Comparison of the effects on disability of Wii Fit U game-based home yoga and supervised yoga programs versus therapeutic exercise in patients with non-specific chronic low back pain: study protocol for a randomized controlled trial

Final Project

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Abstract and Key Words

BACKGROUND

Chronic low back pain (LBP) is the leading cause of disability worldwide. Mostly non-specific (i.e. no specific structural cause), its aetiology is multi-factorial and complex. Disability could be more related to fear-avoidance beliefs rather than pain itself. First line physiotherapy treatment involves pain education, advice to remain active and exercise. Due to the burden LBP represents for health systems, cost-effective approaches are increasingly needed. Home-based exercise could be an inexpensive solution, if patients adhere sufficiently to their program. Non-immersive virtual-reality environments are easily accessible and could increase patient's motivation to engage into exercise. Growing interest in therapeutic yoga has led to recent studies demonstrating its effectiveness for LBP treatment. This study will compare the effectiveness of Wii Fit U game-based home and supervised yoga to exercise, all combined with education and advice to remain active, on the disability reduction of chronic LBP patients.

METHODS

This single centre, 3 arms, single blinded, randomized controlled trial will compare the effectiveness of Wii Fit U game-based home yoga and supervised yoga to supervised exercise for adults with non-specific chronic low back pain.

All participants will receive pain education and advice to remain active, then 3 sessions of 40-45 minutes per week of therapeutic yoga or exercise for 8 weeks.

Disability will be the primary outcome, measured with the Oswestry Disability Index (ODI) and Roland-Morris Disability Questionnaire (RMDQ). Secondary outcomes will include back function (flexibility & endurance tests), pain (NPRS), Kinesiophobia (TKS), pain self-efficacy (PSEQ), adherence (% sessions), physical activity (daily steps), and pain medication use.

They will be assessed pre- and post- intervention, then 3, 6 and 12 months later.

The statistical analysis will use a mixed-model repeated measures ANCOVA, with time as within group factor, intervention as between group factor, and increased analgesic use as covariant, and $p < 0.05$ for statistical significance.

DISCUSSION

Yoga interventions are expected to be more effective than therapeutic exercise in reducing disability and improving other pain-related outcomes. Home-based and supervised yoga being expected to be similarly effective, home-based yoga could be the most cost-effective.

KEYWORDS

Chronic LBP; virtual reality; therapeutic exercise; yoga; home exercise.

HYPOTHESIS

RESEARCH QUESTION

This study aims at evaluating the effects on disability of Wii Fit U game-based home yoga and supervised yoga interventions, both combined with education and advice to remain active, in patients with non-specific chronic low back pain, compared with standard physiotherapy care, composed of education, advice to remain active and therapeutic exercise.

NULL HYPOTHESIS

A Wii Fit U game-based home yoga program or a supervised yoga program is equally effective to therapeutic exercise, all interventions combined with education and advice to remain active, at reducing disability in patients with non-specific chronic low back pain.

ALTERNATIVE HYPOTHESIS

For patients with non-specific chronic low back pain, both a virtual reality Wii Fit U game home-based yoga program and a supervised yoga intervention, combined with education and advice to remain active, better reduce disability than recommended physiotherapy care, composed of therapeutic exercise, education and advice to remain active.

OBJECTIVES

1) The primary aim of this study is to compare the effectiveness on the reduction of disability in chronic low back pain patients between three interventions:

- A home-based yoga program using a Wii Fit U game approach,
- A supervised yoga program performed in a clinical practice,
- A supervised therapeutic exercise program in a clinical practice, as the control group.

2) A secondary aim is to ascertain whether a home-based yoga program, less expensive and based on a non-immersive virtual reality technology easily accessible to the public, can be as effective as a supervised yoga or exercise program to reduce disability.

3) The effectiveness of the interventions will also be compared in terms of back function improvement (with an objective measure of the flexibility and of the endurance of the trunk flexors and extensors).

4) The study will also compare the interventions effect on pain intensity reduction.

5) Pain self-efficacy improvement will also be compared between interventions.

6) The interventions effects will also be compared for the reduction of kinesiophobia.

7) Adherence will be compared between the supervised and home-based interventions.

8) Significant increase in pain medication use will be monitored, as it represents a possible confounding variable for the disability and pain-related outcomes.

9) A final aim is to evaluate if the therapeutic yoga & exercise interventions engage the patient into greater physical activity levels, what will be evaluated with the number of daily steps during both intervention (short term) and follow-up (medium-long term).

INTRODUCTION

Low Back Pain (LBP) is the leading cause of disability worldwide (1), with a high prevalence & disability weight, estimated in Years Lived with Disabilities (YLDs) since the Global Burden of Disease (GBD) study (2). It increased of 33.3% from 1990 to 2010 (2), 54% from 1990 to 2015, with population growth & ageing (1). Prevalence was estimated at 7.6% ~ 568 million people in 2019 (3), affecting similarly men & women of all ages (1). Lifetime prevalence is ~ 80% (4).

LBP is a major challenge for health care systems (5), since they invest substantial resources on keeping people healthy (2). LBP financial impacts lie not only in the direct medical costs, but also in the social support expenses, and indirect costs of work absenteeism or productivity loss (1). LBP is the most common cause of medically-certified sick leave from work and early retirement in Europe, and lost workdays for occupational musculoskeletal condition in the USA (1), where costs already exceed the yearly $100 billion (4) (6). The LBP economic impact is "*comparable to other prevalent, high-cost conditions, such as cardiovascular disease, cancer, mental health, and autoimmune diseases*" (1). Often associated to sedentarity and smoking, LBP can increase the risk of comorbidities such as obesity and cardiovascular diseases (7).

Low back pain is mostly non-specific, >80% having no specific structural cause (8), while only ~1% corresponds to serious pathology (fracture, malignancy…) (1). MRI may identify a specific cause (Modic changes, disc extrusion, spondylolysis) and reasonably correlates with pain, but routine use is not recommended (only for combined red flags), since many findings are also seen in pain-free subjects (1). Radiculopathy or stenosis can be clinically diagnosed (1).

LBP aetiology is multifactorial and complex. Known risk factors include:

- genetic influence (1)
- previous LBP episode (1) (9)
- pain in the leg or at multiple body sites (1)
- other chronic conditions (asthma, headache, diabetes) (1)
- low socio-economical background (low income, short education) (1)
- poor general health & lifestyle factors (smoking, obesity, low physical activity) (1)
- work-related factors (awkward postures, heavy manual tasks, lifting, bending…) (1) (9)
- dissatisfaction at work (situation, supervisor, dead-end job & boredom...) (8) (9)
- workers compensation systems or sick leave funding (8)
- poor mental health (depression, psychological distress, even at a younger age) (1).

Most LBP patients improve substantially in 6 weeks, still report pain at 3 & 12 months but with a much lower intensity (1). 50% present continuing low-to-moderate pain, and 33% will suffer a recurrence within 1 year, while 25% end up with persistent disabling pain (1) (4).

Non-specific chronic Low Back Pain is hence a long-lasting condition (>3 months) of fluctuating low-to-moderate pain with intermittent exacerbations over a very variable course (1).

Psychological factors, long underestimated, increase the risk of developing disability (9). They include *"depression, anxiety, catastrophising (ie, an irrational belief that something is far worse that it really is), and self-efficacy (ie, belief in one's ability to influence events affecting one's life)"* (1). Exposure to health care providers or early medical imaging can worsen patients' pain, evolving from "*a fairly benign part of their daily life*" to "*a problem requiring medical attention*". Such change of perception represents a iatrogenic cause of LBP increased disability (8) (10).

The fear-avoidance model (11) describes how individuals with pain catastrophising, ie, an exaggerated perception of their pain, often show an irrational and debilitating fear of movement & (re)-injury. This "kinesiophobia" tends to keep them hypervigilant (eg, guarded movements) and avoiding activities, what progressively leads them to disuse, depression, and disability. The priority is to tackle the "*myths about pain*" (ie, pain always being caused by tissue damage and requiring medical treatment) (11) and their associated fear-avoidance beliefs (12), as pain-related fear may actually be even more disabling than pain itself (13).

A change of paradigm may be required, as encouraged by the 2018 Lancet "call for action", promoting a "Positive Health" concept (10). Patients expectations should evolve, from the unrealistic hope for a complete cure of pain or precise diagnosis, to the endorsement of better coping strategies aiming at improving their quality of life (8) (10) (14). Passive "rest, massage & medication" approaches, with over-reliance on health care providers, are "*counterproductive patterns of illness behaviour"* that should be replaced by an active participation into exercise programs, to tackle the pain & disability burden and promote *"high-quality, meaningful lives for people with persistent low back pain"* (10). Rather than focusing solely on decreasing pain, treatments should target an "*improved individual adaptation to pain*" (10), i.e., pain self-efficacy (15), the reduction of fear avoidance beliefs (9) (16), pain catastrophizing, fear of movement, and ultimately disability.

