



STUDY PROTOCOL

Psychosocial Assessment as a Key Component in an Integrated, Personalized Care Pathway: A Protocol for a Low Back Pain Randomized Controlled Trial

Anna Anselmo · Maria Pagano · Francesco Corallo · Irene Cappadona ·
Davide Cardile · Fabrizio Russo · Alice Laudisio · Giuseppe F. Papalia ·
Angelo Quartarone · Rocco S. Calabrò

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ABSTRACT

Introduction: Low back pain (LBP) is the primary factor contributing to years lived with disability. In view of the close correlation between the functions of the body, which cannot be examined piecemeal but as an integrated system, a holistic approach allows for a comprehensive assessment of the patient. The main objective

of this study is to evaluate the impact of face-to-face or remote rehabilitation treatment on the psychosocial aspects of patients with chronic low back pain (CLBP) examining all possible related dimensions: cognitive function, anxiety and depression, pain perception, treatment adherence, the sexual sphere, family dynamics, social support, dysfunctional communication, quality of life (QoL), while also considering attribution of causes.

Methods: This prospective, randomized, controlled trial with blinded outcome assessors evaluates the psychosocial functioning of 86 patients with chronic LBP. Participants divided into two groups to compare tele-rehabilitation with face-to-face rehabilitation with a 1:1 randomization based on a web-based system will all undergo neuropsychological, psychological, and associated clinical condition assessment through standardized tests and ad hoc questionnaires at enrollment (T0), after 1 month (T1), 2 months (T2), and 6 months (T3). The analysis involves descriptive statistics, ANOVA, and correlation tests to evaluate treatment effects and psychosocial outcomes at multiple time points.

Planned Outcomes: We expect this study to provide a comprehensive, in-depth, and integrated understanding of the patient, shedding light on the challenges they may face in managing chronic LBP (CLBP). Repeated administration of the questionnaires will allow us to monitor the patient over time, assess any changes in

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A. Anselmo · M. Pagano · F. Corallo (✉) ·
I. Cappadona · D. Cardile · A. Quartarone ·
R. S. Calabrò
IRCCS Centro Neurolesi Bonino-Pulejo, Via
Palermo, S.S. 113, C. da Casazza, 98124 Messina,
Italy
e-mail: francesco.corallo@irccsme.it

F. Russo · A. Laudisio · G. F. Papalia
Operative Research Unit of Orthopaedic and Trauma
Surgery, Fondazione Policlinico Universitario
Campus Bio-Medico, Via Alvaro del Portillo 200,
00128 Rome, Italy

F. Russo · A. Laudisio · G. F. Papalia
Research Unit of Orthopaedic and Trauma Surgery,
Departmental Faculty of Medicine and Surgery,
Università Campus Bio-Medico di Roma, Via Alvaro
del Portillo 21, 00128 Rome, Italy

their health status, and structure an intervention tailored to their needs. By emphasizing these often neglected areas through a comprehensive, multi-step assessment, it will be possible to quantify and analyze how these risk factors can affect patients' wellbeing and hinder the treatment process and recovery.

Trial Registration: Registered on Clinicaltrials.gov (ID: NCT06895317).

Keywords: Low back pain; Psychosocial functioning; Neuropsychology; Depression; Anxiety; Treatment adherence and compliance; Chronic pain; Quality of life

Key Summary Points

Low back pain (LBP) is the leading cause of years lived with disability, significantly impacting quality of life (QoL) and contributing to long-term functional limitations.

It is important to identify the psychosocial factors that could worsen the patient's condition by assessing anxiety, depression, pain, treatment adherence, family dynamics, social support, QoL, and cognitive function, also considering the attribution of causes.

This study aims to evaluate the impact of face-to-face or remote rehabilitation treatment on the psychosocial aspects of patients with LBP. Repeated questionnaire assessments will enable us to track health changes over time and tailor interventions to their needs.

By focusing on these often-overlooked areas through a thorough, multi-step assessment, we can quantify and analyze how these risk factors impact patients' wellbeing and impede treatment and recovery.

