



# BMJ Open Study protocol randomised controlled trial comparison of cost-utility and cost-effectiveness of a face-to-face rehabilitation programme versus a telemedicine programme in the treatment of patients with chronic low back pain

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## ABSTRACT

**Introduction** Chronic lower back pain is a highly prevalent medical condition in Western countries, which that incurs a considerable social and economic burden. Although prescription exercise at home for chronic pain has become a widely used alternative to reduce healthcare costs, the evidence regarding patient adherence and decreased in costs in European countries is scarce and inconclusive. The objective of this study is to examine the cost-utility and cost-effectiveness in patients with chronic lower back pain treated with the McKenzie Method and electroanalgesia via a telemedicine programme versus a face-to-face programme.

**Methods and analysis** This study reports the protocol for a randomised, two-arm, multicentre, parallel controlled trial. A total of 540 patients with chronic lower back pain (onset time  $\geq 3$  months, Roland Morris Disability Questionnaire  $\geq 4$ ) will be recruited in three hospitals in Andalusia. Participants will be assigned to one of two groups (n=270, respectively) to receive electroanalgesia and Mckenzie method exercises through a telemedicine or a face-to-face programme. A total of 24 sessions will be administered three times a week for 8 weeks. Since the study design does not allow participant blinding, the outcome assessor and the statistician will be blinded. Use of health care resources and costs due to work absenteeism will be captured and analysed. In addition, pain, intensity, fear of movement, quality of life and strength of the core muscle and anteflexion lumbar will be recorded at 2 and 6 months after the start of treatment.

**Ethics and dissemination** Human Research and Local Ethics Committee of the 'Hospital Complex Torrecárdenas of Almería, University Hospital of Granada and Virgen Macarena de Sevilla Hospital—Andalusian Health Service'. Study findings will be released to the research, clinical and health service through publication in international journals and conferences.

**Trial registration number** NCT04266366.

## Strengths and limitations of this study

- This protocol describes a randomised controlled trial of a telemedicine intervention for primary care patients with chronic lower back pain who are on the waiting list for rehabilitation.
- The use of the Internet to carry out the intervention may exclude some primary care patients who live in rural areas or who do not have the financial resources to use it.
- This study will explore the possibility of additional telephone support from the physiotherapist to improve adherence of the intervention.

## INTRODUCTION

Dysfunctions that affect the spine are the most frequent cause of activity limitation in people under 45 years of age, with lower back pain (LBP) being the most common cause of disability in the occupationally active population.<sup>1</sup>

Most patients experiencing LBP that limits activity have recurrent episodes, with estimates ranging between 24% and 33%.<sup>2</sup> Different studies have shown that 42%–75% of patients with intermittent LBP that persists after 12 months represent the highest expenses in healthcare systems and disability, being one of the main causes of consultation in hospital emergency services.<sup>3–5</sup> It has been estimated that the direct economic cost associated with LBP in Europe ranges from 187 million to 4.2 billion euros in the Netherlands.<sup>6</sup>

The alterations of the motor control of the deep local muscles of the lumbopelvic region and persistent arthrogenic muscle inhibition of lumbar multifidus result in segmental instability of the lumbar spine and, consequently, in recurrent back pain.<sup>7–12</sup> If the alterations in one or more of the spine's stabilising mechanisms do not resolve during the acute period, tissue damage is caused that causes LBP persist.<sup>8</sup> Numerous studies have shown that specific exercises aimed at local lumbar muscles result in improvements in pain and disability, as well as a lower incidence of recurrence and absenteeism in the chronic LBP population.<sup>12–18</sup> Nonetheless, these exercise programmes are relatively expensive, require a lot of time from the patient and the therapist, and most do not use diagnostic tests to identify those patients who will benefit from one type of exercise or another in advance. Although exercise is the most commonly recommended treatment for patients with chronic LBP, clinical practice guidelines recommend many other interventions.<sup>19 20</sup>

Some authors have even compared this to a super-market, since, in addition to being endless, treatment options are becoming more commercial and competitive every day.<sup>21</sup>

Transcutaneous electrical nerve stimulation (TENS), alone or in combination with other interventions, is one of the most common techniques for pain relief in chronic LBP.<sup>22–26</sup> Some studies have shown that TENS can lead to decreased use of pain medications and should be incorporated into the treatment arsenal for chronic LBP.<sup>22</sup> In spite of this, there is some controversy in the clinical evidence about its use as the only treatment in chronic LBP.<sup>19 26 27</sup> According to Gladwell *et al*,<sup>27</sup> training in the use of equipment (electrode placement and TENS adjustments) could improve the clinical benefit provided by TENS.