Treatment recommended by clinical guidelines for non-specific chronic LBP primarily consists of 3 first line modalities, more effective when combined (5) (9) (14) (16) (17) (18) (cf Annex A):

- Education & self-care, with advice to remain active,
- Exercise therapy, progressive & individualized to improve function & prevent worsening
- Cognitive Behavioural Therapy (CBT).

Manual therapy, yoga, massage, NSAIDS are adjunctive treatment options (5) (9) (14) (18).

It is recommended to discourage medical approaches, such as *"pain medication, steroid injections & spinal surgery, and instead promote physical & psychological therapies"* (5) (14).

However, many health systems are not exactly "*designed to support this approach*" (5). The integration of psychological therapies requires multi-disciplinary pain management centres, not accessible to most patients. Education, advice to remain active and therapeutic exercise represent a more affordable approach, keeping the psychological treatment for persistent disabling LBP not responding to previous treatment (14).

Efficiency (cost-effectiveness) (19) of LBP treatments is a major health care priority, due to the current huge costs of unnecessary care discordant with international guidelines (5). "*Health systems need to develop effective and affordable strategies to respond to [the LBP] growing and nearly universal burden*" (2). Educational sessions performed by a physiotherapist are low cost, although having a huge impact (20), while manual therapy is much more expensive but not more helpful (8). The therapeutic exercise efficiency still needs to be demonstrated (9).

Education "myths about pain" (11) deconstruction should defocus from anatomical structures, presenting instead chronic pain-related concepts such as pain sensitization, neuroplasticity, facilitation and inhibition, as well as effective coping strategies, and advice to remain active "*despite the pain*" (20). Patient should leave their fear-avoidance maladaptive behaviours to actively engage into physical activity and therapeutic exercise, the ultimate goal not being pain disappearance but the *"return to the highest level of function while managing the pain"* (13).

Saracoglu et al 2020 study on chronic LBP patients concluded that pain education added to manual therapy and home exercise was more effective in reducing pain & kinesiophobia (21), confirming similar results of disability reduction in a 2015 study on chronic neck pain comparing supervised to home exercise, combined with manual therapy and education (22). Their pain education intervention is described in Annex B. The Louw, Nijs & Puentedura 2017 review strongly suggests that a key factor of the success of pain education on chronic musculoskeletal pain lies in its combination with movement (whether it is passive or active) (20).

Therapeutic exercise goals extend far beyond addressing the physical impairments. It should always be individualized, and take into account activity limitations and participation restrictions (23) related not only to chronic pain, but also to associated depression and lack of sleep (13).

No regimen has yet clearly proven its superiority (9) (14), although aerobic exercise is strongly recommended (9) (16) (23), strengthening & stabilization exercises moderately (16) (23) (24). Stretching or core strengthening is recommended, not in isolation, but as part of a multimodal interventions (16). The type of exercise should be chosen according to the patient's needs and capabilities, but also preferences, as motivation improves adherence & outcomes (14) (13). "*The activity that the patient will adhere to is believed to be the one most likely to be effective, given that compliance is a recognized problem*" (16).

Supervised exercise target symptom reduction and functional improvement, but also guidance toward autonomous exercise program management (16). A major goal is indeed to engage the patient into greater levels of physical activity over the long term. Opting for an exercise modality easy to pursue independently after intervention should hence be encouraged.

Home-based exercise programs effectiveness evidence remains mixed. The North American Spine Society (NASS) 2020 Guidelines (9) give a grade A recommendation to back school for greater benefits than medical or modality care (9), and the 2010 "Japan LBP study" (25) for superiority to NSAIDS, while a 2003 WHO bulletin only mentions educational benefits (8).

Logistical constraints, such as travelling time, and out-of-pocket costs decrease compliance to exercise programs (26). The flexibility of home-based interventions address these limitations, but the absence of supervision can reduce adherence (15).

The American College of Occupational & Environmental Medicine (ACOEM) 2016 guidelines suggest daily exercise if self-directed, instead of 1-3 session(s) / week for up to 4 weeks (16).

Bronfort et al 2011 evaluated high dose supervised exercise to be slightly superior to low dose home exercise for chronic LBP patients' pain, disability, general health, and use of medication, but with no statistical difference, although the supervised intervention had a higher dosage (4).

Matarán-Peñarrocha et al 2019 study, comparing a core stability program between supervised and home exercise groups for chronic LBP patients, concluded that the supervision conferred little additional benefit, statistically significant, but "*not worth the extra effort*" (27). The authors believe that the use of a session record booklet improved compliance and outcomes (27).

Yoga is recommended by clinical guidelines for its improvement of back pain and function, better than no treatment or usual care, but with mixed and limited evidence (9) (16) (28) (29). The ACOEM recommends it for "*highly motivated patients"* (16), and the NASS (with grade B) for mild chronic LBP patients, "*although improvements are not clinically meaningful due to low baseline pain/disability"* (9). A 2017 Cochrane review of 12 trials concluded in low to moderate evidence of back function and pain improvement at 3 & 6 months, but not clinically significant, and uncertain regarding any difference with other exercise interventions (30) (Annex C), while a 2005 RCT from Sherman et al concluded in the superiority of yoga versus exercise (31).

Therapeutic yoga has not yet been standardized for chronic LBP. It usually involves breath control, stretches, postures and relaxation (16) (32). Most interventions use (modified) Iyengar, Hatha or Vinyasa yoga, with 1 to 3 sessions per week of 45 to 90 minutes (30). A study showed that, to decrease work absenteeism, yoga should be practiced at least twice a week (33). A WHO 2019 bulletin evaluated that yoga is effective from 12 sessions to reduce LBP (5), but most studies exercise and yoga programs consist of 3 sessions per week, over 6 to 12 weeks. Further research is needed to confirm yoga effectiveness on chronic LBP, especially over the

long term (30), refine the intervention modality and dosage, and check to what extent the above conclusions of home-based versus supervised modality apply to yoga interventions. Yoga is estimated low cost, or even very low cost if self-administered (16), home-based modality being less costly than its supervised counterpart. Several studies concluded in greater low back pain improvements for supervised exercise rather than home-based, but not clinically significant nor worth the extra costs (4) (27) (15). Home-based exercise could become a commonly recommended LBP treatment modality, especially if combined with education and advice to remain active, providing that the compliance is sufficient. Innovative strategies to increase adherence to home-based exercise should be encouraged.

Digital games are a powerful medium to motivate individuals to engage into physical activity and adopt a healthier lifestyle. In 2011, 72% of American households were estimated to play computer or video games, with individual rates of 18% <18yo, 53% 18-49yo & 29% ≥50yo (34). Gamification in the medical field consists in integrating game features (rewards, challenges) into non-game health software products to make them enjoyable and attractive incentives for the patients to engage into healthier behaviours (34). Its increasing use is partly linked to the technical revolution of mobile applications and democratization of virtual reality (35).

Virtual Reality corresponds to digital technology with artificially created sensory experiences within an immersive, non-immersive, or interactive Virtual Environment (VE). Immersive VR requires full-body movement sensors, real-time graphics and advanced interface devices like head-mounted devices (HMD), to simulate a very realistic VE. Non-immersive VR only requires display interface such as a flat screen, and controller, joystick or keyboard for user feedback. Interactive VR focuses on user's interactions with virtual objects through devices giving the impression of manipulating them, like gloves or digital glasses (36).

Exergaming, exercise gaming, or VR-integrated exercise, i.e., VR video games combined with exercise, have been shown to "*enhance the psychological benefits of exercise and increase the likelihood of long-term adherence to exercise*" (37) (38), possibly because it is perceived more enjoyable in a virtual environment with audio-visual stimuli facilitating patient's motor persistence, concentration on the game objectives, and competitive spirit (36). VR-integrated exercises can motivate players through positive feedback based on motion-sensing devices, such as the Nintendo Wii Fit U remote and balance board, displaying or not an Avatar as a real-time representation of the subject physically exercising (34) (35).

Zadro et al 2018 investigated the effects of Wii Fit U exercises in elderlies with chronic LBP. Pain and function improved immediately after intervention, and pain self-efficacy at 6 months, but with questionable clinical importance. The intervention had no effect on disability, physical activity or kinesiophobia (15). A secondary 2020 analysis concluded that a family history of

LBP negatively influences physical activity levels in this population (39). Kim et al 2014 concluded on positive effects on physical improvements of a VR-based Wii Fit home yoga intervention for middle-aged women with non-specific chronic LBP (40).

VR-related attentional distraction induces hypoalgesia for acute pain (41), but also for chronic LBP, as recently shown by Matheve et al 2020 (42). It increases with the immersion level, but non-immersive systems are more widely used in rehabilitation for their reduced constraints and costs (43), but also fewer side effects than HMD (motion sickness) (36). Full body movement detection with 3D-sensors provide better real-time interactions, such as in the Parsons & Trost 2014 VR graded exposure therapy study on pain-related fear and disability in chronic pain (34). However, the Xbox Kinect has been discontinued since, and no equivalent technology is yet available to the public, only developer kits (44).

