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Guillaume Thébault, Claire Duflos, Gaël Le Perf. Effectiveness of a pain neuroscience education programme on the physical activity of patients with chronic low back pain compared with a standard back school programme: protocol for a randomised controlled study (END-LC). *BMJ Open*, 2024, 14 (6), pp.e080079. 10.1136/bmjopen-2023-080079 . hal-04670588

HAL Id: hal-04670588

<https://imt-mines-ales.hal.science/hal-04670588v1>

Submitted on 12 Aug 2024

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BMJ Open Effectiveness of a pain neuroscience education programme on the physical activity of patients with chronic low back pain compared with a standard back school programme: protocol for a randomised controlled study (END-LC)

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To cite: Thébault G, Duflos C, Le Perf G. Effectiveness of a pain neuroscience education programme on the physical activity of patients with chronic low back pain compared with a standard back school programme: protocol for a randomised controlled study (END-LC). *BMJ Open* 2024;**14**:e080079. doi:10.1136/bmjopen-2023-080079

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<https://doi.org/10.1136/bmjopen-2023-080079>).

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Received 20 September 2023
Accepted 15 April 2024



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For numbered affiliations see end of article.

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ABSTRACT

Introduction Education is recognised as an effective and necessary approach in chronic low back pain. Nevertheless, data regarding the effectiveness of education in promoting physical activity in the medium term or long term are still limited, as are the factors that could lead to successful outcomes. Our study aims to assess the effectiveness of a pain neuroscience education programme compared with traditional back school on physical activity 3 months and 1 year after educational sessions coupled with a multidisciplinary rehabilitation programme. Additionally, we seek to evaluate the effects of these educational interventions on various factors, including pain intensity and psychobehavioural factors. Finally, our goal is to identify the determinants of success in educational sessions combined with the rehabilitation programme.

Methods and analysis The study will involve 82 adults with chronic low back pain. It will be a monocentric, open, controlled, randomised, superiority trial with two parallel arms: an experimental group, 'pain neuroscience education', and a control group, 'back school'. The primary outcome is the average number of steps taken at home over a week, measured by an actigraph. Secondary outcomes include behavioural assessments. Descriptive and inferential analysis will be conducted. Multivariate modelling will be performed using actimetric data and data from the primary and secondary outcomes.

Ethics and dissemination

The Committee for Personal Protection of Ile de France VII (CPP) gave a favourable opinion on 22 June 2023 (National number: 2023-A00346-39). The study was previously registered with the National Agency for the Safety of Medicines and Health Products (IDRCB: 2023-A00346-39). Participants signed an informed consent during the inclusion visit. This protocol is the version submitted to the CPP entitled 'Protocol Version N°1 of 03/29/2023'. The results of the study will be presented nationally and internationally through conferences and publications.

Trial registration number NCT05840302.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The effectiveness of an education programme for chronic low back pain is evaluated using an actigraph as a means of measuring physical activity within ecological context.
- ⇒ The follow-up is 3 months and 1 year after the rehabilitation programme.
- ⇒ The study includes an analysis of actimetric data, and behavioural, occupational and psychological variables to determine the predictive factors for the success of educational sessions.
- ⇒ The monocentric design of this study is a limitation.

INTRODUCTION

Background and rationale

Low back pain remains a significant challenge for researchers, clinicians and health-care professionals worldwide. It is a challenge to understand and model multiple processes entangled in low back pain and more widely in the persistence of pain or symptoms, to improve primary care, rehabilitation and cognitive therapies.¹⁻⁴ Despite theoretical advancements, innovative approaches and numerous clinical studies, low back pain remains a prevalent health concern with substantial associated costs.⁵ Recent epidemiological data underscore the gravity of chronic low back pain, indicating a 50% increase in its prevalence over the past two decades. It represents the sixth leading cause of disability in the world.^{6,7}

Education and interdisciplinary rehabilitation are treatments that have shown evidence of efficacy.^{1,8} They are highlighted for people suffering from chronic low back pain in most international recommendations



and international authors have recently emphasised their interest.⁹

First, education aims to change misconceptions that people with chronic low back pain may have due to prior beliefs, avoidant attitudes, or catastrophic thoughts that have become established over the course of the life history of chronicisation of pain.