Self-management is constantly recommended in the international guidelines on the management LBP.<sup>24 27</sup> Home exercise programmes based on self-managing LBP can be effective in avoiding recurrent LBP and reduce the reliance on, and cost of, primary care services.<sup>28</sup> However, studies have shown that adherence to prescribed exercises at home in patients with LBP is low, with 50%–70% of patients not adhering to the prescribe exercise routine.<sup>29 30</sup> A systematic review has highlighted that the most commonly cited reasons that prevent patients incorporating the exercises into their daily routine include the lack of time to perform the exercises and the inability to remember them.<sup>31</sup>

It is, therefore, essential to look for alternative models of health service delivery that can improve treatment adherence in patients with chronic LBP and, as a result, enable increased uptake and implementation.

The self-management approach of exercise based on the McKenzie method (of Mechanical Diagnosis and Therapy, MDT) plus TENS through digital applications can be an effective alternative to traditional models. It has been shown that e-Health treatments enable personalised medical attention at a distance through digital applications

such as mobile phones, which is promising in terms of effectiveness and profitability in improving results such as: patient health and satisfaction, self-control of symptoms (improves understanding of treatment and allows the patient to get involved in their self-management) and the costs of medical care in patients with chronic diseases.<sup>32–34</sup> In addition, MDT has been shown to have important advantages over the general exercises and other interventions for chronic LBP.<sup>35–38</sup>

### Aims of the study

The study aims to assess the cost-effectiveness and cost-utility of an MDT-based telemedicine programme with electroanalgesia and self-administered exercises compared with the same programme delivered face to face in patients with chronic LBP.

Specific objectives are: (1) to assess the mean per-patient cost associated with the two delivery options, (2) to compare the effectiveness of both interventions, in terms of disability, pain intensity, movement phobia, quality of life, isometric resistance of the flexor muscles of the trunk, lumbar mobility in flexión and (3) to calculate and report incremental costs and benefits associated with delivering the intervention through telemedicine compared with face-to-face administration.

### Trial design

This study is a two-arm, double-blind, multicentre, randomised controlled trial.

## METHODS/DESIGN

### Study design and study setting

Cost-effectiveness and cost-utility analysis (CUA) of a multicentre randomised clinical trial protocol that compares patients with chronic non-specific LBP treated with a telemedicine programme, with a control group participating in face-to-face programme. The study participants will be randomly allocated to one of two groups (the telemedicine group or control face-to-face group) with a ratio of 1:1. This protocol is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials 2013 statement (online supplemental additional file 1). The study is conducted in collaboration of the physiotherapy department of the University of Almeria. Ethical approval for this trial was granted by the Human Research and Local Ethics Committee of the 'Hospital Complex Torrecárdenas of Almeria, University Hospital Complex of Granada and Virgen Macarena de Sevilla Hospital—Andalusian Health Service'/Almeria University, Andalucía, CE-IP00562/NCT04266366.

We contacted three Primary Healthcare Centres (PHCC) of Andalucía (Spain), in the provinces of Almeria, Sevilla and Granada, presented the study to their staff members and invited them to participate. Patients who received an indication for outpatient rehabilitation treatment at any of the three PHCC, will be selected from March

2020 to May 2020 (anticipated), based on the eligibility criteria listed below. The potentially eligible subjects will be invited to participate via a text message after informed consent is obtained by the hospitals' staff members (physiotherapists and general practitioners (GPs)).

A total of 540 participants with diagnosed chronic non-specific LBP will be recruited. Participants will receive treatment three times per week over a period of 8 weeks in the outpatient department or at home, with follow-up assessment at 2 and 6 months after start of treatment. On their first visit, participants will be selected for study eligibility according to the study's inclusion and exclusion criteria, and will be evaluated by a therapist blinded to the intervention in each PHCC. After this face-to-face evaluation, patients will be randomly assigned to one of the two groups, and will be informed by message about their second visit (place and time). From the second visit, participants will receive treatment for LBP according

to their random assignment group by two therapists belonging to the research group and trained in MDT (schedule of enrolment, interventions and assessments is provided in [figure 1](#)).