VR-induced hypoalgesia could facilitate therapeutic exercise for chronic LBP patients: if they feel less pain during exercise, they are more likely to adhere to their program, decrease their fear-related activity avoidance, and ultimately engage into greater levels of physical activity. Although the distraction effect only takes place during the intervention itself, its promotion of patient's motivation could help for the exercise prescription to improve their LBP disability. VR's potential for LBP treatment is promising but needs further research (45).

Therefore, if exercise prescription, combined with pain education and advice to remain active, has been confirmed as first line physiotherapy treatment, a knowledge gap remains about:

- What exercise regimens are most effective (type of exercise and dosage)?
- Can yoga be more effective than another type of therapeutic exercise?
- Can home-based yoga be as effective as supervised yoga?
- Can virtual reality games encourage adherence to home-based programs?

In this study, we will investigate the effects of a yoga intervention on non-specific chronic LBP, compared to therapeutic exercise, all combined with education and advice to remain active. We will primarily monitor disability, targeting patient's quality of life improvement, rather than focus on pain. A major objective will consist in evaluating if a home-based intervention could be as effective as its supervised counterpart. To increase adherence, the home yoga program will use a non-immersive VR technology easily accessible to the public, a Nintendo Wii Fit U yoga program with a balance board device. VR home-based yoga, if proven as effective as supervised yoga, would represent a cost-effective modality that could be recommended by health care systems for chronic LBP, especially for patients with accessibility issues.

STUDY DESIGN

This protocol describes a prospective, single centre, 3 arms, randomized controlled trial (RCT) with concealed allocation, intention-to-treat analysis, and with the assessors, allocator, and statistician analyst single-blinded to the treatment allocation.

The clinical trial will compare the effects of a therapeutic yoga program to therapeutic exercise as “usual physiotherapy care” (control), all groups also receiving pain education and advice to remain active, according to most recent clinical guidelines recommendations (14).

The yoga intervention will be performed within two different groups, to compare the relative effectiveness of supervised yoga versus Wii Fit U game-based home yoga.

The study will take place at the Bellvitge Campus of the University of Barcelona, in cooperation with the rehabilitation service of the Bellvitge University Hospital (46).

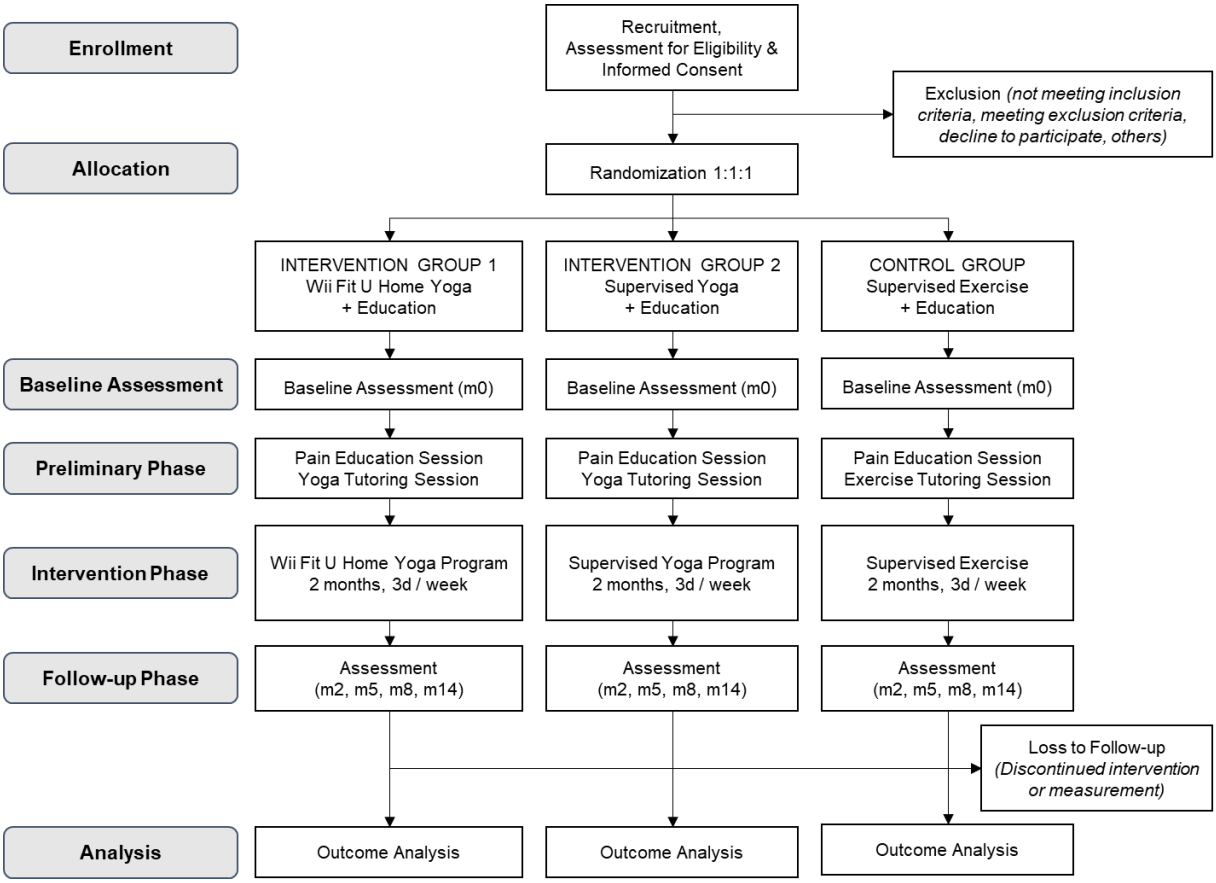
The protocol follows the SPIRIT 2013 Statement 33-item checklist for study protocols (47).

The intervention is documented according to the Template for Intervention Description and Replication (TIDieR) checklist (48), and the trial will be reported according to the CONsolidated Standards OF Reporting Trials (CONSORT) statement (49).

It will be registered prospectively, before the start of the recruitment, in the ClinicalTrials.gov Protocol Registration and Results System (PRS) (50), a registry approved by the International Committee of Medical Journal Editors (ICMJE) (51), referenced on the WHO International Clinical Trials Registry Platform (ICTRP) (52). The WHO Trial Registration Data Set (53) (Annex D) will be displayed on the registry and completed with the trial results once finished.

The protocol will be reviewed and approved by the Research Ethics Committee (CRE) of the Bellvitge University Hospital (HUB) before being registered (54). The protocol current version is V1.0 (16/12/2020). Informed Consent will be signed by every participant before the start of the study. Any protocol modification will be notified to the CRE, and consent will be reobtained from participants if necessary.

FLOW DIAGRAM OF THE STUDY DESIGN



STUDY SETTING & RECRUITMENT

STUDY SETTING

The study will take place at the Bellvitge Campus of the University of Barcelona (UB), for the recruitment eligibility assessment, the study assessments, and the supervised interventions, in dedicated physiotherapy classrooms.

RECRUITMENT

The recruitment team will be led by the study coordinator and include research assistants who will not take part in the assessment (except for eligibility criteria), intervention, or data analysis.

The recruitment will mostly take place at the rehabilitation building of the Bellvitge University Hospital (HUB) in Barcelona (46), where a therapeutic exercise program is already proposed to chronic LBP outpatients. Patients attending their LBP rehabilitation program will be offered by their physiotherapist to join the trial, as well as outpatients visiting their doctor for routine LBP management appointment. They will be given a flyer with a brief presentation of the study, its key objectives, and the contact of the recruitment team.

Patients having participated in a chronic LBP rehabilitation program in the past 6 months will also be contacted by phone by their physiotherapist and will receive an email with the digital version of the flyer or directly an appointment with a recruiter, as preferred.

The study will also be advertised through flyers and posters displayed at the welcome desk, waiting rooms, corridors, and main rehabilitation rooms of the HUB rehabilitation service.
A brief presentation of the study will be displayed in the "Research" tab of the rehabilitation service web page (46), with a video presenting the study, and the flyer available for download.

Individuals interested in the study will be contacted by a recruiter to clarify over the phone the inclusion & exclusion criteria and perform a preliminary screening. If meeting the inclusion criteria and willing to join the study, the patients will be sent the informed consent with detailed study information, and given an appointment to assess exclusion criteria and sign the informed consent. During the recruitment, but also at any time during the study, participants may ask any question to the research team, and withdraw without need for justification.

The recruitment phase should stop once three times the sample size is reached (the sample size being calculated for an intervention group), with an extra 15% for the risk of loss to follow-up during the intervention or follow-up, and another extra 5% for the risk of drop-out before the study beginning (during the recruitment). This extra 5% will be included in the randomization process and will be put on a waiting list for each group prior to the beginning of the intervention.