INTRODUCTION

Low back pain (LBP) is the leading factor contributing to years lived with disability. Non-specific LBP is defined as LBP not attributable to a known cause and accounts for 90–95% of LBP cases. The estimated prevalence of non-specific LBP is 18% [1]. The prognosis for back pain is not as positive as previously thought, particularly due to the frequent relapses or transition to chronic back pain [2]. Over the course of the disease, many patients report persistent symptoms such as pain, fatigue, stiffness, and sleep disturbances that affect daily activities, even despite potent anti-inflammatory treatment according to current standards of care. Central sensitization (CS) has recently been suggested as a potential contributing cause of these persistent symptoms and therefore may affect quality of life (QoL) [3]. Central sensitization has recently been defined as “the hyperexcitability of the central nervous system” and plays a crucial role in the persistence of chronic and widespread pain and other symptoms that are medically unexplained [4]. Despite the high prevalence of back pain and the enormous personal and social costs, the healthcare system's response has been inadequate. The adoption of the biomedical model for the treatment and management of chronic pain pathology has proven insufficient due to the focus on signs and symptoms of the pathology at the expense of other variables. In fact, the biomedical model views the disease as a biological phenomenon caused by physical or chemical dysfunction of the body, without taking into account the psychological or social aspects of the patient. It focuses on the diagnosis and treatment of disease through medical interventions [5]. Since social and psychological factors are involved in the pathogenesis of chronic back pain, assessing the patient's condition is not a simple task [6]. The failure of the biomedical model to produce better outcomes for chronic back pain has led to the adoption of a biopsychosocial model [1]. The biopsychosocial model provides a framework to explain the complexity of disabling back pain through a multidimensional clinical approach, incorporating the interaction between the social, psychological,

and biological dimensions of pain, context, and behavioral conditioning [7, 8]. Patients with chronic pain have higher rates of depression compared to the general population, and many of those with chronic LBP (CLBP) endure distressing experiences characterized by catastrophization, passive coping, low self-efficacy, and high levels of anxiety, which are linked to job loss, socioeconomic deprivation, and social isolation [9, 10].

Psychological risk factors for an unfavorable prognosis can be clinically identified and addressed within interventions [11]. Kendall et al. [12] coined the term “yellow flags” to understand psychological risk factors and social and environmental risk factors for prolonged disability and failure to return to work due to musculoskeletal symptoms caused by LBP [13, 14]. More recently, a distinction has been made between psychological risk factors that could be considered “normal” but unhelpful psychological reactions to musculoskeletal symptoms (e.g., the belief that pain necessarily implies damage) and “abnormal” psychological or psychiatric factors or disorders (e.g., post-traumatic stress disorder, major depression) [15]. Psychological reactions defined as “normal” should be described as yellow flags, while those that meet the criteria for psychopathology should be termed orange flags [16]. Early identification of these factors could be key to structuring more effective interventions to reduce or prevent chronic or recurring disability. Moreover, since LBP imposes a significant economic burden on healthcare systems, it may be more cost-effective to address a broader target population early with simple, low-cost interventions rather than spending extensive time and resources rehabilitating a smaller group of patients with back pain who have become disabled due to chronic pain [17]. Early active management of LBP is indeed a useful strategy to reduce the risk of transition to chronic LBP (CLBP). Through the use of digital platforms, wearable sensors, and artificial intelligence, an innovative solution emerges to enable a personalized and integrated approach to the diagnosis and rehabilitation of CLBP [18]. These technologies have the potential to revolutionize care delivery, providing personalized interventions and improving patient outcomes. They can

contribute to early screening and, more importantly, to interventions delivered remotely, making them accessible to a large portion of the population, thereby making not only diagnosis but also treatment more accessible, promoting a positive prognosis, and more functional pain management, so that a good QoL is safeguarded and preserved [19–21]. It is important to establish an effective therapeutic relationship from the start, which helps the patient understand that they are embarking on a different path where they must also be an active participant in their own care [22]. Indeed, with the help and support of professionals, the patient can mobilize latent strengths and resources to establish an alliance and pursue a shared goal [23]. This article describes the research project “Chronic Low Back Pain: Innovative e-health Diagnostics and Rehabilitation toward Integrated and Personalized SPINE (TOTALSPINE) Care (PNRR-MCNT2-2023-12378359).” This document outlines in more detail how the research project is designed, particularly focusing on the component related to our operational unit, which is centered on neuropsychological assessment of patients with CLBP. Given that the development and outcomes of the disease are influenced by numerous interconnected factors, these cannot be assessed in isolation but rather as part of an integrated system.