Historically, the first education programme in this field was developed in Sweden under the name of back school.¹⁰ The basis of the education was the presentation of biomechanical aspects, such as the increase in interdiscal pressure during physical stress. The presentation of ergonomic posture aimed to help patients 'protect' their back and prevent future spinal pathologies. Subsequently, many variants developed in North American countries. For example, Penttinen and colleagues¹¹ proposed 10 lessons to increase physical activity in daily life and to train participants in ergonomic work techniques. This education aligns well with the biomedical model, emphasising the biological or mechanistic nature of back pain: the pain emanates from a mechanical dysfunction that persists in the spine. Two literature reviews showed weak or conflicting evidence for the effectiveness of back school, from very heterogeneous studies.^{12 13} However, when the back school is based on a biopsychosocial model in addition to a rehabilitation programme, it is recommended in certain guidelines.¹⁴

Indeed, the changes in therapeutic approaches over the last few decades have been developed from the biopsychosocial model, integrating psychological aspects and social factors.¹⁵ As an extension of this paradigmatic change, other types of education have emerged, such as pain neuroscience education.¹⁶ This approach involves didactic learning of the physiological mechanisms of pain, understanding the influence of psychoaffective factors, and central neurological processes. In other words, patients with chronic low back pain are provided with an understanding of pain as arising from the dynamics of multiple processes rather than a single stable mechanism. Fundamentally, chronic pain is embodied and alters perceptual processes.^{17 18}

Moseley and colleagues^{16 19} demonstrated that pain neuroscience education is more effective than traditional back school education based on anatomy and biomechanics.

Through this brief literature review, we observe that the two educational techniques (back school vs pain neuroscience education) differ in their fundamental approaches, one being biomedical and the other biopsychosocial. Debates on the conceptual approach to low back pain are still ongoing.^{20 21} Beyond these discussions, it is essential to understand which educational content has a positive and lasting influence on individuals with low back pain.

Second, rehabilitation is considered as an adjunctive treatment option that focuses on physical activity in order to fight against disability.¹ In view of the importance of physical activity, in France, the message delivered by health insurance is: 'good treatment is movement'

because some mechanisms (eg, fear avoidance) lead to a significant reduction in physical activity with deleterious consequences for the person with low back pain (in terms of social, professional, family repercussions, and the physiological consequences that this entails). In this line, a recent review showed that the level of physical activity was associated with the prevalence of chronic low back pain: people with a medium level of physical activity have a 10% lower risk of low back pain than people with a low level.²² Moreover, it is well established that physical well-being and physical exercise can protect against chronicity.²³ In chronic low back pain, the number of steps is commonly used to quantify the level of physical activity.^{24 25}

Furthermore, extensive literature reviews have consistently demonstrated the beneficial impact of education in the short term and medium term on pain perception, disability, catastrophising and enhancement of physical performance, particularly when integrated with a rehabilitation regimen focused on physical exercises.^{26 27} However, it is noteworthy that the assessment of participants' physical activity level is predominantly reliant on self-reported questionnaires pertaining to disability, rather than direct measurement. Consequently, despite the recognised importance of physical activity, current literature fails to ascertain whether education in pain neuroscience or participation in back school alongside a rehabilitation programme influences individuals' physical activity levels in the medium term to long term. Additionally, there is often an acknowledgement of the need for further investigation to assess effectiveness beyond the initial 6-month period.²⁸

Thus, the ecological and direct measurement of physical activity in daily life is of relevant interest in the context of chronic low back pain in order to assess the effect of a rehabilitation programme and educational sessions and to measure changes in the dynamic of chronicisation.

Taken together, these results indicate that education is relevant for people with chronic low back pain. Additional investigations are necessary to measure the long-term effects on physical activity of these educations. Moreover, literature reviews show positive effects for both types of education although the efficacy of back school is more uncertain.^{12 29} This is the reason why we hypothesise that physical activity will be greater at 3 months and then 1 year after providing education in the neuroscience of pain than after participating in a back school combined with a rehabilitation programme. More specifically, we expect that the number of steps taken per day following neuroscience education will be greater than after attending back school.