The study results will be communicated to the participants via email and sent for publication in peer-reviewed physiotherapy journals.

SAMPLE SIZE

Disability will be measured with two valid tools for chronic LBP disability (55):

- the Oswestry Disability Index (ODI) (56) (cf Annex E),
- the Roland Morris Disability Questionnaire (RMDQ) (57) (cf Annex F).

ODI MCID : Different MCID have been proposed in the literature: 9.5, 12.8, 12.88 or 15 (56). The most recent value of 12.88 with 88% sensitivity and 85% specificity proposed by Johnsen et al in 2013 (58) will be used to calculate the sample size.

RMDQ MCID : The MCID suggested for LBP varies between 3 & 5 points depending on the sources and on the baseline score (57). Without additional information for decision-making, the greatest value of 5 points will be used for sample size calculation.

Sample Size Calculation: The sample size should be calculated twice, based on the Minimal Clinical Important Difference (MCID) for each primary outcome, and the greater estimation of the sample size should be kept for the study.

PARTICIPANTS ELIGIBILITY CRITERIA

INCLUSION CRITERIA

Participants will be potentially eligible for the study if they meet the following criteria:

- Non-specific chronic low back pain persisting for at least 3 months
- Aged > 18 years and ≤ 65 years, like most similar studies (42) (27) (21) (59) (25), to include adults but not elderlies, more at risk of serious spine pathologies
- Male or female sex indifferently, to increase generalisability hence external validity
- Geographic area maximum 1h away by usual mean of transport from the site of the study intervention (Bellvitge campus of the University of Barcelona), to reduce the risk of poor adherence to supervised programs due to significant travelling time
- Disability RMDQ baseline score ≥ 4 and ≤ 20, similarly to other studies (27), to allow for detection of clinically meaningful improvement (60) (cf Annex F).

EXCLUSION CRITERIA

Participants will be excluded from the study if they meet the following criteria (risk of injury for the individual, or potential confounding variable affecting the validity of the study results):

- History of spinal, pelvis or hip surgery
- Diagnosis of chronic pain condition (fibromyalgia, complex regional pain syndrome)
- Uncontrolled photosensitive epilepsy, to avoid video game-related seizure (61)
- Specific spinal pathology (fracture, osteoporosis, disc extrusion, lumbar stenosis, radiculopathy, spondylolisthesis, cauda equina syndrome, metastatic disease…) (62)
- Central or peripheral nervous system condition (stroke, multiple sclerosis…)
- Corticosteroids injection (≤ 6 months before intervention)
- Other physiotherapy or exercise program (during or 1 month before the study)
- Insufficient English skills, hearing, vision, or cognition to understand instructions
- No high-definition multimedia interface or compatible television at home (15)
- No smartphone compatible with the installation of the study mobile application
- Participants with a high disability score (ODI 61% to 100%) as they could either require surgery or exaggerate their symptoms (56) (cf Annex E)
- Pain Self-Efficacy Questionnaire (PSEQ) score < 17, as patient beliefs about pain may then represent a limitation to start an exercise program (63) (Annex G)
- Cardiovascular risks assessed with the Physical Activity Readiness Questionnaire (PAR-Q+), recommended for exercise prescription (64) (65) (66) (Annex H)
- Moderate to severe depression, ie score ≥ 10 with Patient Health Questionnaire-9 (67), as it may require anti-depressant or psychotherapy (but a score of 5 to 9 is accepted, as chronic LBP can cause mild depression) (Annex I)
- Any medical condition that could significantly limit participation (eg knee injury)

Participants should attend 80% of their planned sessions during the intervention phase to be considered as having completed treatment. This threshold is similar to other studies with yoga or exercise prescription for chronic low back pain patients: 71% Zadro et al 2018 (15), 75% Sherman et al 2005 (31), 80% Bronfort et al 2011 (4), 85% Zadro et al 2018 (39), 90% Matarán-Peñarrocha et al 2019 (27). Subjects attending less than 80% of their planned sessions (i.e., missing ≥ 5 sessions over the 8 weeks intervention) will be considered as not having completed their program, but will remain in the intention-to-treat analysis as their assessment data allows, and will be analysed distinctively from participants having completed their program.

Note: The population was not restricted to middle-age or only female patients like in the Kim et al 2014 study (40) to better meet the sample size, and also to improve the generalisability (external validity). It is unclear if younger patients could be more accustomed to the use of video games, or women more interested in therapeutic yoga than exercise. A secondary post-hoc analysis will focus on these variables to search for differences between subgroups.

In the study from Seong-Sik et al (40), the demographic data indicate a mean age of ~44 years in the Wii Fit U group versus ~50 years in the control group, for a sample size of 30 subjects. This represents a risk of confounding variable that was not mentioned in the study limitations (statistically significant difference verifiable with a t-student test, $p < 0.05$).

RANDOMIZATION

After the enrolment phase, patients will be randomly assigned (1:1:1) to their group:

- Wii Fit U game-based home yoga (intervention group 1),
- Supervised therapeutic yoga (intervention group 2),
- Supervised therapeutic exercise (control group).

A research assistant who will not be further involved in the study will randomly assign each participant to a group using the GraphPad QuickCalcs online tool (68) (*Random numbers > Randomly assign subjects to groups > Randomly choose a group for each subject*).

A **stratified randomization** will be used to balance the distribution of two possible confounding variables (gender (40) and family history of LBP (39)) between groups.
This method is recommended for small trials (<400 patients) as the risk of unequally distributing subjects with a given covariate increases with smaller groups (69) (70).
It reduces Type I errors, i.e. false positive or "*the probability of finding a statistically significant or clinically significant difference between groups when none exists"* (70).

Stratified randomization is achieved in 2 steps:

1) creating a block for each combination, assigning the subjects to the correct block:

BLOCKS	Family history of LBP	No family history of LBP
Male	A = (male, LBP family history)	B = (male, no LBP family history)
Female	C = (female, LBP family history)	D = (female, no LBP family history)

2) performing a simple randomization for each block to assign subjects to groups (69).
   (ie sequentially randomize the subjects of the blocks A, B, C & D to the 3 groups)

Multiplying covariate combinations critically increasing the randomization method complexity, it should be limited to key confounding variables, preferably dichotomous.

During the eligibility assessment, all subjects will provide demographic data to the recruiter to later enable the statistician analyst to control the homogeneous distribution between groups (not only gender and family history of LBP, but also age, education level, history of video games use…). A similar verification will be performed regarding clinical data (particularly the baseline pain & disability levels, and analgesics use).

BLINDING

The patients and physiotherapists performing the interventions obviously cannot be blinded, as the nature of the intervention does not allow it.

The assessors, allocator and statistician analyst will all be external to the investigation and single blinded to the allocated intervention and study objectives, to reduce the risk of bias.
The study coordinator will not perform the assessments, randomization, interventions, and statistical analysis, to reduce the risk of bias.

The random allocation will be provided to a research assistant external to the investigation in sealed opaque envelopes to remain concealed from the study team until the beginning of the intervention. Participants will be informed of their allocated intervention after their baseline assessment, at the time of their preliminary session of education and tutoring.

The patients will be asked to not mention their intervention to their assessor, an experienced physiotherapist trained with the measurement tools. The same assessor will perform all of their assessments to improve consistency between subsequent measures. Collected data will be saved on a laptop with password protection for confidentiality and stored in a closed locker. Once all outcomes are available numerically, they will be transmitted to the statistician analyst. Access to the data will always remain protected by personal authentication.

The statistician will analyse the demographic and clinical data to identify statistical differences between groups, including baseline distribution and post-hoc subgroups analysis to identify potential covariates, without knowing which intervention is associated to each group.

The study coordinator will perform the final data analysis, once the statistician has established the presence or absence of statistically significant differences between groups, further analyse and complete the reporting of the study results, discussion, and limitations.

INTERVENTION OVERVIEW (ALL GROUPS)

As recommended by most guidelines, all groups (home yoga, supervised yoga and supervised exercise) will receive education and advice to remain active. It will be delivered face-to-face during a preliminary session at the University of Barcelona (UB), before the first intervention, by a physiotherapist trained in pain & neuroscience education.

The education part will present the following concepts (cf Annex B for similar interventions):

- Chronic pain physiology, peripheral/central sensitization, allodynia, and hyperalgesia,
- Fear-avoidance beliefs, fear catastrophizing, maladaptive behaviours,
- Coping strategies, benefits of exercise, relaxation, and positive behaviours.

It will use a PowerPoint presentation for visual support, should last around 1h and encourage the participant to interact and ask questions. The participant will be provided with a booklet containing a summary of the concepts, and encouraged to read the “Explain pain” book from Butler & Moseley for more information about pain (71).