The main aim of this study is to evaluate the impact of face-to-face or remote rehabilitation treatment on the psychosocial aspects of patients with CLBP.

In particular, this article focuses on the part of the project related to the evaluation of the patient’s overall functioning. The psychosocial assessment will indeed include all areas affected by the condition of chronic pain, all contexts in which the patient is involved, and all aspects that are negatively and persistently impacted by the pathology, contributing to a reduced QoL. This is to gain a holistic view of the patient’s health. The specific objectives of our operational unit in the project are as follows:

1. Evaluation of the psychological aspects of LBP before and after treatment.
2. Assessment of functional status.
3. Evaluation of cognitive performance.

4. Assessment of mood and related psychopathologies.
5. Evaluation of health-related QoL.
6. Assessment of social support.
7. Evaluation of sleep quality.
8. Assessment of the burden of comorbidity.
9. Evaluation of treatment adherence.

For a detailed view of the areas examined from a holistic perspective and their interaction with each other, see Fig. 1

MATERIALS AND METHODS

Study Design

The study design is single-center, prospective, randomized, and controlled with blinded outcome assessors, using psychosocial assessment within a design comparing tele-rehabilitation with face-to-face rehabilitation in patients with discogenic CLBP, and is expected to last approximately 24 months. The overall duration will be related to the time required for enrollment of

all planned subjects, data analysis, and publication of results. The protocol of the entire project has received approval from the ethics committee CET Lazio Area 2 (ID NUMBER: 181.24 CET2 cbm of 31/07/2024).

Sample Selection Study Population

Based on the power analysis, we estimated that to achieve 80% power at the 5% significance level with equal allocation, a sample size of $N=70$ ($N=35$ for Telerex) was recommended. In order to compensate for dropouts in the follow-up measurements, with an estimated dropout rate of 20%, we considered a sample size of $N=86$ ($N=43$ for the telerehabilitation group and $N=43$ for the control group). Therefore, a minimum of 86 patients will participate in the study, divided into two groups. Patients will be randomized in a 1:1 ratio, resulting in a total of 43 patients per group. Randomization will be performed using a web-based randomization service.

The inclusion criteria that a patient must meet to be included in the study are: (I) age

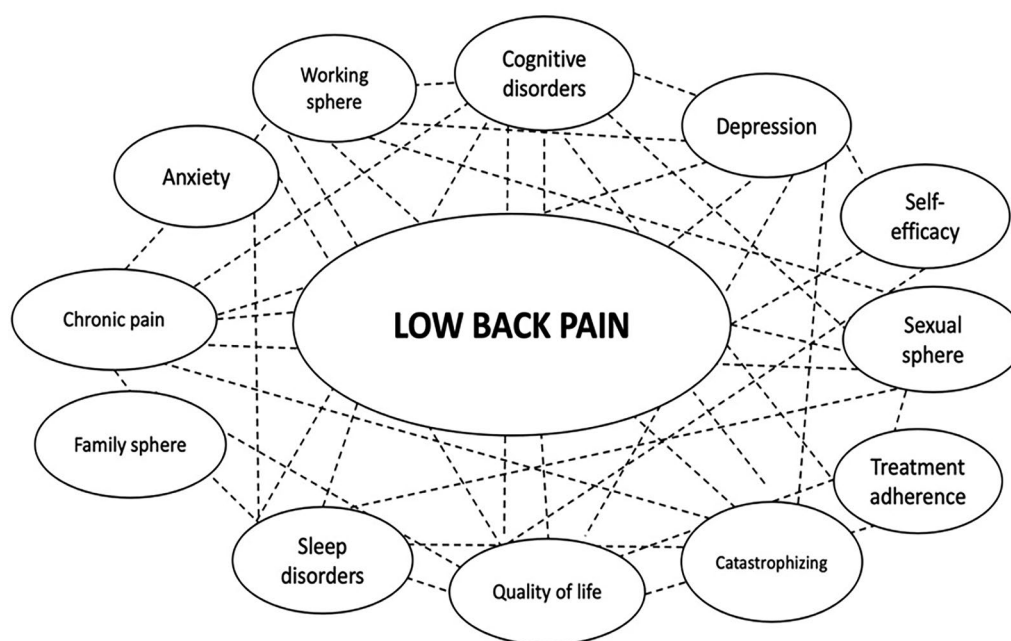


Fig. 1 Mutual interaction of the areas examined in patients with LBP

between 18 and 65 years; (II) CLBP of discogenic origin rated above 4 on a numeric rating scale (NRS) in the 2 weeks prior, ongoing for the last 6 weeks up to 12 months before inclusion (III) Chronic persistent pain symptomatology for at least 12 weeks to place CLBP diagnosis.

