBP is one of the leading worldwide health problems; however, it is benign. It is now accountable for more years lived with disability (YLDs) than any other chronic health problem.[2]

CLBP caused 72 million YLDs in 2013 approximately, which is 1.5 times greater than that of depression and twice as high as that of diabetes.[2] Further, in 2020, around 615 million individuals globally were affected by disabling chronic lower back pain.[3] CLBP affects almost every age group and is the prominent cause of pain and disability in all low-, middle- and high-income countries around the world.[4] Additionally, CLBP and its accompanying disability also have a major economic burden on the country.[5 6]

According to an estimation, between 5% and 10% of low back pain cases will develop CLBP, which is ultimately accountable for the increased cost of treatment, a high number of sick leaves and individual suffering[7–9] and also one of the leading cause for individuals seeking healthcare services.[10 11] Disparagingly, the issue of CLBP is not well understood in

developing countries like Pakistan, Sri Lanka, India and Bangladesh, which are in the process of development and experiencing economic development and a double burden of diseases.[12]

The CLBP prevalence in Southeast Asian countries is reported to be very high, for instance, much higher than that reported in the Western world. The prevalence of CLBP in Bangladesh is 64%, followed by Pakistan, which has a 40% prevalence rate and Sri Lanka and India at 36% and 19%, respectively.[13] This increased prevalence might be because these countries consist of different societal structures[14] and decreased literacy rates in addition to below-average healthcare and occupational structures, which worsen the CLBP condition in these countries.[15 16]

Previous research studies have focused on the documentation of factors that are termed 'yellow flags', which induce, aggravate and enhance pain and disability in CLBP patients.[17] Psychological and social factors are considered important contributing factors in the biopsychosocial approach for CLBP management[18] and its relationship with disability.[19 20]

Moreover, the risk factors for CLBP are also poorly understood. The most often described factors are twisting, heavy physical work, pulling, frequent bending, lifting, pushing, repetitive work, vibrations and static postures.[21] However, it is suggested that research should focus on pain and disability and individuals' perception of their own pain and functional ability that impacts the quality of life and hinders the normal routine.[22]

Since the early 20th century, the medico-legal interest in CLBP continued the debate about its association with trauma and hysteria.[23] However, the increasing extensive use of X-rays to validate CLBP has become the central issue for the patient's diagnosis. Thus, CLBP remains a disputed problem even today.[1]

Moreover, this study aligns with the UN SDG 2030 plan, Goal 3.d, that is, to 'strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks'.

This study protocol will be a randomised controlled trial designed to compare the effectiveness of biofeedback surface electromyography (sEMG) for CLBP in the Pakistani population.

METHODS

Study design

A randomised controlled trial (intervention) design will be used for the study's execution among individuals suffering from CLBP. Participants will be selected from Karachi, representing a range of socioeconomic strata. The patients will be asked to take part in the study through the information provided by their doctors and the advertisements posted on the hospital's notice boards. The study will be conducted in three phases (figure 1).

Phase 1: Participants will be randomised 1:1 to Group A, the control group and Group B, the intervention group (sEMG), based on eligibility criteria. Randomisation will be performed using computer-generated random numbers. Each participant who will be included receives a unique code after their basic information is collected. Participants will receive an information sheet with details about their sociodemographic traits. The participants will then be given the booklet containing all instructions relating to the intervention based on the groups they will be assigned, as well as the baseline screening questionnaire (Brief Pain Inventory (BPI), State-Trait Anxiety Inventory (STAI), The Oswestry Disability Index (ODI) and the quality of life questionnaire). For the convenience of the participants, the intervention's original instructions will be translated into Urdu.

Phase 2 is the intervention phase based on allocating the participants to the two groups. Group A is the study control intervention (continued care group), and Group B is the experimental intervention (surface EMG group). Group A will receive three sessions, each lasting roughly 20 min, for their usual care during the research without being made aware of the intervention. Two weeks following the initial assessment, the continuous care session will be conducted, and after that, Group B will have eight consecutive one- to one-and-a-half-hour sEMG sessions as part of this intervention. The sessions will be conducted twice a week for nearly 4 weeks. The Alive Pioneer biofeedback device with GP8 Amp will be used for this investigation. The GP8 Amp can record EMG to measure muscular tension. From the first to the eighth session, subjects will receive biofeedback training that gradually relaxes their muscular activity by aided EMG biofeedback. The CLBP intensity will also be modified following variations. After that, six sessions will be conducted twice a week for 4 weeks. All outcome measures will then be assessed at the end of the intervention phase.