Afterwards, all participants will be provided a face-to-face tutoring session corresponding to the modality of their group at the UB, to learn how to correctly perform each exercise without further need for feedback during the intervention. The same yoga exercises will be performed by both yoga groups 1 & 2. The physiotherapists in charge of these 2 groups will be trained together prior to the interventions, with Wii Fit U yoga exercises displayed on a flat screen and balance boards, to ensure the delivery of homogeneous yoga teaching between groups.

The exercises will be introduced by an experienced physiotherapist trained in the therapeutic modality (yoga or exercise), with the help of a PowerPoint presentation for supervised groups, or directly on a flat screen for the Wii Fit U yoga modality. All participants will receive a booklet recapitulating all exercises, also available in the study mobile application, to encourage home practice later during the follow-up phase.

During the intervention phase, all groups will perform 3 sessions of ~45 minutes per week over 8 weeks (24 sessions in total). Participants should miss less than 5 sessions to be considered as having completed the treatment (80% compliance). Supervised groups will receive “Wii Fit U-like” feedback, to better enable the comparison of the yoga program delivery modality. All participants will be asked to download and install a mobile application to monitor their daily steps and record their home sessions time, and pain level (before and after each session).

Once the intervention is finished, participants will be encouraged to continue exercising regularly, maintaining at least one session per week of their therapeutic modality at home (yoga for the groups 1 & 2, exercise for the control group) during the follow-up phase. This will not be mandatory but monitored, as greater levels of physical activity after the end of the intervention is a desired outcome.

WII FIT U GAME-BASED HOME YOGA INTERVENTION (GROUP 1)

During the preliminary session at UB, participants will be taught in face-to-face how to perform each yoga exercise by an experienced physiotherapist trained in therapeutic yoga, but also on how to use the Wii Fit U equipment. The duration of this 1h to 2h tutoring will be adjusted to their level of understanding and confidence to use the program once left unsupervised (15).

A research assistant will then arrange an appointment to set-up the Wii U console for the first home session and ensure that it can start without technical issue. The video-game equipment (Nintendo Wii U console, software, remote, and balance board) belongs to the University of Barcelona and will be loaned to the participants for the study period (including follow-up).

The subjects will record in their mobile application every time they perform a home session, indicating their level of pain before and after starting to exercise.

The Wii Fit U yoga program is composed of 18 exercises: Deep Breathing, Half Moon, Warrior, Tree, “Sun Salutation”, Standing Knee, Palm Tree, Chair, Triangle, Downward Facing Dog, Dance, Cobra, Bridge, Spinal Twist, Shoulder Stand, Spinal Extension, Gate, Grounded V. The last 4 being harder to perform without guidance, they will be excluded from the Wii Fit U home yoga program: shoulder stand, spinal extension, gate, and grounded V (cf Annex J).

The Kim et al 2014 study (40) described using 7 Wii Fit yoga exercises, but not which ones. Sherman et al 2005 (31) supervised yoga sessions included initial & final breathing exercise, 5 to 12 postures selected from a core of 17, repeated 3 to 6 times (not held), and a guided deep relaxation. Many postures were similar to the Wii U yoga program, which focuses slightly more on standing postures, more adapted to the Wii balance board. Since it is not possible to customize the Wii U yoga exercises, they will be the ones used for both groups 1 & 2.

Each Wii Fit U yoga sessions will start & finish with 2-3 minutes of deep breathing and include a subset of 6 to 12 of the 14 postures, every exercise being repeated 3 to 6 times, for an overall session duration of ~45 minutes. A pre-selection of the postures for all sessions will be prepared by the physiotherapist during the tutoring session, based on patient’s capacities.

The Wii Fit U virtual coach provides instructions for every exercise, and feedback adjusted to the level of neuromotor control as evaluated with the Wii balance board. The soothing audio-visual Wii Fit U environment participates in creating a relaxing atmosphere, while the feedback from the virtual coach helps increasing participant motivation and concentration.

Patients will be instructed to keep one day of rest between sessions, and to adjust the number of repetitions, rest duration and postures selection based on their pain 24h post exercise. A weekly call with the physiotherapist will be set to provide an opportunity to ask questions, adjust progression or raise issues, and also to improve adherence to the yoga program (15).

SUPERVISED YOGA INTERVENTION (GROUP 2)

The supervised yoga intervention will be composed of the same exercises than the 1st group, to enable the comparison between the supervised and home game-based modalities.

The preliminary face-to-face session will allow participants to be taught yoga exercises by an experienced physiotherapist trained in therapeutic yoga at the UB, like for group 1. This tutoring session should last about 1h only, since it does not include the Wii Fit U presentation.

All subsequent sessions will also take place face-to-face at the University of Barcelona, in a dedicated room, starting and ending with 2-3 minutes of deep breathing, and including a subset of 6 to 12 of the same 14 postures than in group 1, every exercise being repeated 3 to 6 times, for an overall session duration of ~45 minutes. A pre-selection of the postures for all sessions will be done by the physiotherapist during the tutoring session, based on patient's capacities, and eventually adjusted every week, just like for the 1st group.

The subjects will record in their mobile application their level of pain before and after starting each session, like the other groups. The application will also automatically monitor their daily steps. During the follow-up phase, they will be asked to similarly register their pain intensity every time they do a home yoga session. They will be encouraged to continue exercising at least once a week, using the booklet as a support to remind them the yoga program exercises.

More detailed information on the yoga postures and deep breathing techniques can be found in pedagogic yoga books such as "Yoga Encyclopédie" by André Von Lysebeth (72), "Anatomy of Hata Yoga" by David Coulter (73), or "Yoga as Therapeutic Exercise" by Worle & Pfeiff (74).

SUPERVISED THERAPEUTIC EXERCISE INTERVENTION (CONTROL GROUP)

Like both intervention groups 1 & 2, the control group participants will be taught the exercises during a preliminary face-to-face session at the UB by an experienced physiotherapist trained in therapeutic exercise prescriptions. This tutoring session should last about 1h and enable to adjust the exercise selection and dosage (number of sets and repetitions) for the first week. The exercise sessions intensity will then be weekly adjusted, similarly to other groups.

All subsequent sessions will also take place in face-to-face at the University of Barcelona, in a dedicated room, under the supervision of the same experienced physiotherapist. The content of the therapeutic exercise program has been inspired from the 2019 Matarán-Peñarrocha et al study (27), as they described their intervention with more details than other similar studies proposing similar lumbo-pelvic stabilization programs (40) (21) (4) (25). It includes mostly stretching and strengthening exercises, with a focus on abdominal muscles (transversus & rectus abdominis), lumbar muscles (multifidus & erector spinae), gluteus, quadriceps and hamstrings. It is composed of 9 exercises, each performed once at every session, the dosage (usually 3 sets of 10 repetitions) and rest time being adjusted to the patient's capacities:

1) diaphragmatic breathing (2-3 minutes); 2) pelvic girdle; 3) supine spinal twist; 4) abdominal curl ups; 5) back extensors strengthening ("Prone Superman"); 6) quadruped "cat camel"; 7) quadruped opposite arm & leg lift; 7) front plank; 8) supine spinal; 9) glute bridge (Annex K).

All these exercises belong to the therapeutic exercise program from the Bellvitge University Hospital (HUB) (75). Two exercises have been changed from the initial Matarán-Peñarrocha et al program for more consistency with other programs, including HUB's: the side plank exercise replaced by quadruped arm & leg lift, and the lateral leg raise by spinal twist. It is consistent with principles explained in the "Therapeutic Exercise - Moving Toward Function" book from Brody & Hall (13), although their approach is very "structural anatomy-centered".

Like groups 1 & 2, participants will record their pain level before and after each session in their mobile application, that will monitor their daily steps. During follow-up, they will be asked to continue register their pain for every home session and encouraged to continue exercising at least once a week, using the booklet to remind them the exercise program content and dosage.

OUTCOMES

PRIMARY OUTCOME

The patient's level of disability will be measured with two valid tools for LBP disability (55):

- the Oswestry Disability Index (ODI) (56) (cf Annex E),
- the Roland Morris Disability Questionnaire (RMDQ) (57) (cf Annex F).

It has been decided to use both tools, as similar studies on chronic low back pain tend to use them almost equally, or even sometimes both (40). For example, amongst the 12 yoga trials of the 2017 Cochrane review, 6 studies used the RMDQ while 5 used the ODI (30). Therefore, to better enable comparison with other studies, both questionnaires have been included.

- Oswestry Disability Index (ODI) (56) (cf Annex E)

This self-report questionnaire is composed of 10 items, each rating from 0 (no disability) to 5 (worst), a higher score corresponding to more severe disability. For each item, the participant is asked to select the statement best corresponding his/her current condition. The items cover pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex (if applicable), social, and travel. The score of 0 to 50 is calculated as (total / (5 x nb items answered)) x 100%. The MCID value of 12.88 (58) has been selected for the study (cf sample size calculation). The ODI is recommended by the WHO for every study related to chronic LBP (8).