On the other hand, among the exclusion criteria there are: (I) Past or present medical history of cancer, fractures, infections or specific causes of non-discogenic LBP; (II) Having received physical therapy for LBP in the last 6 months; (III) Previous spinal surgery; (IV) Severe or progressive neurological deficits; (V) Any serious medical comorbidity that, in the opinion of the Principal Investigator (PI), would make participation unsafe or impossible.

All patients will be informed in detail about the mode, timing and purpose of the study in order to be able to provide both oral and written informed consent.

Measurements

For the psychosocial assessment of patients with chronic LBP, it is necessary to use standardized tools and purpose-built questionnaires to highlight all the risk factors present that promote chronicity of the condition and negatively affect all the areas and contexts in which the subject is placed. Considering the absence of a standard and shared procedure, as well as a thorough evaluation, we tried to compensate for this gap by structuring two ad hoc questionnaires (available as supplementary material) designed to investigate all the areas involved and the dimensions of the patient that are affected by chronic LBP. A summary of both standardized and ad hoc instruments is provided in Table 1.

Data Collection

The study design can be subdivided into four phases: structuring, administering, validating and analyzing data obtained by the aforementioned instruments.

In the first phase, each patient who is eligible for the study, based on the inclusion and exclusion criteria, will be presented with the purpose of the study and will freely decide whether to

join. Informed consent will then be signed by the patient or legal representative. In addition, each subject will be assigned an identification code for the duration of the study.

In the second phase at T0, demographic data, the patient's clinical history, and information regarding the history of the condition and comorbidities will be collected. All patients will undergo primary outcome measures, which are The Pain Self-Efficacy Questionnaire (PSEQ), Oswestry Disability Index (ODI), Pain Catastrophizing Scale (PCS), SF-12 Questionnaire, Beck's Anxiety Inventory (BAI), Center for Epidemiologic Studies—Depression Scale (CES-D), Patient Health Engagement Scale (PHE-s), the Montreal Cognitive Assessment (MoCA), and two specially designed questionnaires. For the psychosocial assessment that will be conducted at baseline, 1 month, 2 months, and 6 months, standardized tests and ad hoc questionnaires will be administered as outlined and described in Table 1. The experimental group will undergo a home-based telerehabilitation program using exercise software. The web-based telerehabilitation platform will provide the program to patients in audio–video format with detailed instructions and explanations. The exercise program will be explicitly prescribed based on the patient's condition, and the exercises will be continuously tailored to the user's fitness level. Patients will be asked to participate in telerehabilitation sessions for 50 min, 3 days a week, for 2 months, in synchronous mode with a physiotherapist. The details of the treatment are summarized in Table 2. During and after the treatment, both neuropsychological and psychosocial tests administration will be repeated for each patient after 1, 2, and 6 months. A descriptive analysis of the groups will be performed for the psychosocial and demographic variables.

Data Analysis

In the last analysis phase, the Shapiro–Wilk test will be applied to assess the distribution of the variables. Subsequently, continuous variables will be expressed as mean \pm standard deviation (SD), while categorical variables will be presented as frequencies and percentages. An