Phase 3: It will be a follow-up phase that will be conducted 3 months after the intervention of both groups, assessing all the outcome measures as assessed at the baseline and immediately after the intervention phase.

Study sample size

With a two-sided test using G-Power 3.1.3, the sample size will be determined using an estimated effect size, an alpha of 0.05 and a power of 0.80. Since at least 100 participants will be assigned to each group (n=200 combined of two groups), there will be an 80% chance that the sEMG group will show a statistically significant variation in CLBP compared with the control group.

Inclusion and exclusion criteria

The inclusion criteria for the study will be set as (1) either gender, (2) aged between 25 and 75 years, (3) participants should be able to write, speak and understand both English and Urdu languages, (4) individuals who constantly experience low back pain for the last 3 months, (5) individuals who seek care from healthcare provider due to low back pain, (6) individuals with

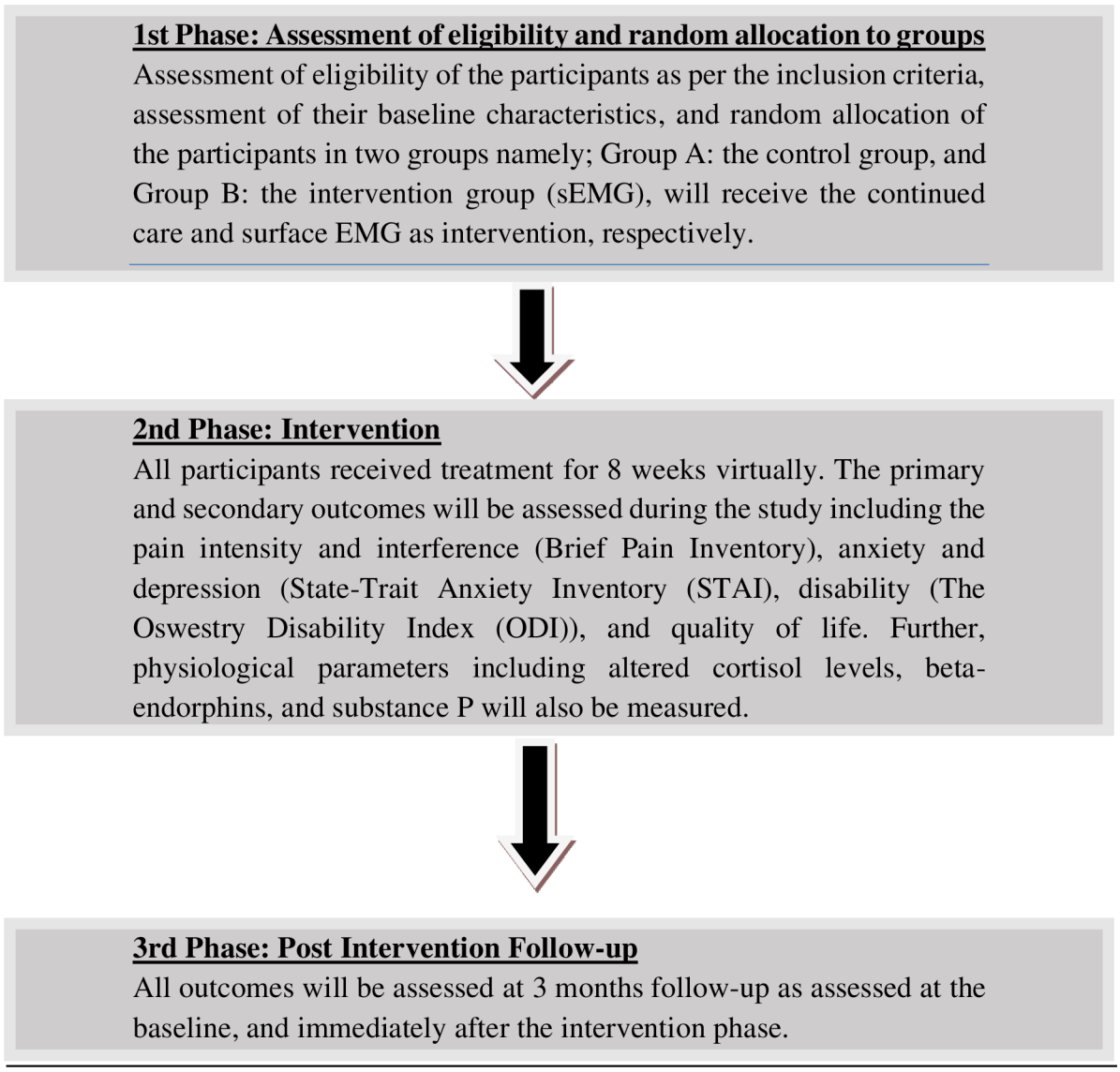

Figure 1 The study design Process.

average pain intensity, were assessed using the BPI over the past week of ≥2 on a 0–10 scale, (7) individuals with an average Oswestry Disability Index (ODI) score of ≥4 and (8) individuals with State-Trait Anxiety Inventory (STAI) score of ≥20.