- Roland Morris Disability Questionnaire (RMDQ) (57) (cf Annex F)

This self-report questionnaire is composed of 24 items about how LBP affects the participant's functional activities. Each item scoring 0 (no, item not applying) or 1 (yes), the total score ranges from 0 (no disability) to 24 (severe disability). A MCID of 5 points has been selected. The RMDQ has demonstrated *"good validity, reliability and sensitivity for detecting changes in disability over time in people with LBP"* (15).

SECONDARY OUTCOMES

- Back Function (flexibility & endurance)

Disability's ODI & RMDQ evaluations being subjective, the back function will also be evaluated objectively with the FingerTip-To-Floor (FTTF) test (76) to evaluate posterior muscle chain flexibility, and isometric endurance testing of the trunk flexors and extensors, respectively with the Shirado and Biering-Sorensen (BS) tests (Annex L). Amongst the tests valid to assess lumbar muscle endurance & fatigue in chronic LBP patients, Biering-Sorensen is the shortest, simplest, and cheapest (77). The Shirado test is a cheap and simple measure to discriminate chronic LBP patients (78). Both are much cheaper and easier to perform than isokinetic testing.

For each test, it is important to respect pain as tolerated by the patient. For the endurance tests in particular, if the patient feels unable to perform them, he/she will score 0 seconds and the reason for not performing the test will be recorded (pain, fear, weakness…).

FTTF test: (79) the participant stands erect on a 20-cm high platform, with shoes off and feet together, and is asked to bend forward as far as possible, while maintaining fully extended knees, arms, and fingers. The vertical distance between the middle fingertip and the platform is measured in centimetres with a flexible tape. It is positive if the participant does not reach the platform, and negative if he/she can go further down below the platform.

Shirado test (trunk flexors endurance): (78) the participant starts in supine position (on a table or mat), with hips & knees flexed at 90 degrees, arms across the chest, and hands on opposite shoulders. The patient is asked to maintain a "crunch" position (scapulae off the table) as long as possible. The test stops when the patient re-establishes contact with the table/mat, or if in significant pain. If the patient cannot hold the position at all, then the score is 0 second and the assessor writes down the reason for it (fear, pain, weakness not allowing to hold…).
Endurance is around 41 seconds for LBP patients, versus 156s for healthy subjects (78).

Biering-Sorensen test (trunk extensors endurance): (80) the subject starts in a prone position, with the lower body fixed (by straps) on a table, below the anterior superior iliac spines, and the trunk off the table. Initially, the patient is resting with the forearms on a chair, supporting the weight of the upper body. The patient is asked to lift and cross the arms over the chest, maintaining as long as possible the trunk in a horizontal position. The test stops if contact is re-established with the chair, or in significant pain or fatigue, or reaching 240 seconds. If the patient cannot hold the position at all, then the score is 0 second and the assessor writes down the cause (fear, pain, weakness not allowing to hold…).
The Minimal Detectable Change is 24,1 seconds in LBP patients (no MCID is yet defined) (80).
Chronic LBP patients usually hold around 93-98s, versus 130-146s for healthy subjects (81).

- Pain

Like most studies on chronic LBP(4) (15) (21) (27) (40) (42), pain will be evaluated with the self-reported Numeric Pain Rating Scale (NPRS) (82), very similar to the Visual Analog Scale (VAS), except that the patient provides a numerical value from 0 (no pain at all) to 10 (worst imaginable pain), instead of showing this level on a graduated straight line.

Pain will be graded by participants in their mobile application, at the beginning and end of every session, during both intervention and follow-up phases. Mean pain over last week will also be recorded at every study assessment, in addition to this "continuous" pain level monitoring.

The 11-point NRS (integer numbers from 0 to 10) is widely used to assess pain intensity in chronic LBP population and has been recommended for clinical trials (42), but a 101-point scale including a decimal provides more accuracy. This is particularly important to compare the pain level recorded at the beginning and end of each session, since slight pain relief may go unnoticed if the measures are restricted to integers only.

The NRPS MCID is reported as 1.7 points or a reduction of ~28% in chronic LBP, although some studies may round this at a 2 points reduction (21).

- Increased pain medication use

The patients will be asked to report if they significantly increased the frequency of their pain medication use (Paracetamol, NSAIDs or other analgesics) over the last week ("yes" or "no") at each study assessments, to evaluate the risk of confounding variable for disability and pain-related outcomes (4).

- Fear of movement / Kinesiophobia

Kinesiophobia can be defined as *"an excessive, irrational, and debilitating fear of physical movement and activity resulting from a feeling of vulnerability to painful injury or reinjury"* (83).

Patients' fear of movement will be evaluated with the 17-items Tampa Scale for Kinesiophobia (TSK-17) (84) (85) (Annex M), like similar studies on chronic LBP (15) (21) (42).

This self-reported questionnaire contains 17 subjective items assessing fear of movement or re-injury due to physical activity. Each item scores from 1 (strongly disagree) to 4 (strongly agree) on a 4-point Likert scale. The total is calculated after inversion of the scores of items 4, 8, 12 & 16, and ranges from 17 to 68, higher scores indicating greater kinesiophobia (21) (42).

TSK has demonstrated good validity, reliability and responsiveness to assess changes in fear-related activity avoidance in chronic LBP patients (21) (42). A high score may reflect reluctance to engage in exercise programs (86). The MCID for TSK is reported as 8 points (21).

- Pain self-efficacy

The Pain Self-Efficacy Questionnaire (PSEQ) (63) (Annex G) is a 10-item self-reported tool assessing the strength of patients beliefs in their ability to accomplish activities despite their pain. Each item scores from 0 (not at all confident) to 6 (completely confident) on a 7-point Likert scale, and total score from 0 to 60, a higher score indicating stronger self-efficacy beliefs (87). A very low score, such as < 17, could mean that the patient believes pain relief to be necessary prior to become active, hence a possible limitation to start an exercise program (63). It is a valid and reliable tool to detect changes in people with chronic pain over time (15) (88). There is no MCID consensus for PSEQ in chronic LBP population, however a 30 % reduction in pain-related outcomes is considered clinically meaningful for chronic LBP (89). The smallest change in score that patients perceive as important, i.e., the Minimal Important Change (MIC), has been estimated as 5.5 points (90).

- Adherence

Adherence to the yoga or exercise program will be measured as the percentage of the number of sessions realized during the intervention over the total planned (24, corresponding to the 3 sessions per week over 8 weeks), like in similar studies (15) (27). It will be calculated based on the patient's indication in the study mobile application that a session has been performed. This will be a "continuous" evaluation throughout the entire intervention phase, instead of a measure done at the study assessments.

An adherence of 80% minimum is required to be considered as having completed the yoga or exercise program, i.e., missing less than 5 sessions over the 8 weeks. Patients not complying this requirement will be considered as not having completed the program but will remain in the intention-to-treat analysis, as their assessment data allows.

- Physical Activity

The mobile application will automatically register the daily steps of the participants to provide an estimation of their level of physical activity (PA), not only during the intervention phase, but also during follow-up, since an increase in this outcome would represent an improvement in terms of a healthier lifestyle for the individual.

SOCIODEMOGRAPHIC DATA

Participants will be asked to provide information on their age, weight, height, sex, duration of chronic LBP, educational level, work activity, family history of LBP, history of video-game use.

ASSESSMENTS

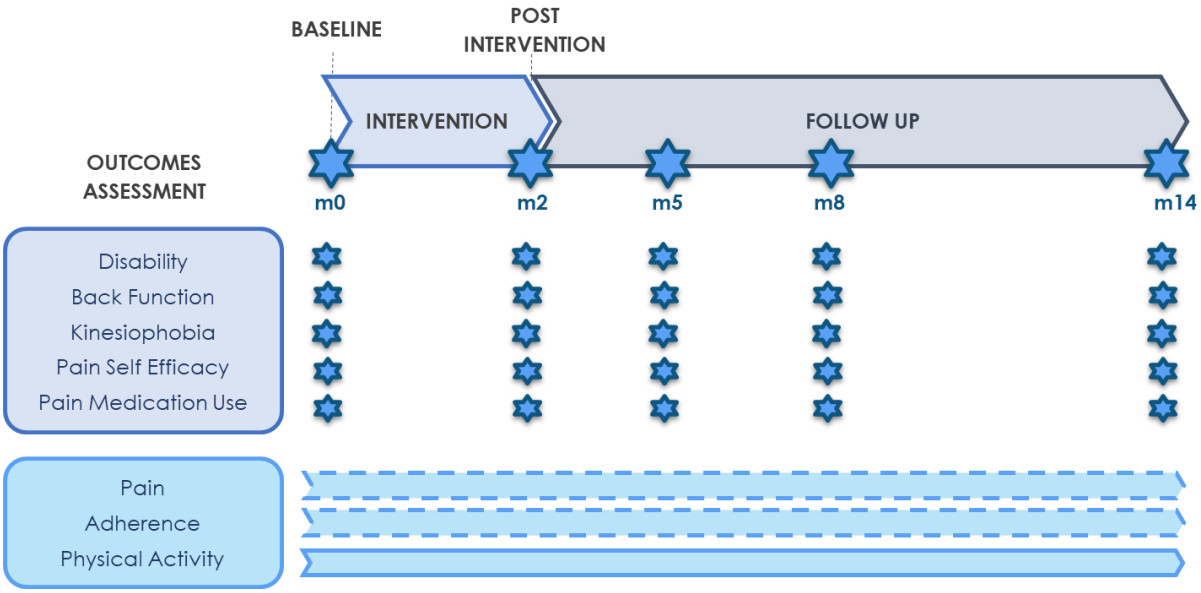
Most study outcomes (disability, back function, kinesiophobia, pain self-efficacy and increased pain medication use) will be assessed at the key time points of the study:

- M0 = at baseline, after the randomization and before the beginning of the intervention
- M2 = at the end of the 2 months intervention
- M5 / M8 / M14 = 3, 6 & 12 months respectively after the end of intervention

Qualified physiotherapists, external to the study, blinded to the intervention, and trained on the measurement tools, will perform all the assessments of their assigned participants to ensure consistency between subsequent outcome measures. Each study assessor will be randomly assigned a group of 10 to 20 patients before the baseline assessment.

Pain intensity and adherence will be “semi-continuously” assessed in the mobile application, every time the participant performs a session, during the study intervention & follow-up.

The physical activity will be continuously monitored during the intervention and follow-up phases via the mobile application, recording the number of daily steps of the participant.



STATISTICAL ANALYSIS

The IBM ® SPSS ® Statistics software will be used in its latest available version (now 27.0.1.0) for the statistical analysis (91). It will be conducted following intention-to-treat analysis by a researcher blinded to treatment allocation and external to the investigation.

An alpha level of p value < 0.05 will be considered statistically significant for all statistic tests.

The increased use of analgesics is a dichotomous outcome, “yes” or “no”, for a given sample, i.e., at the individual level. It is monitored because it represents a possible confounding variable for other outcomes. Its individual evolution with time can be analysed with a Fisher exact test.

Conversely, the number of “yes” in each group for this pain medication increase is actually a quantitative outcome, which can be compared between the 3 groups using an ANalysis Of VAriance (ANOVA) at any assessment (baseline or subsequent endpoints).

All the other study outcomes are quantitative (>2 values), most of them evaluated at the study assessments (disability, flexibility, endurance, kinesiophobia & pain self-efficacy scores), while several are assessed at every session (pain & adherence) or even continuously (physical activity level). The intervention effects on an outcome can be assessed with a student t-test for each independent sample between pre- and post- intervention. To compare interventions effectiveness, the outcomes means will be compared between the 3 groups using an ANalysis of COVAriance (ANCOVA) (92), the covariant being the increased use of pain medication.

Baseline values will be compared between groups using a one-way ANOVA. A Kolmogorov–Smirnov test will be performed to check for the normal distribution of the data (p>0.05) for all baseline variables (both sociodemographic and clinical).

The effects of interventions on all quantitative outcomes will be assessed using a mixed-model repeated measures ANCOVA, the within group factor being time (baseline and subsequent assessments m2, m5, m8, and m14), the between groups factor being the allocated group (home yoga, supervised yoga or supervised exercise), and the covariant being the significant increased analgesics use. To enable this analysis, the covariant needs to be “*continuous*” (i.e., constant) (93), hence it will be set to “yes” if it takes this value at least once during the study.

For each quantitative outcome, the analysis will enable to check if the MCID value has been reached, and if statistically significant difference can be noted between the 3 groups (p<0.05).

This analysis will be done between pre- and post- intervention (m2), but also for subsequent assessments, to track significant differences on the medium (m5, m8) and long term (m14).

Post hoc subgroup analysis will be performed on sex, age, family history of LBP and history of video game use, to evaluate if they could be confounding. Participants not having completed the intervention (<80% adherence) will be studied as a specific “intention to treat” subgroup.

ETHICS

This clinical trial will follow the main internationally accepted bioethical codes, the Good Clinical Practice (GCP) guidelines and the principles of the Helsinki Declaration, as well as all applying current legal regulations, such as the Personal Data Protection and the guarantee of digital rights (organic law 3/2018), the European General Data Protection Regulation (No 2016/679), the regulation of Biomedical Research (14/2007), and the general regulations of patient autonomy, rights and obligations regarding information and clinical documentation (organic law 41/2002), among others (94).

The protocol will be reviewed and approved by the Research Ethics Committee (CRE) of the Bellvitge University Hospital (HUB) before being registered (54).

All participants in this trial will receive an Informed Consent prior to engaging into the study, that describes the objectives, criteria, interventions, risks (cf Annex N). Only subjects accepting and formally signing this Informed Consent can participate in the study.

Participation to the study is voluntary and free, and any participant can withdraw at any time, without the need to justify. In that case, participants should just give back any material they have been provided for the study needs.

Any protocol modification will be notified to the Research Ethics Committee, and consent will be reobtained from participants if necessary.

CALENDAR/PLANNING

STUDY CALENDAR	Enrollment	Allocation	Baseline Assessment	Intervention	Post Intervention Assessment	Follow-up Assessment	Analysis
Timepoint	≤ d0 - 1m	d0 - 2w	d0	m0 to m2	m2	m5 + m8 + m14	≥ m14
ENROLLMENT							
Eligibility	X						
Informed Consent	X						
Random Allocation		X					
INTERVENTION							
Group 1 = Wii Fit U home yoga				X			
Group 2 = supervised yoga				X			
Control = supervised exercise				X			
ASSESSMENT							
Disability (ODI & RMDQ)			X		X	X	
Function (flexibility & endurance)			X		X	X	
Pain (NPRS)			X	X	X	X	
Medication use increase (Y/N)			X		X	X	
Kinesiophobia (TSK)			X		X	X	
Pain self efficacy (PSEQ)			X		X	X	
Adherence (% sessions)			X	X	X	X	
Physical Activity (daily steps)			X	X	X	X	
ANALYSIS							
Statistical Analysis							X
Final Analysis & Reporting							X

LIMITATIONS

BLINDING

A first limitation of the study lies in the fact that neither patients nor physiotherapists providing the interventions can be blinded, what causes an inherent risk of bias. Patients reluctant to yoga practice or preferring therapeutic exercise may not be sufficiently motivated to perform their exercises, especially for the home-based modality, what could cause the intervention to be less efficient. The opposite is also true: patients preferring yoga to exercise but allocated to the control group could show limited motivation, what could also decrease the efficiency of the control program. Regarding physiotherapists, their preference for any modality could also influence the way they teach the exercises and encourage the participants to perform them. It is difficult to evaluate either direction or magnitude of this preference influence.

POPULATION

The study sample being recruited mostly in a rehabilitation service of a hospital and composed of chronic LBP patients having already participated in a therapeutic exercise program, it may not be representative of the overall chronic LBP population. The outcomes improvements likely to be inferior to what could be expected if participants had not already taken part in a previous therapeutic exercise program: the past program may have been ineffective and reduced patient's expectation and motivation, or, conversely, it could have been effective, and the patient could have already reached an improvement plateau. This is true for all groups, although the effect of "novelty" of yoga interventions may reduce this influence, and slightly increase the effectiveness of yoga interventions versus the control group. A study comparing the benefits of a therapeutic yoga program with or without previous participation into any sort of therapeutic exercise could help to identify this risk of confounding variable.

CONTROL GROUP

The modality for the control group remains debatable, since no intervention at all could also be considered, or medical intervention (NSAIDs), or a full multi-disciplinary treatment with cognitive behavioural therapy. The literature is very heterogeneous regarding control modality. The intervention effectiveness could be over- or under-estimated depending on the chosen control modality. The effectiveness of the yoga intervention would probably be much greater if compared to no intervention at all, rather than to another therapeutic exercise modality.

ROLE OF THE INVESTIGATORS

This trial is funded by the Bellvitge University Hospital (HUB), the Catalan Health Service (CatSalut), and the Generalitat de Catalunya (GenCat). It is sponsored by the Escola Universitaria de la Salut I l'Esport (EUSES), via the inter-university physiotherapy degree from the University of Girona (UdG) and the University of Barcelona (UB). The study will take place at the Bellvitge Campus of the University of Barcelona, in cooperation with the rehabilitation service of the Bellvitge University Hospital (46).

The funding sources and sponsors have no role in designing the study; collecting, analysing, interpreting the data; writing the report; or deciding to submit the manuscript for publication. All these activities fall within the study coordinator responsibilities.

The study coordinator will organize and supervise the study, coordinate the different actors, fulfil administrative and legal procedures, lead the recruitment team for the participants enrolment, prepare the assessment procedures and documents, provide material and logistical support, perform the final analysis, write the study report and associated documentation, and be in charge of the final study publication and communication. The study coordinator will not perform the assessments, allocation to treatment, interventions, and statistical analysis.