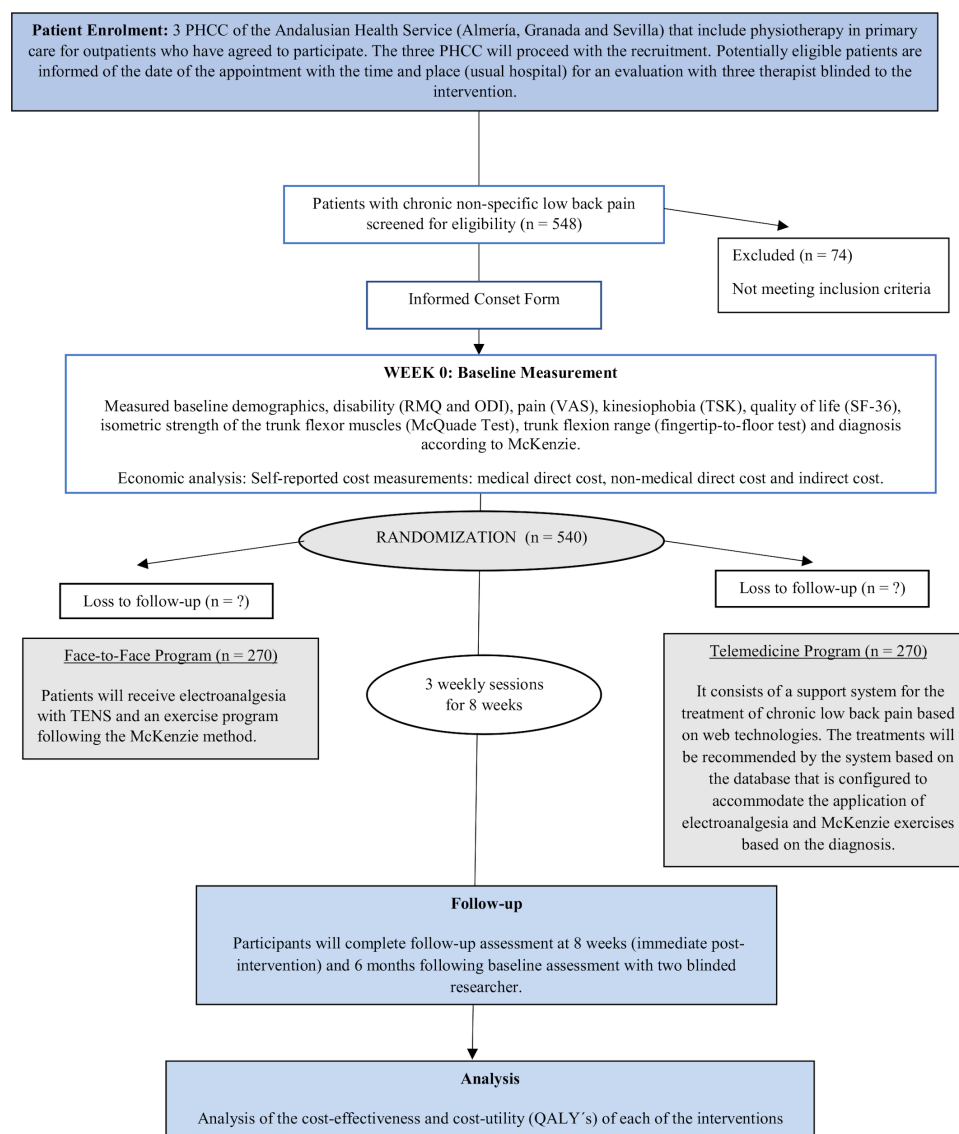
### Patient and public involvement

Patients and the public were not involved in designing this protocol and statistical analysis plan. The GPs and physiotherapists of the hospitals where the study will be carried out will provide support for recruitment. The results of the study will be disseminated to the public on completion of the trial and the individual test results will be provided to participants on request.

### Participants

#### Inclusion criteria

- Patients age 30–67 years old.



**Figure 1** Design and flow of participants through the trial. ODI, Oswestry Disability Index; PHCC, Primary Healthcare Centres; QALYs, quality-adjusted life year; RMQ, Roland-Morris Questionnaire; SF-36, Short-Form Health Survey 36; TSK, Tampa Scale of Kinesiophobia; VAS, Visual Analogue Scale.