Objectives

The main objective of the study is to evaluate the effectiveness of pain neuroscience education on physical activity 3 months after the intervention compared with back school in patients with chronic low back pain attending a multidisciplinary rehabilitation programme. The main measure is the average number of steps taken

by participants over a week at home. This variable is at the heart of our study because we believe that it is, on the one hand, a criterion for judging the functional benefit of an education programme, and on the other hand, an extension of recent work on chronic low back pain, a main criterion to measure behavioural changes essential to modifying the dynamics of chronicisation through physical activity.

The secondary objectives are grouped into three categories. The first concerns comparing the effectiveness of the two education programmes at 3 months and 1 year on other variables measuring physical activity, occupational performance, pain intensity, central sensitisation, psychological variables specific to chronic pain (catastrophising and kinesiophobia), and quality of life. The second involves comparing the changes in these variables over time between the two groups. The third involves exploratory analyses to determine the predictors of maintaining physical activity for each programme to identify the success factors of the programmes.

METHODS AND ANALYSIS

Trial design

This single-centre study is an open-label, controlled, randomised, superiority trial with two parallel arms: an experimental ‘pain neuroscience education’ group and a control ‘back school’ group. The duration of the inclusions will be 34 months, and the duration of participation for each patient will be 14 months. After requesting hospitalisation, the investigation team will contact the patient to inform him and present the study. If the patient agrees, the team will then verify the inclusion and exclusion criteria. If the patient is eligible and agrees to participate, they will receive the study information letter (V0). A meeting will then be arranged during which the patient will benefit from a preadmission medical consultation, followed by a visit with one of the study’s investigators. This visit (V1) will serve to recheck the eligibility criteria, provide necessary information to the patient and obtain their consent. The purpose of this visit will be to attach an actigraph to the patient, which they will wear for 7 days. Fifteen days to 1 month after this visit, the patient will be admitted to the establishment (V2). The hospitalisation will be carried out as part-time (the patient is discharged on weekends) and will last for 4 weeks. During hospitalisation, the patient will benefit from a multidisciplinary rehabilitation programme and attend 10 education sessions (pain neuroscience education or back school). The patient will then have a follow-up visit 3 months after discharge (V3) for a new application of the actigraph, which will be worn for 1 week. Finally, a last visit will be conducted 1 year before release (V4) for a final installation of the actigraph (figure 1).

Participants

Eighty-two participants with chronic low back pain will take part in the study. All participants will benefit from

specific education (pain neuroscience education vs back school) coupled with a multidisciplinary rehabilitation programme. The study will be conducted in a French hospital centre (Lamalou-les-bains, Occitanie).

Inclusion criteria

1. Patient over 18 years old.
2. Common low back pain according to Haute Autorité de Santé (HAS) 2019 (‘Common low back pain is defined by pain located between the thoracolumbar hinge and the lower gluteal fold (AE) [which may] be associated with radiculalgia corresponding to pain in one or both lower limbs at the level of one or more dermatomes (AE) which do not show warning signs (see “red flags”)’ (HAS, 2019)) criteria.³⁰
3. Chronic low back pain (> 3 months).
4. Start Back Screening Tool Score >3 (presence of psychosocial factors associated with a medium or high risk or chronic low back pain).
5. Part-time hospitalisation at the hospital centre for a multidisciplinary rehabilitation programme.

Exclusion criteria

1. Subject with a gait-limiting comorbidity (eg, central neurological disorder).
2. Subject with current psychiatric or cognitive comorbidity that does not allow education programmes to be carried out.
3. Surgical intervention less than 3 months ago.
4. Other specific treatment for low back pain planned during the 3 months of follow-up (surgery, infiltration).
5. Patient participating in another clinical trial related to low back pain.
6. Subject not understanding the French language.
7. Pregnant, parturient or breast-feeding women.
8. Subject having a measure of legal protection (tutorship, curatorship).
9. Subject under safeguard of justice.
10. Subject who did not sign the informed consent form.
11. Subject not affiliated to a social security scheme or not a beneficiary of such a scheme.