Table 1 Summary of questionnaires chosen for this study

	Investigated variables	Administration time
Standardized instruments		
The Pain Self-Efficacy Questionnaire (PSEQ)	Self-efficacy in managing chronic pain	Approximately 5–10 min
Oswestry Disability Index (ODI)	Level of disability associated with chronic pain	Approximately 5 min
Pain Catastrophizing Scale (PCS)	Degree of catastrophizing associated with chronic pain	Approximately 5–10 min
SF-12 Questionnaire	Measures a person's quality of life (QoL) by assessing physical and mental health	Approximately 10 min
Beck's Anxiety Inventory (BAI)	Assess the intensity of physical and cognitive anxiety symptoms	Approximately 15 min
Center for Epidemiologic Studies-Depression Scale (CES-D)	Measure the severity of depressive symptoms in the general population	Approximately 10–15 min
Patient Health Engagement Scale (PHE-s)	Diagnose and study patients' experience of active involvement in its prevention and treatment pathway	Approximately 10 min
Montreal Cognitive Assessment (MoCA)	Assess the subject's global cognitive functioning	Approximately 10–15 min
Ad hoc instruments		
LBP and health-related QoL	Assess all dimensions related to the patient's QoL that may be affected by chronic low back pain (CLBP)	Approximately 20 min
Attribution of causes of chronic pain	Evaluate the attribution of causes related to CLBP	Approximately 10 min

Table 2 Summary of rehabilitation sessions

Group	Type of rehabilitation	Session duration	Number of weekly sessions	Duration in months
Experimental group	Telerehabilitation	50 min	3 days a week	2 months
Control group	Standard rehabilitation	50 min	3 days a week	2 months

intra-group analysis will be conducted to compare clinical scales across time points using a one-way repeated measures ANOVA (parametric test) or Kruskal–Wallis test (non-parametric test) with post hoc correction by Tukey or Dunn, respectively. Groups will be compared using the independent *t* test or Mann–Whitney *U* test to

assess differences at each time point. The difference between T0 and T2 on clinical scales and instrumental measures will be determined, and a correlation analysis will be conducted to evaluate the relationship between the results of all the questionnaires reported in Table 1. Furthermore, the effects of the different treatments will be

analyzed in relation to clinical and neurophysiological data using a mixed model with random intercept, considering the group, time, and the group time interaction. The least-square means estimation will be used for group comparisons and treatment effects within each group during the observation period. A detailed flow chart of the study design is provided in Fig. 2.

Planned Outcomes

We expect this study will offer a comprehensive, in-depth, and integrated understanding of the patient, shedding light on the challenges they may encounter in managing chronic low back pain.

At T0, questionnaires will be administered to assess anxiety, depression, cognitive deficits, sleep disturbances, QoL, emotional and psychological burden, treatment adherence, pain

perception, and attribution of causes, which will provide a holistic view of health and identify different aspects that may influence disease management and outcome.

In addition, the integrated assessment of these disorders can help identify the interactions among them and develop a more comprehensive and personalized treatment plan.

We expect that the 'remote and in-person physiotherapy rehabilitation intervention will produce positive changes in the patient's cognitive and psychological wellbeing and allow us to assess how the two approaches are functional, especially with regard to adherence to the proposed treatment. In addition, re-administration of the questionnaires will allow us to monitor the patient over time, to assess any changes in his or her health status, and to structure an intervention tailored to his or her needs.