- ▶ Patients with chronic LBP (pain duration of  $\geq 3$  months).
- ▶ Patients who have a lower back disability  $\geq 4$  on the Roland-Morris Disability Questionnaire (RMDQ).
- ▶ Patients currently not receiving any other physiotherapy treatment.

#### Exclusion criteria

- ▶ Patients diagnosed with severe pathologies that may be the main cause of chronic LBP (eg, presence of lumbar stenosis, spondylolisthesis, fibromyalgia, etc).
- ▶ Patients who have taken treatment with corticosteroids or oral medication in recent weeks.
- ▶ Patients with a medical history of spine surgery.
- ▶ Patients who do not have contraindicated of analgesic electrical therapy.
- ▶ Patients who have previously received a treatment of electrical analgesia or exercise.
- ▶ Patients with severe concurrent central or peripheral nervous system disease.

#### Randomisation and allocation concealment

Subjects will be divided into two groups by means of a random number table generated by computer software (Epidat V.4.2). The randomisation will be conducted for each study site. On randomisation within each study site, participants will be allocated to either the control or experimental group according to the allocation code, and the number of participants in each group will be identical between groups for all study sites. The randomisation sequence will be performed by the principal investigator.

The number of participants for each study site will be 90. The results of random allocation will each be sealed in opaque envelopes before being sent to each study site and will be stored in double lock cabinets.

The random numbers assigned to each participant will be recorded in the electronic records of their medical history and patients will be removed from the waiting lists until the end of the study (figure 1).

#### Blinding

The study's outcome assessor and statistician will be blinded for the entire process. The outcome assessor will not take part in treatment and will not try to guess the treatment allocation group to which the participant may be allocated. The computerised outcome measures passed on to the statistician will not contain any information identifying patients as part of either of the two groups.

#### Interventions

After the initial evaluation, 540 patients with chronic LBP will be randomly assigned to two groups in each PHCC: electroanalgesia therapy and exercise through a telemedicine programme (experimental group) or the same care delivered through a face-to-face programme (control group). Within both groups, these patients will be divided into three subgroups (postural, dysfunction and derangement) according to the McKenzie therapeutic

classification (clinical presentation of pain). All participants will receive three sessions per week, to complete a total of 24 sessions. The treatment will be carried out on alternate days: Mondays, Wednesdays and Fridays. Patients will have to perform 90% of their scheduled treatment sessions to be considered and remain in the intention-to-treat analysis.

During the study, the participants can only receive the assigned treatment; they cannot combine the treatment with drugs or any other treatments. Any interference in the treatment will be grounds for exclusion. Patients can leave the study at any point and the allocated interventions will be modified for a given participants of trial in response to the improvement or deterioration of LBP. Aspects such as execution time, level of difficulty, intensity and progression will adjust individually.

The exercise programme is as follows:

1. Prone position: patient lying prone with the arms by their sides and their head lying on either side. The lumbar spine falls directly into the lordotic position (time: 60 s).
2. Prone position in extensión: the elbows are just below the shoulders, patient raises the upper part of their torso, resting on their forearms (time: 60 s).
3. Extension in prone position: the patient is lying in a manner similar to the previous exercises. Hands at shoulder level. Extending the arms raises the upper part of the torso. Then the patient lowers their torso (10 times).
4. Prone extension with fixation of the pelvis: position and movements equal to 3. A fixation is made with an exercise belt just at the level of the pelvis (10 times).
5. Sustained extension in recumbency: patient lying prone on a surface that allows the degree of torso extension to be passively increased. Returning to the horizontal position should be done slowly and progressive way (time: 2–10 min).
6. Extension stopped in standing position: patient standing with feet apart, hands on waist with fingers pointing down. Extends by using the hands as the fulcrum of the movement (5–10 times).
7. Supine flexion: patients bring both legs flexed to the chest (time: 30 s).
8. Seating flexion: from the seated position, patient brings their hands to their feet (10 times).
9. Flexion stopped in standing position: patient touches the floor with their fingers, keeping their knees extended (10 times).
10. Autocorrection of lateral displacement: 'push in distraction'. The shoulders push towards the pain and pelvis on the opposite side (time: 30–60 s).

Simultaneously with the performance of the exercises: TENS (TENStem eco basic, schwa-medico Medizinische Apparate Vertriebsgesellschaft mbH, Wetzlarer/35630/Ehringshausen, Deutschland) of low frequency and high phase duration (80 Hz / 200  $\mu$ s) applied directly to the lower back using four electrodes (5 $\times$ 9 cm) at the bilateral paravertebral level.