Randomisation

The randomisation will be carried out after obtaining the level of activity, measured by the actigraph during the week following V1. It will be balanced and centralised using the Ennov Clinical software. A minimisation algorithm will balance the level of activity between groups. We will use the levels of activity defined by Lotzke and colleagues,²⁴ that is: sedentary (<5000 steps by day), low activity (between 5000 and 7499 steps by day), active (between 7500 and 10 000 steps by day) and very active (>10 000 steps by day).

Blinding

Due to the type of intervention, participants and staff will know the randomisation arm.

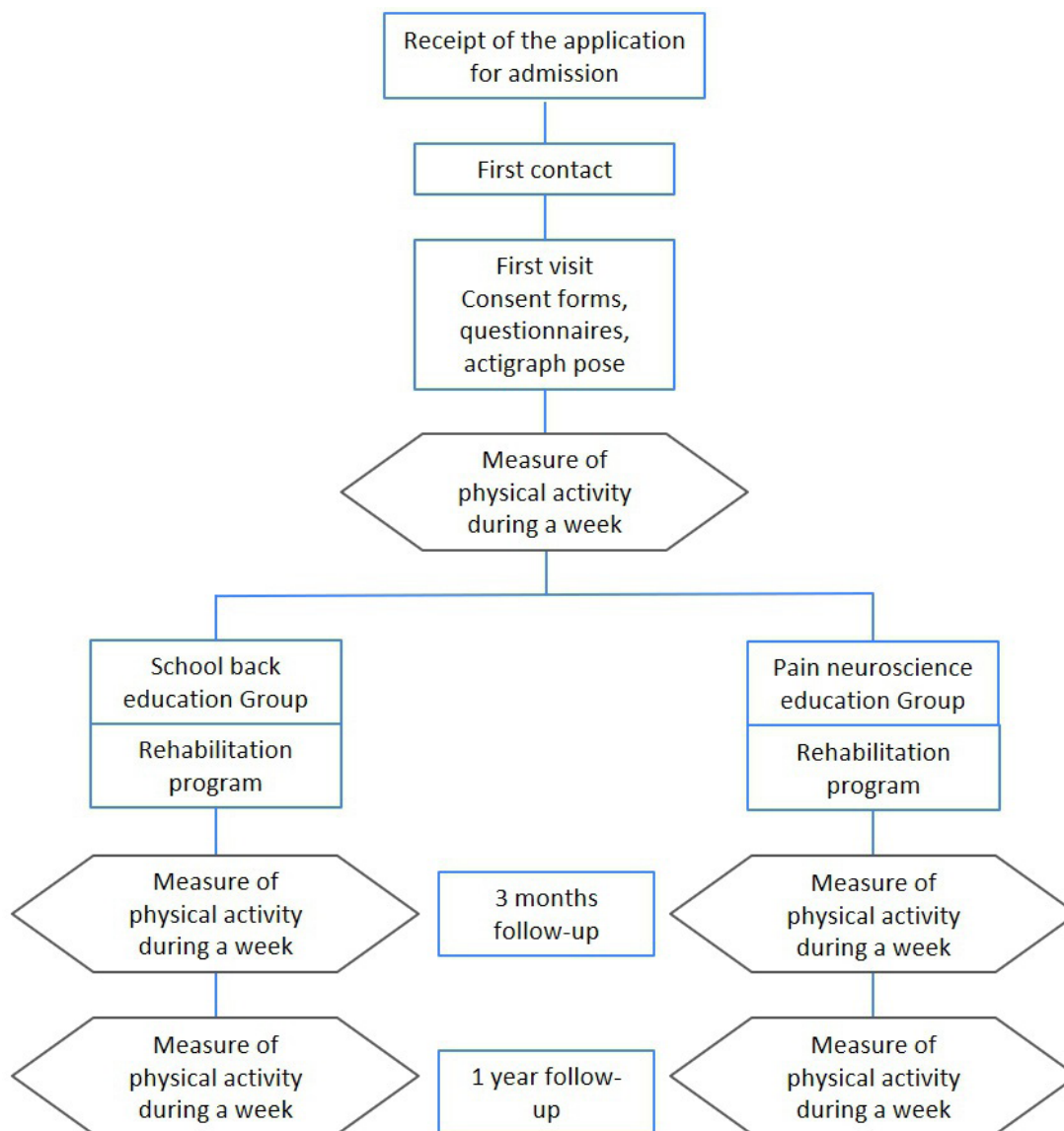


Figure 1 Study flow chart.

Risk of contamination bias

In order to prevent participants from knowing the content of the educational programme of the other group, they will undergo hospitalisation at two different sites within the same hospital centre. This is important not only to maintain the integrity of the study but also because combining these two educational programmes may decrease their efficacy. However, it is important to note that aside from the educational programme, the content of the rehabilitation programme is strictly similar between the two sites. Moreover, close monitoring of patients during rehabilitation will allow for precise assessment of potential protocol deviations.

Interventions

Both groups will benefit from 10 education sessions and a multidisciplinary rehabilitation programme. The educational sessions will be carried out in different dedicated rooms (in the respective places of care). The groups will

consist of three to six participants. Some people may not be part of the study but they will all have a problem of chronic low back pain.

Pain neuroscience education group

The educational sessions of the pain neuroscience education group are based on the work of Moseley and colleagues.^{16 19} The target concepts are presented in [table 1](#). The essence of the education lies in considering pain not solely in the head, brain, body, or in isolation from our thoughts and emotions, but rather through all of these aspects (ie, biopsychosocial model). Chronic pain is multifactorial and cannot be explained solely through X-rays, for example. These sessions aim to modify misconceptions about pain and alter beliefs (ie, catastrophising). Moreover, the objective of this understanding of pain is to empower participants to make changes in their attitudes, actions and thoughts when experiencing pain, or