The exclusion criteria of the study will include (1) age below or above 25 and 75 years, respectively; (2) females who are pregnant, lactating or anticipate becoming pregnant in the next 3–6 months; (3) individuals having any diagnosed chronic disease; (4) individuals having any diagnosed neurological disorder including Alzheimer's, amyotrophic lateral sclerosis, multiple sclerosis, Parkinson's or stroke; (5) individuals having any diagnosed motor disorder or had pathologic fractures of the spine, avascular necrosis or osteonecrosis or severe osteoarthritis, including a history of spine surgery or hip arthroplasty; (6) individuals with active cancer; (7) blind individuals; (8) individuals having a body mass index of greater than 35 kg/m2; (9) individuals with clinical depression, that is, having a score of 24 or higher on the Centre for Epidemiology Depression Scale; and (10) individuals who have used narcotics or muscle relaxants within 30 days before study enrollment.

Outcome measures

Pain intensity and interference

The BPI will assess the severity of CLBP and its impact on lower back functioning. The participants will rate the degree of interference and the intensity of pain. Employing a scale from 0 to 10, where 0 to 4 represents mild pain, 5 to 6 represents moderate pain, and 7 to 10 represents severe pain.

Lower back pain-related disability

The ODI will be used to categorise the degree of disability in CLBP patients. On a 0–5 scale, where 5 is the most handicap, each section is scored. The cumulative score is divided to determine the index, which is then given as a percentage, whereas 0–20 denotes no disability, 20–40 denotes moderate disability, 40–60 denotes severe

Table 1 Variables analysed as the primary and secondary outcome measures

Primary outcome measure	Measure description
Pain intensity and interference	The Brief Pain Inventory (BPI) will assess the severity of chronic low back pain (CLBP) and its impact on lower back functioning. Participants will rate the pain severity and the degree of interference. Using a 0–10 scale, where 0–4 corresponds to mild pain, 5–6 corresponds to moderate pain and 7–10 corresponds to severe pain.
Lower back pain-related disability	The Oswestry Disability Index will be used to categorise the degree of disability in CLBP patients. Each section is scored on a 0–5 scale, where 5 represents the greatest disability. The index is calculated by dividing the summed score and expressed as a percentage where 0–20 indicates mild disability, 20–40% indicates moderate disability, 40–60% indicates severe disability, 60–80% indicates disabling and 80–100% indicates bedridden or functional impairment.
Quality of life with CLBP	The quality-of-life questionnaire will assess the patient's perspective of their quality of life. The score can range from 6 to 112. A higher score indicates a higher quality of life, whereas a score of 90 is the average for a healthy population.
Pain- and disability-related anxiety	The State-Trait Anxiety Inventory will be used for anxiety screening. It is a 20-item scale with a score range of 20–80, where a higher score indicates higher levels of anxiety symptoms.
Secondary outcome measure	
Substance P	Changes in substance P levels will be observed during the study in the control and intervention groups.
Cortisol	Changes in cortisol levels will be observed in the control and intervention groups during the study.
Beta endorphins	Changes in beta-endorphin levels will be observed during the study in the control and intervention groups.

disability, 60–80% denotes crippling disability and 80–100% denotes bedridden or reduced function.

Pain- and disability-related anxiety

The State-Trait Anxiety Inventory-STAI will be used for anxiety screening. A higher score on this 20-item scale, which has a scoring range of 20 to 80, reflects higher degrees of anxiety symptoms.

Quality of life with CLBP

The quality-of-life questionnaire will assess the patient's perspective of their life quality. The possible scores are 6–112. A higher score denotes a better standard of living, whereas a score of 90 is the average for a healthy population

Cortisol, beta-endorphins and substance P levels

The secondary physiological parameters will also be evaluated, including altered cortisol levels, beta-endorphins and substance P. Standard methods for determining absolute biomarkers will be estimated using results from enzyme-linked immunosorbent assays that require fresh (<18 hours old) blood samples and will be outsourced. Changes in substance P, cortisol and beta-endorphin levels will be observed during the study in the control and intervention groups (table 1).