### Experimental group: telemedicine

During the first two sessions, patients will be instructed in the placement of the electrodes, the operation of the TENS, the ‘Stop LBP’ web application and the performance of the exercises. After the two session, the patient will carry out the treatment through a support system for the treatment of chronic LBP based on Web Technologies and accredited as a health website. This system has a structure based on four sections: database treatment, database user profiles, recommendations and feedback/biofeedback procedures. This system allows a subject to be registered and introduced and treatments to be modified with electroanalgesia and exercises, according to the symptomatic evolution of pain.

This is based on an initial patient evaluation system: once the initial diagnosis of the patient has been made according to McKenzie’s clinical subtypes of LBP, the video applications of the combined application, the electroanalgesia and exercises, will be shown to patients who use their computer or mobile device to access the platform via the internet.

The treatments will be recommended by the system: the database is configured to accommodate the application of electroanalgesia and McKenzie exercises based on the diagnosis according to the McKenzie method. Each subgroup corresponds to a programme and a series of exercises based on scientific evidence for the treatment of LBP<sup>39 40</sup>:

- ▶ Postural syndrome: correction of posture and prophylaxis (exercises 1–3).
- ▶ Dysfunction syndrome: exercise 3, exercise 6 and exercise 7.
- ▶ Disorder syndrome (DS): DS1 (exercises 1–4, exercise 6, with extension in recumbency); DS2 (beginning in prone position and patients will continue with the DS1 regimen, along with exercise 5); DS3 (DS1 regimen, exercise 7 and rotation maintained for 2 min); DS4 (exercise 7, exercises 2 and 3, and DS1 regimen); DS5 (exercises 7 and 8, and exercise 1–3); DS6 (DS4 regimen; then DS1 and DS3); DS7 (exercises 7–10).

During the first two sessions, patients will also be instructed in the use of a portable TENS.

Patients perform the exercises with the electrodes on.

To ensure patient adherence, inputs to the application and the time they spend on it each login are controlled. In addition, participants in both groups are called every 2 weeks to remind and encourage them to perform the exercises.

### Control group: face-to-face programme

This group performs the same treatment but in person. Electroanalgesia therapy and the McKenzie exercise protocol will be applied by six therapists with over 10 years of experience (two therapists in each PHCC). This programme will be developed in the rehabilitation service of the study health centres.

### Outcome measures

At baseline, demographic data including age, gender, education, occupational and marital status and clinical presentation will be documented. Assessments will be performed at baseline (before start of treatment) and at 2 (immediately after the last session) and 6 months after the last session (follow-up).

### Effectiveness and quality of life measures

Most of these measures are specific for LBP, and this have been validated for this pathology, which is a sufficient source of data to evaluate the clinical efficacy of the applied interventions. The primary effectiveness measures of the study consist of:

#### Roland Morris Disability Questionnaire

This is a self-reported questionnaire consisting of 24 items reflecting limitations in different activities of daily living attributed to LBP, including walking, bending over, sitting, lying down, dressing, sleeping, self-care and daily activities. Ranging from 0 points (best) to 24 points (worst) disability.<sup>41</sup>

#### Oswestry Disability Index

The Oswestry Disability Index (ODI) evaluates daily life activity limitations in 10 dimensions, each scored on a 6-point scale (0–5 points). Higher scores mean a worse outcome; the total points scored are expressed as a percentage, used to classify individuals as minimally disabled (0%–10%), moderately disabled (20%–40%), severely disabled (40%–60%), crippled (60%–80%) or bedbound (80%–100%).<sup>42</sup>

#### Visual Analogue Scale for pain

The subjects participating in the study will indicate the intensity of their pain by means of a Visual Analogue Scale (VAS) of 100 mm. They must indicate on a 100 mm horizontal line where they would place their pain, where 0 mm indicated ‘no pain’ and 100 mm would be ‘the worst pain imaginable’.<sup>43</sup>

#### Short-Form Health Survey 36 Quality of Life Questionnaire

The Short-Form Health Survey 36 (SF-36) is a multipurpose, SF-36 questions. The instrument yields an eight-scale profile of scores as well as physical and mental health summary measures: Physical Function, Physical Role, Body Pain, General Health, Vitality, Social Function, Emotional Role and Mental Health. Range from 0% to 100% and indicate the self-perceived health-related quality of life.<sup>44 45</sup>