Table 1 Pain neuroscience education sessions

| | Title of session | Key concepts |
|------------|--------------------------------------|---|
| Session 1 | What is pain? | The pain is normal and very real |
| Session 2 | Physiology of pain I | Learning about pain can help the individual and society |
| Session 3 | Physiology of pain II | The link is weak between pain and tissue damage |
| Session 4 | Physiology of pain III | There are danger sensors but not pain sensors |
| Session 5 | What happens when the pain persists? | Pain depends on the context |
| Session 6 | Good news, we are plastic | Pain depends on the danger/safety balance |
| Session 7 | Physical activity | Pain involves sprawling brain activity |
| Session 8 | Psychosocial aspects of pain | Pain is one of several protective responses |
| Session 9 | Protectometer | We are bioplastics |
| Session 10 | Synthesis | Active treatment strategies promote recovery |

more generally, to respond more appropriately in their environment. Two professionals, a physiotherapist and a psychologist, will deliver neuroscience education. To ensure the quality of the educational message, they have received training from an instructor affiliated with the Neuro Orthopaedic Institute Group.

Back school

Back school sessions are based on the conservative and preventive idea following back pain, in the spirit of Forsell's work.¹⁰ This back school consists of promoting prophylactic gestures during daily activities (eg, bending down to lift a load). The programme will consist of presenting the anatomical bases of the back and anatomophysiology related to back pain.^{11 31} Occupational therapists trained in posture and spinal ergonomics during their studies carry out the back school. The team of occupational therapists designed the content collectively. **Table 2** presents the different elements that will be covered during the back school.

Rehabilitation programme

The 4-week multiprofessional rehabilitation programme is part of the patient's usual care.

This programme will include daily, 5 days a week:

- ▶ Collective sessions of 30 min of adapted physical activity (muscle awakening, aerobic exercises, muscle strengthening, relaxation and muscle stretching).
- ▶ One or two 30 min individual physiotherapy sessions (assessment, targeted strengthening exercises, motor control, self-exercise training, etc).
- ▶ A 30 min collective balneotherapy session (aquagym).
- ▶ A 20–30 min session of physiotherapy (cryotherapy, thermotherapy, analgesic electrotherapy, etc).