Screening, management and standardization

At least two researchers will be involved in the recruitment and evaluation processes. The primary investigator will conduct previous training sessions to acquaint the researchers with the objectives and protocols of the investigation. After a more thorough description of the study's objectives, the participants will be sent to the researchers, who will then conduct their assessment. On giving all interested participants comprehensive information about the study, including its goals, aims, objectives and length, each participant will provide signed informed consent. Participants will receive an information sheet with details about their sociodemographic traits. Before the study starts, the participants must provide written, informed permission.

Consent and data protection

Consent will be obtained per the Helsinki Declaration, ensuring the protection of participants' rights. Personal identifiers will be stored separately from research findings to maintain confidentiality and data security, using distinct computing systems and unique codes. Original datasets will be securely encrypted and backed up, with access limited to authorised individuals only. Participants will also provide explicit consent to be contacted in the future for feedback on their physical and psychological assessments, as well as for additional analyses.

Statistical analysis

The current study's findings will be presented as mean±SD, and SPSS version 22.0, a statistical tool for social science, will be used for analysis. A multivariate analysis of covariance will be used to compare the pre- and post-measures of all the assessment scale scores, including the ODI

scale, STAI, quality of life and brief pain inventory. To determine whether surface EMG biofeedback therapy is an effective measure when compared during two physiological modes, which will be at the baseline (0) and at the eighth sessions of the biofeedback training, the data will also be analysed using a 2×2 mixed factorial design analysis of variance (ANOVA). An adjusted ANOVA will also be conducted to ascertain the impact of sociodemographics on the variation in findings between the two groups, maintaining sociodemographic and other variables as covariant. A regression-based method will be used to examine how sEMG affected the meaning produced.

DISCUSSION

Biofeedback is a self-regulation method that gives people immediate feedback on their physiological reactions, enabling them to control physiological functions. To address the psychological and psychophysiological impacts of persistent lower back pain, this study will investigate the potential of biofeedback.

Psychophysiological research has shown that biofeedback training can be especially helpful for those with CLBP who experience a reduced quality of life and disability. To treat CLBP, sEMG biofeedback therapy has drawn interest as a non-invasive and potentially effective method. With surface electrodes applied to the skin, this therapy measures and provides feedback on muscle activity, giving patients real-time information on their degrees of muscle tension. People can learn to deliberately relax and minimise excessive muscle contractions by receiving real-time feedback on their muscle activity, which will lessen their pain.

Aberrant muscle activation patterns are frequently linked to persistent lower back pain problems. By helping muscles retrain themselves to use more efficient activation patterns, sEMG biofeedback improves spinal stability and lessens lower back pain. sEMG biofeedback therapy makes it possible to manage CLBP uniquely and customised. The core causes of pain can be addressed by creating treatment programmes based on the unique muscular imbalances and maladaptive movement patterns seen in each patient.

Aberrant muscle activation patterns are frequently linked to persistent lower back pain problems. By helping muscles retrain themselves to use more efficient activation patterns, sEMG biofeedback improves spinal stability and lessens lower back pain. sEMG biofeedback therapy makes it possible to manage CLBP uniquely and customised. The core causes of pain can be addressed by creating treatment programmes based on the unique muscular imbalances and maladaptive movement patterns seen in each patient.

It is indicated that patients receiving sEMG biofeedback therapy may continue to benefit even after their treatment is over. Long-term pain management is aided by enhanced muscular activation patterns and acquired self-regulation skills. When combined with other therapeutic modalities like physical therapy or exercise regimens, sEMG biofeedback is frequently employed. This multidisciplinary strategy improves CLBP management's overall efficacy.

sEMG biofeedback has been shown in numerous trials to be beneficial in lowering CLBP. These studies frequently document increases in the degree of pain, functional capacity and quality of life in patients receiving biofeedback therapy.[24 25]

Contributors The corresponding author will act as the guarantor on behalf of all the authors of this study. SA conceptualised the study. AF and SA participated in methodology deliberations. AF prepared the original draft. BA and SA contributed to the review and writing process. SN provided critical insights at all stages. All authors reviewed the final paper.

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Competing interests None declared.

Patient and public involvement This protocol was designed in collaboration with a patient partner and coauthor, SN. SN will remain involved as a patient partner throughout the study.

Patient consent for publication Not applicable.

Ethics approval The study protocol was approved by the Advanced Studies and Research Board (ASRB) of the University of Karachi (ASRB/No./07784/Sc.) and registered by Clinicaltrials.gov with registration number NCT06306833.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. No data are available as this is the protocol paper for a planned study.

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