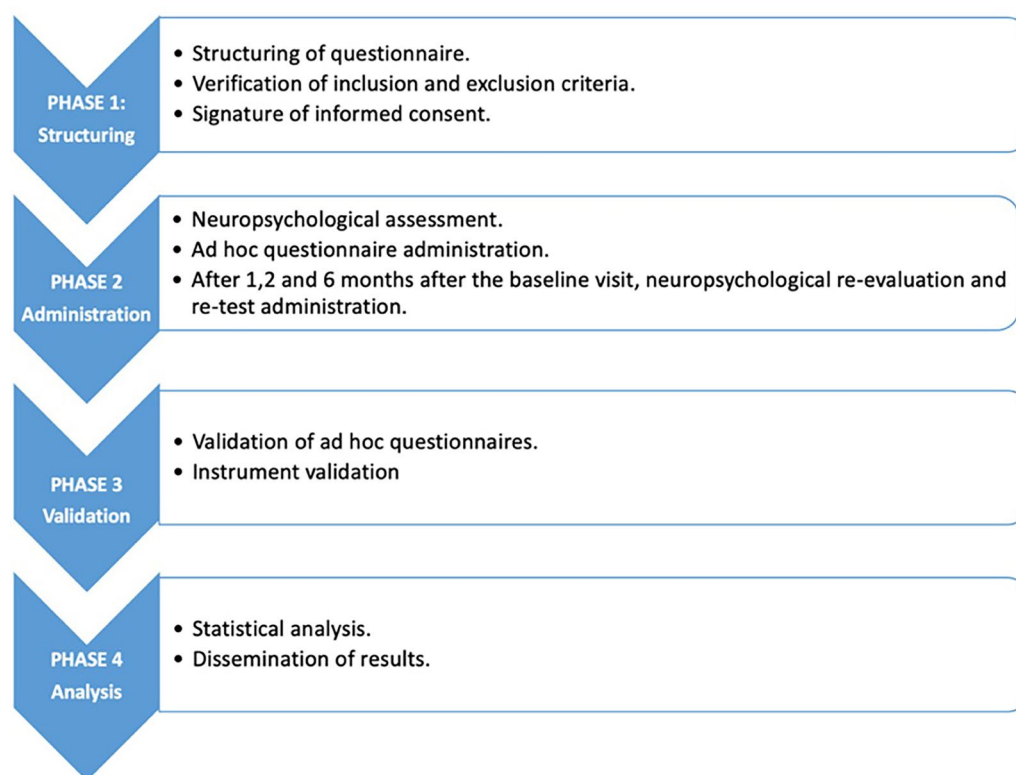


Fig. 2 Study design stages

DISCUSSION

CLBP is a complex biopsychosocial issue with financial implications for society, particularly due to the associated use of healthcare resources [24]. Current international guidelines emphasize that LBP should be managed at the primary care level, as few cases are considered medical emergencies [25].

The diagnosis and treatment of CLBP have been subjects of debate, and there is no clear consensus on optimal management [26]. Therefore, it is essential to establish clear, accessible, and personalized care pathways that promote patient adherence to treatment. For patients experiencing CLBP, there is an inevitable concern about maintaining their QOL [27]. Early and better involvement of patients in the care pathways, along with the recognition of psychosocial factors as risk factors for chronicity, are key points that must be addressed to improve overall care management and increase the likelihood of a favorable prognosis [28].

Physical rehabilitation is essential for the treatment of CLBP, but it must primarily be carried out with the appropriate level of patient adherence. It should be accessible, personalized, and, most importantly, integrated, given the significant impact of psychosocial factors in maintaining the chronicity of the condition [29].

One of the proposals of this project is, in fact, to leverage digital health to improve the management of patients with LBP. Pursuing the primary goal of this study would also allow us to highlight the limitations of current approaches by developing and optimizing an electronic health system to ensure not only a multidimensional approach but also one that is more easily accessible and tailored to the individual needs of each patient [30].

Through the use of digital platforms, it is possible to provide a personalized and integrated approach to diagnosis and treatment, thereby facilitating effective management and comprehensive care for the patient [31].

What has been seen is that LBP is a multidimensional condition that involves not only the physical component but also the

psychological one, which correlates with all the areas in which the patient is engaged [32].

These comorbidities weaken the success of rehabilitation treatment, leading to the chronicization of negative symptoms. The interaction between pain and psychopathological sequelae impacts the cognitive performance of patients with chronic LBP. CLBP [33] can indeed affect cognitive functions. Patients show a reduction in problem-solving abilities, slower information processing speed, and memory impairments [34].

In [35] demonstrated that both pain intensity (VAS) and depression/anxiety scores were correlated with working memory (TMT-B) in patients with CLBP. These results also indicate the interaction between pain, depression, anxiety, and cognitive impairment. However, the reason for these cognitive deficits remains uncertain [36]. Pain may be a contributing factor because the pain itself can have an excitatory effect or act as a mental stressor. The reduction of pain-induced stress could positively affect cognitive profile [37].

In particular, psychological factors such as fear-avoidance beliefs, depression, anxiety, catastrophic thinking, and family and social stress are often poorly identified and inadequately assessed, and it has been shown that they alter pain processing pathways, perceptions, and adaptive responses [38].

Depression is frequently associated with chronic LBP, with a prevalence 2–3 times higher than in the general population [39, 40]. In patients with significant pain-related disability, such as those attending pain clinics, the prevalence is even higher, affecting the majority of them [41].

Depression tends to increase with the intensity of pain, especially when it is associated with multiple painful issues, when there are no adequate medical explanations, or when the pain becomes chronic [42].

The coexistence of depression and chronic conditions is linked to greater impairment of daily functions, an increase in symptoms without clear physical causes, greater reliance on healthcare services, and an increase in healthcare costs [5].