In addition, the patient will benefit from group relaxation sessions, an individual dietary consultation during his stay (assessment and dietary recommendation), and one or more psychological consultations for evaluative or therapeutic purposes.

Each patient will be given a form allowing them to check off the activities they carry out daily; this form will be returned to one of the investigators at the end of the stay. It will make it possible to check the volume of rehabilitation carried out in each group.

Outcomes measures

Primary outcome

The primary outcome uses the actimetry medical device ActiGraph wGT3X-BT and the associated software,

Table 2 Back school sessions

| | Title of session | Key concepts |
|------------|----------------------------------|--|
| Session 1 | Anatomopathological reminders I | The structure of the spine, disc |
| Session 2 | Anatomopathological reminders II | Curvatures |
| Session 3 | Lying position | Spinal pathologies |
| Session 4 | Sitting | Specific mattresses and pillows |
| Session 5 | Gestures and postures | The positions turn around, get up, lie down |
| Session 6 | Domestic activities I | The different sitting positions |
| Session 7 | Domestic activities II | The position in front of a computer |
| Session 8 | Hobbies | Principles and techniques of charging |
| Session 9 | Car driving | The different positions for catching a load |
| Session 10 | Sexuality | Move with a load |
| | | Demonstration or realisation of activities taking into account the principles of spinal economy |
| | | The positions to be preferred according to the type of pain and the partner suffering from chronic low back pain |

'ActivLife', whose reliability and validity of the measurements of the number of steps and activity in an ecological situation are robust.^{32 33} The ActiGraph wGT3X-BT captures and records high-resolution raw acceleration data, which are converted into a variety of objective activity measurements using validated algorithms. As recommended by Migueles and colleagues,³⁴ the device will be worn at the right hip, USB port cover up, using an elastic waistband, for 7 days, during awake time, excluding wet activities. The sampling frequency will be 30 Hz; we will use time windows of 1 s for the categorisation of activities (eg, such as standing, sitting or lying down).³⁵

The measurements will be exported in comma-separated values format from the 'Activlife' software. The file will be anonymised according to the procedure provided for in the protocol, and stored on the hospital server.

Secondary outcomes

- ▶ Intensity of pain will be measured by the Numerical Rating Scale (NRS)³⁰ (value between 0 and 10). The value indicated by the participant will represent the raw data used. Data will be collected during the enrolment, at 3 months and 1 year.
- ▶ Central nervous system pain sensitisation will be evaluated by the Central Sensitisation Questionnaire³⁶ at the enrolment and at 3 months and 1 year.
- ▶ Psychological variables will be explored by the Catastrophising Scale,³⁷ the Kinesiophobia Scale³⁸ and the Hospital Anxiety and Depression Scale³⁹ at the enrolment and at 3 months and 1 year.
- ▶ Physical activity and occupation will be measured by the Global Questionnaire on the Practice of Physical Activities⁴⁰ and the Canadian Measure of Occupational Performance⁴¹ during the first week of rehabilitation and at 3 months.
- ▶ Quality of life will be evaluated by the SF-36.⁴² Data will be collected during the enrolment, at 3 months and 1 year.

Additional data

These data will be collected at the entrance to the hospital centre:

- ▶ The questionnaire on the ability to change in the face of pain.⁴³ This self-questionnaire measures the degree of aptitude for change.
- ▶ The Chronic Pain Acceptance Questionnaire⁴⁴ indicates psychological flexibility in the face of pain.
- ▶ The Agency Scale⁴⁵ measures the feeling that the person has to determine himself as the actor of his own actions.
- ▶ Start Back Screening Tool to define the degree of chronicisation.⁴⁶
- ▶ Sociodemographic data: age, sex, socioeconomic level (profession, level of study), marital status.
- ▶ Clinical and medical data: height, weight, body mass index, main diagnosed spinal pathology, main history, anteriority of the pathology,

consumption of pain-related treatments (analgesics, anti-inflammatories).