#### EuroQol 5-dimension-5 level

The EuroQol 5 dimensions (EQ-5D) is a widely recommended generic measure of health-related quality of life that enables the calculation of quality-adjusted life years (QALYs).<sup>46 47</sup> The study will use the latest, five-level version of the questionnaire (EQ-5D-5L). The descriptive part of the EQ-5D-5L questionnaire comprises questions on mobility, self-care, usual activities, pain/discomfort,

anxiety/depression, each of which can be answered in relation to five levels of severity and is accompanied by a VAS.<sup>48</sup> Collected data from the EQ-5D-5L descriptive system will be subsequently translated into preference-based health-related quality of life indices (utilities) using the recommended Spanish value set,<sup>49</sup> with a view to using these indices in the calculation of QALYs.

#### Tampa Scale of Kinesiophobia

This is a 17-item questionnaire that measures the fear of movement and (re)injury. Patient rate beliefs about their kinesiophobia on a 4-point scale ranging from strongly disagree to strongly agree.<sup>50 51</sup>

#### McQuade test

This test allows to evaluate the isometric resistance of the trunk flexor muscles. In the supine position, the subject is asked to flex the head and shoulders until the scapula is separated from the stretcher. The number of seconds that hold that position is recorded.<sup>52</sup>

#### Lumbar flexion mobility (Fleximeter UM 8320-3RJ)

With the legs extended, patients are asked to do an anterior torso flexion from an upright position to try to touch the ground. The patient should stop when pain or limitation of movement appears.<sup>53</sup>

#### Resource use and costs measurement

Key healthcare resource use and costs will be collected alongside the proposed trial through patient questionnaires administered at baseline, and subsequently, at the 2 and 6 months follow-up points. A detailed list of relevant resource use categories, sources of usage data and unit costs is given in [table 1](#). In brief, relevant resource use and costs will include those incurred due to care received in the primary care and hospital settings, costs accruing due to diagnostic tests, as well as other costs incurred to patients (eg, out-of-pocket expenditures for transportation) and to society due to absenteeism resulting in productivity loss. Information on the resource consumption of each participant will be collected through an inventory of receipts. For each follow-up session (at the beginning and at 2 and 6 months after the beginning), participants will be asked to recall their use of the resources described above during the preceding months. Use of healthcare resources will be converted into costs according to unit cost values taken from up-to-date sources including the Andalusian Board for the public health services (see [table 1](#)).

#### Timeline

The recruitment of patients started on 1 March 2020 and will be completed by 31 May 2020. All data for all

**Table 1** Self-reported cost measurements

Costs for	Specification	Source of costs per 'unit'	Cost calculation
<b>Medical direct costs</b>			
Primary healthcare consultations	General practitioner (GP) Practice nurse Physiotherapist	Andalusian health service provider	No of visits×tariff per visit
Hospital emergency visits	GP Practice nurse	Andalusian health service provider	No of visits×value per visit
Referrals to other departments	Traumatology, rehabilitation, other therapies	Andalusian health service provider	Services provided×tariff per visit
Home help received	Ambulance GPs Practice nurse	Andalusian health service provider	Services provided×tariff per services
Diagnostic tests	Radiology, MR, scanner, electromyogram	Andalusian health service provider	Tests done×price per test
Pharmaceutical products	Muscle relaxants, analgesics, NSAIDs, corticoids, anti-inflammatory creams and gastric protectors	Standard pharmaceutical prices by the General Council of Official Pharmaceutical Colleges	Medicines bought×price per medicine
<b>Non-medical direct costs</b>			
Patient expenses in transportation	Bus Taxi Gasoline particular car	Patient	No of times×price per time
<b>Indirect costs</b>			
Absenteeism	Days of work sick leave	Self-reported and according to profession classification assigned (Spanish National Institute of Statistics)	Days of work sick leave×salary

NSAIDs, Non-steroidal Anti-inflammatory Drugs.