Although in many cases depression is a response to pain and to life experiences associated with it, in some instances, it can precede the onset of pain. While study results are not always in agreement, some research suggests that depression may predispose individuals to develop back pain [43]. When a subject is already depressed at the time of an injury, or with a history of recurrent depression, may have more negative cognitive patterns, a more passive coping style, and fewer psychological and social resources to adequately deal with the injury itself [44].

Anxiety disorders are a common comorbidity in patients with chronic pain and can significantly affect pain perception and the patient's functionality; chronic pain can also exacerbate anxiety symptoms [45].

Although many psychological factors influence the pain experience, anxiety has independent and additive adverse effects on individuals' functional status and their response to pain treatment [46].

Patients with undiagnosed generalized anxiety disorder (GAD) are more likely to progress from subacute pain to chronic pain [47]. The failure to recognize GAD in patients with concomitant CLBP can lead to inadequate treatment and further disability. Since both fatigue and depressive mood are subjective, early screening for each symptom and clarification of the meaning of each symptom for the patient can personalize therapeutic approaches to manage the symptom burden in CLBP [48].

Social relationships can also play an important role in LBP [49]. Psychosocial factors both in private life (e.g., poor emotional support) and at the workplace (poor social support at work, low job satisfaction) are risk factors for CLBP [50]. CLBP often has a significant negative impact on self-perception and a sense of self-efficacy. If patients feel misunderstood by others and have difficulty managing their social interactions both at home and in the workplace, there is a consequent significant perception related to the loss of their social role [51].

On the other hand, functional social relationships can provide support for patients with LBP, and this positive social support should be

promoted to reduce the impact of the disease in daily life contexts [52].

Targeted therapeutic approaches will improve the clinical management of patients with a higher symptom burden, which exacerbates their pain and erodes their QoL [53]. Additionally, our protocol could be useful for testing a composite assessment tool to evaluate concomitant symptoms in patients with CLBP.

Such a standardized approach can help physicians prescribe targeted strategies for a patient presenting with multiple symptoms, as opposed to a patient who does not report other concomitant symptoms [54].

To reduce the burden of disability, it is crucial that screening for known risk predictors is performed early and functionally, and that appropriate, problem-targeted therapy is included from the outset to improve care [55]. Sensitivity to these factors could also enhance the therapeutic alliance between professionals and patients, increasing adherence to advice and treatment, as negative rehabilitation outcomes are often due to patient dropout and low levels of engagement [56].

In the long term, addressing the predictors of negative outcomes in the early stages of LBP could improve results and reduce costs by tailoring interventions to the needs of the patients [57].

The goal of our protocol is to identify all psychosocial risk factors that could worsen the patient's condition at the time of diagnosis. To achieve this, we wanted to prepare an ad hoc assessment that took into account the under-researched dimensions, such as the sexual sphere, family dynamics, dysfunctional communication, appetite-related issues, and potential links to eating disorders, even considering the attribution of causes. Place emphasis on those often-overlooked areas allow to quantify and analyze how these factors may impact patients' wellbeing and hinder the care process and recovery. In this way, it could fill the gap by creating a holistic and validated methodology capable of early identification of patients at risk of psychological deterioration, while also enabling timely intervention. This would not only improve patient wellbeing but also reduce the risk of long-term complications and, as a result,

decrease the economic impact associated with the disease, both in terms of direct and indirect health care costs (e.g., absenteeism from work).

We expect a shift in the treatment of CLBP, shifting from a model predominantly focused on the physical component of pain to a more integrated model that considers all the aspects contributing to the patient's wellbeing.

This is because the challenge associated with treating non-specific CLBP lies in the complex and multifactorial interaction between genetic, bio-physical, psychosocial, health, and lifestyle factors, which are largely individualistic [58].

A patient with better disease-specific knowledge—who understands the cause and the pathophysiological mechanism of the disease and has a proper understanding of prevention and treatment options—can more effectively and actively participate in prevention or rehabilitation. Therefore, patient education is an essential part of primary prevention to prevent the disease, secondary prevention to reduce the impact of the disease, and tertiary prevention to mitigate the disease's impact [59, 60].

STRENGTHS AND LIMITATIONS

The main strength of our study lies in the fact that, to the best of our knowledge, this study protocol is the first one that emphasizes a holistic perspective to promote overall wellbeing and avoid considering the different areas investigated in a piecemeal way, using the most advanced technologies and multidisciplinary intervention.