Table 3 provides an overview of measurements by steps of the study.

Sample size calculation

In their cross-sectional study of 118 patients with chronic low back pain, Lotzke and colleagues²⁴ measured that 56% of their sample took less than 7500 steps per day and 16% took only 5000. The WHO recommends 10 000 steps per day and the HAS in France, in its physical activity promotion guide, recommends a gradual increase from 1000 to 3000 daily steps in order to adapt to individual abilities. For our study, we chose a difference between the two groups of 2000 daily steps, which corresponds to the average recommendation of the HAS.³⁰ The normative value of the primary endpoint is 8609 daily steps (SD 2625).⁴⁷ To show a significant difference between the groups at an alpha risk of 5%, and with a power of 90%, it is necessary to analyse 37 patients per group. Taking into account a rate of loss of follow-up of 10%, it will be necessary to recruit 41 patients per group, that is, 82 patients in total.

In order to take into account patients who have not started the multidisciplinary rehabilitation programme, we plan to include up to a maximum of 100 subjects; inclusions will be stopped as soon as 41 patients per group are obtained.

Statistical analysis

The significance threshold is set at 5% on the basis of a two-sided test. All analyses will be carried out under SAS Enterprise software Guide 8_2.

Analysis population

The included population (IP) is the entire population included in the study. The intention-to-treat (ITT) population includes all randomised patients in whom the primary endpoint will be effectively measured. The per-protocol population includes all patients who have been randomised and who have participated in at least 90% of the education sessions. The safety population is all included and randomised patients who have completed at least one education session.

Descriptive analysis

A simple descriptive analysis will be carried out on the entire ITT population and then on the two randomisation groups. This analysis will cover all the data from the study. The continuous variables will be described by mean, SD, median and quartiles, and the qualitative variables by their counts and percentages. A flow diagram will be produced from the IP.

Analysis of the primary and secondary outcomes

The analysis will be conducted on the ITT population. We will first assess the normality of the distribution of results in both groups. Subsequently, in cases where the distributions are normal, we will conduct a parametrical test

Table 3 Visit details; the hetero questionnaires will be carried out by trained professionals and experts in the field (eg, occupational therapist for COPM)

| Visits and date | Study visit T information and enrolment (T30 to T15) | Admission, interventions (educational sessions) and rehabilitation programme (T0 to T28) | | | | | Follow-up (T120 ± 15 days) | Follow-up (T395 ± 30days) |
|---|---|--|-------|-------|-------|-------|----------------------------------|---------------------------------|
| | | T0 | Week1 | Week2 | Week3 | Week4 | | |
| Subject Information | X | | | | | | | |
| Collection of consent | X | | | | | | | |
| Inclusion and non Inclusion criteria verification | X | | | | | | | |
| Sociodemographic data collection | | X | | | | | | |
| Collection of clinical and medical data | | X | | | | | | |
| Pain intensity | X | | | | | | X | X |
| Self-questionnaires | X | | | | | | X | X |
| Heteroquestionnaire (COPM, GPAQ) | | X | | | | | X | |
| Admission questionnaires | | X | | | | | | |
| ActiGraph wGT3X-BT | X | | | | | | X | X |
| Randomisation | X | | | | | | | |
| Rehabilitation programme | | | X | X | X | X | | |
| Educational sessions | | | | X | X | | | |
| Collection of life events (eg, family, professional, physical) | | | | | | | X | X |
| Collection of adverse events | | X | | | | | X | X |

COPM, Canadian Measure of Occupational Performance; GPAQ, Global Questionnaire on the Practice of Physical Activities.

such as the t-test for independent samples, or if normality is not met, a non-parametrical Mann-Whitney test will be performed. If the value of p of the test is below the 5% threshold, then the programme followed by the group with the higher mean will be considered superior. The difference between the means of the two groups will be presented along with its 95% CI. The same procedure as that for the primary outcome will be applied to the secondary outcomes. To control the alpha risk within each of the first two families of secondary outcomes, a Hochberg procedure will be applied.