TIMEPOINT	STUDY PERIOD											
	Enrolment		Active treatment (Post-allocation)							Follow up		
	0 W	1W	2W	3W	4W	5W	6W	7W	8W	9W	2M	6M
	March-May 2020		May-July 2020							August/January 2021		
<b>SCREENING AND ENROLMENT:</b>												
Eligibility screen RPTs	✓											
Informed consent	✓											
Eligibility screen face to face to blinded evaluator		✓										
Allocation Principal Investigator		✓										
<b>INTERVENTIONS:</b>												
Telemedicine program (experimental group)									3 times per week			
Face-to-face program (control group)									3 times per week			
<b>ASSESSMENTS:</b>												
<b>Demographic variables</b>												
Age, gender, education, occupational and marital status.		✓										
<b>Clinical presentation of pain according McKenzie</b>												
Type												
Location		✓								✓	✓	
Interrogation												
Worsens												
Improvement												
<b>Clinical variables:</b>												
RMDQ												
ODI												
SF-36												
EQ-5D		✓								✓	✓	
VAS												
TSK												
McQuade Test												
Fingertip-to-floor.												
<b>Economic evaluation</b>												
Medical cost		✓									✓	✓
Time-related cost												
Lost productivity cost												

**Figure 2** Time points of each assessment index. EQ-5D, EuroQol 5 dimensions; ODI, Oswestry Disability Index; RMDQ, Roland-Morris Disability Questionnaire; SF-36, Short-Form Health Survey 36; TSK, Tampa Scale of Kinesiophobia; VAS, Visual Analogue Scale.

follow-up sessions is expected to be collected before to 31 July 2020. The data analysis, writing of scientific manuscripts and submissions to peer-reviewed scientific journals will be carried out between August 2020 and January 2021. A summary of the study outline is given in [figure 2](#).

### Sample size

The sample size was calculated according to the specifications established by Willian.<sup>54</sup> The calculations were based on the detection of differences of 2.5 points in the RMDQ (minimally detectable mean difference-estimated for a variance in patients with chronic LBP of 10 points), assuming a SD of 2.5 points, a two-tailed test, an alpha ( $\alpha$ ) level of 0.05 and a desired potency (beta) of 85%. The estimated desired sample size has been calculated in 270 subjects per group (6 groups per 90 subjects).

On the other hand, the following specifications will be considered: correlation coefficient between efficiency and cost of 0.1,  $\alpha=0.05$ , statistical power of 85% and follow-up loss of 10%. The sample size calculation resulted in 93 participants that will be randomly allocated into six intervention groups (an experimental group and a control group in each PHCC).

### Statistical analysis

The statistical analysis will be carried out using SPSS V.21.0 and STATA V.14, it will follow intention-to-treat principles. Cost, clinical outcomes measures and use of resources will be reported as mean values with SD for each

intervention arm. Comparisons will be done between arms on the study population's.

Differences after 8 weeks of treatment will be calculated (short term outcomes), as well as after 6 months (long-term outcomes).

The efficacy variable for this clinical trial is the difference in continuous outcomes (ie, RMDQ, ODI, VAS, Tampa Scale of Kinesiophobia, EQ-5D-5L, SF-36, McQuade Test and Range of motion of the torso in flexion) between baseline and predetermined time points (Telemedicine programme vs face-to-face programme):

- ▶ The Kolmogorow-Smirnov test will be carried out to assess the normality of each continuous variable.
- ▶ For the contrast of the equality of means of intra-group hypotheses, Student's t-test for paired clinical variables will be applied in the case of parametric distributions and Kruskal-Wallis H for nonparametric distributions.
- ▶ For the contrast of the intergroup hypothesis, one-factor analysis of variance will be used in the case of parametric distributions and Kruskal-Wallis H for non-parametric distributions.
- ▶ Post hoc analysis will be obtained for parametric distributions and Mann-Whitney's U for non-parametric distributions.
- ▶ The CI will be established at 95%, and the significance level at 0.05.

### Economic evaluation

An economic evaluation, in the form of a CUA and a cost-effectiveness analysis (CEA) will be undertaken to explore and determine the incremental costs and benefits of the telemedicine and face-to-face programmes over a 6-month time horizon. This follow-up period aims to capture the direct effects of the interventions and offer insights into outcomes and costs accruing in the months after the intervention is completed. In line with recommendations, the economic evaluation will adopt a societal perspective.<sup>55</sup>