The main limitation of this study, however, lies in the complexity of the areas covered, which makes a comprehensive investigation difficult. Nevertheless, the introduction of new assessment tools and the integration of multidimensional approaches could be a key step toward more comprehensive management of CLBP. The tools we suggest would allow early screening for risk factors and targeted, individualized interventions, addressing not only the physical but also the social and emotional aspects of pain. The innovation of this study is to identify possible psychosocial factors that

influence treatment adherence, thus enabling the development of personalized interventions related to a dynamic evaluation of the effectiveness of these interventions at different stages of treatment. Furthermore, taking advantage of the potential offered by telemedicine, our goal is to integrate the analysis of psychosocial factors with the implementation of a remote rehabilitation system to optimize the treatment approach.

ETHICS AND DISSEMINATION

The research protocol adhered to the principles outlined in the Helsinki Declaration of Human Rights and the protocol of the entire project has received approval from the ethics committee CET Lazio Area 2 (ID NUMBER: 181.24 CET2 cbm of 31/07/2024). In addition, this protocol has been registered on Clinicaltrials.gov (ID: NCT06895317). Written documentation of informed consent will be required from each participant prior to enrollment. Study results will be disseminated to a medical/scientific audience through scientific conferences and published manuscripts, meeting the criteria of current regulatory requirements.

CONCLUSIONS

Scientific evidence has demonstrated that neglecting the psychological and social aspects associated with chronic pain can severely impede physical recovery, slowing the healing process and, in some cases, even exacerbating it.

Therefore, it is essential to adopt a comprehensive and standardized assessment that is developed in several stages, taking into account the whole individual and all related areas. This approach makes it possible to identify risk factors early, personalize treatment pathways, promote healthy lifestyles, identify emotional difficulties, and monitor the evolution of symptoms over time, providing a comprehensive view that facilitates optimal disease management and improved quality of life. In the future, it will be crucial to leverage the potential of emerging technological advancements, such as

telemedicine and artificial intelligence, not only for physiotherapy treatment but also to support psychosocial assessment and enhance the psychological wellbeing of patients. Adopting these innovative tools is expected to make services more accessible, reduce costs, and enable continuous monitoring, all while contributing to the overall improvement of patient wellbeing through the dynamic interaction of all involved factors.

Author Contributions. Conceptualization: Francesco Corallo and Anna Anselmo; methodology: Francesco Corallo, Anna Anselmo, and Maria Pagano; resources: Irene Cappadona, Fabrizio Russo, and Alice Laudisio; validation: Francesco Corallo; investigation: Irene Cappadona, Francesco Corallo, Anna Anselmo, Maria Pagano, and Davide Cardile; writing—original draft preparation: Anna Anselmo, Fabrizio Russo, Alice Laudisio, Giuseppe Francesco Papalia, Angelo Quartarone, Rocco Salvatore Calabrò, and Francesco Corallo; writing—review and editing: Maria Pagano, Irene Cappadona, Davide Cardile, Francesco Corallo, and Anna Anselmo; supervision: Rocco Salvatore Calabrò; data curation: Giuseppe Francesco Papalia and Angelo Quartarone. All authors have read and agreed to the published version of the manuscript.

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Declarations

Conflicts of Interest. Anna Anselmo has nothing to disclose; Maria Pagano has nothing to disclose; Francesco Corallo has nothing to disclose; Irene Cappadona has nothing to disclose;

Davide Cardile has nothing to disclose; Fabrizio Russo has nothing to disclose; Alice Laudisio has nothing to disclose; Giuseppe F. Papalia has nothing to disclose; Angelo Quartarone has nothing to disclose; Rocco S. Calabrò has nothing to disclose.

Ethical Approval. The research protocol adhered to the principles outlined in the Helsinki Declaration of Human Rights and the protocol of the entire project has received approval from the ethics committee CET Lazio Area 2 (ID NUMBER: 181.24 CET2 cbm of 31/07/2024). In addition, this protocol has been registered on Clinicaltrials.gov (ID: NCT06895317). Written documentation of informed consent will be required from each participant prior to enrollment. Study results will be disseminated to a medical/scientific audience through scientific conferences and published manuscripts, meeting the criteria of current regulatory requirements.

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