Exploratory analysis

In addition to the data directly calculated by the Activlife software (type of activity and time spent on each activity, number of steps, energy expended), the raw accelerometric data will be analysed. Different movement markers (acceleration, jerk, orientation) will be calculated at each instant, enabling a detailed characterisation of the subjects' activity. Additionally, factors potentially associated with the practice of physical activity at 3 months and 1 year will also be included in this analysis (ie, pain intensity, catastrophising, central sensitisation, kinesiophobia, number of steps before the rehabilitation programme, capacity for change, acceptance of chronic pain, agency, anxiety and depression, sociodemographic, clinical, and medical data). The association between each of these data (accelerometric and others) measured at baseline and the number of steps at 3 months and 1

year will first be evaluated univariately in the entire ITT population, using a potentially predictive variable model. Second, the interaction between the group and the variable will be included in the model to explore differences in the effect of pain neuroscience education compared with back school based on this variable. The eight variables most associated with the number of steps will then be introduced into a multivariate model.

Management of changes to the initial statistical plan

Any modification to the initial statistical analysis plan will be discussed between the investigator, the methodologist and the sponsor, and will be the subject of a request for substantial modification to the Committee for the Protection of Persons.

Management of missing data

Patients wishing to abandon the programme before the end of the 4 weeks can complete the evaluation of the primary endpoint (V3), if they agree. The values of the endpoints obtained at the end of the study will be used for the analyses. If the rate of missing data is greater than 5% for a judgement criterion, a sensitivity analysis by multiple imputation will be carried out on this judgement criterion.

Status of the study

Recruitment began in October 2023. As of March 2024, 23 participants were included. The planned inclusion

period is 34 months and the expected duration of the study is 48 months.

Data security and handling

The study data will be entered into an electronic information notebook developed using the ENNOV CLINICAL software, which allows real-time data quality control. The self-questionnaires will be completed online directly by the patient via the ENNOV CLINICAL software. The connection to the self-questionnaires is done by a password and a unique identifier specific to each 'patient' user. All 'patient' user data are stored encrypted in the database (AES 128 bit encryption). The patient's personal information that may be stored (last name, first name, email) is only visible when the patient is created by ENNOV CLINICAL software. So, the patient's identity will not be disclosed.

The data will be accessible to the principal investigator, the project leader and the methodologists associated with the project.

Patient and public involvement

None.

ETHICS AND DISSEMINATION

A favourable opinion was given by the Committee for Personal Protection of Ile de France VII on 22 June 2023 (National number: 2023-A00346-39). The study was previously registered with the National Agency for the Safety of Medicines and Health Products (IDRCB : 2023-A00346-39).

The participant's signed informed consent will be collected during the inclusion visit and before any study-specific procedures are performed. A copy of the signed consent (see online supplemental file 1) will be given to the patient.

The results collected from this protocol will be presented at national or international conferences. The results will be published in peer-reviewed journals aimed at physicians, medical auxiliaries (physiotherapists, occupational therapists), psychologists and in the field of therapeutic education. However, the promoter will send the Committee for the Protection of Persons the results of the research in the form of a summary of the final report within 1 year after the end of the research.

Any written or oral communication of research results must receive the prior agreement of the coordinating investigator.

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Acknowledgements The authors thank Sylvie Grandemange of the Research and Innovation Department of the CHU Montpellier, Claire Belloc, Denis Mottet and

Philippe Mugnier for their advice and support. The authors also thank the entire hospital team who invested in the realisation of this study.

Contributors GLP and GT developed the study idea and elaborated the scientific aspects of the study. GLP, GT and CD elaborated the methodological aspects of the study. GLP submitted the project for financing. The authors jointly developed the final protocol. GLP is the principal investigator of the study. GT is a project leader and associate investigator. CD is the study methodologist. GT formatted the article for publication.

Funding This study is supported by the Ministry of Solidarity and Health under a Hospital Program for Nursing and Paramedical Research (Grant Number: PHRIP-20-0259) and by the National Council of the Order of Physiotherapist (CNOMK) (Grant Number: 2022-03).

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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