Missing cost or outcome data will be accounted for by using appropriate techniques, such as multiple imputation, depending on the extent and type of missing items. As the distribution of cost is usually skewed by the existence of patients with very high costs, the calculated mean per-patient cost will be given alongside confidence intervals obtained through non-parametric bootstrap methods.<sup>56</sup> Incremental analysis will be undertaken to calculate the difference in costs and the difference in outcomes (improvements in effectiveness measures and QALYs) associated with the telemedicine and face-to-face programmes. QALYs will be calculated as the area under the curve connecting utility scores reported at baseline and the subsequent follow-up points. Results will be presented in the form of incremental cost-effectiveness ratios, reflecting the extra cost for an additional unit of outcome. To account for the inherent uncertainty due to sampling variation, the joint distribution of differences in cost and outcomes will be derived by carrying out a



large number of non-parametric bootstrap simulations.<sup>57</sup> The simulated cost and outcome pairs will be depicted on a cost-effectiveness plane and will be plotted as cost-effectiveness acceptability curves, showing the probability of each of the compared options being cost-effective across a range of possible values of willingness to pay for a QALY.<sup>58</sup> Different willingness to pay threshold values for a QALY have been put forward and used in cost-effectiveness studies<sup>59</sup>; in the Spanish context, recent estimates suggest a cost per QALY willingness to pay threshold between €22 000 and €25 000.<sup>60</sup> Sensitivity analysis will be performed to assess the robustness of the results to different values, assumptions and methodological approaches.<sup>61</sup> Due to the short time horizon of the study, discounting of costs and benefits will not be necessary. The CEA will be reported in accordance with the Consolidated Health Economic Evaluation Reporting Standards.<sup>62</sup>

### Adverse events

Adverse events refer to undesirable and unintentional signs, symptoms or disease occurring after treatment during the process of the clinical trial, which does not have to have a causal relationship with the treatment intervention.

At present, no potential risks have been described. The electroanalgesia to be applied is low risk, no adverse reactions have been described beyond the discomfort in the placement of the electrodes.

As for the exercises, all are proposed after evaluation and adaptation to the patient's situation, therefore, the potential risks are only associated with poor execution by the patient, which could cause short-term and reversible discomfort within 48 hours.

Investigators will be recorded all description of adverse events. If these exist, occurrence frequency between groups will be analysed. Any patient with questions or who require additional information about any symptoms can contact the AMC-S coordinator by telephone or email.

### Ethics, data security and dissemination

This study was approved by the Human Research and Local Ethics Committee of the 'Hospital Complex Torrecárdenas of Almería, University Hospital of Granada and Virgen Macarena de Sevilla Hospital—Andalusian Health Service'/Almería University, Andalucía, CE-IP00562/NCT04266366.

All patients, GPs and physiotherapists will receive specific information on the study in writing and will have a chance to discuss procedures with a member of the study team before consenting to take part. They will also be informed that they can leave the study at any point. Participants that agree to participate in the study will sign two copies of the informed consent, one that will be kept in the trial records and one for the participant.

The data collected from each patient will be stored in a closed locker in office of the University of Almería and only the evaluators will have access to that information.

Subsequently, the data will be entered and saved by the statistician on a laptop with password protection to maintain confidentiality. Eligibility criteria, results and analysis will not be modified after registration of the first participant.

The results will be published in journals indexed in Journal Citations Report and presented at national and international conferences.

### DISCUSSION

While exercise has proven to be the physical therapy treatment that has the most positive and lasting effects on chronic LBP,<sup>63 64</sup> the results of the analgesic effect of TENS in these patients have been contradictory depending on the duration, dose.<sup>65 66</sup> Therefore, new research is required to evaluate the specific components of the treatments used by the therapist, by comparing their use combined with the CUA.

Some studies have suggested a high social acceptance and confidence of patients towards telehealth in trauma care, especially for real-time diagnosis and remote treatment.<sup>67</sup> Through this study, we can contribute to a better understanding of the cost-effectiveness of telemedicine programmes versus face-to-face rehabilitation programmes in patients with chronic LBP in the short and medium term. The results of this study can help GPs and physiotherapists to understand if LBP can be prevented and treated at home through telemedicine, thereby reducing family and absenteeism costs significantly for these patients.

Through these remote interventions via the Internet, patients can learn to control the evolution of their LBP, by preventing its evolution to stages of greater pain and disability. If the painful symptomatology improves without having to cease work activity, the worker's labour and productivity costs are reduced, along with healthcare costs and waiting lists for the rehabilitative therapeutic approach, thereby favouring greater savings.

In addition, the specific e-Health and telemedicine programmes implemented in the evaluation and treatment of musculoskeletal problems can reduce health costs, generate a significant impact on patients living in rural or remote areas and increase adherence to treatment.

### Trial status

This is the first and definitive protocol version. Participants will be recruited between March and May 2020. Study completion is expected to be January 2021.

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