For the recruitment, the study coordinator will be assisted by research assistants who will not take part in the assessment (except for eligibility criteria), intervention, or data analysis.

RESOURCES

HUMAN RESOURCES

A research assistant external to the investigation will perform the random allocation.

Experienced physiotherapists (PT) trained in the outcome measurement tools, blinded to the intervention allocation and external to the investigation will perform the assessments. Each one will be in charge of 10 to 20 patients, for whom they will perform all study assessments.

Experienced PT trained in pain & neuroscience education, therapeutic yoga and/or exercise, external to the investigation, will deliver the respective interventions. Each PT will take care of 10 to 20 patients. They will not be assessors for their assigned patients, but can be assessors for other participants, who will never mention which intervention they are allocated to.

A statistician analyst external to the investigation will perform the statistical analysis.

ELECTRONIC MATERIAL

A set of video-game equipment (Nintendo Wii U console, software, remote, and balance board) belonging to the University of Barcelona will be loaned to the participants of the intervention group 1 (Wii Fit U game-based home yoga) for the entire duration of the study.

All participants will be provided free access to the mobile application used for the study.

EDUCATIONAL MATERIAL

All study subjects will receive a pain education booklet, as well as free access to the “Explain pain” book from Butler & Moseley (71).

PHYSIOTHERAPY MATERIAL

All participants will be provided with a yoga mat, whatever their assigned group, as well as a booklet recapitulating the exercises corresponding to their intervention.

The only fungible material that will be used for the study is for standard hygiene requirements.

SOFTWARE

For the randomization, the free online tool QuickCalcs from GraphPad will be used (no fees).

For the statistical analysis, the study will use a license for the IBM ® SPSS Statistics software.

A mobile application designed by the UB research team will be developed specifically for the study purposes, available for both Apple ® & Android ® smartphones and tablets, and will be made easy to customize for later studies.

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ANNEXES

A. CHRONIC LOW BACK PAIN TREATMENT RECOMMENDATIONS

The figure below presents the overview of interventions endorsed for non-specific low back pain in evidence-based clinical practice guidelines (14):

	Acute low back pain (<6 weeks)	Persistent low back pain (>12 weeks)
Education and self-care		
Advice to remain active	First-line treatment, consider for routine use	First-line treatment, consider for routine use
Education	First-line treatment, consider for routine use	First-line treatment, consider for routine use
Superficial heat	Second-line or adjunctive treatment option	Insufficient evidence
Non-pharmacological therapy		
Exercise therapy	Limited use in selected patients	First-line treatment, consider for routine use
Cognitive behavioural therapy	Limited use in selected patients	First-line treatment, consider for routine use
Spinal manipulation	Second-line or adjunctive treatment option	Second-line or adjunctive treatment option
Massage	Second-line or adjunctive treatment option	Second-line or adjunctive treatment option
Acupuncture	Second-line or adjunctive treatment option	Second-line or adjunctive treatment option
Yoga	Insufficient evidence	Second-line or adjunctive treatment option
Mindfulness-based stress reduction	Insufficient evidence	Second-line or adjunctive treatment option
Interdisciplinary rehabilitation	Insufficient evidence	Second-line or adjunctive treatment option
Pharmacological therapy		
Paracetamol	Not recommended	Not recommended
Non-steroidal anti-inflammatory drugs	Second-line or adjunctive treatment option	Second-line or adjunctive treatment option
Skeletal muscle relaxants	Limited use in selected patients	Insufficient evidence
Selective norepinephrine reuptake inhibitors	Insufficient evidence	Second-line or adjunctive treatment option
Antiseizure medications	Insufficient evidence	Role uncertain
Opioids	Limited use in selected patients, use with caution	Limited use in selected patients, use with caution
Systemic glucocorticoids	Not recommended	Not recommended
Interventional therapies		
Epidural glucocorticoid injection (for herniated disc with radiculopathy)	Not recommended	Limited use in selected patients
Surgery		
Discectomy (for herniated disc with radiculopathy)	Insufficient evidence	Second-line or adjunctive treatment option
Laminectomy (for symptomatic spinal stenosis)	Insufficient evidence	Second-line or adjunctive treatment option
Spinal fusion (for non-radicular low back pain with degenerative disc findings)	Insufficient evidence	Role uncertain

B. EXAMPLES OF PAIN EDUCATION INTERVENTION

The Beltran Alacreu 2015 study on chronic neck pain (22) used the below components for their therapeutic pain education (TPE) intervention, consisting of two one-to-one sessions of 20 minutes based on a behavioural approach with 3 parts (cognitive, operant and respondent). The first session, taking place after the first treatment intervention, explained the cognitive concepts, while the second session took part during the second half of the intervention period, and focused on the operant and respondent concepts.

	Method	Approach	Skills
Cognitive	Education on the basic physiology of pain and chronic pain	Explanation of maladaptive belief about pain and disability	Reinforce positive beliefs
	Education on the basic anatomy of the cervical region		Ergonomic
	Physiologic and biomechanical bases of motor behavior		Interrupting and reversing of maladaptive craniocervical postures
Operant	Eliminate inappropriate behavior (e.g., sedentary lifestyle)	Exposure to graded activity	Gradual progression of cervical movements
	Promoting positive behaviors (e.g., exercise, return to work)		Gradual progression of low-intensity aerobic exercise (e.g., walking 30 mins/day)
Respondent		Self-treatment techniques	Autotraction techniques
			Diaphragmatic breathing and relaxation techniques (e.g., Jacobson relaxation technique)

"The purpose of the TPE was to modify any erroneous beliefs about pain and disability and to promote coping strategies and self-efficacy through a graded activity. (…)
In the first session, with the support of a PowerPoint presentation using diagrams, images, and texts, the physiotherapist explained the cervical engine behavior, the neurophysiologic basis of pain, the importance of the participant's involvement in the treatment (e.g., coping and motivation), and the maintenance of good ergonomics. Furthermore, the patients were given an information booklet containing the most relevant aspects of the educational session talk and were encouraged by the physiotherapist to ask any questions about it.
In the second session, the content covered in the first session was reviewed and continued with the respondent section, which was aimed at modifying the physiologic response to pain system. Then, it continued with the operant section, in which the physiotherapist explained self-treatment techniques, such as stretching, autotraction, diaphragmatic breathing, and relaxation techniques (Jacobson relaxation technique) to provide the patients with coping strategies and reduce their attention to pain. In addition, patients received another booklet that contained a detailed description of these self-treatment techniques. Finally, it was determined that the patients had understood everything that was explained and the physiotherapist urged the patients to ask any questions about any doubts they may have had."

The Saracoglu 2020 chronic LBP study (21) provided 4 one-to-one sessions 40-45 minutes of Pain Neuroscience Education (PNE), one every week during the intervention phase, each before a Manual Therapy (MT) session, conducted by the physiotherapist performing the MT session and trained on PNE at the International Spine and Pain Institute.

The PNE was carried out according to the method recommended by Louw, Nijs & Puentedura (2017) (20), and consisted of using metaphors, anecdotes, and pictures via a PowerPoint slide presentation including the below content.

1. session	Peripheral neuropathic pain, peripheral nerve sensitization, allodynia, central sensitization, hyperalgesia
2. session	Neuroplasticity, spreading pain, central sensitization, hyperalgesia, allodynia
3. session	Stress biology, immune response, emotional overload, fear, catastrophization and pain
4. session	How to cope with pain? The role of exercise and manual therapy

C. YOGA TREATMENT FOR CHRONIC NON-SPECIFIC LBP – A COCHRANE REVIEW

The results from the 2017 Cochrane review from Wieland et al on "Yoga treatment for chronic non-specific low back pain" (30) are summarized below.

MAIN RESULTS

12 trials (1080 participants) in the USA (7), India (3), and the UK (2).

Funding: unfunded (1), funded by a yoga institution (1), funded by non-profit or government sources (7), or unknown (3).

Yoga form: mostly Iyengar,Hatha, or Viniyoga

Comparison with: no intervention or a non-exercise intervention such as education (7), an exercise intervention (3), or both exercise and non-exercise interventions (2).

Risk of bias: high risk of performance & detection bias for all studies (because participants and providers were not blinded to treatment assignment, and outcomes were self-assessed).

→ all outcomes downgraded to 'moderate' certainty evidence because of risk of bias, and when there was additional serious risk of bias, unexplained heterogeneity between studies, or the analyses were imprecise, the certainty of the evidence was further downgraded.

AUTHORS' CONCLUSIONS

"There is low- to moderate-certainty evidence that yoga compared to non-exercise controls results in small to moderate improvements in back-related function at three and six months. Yoga may also be slightly more effective for pain at three and six months, however the effect size did not meet predefined levels of minimum clinical importance.

It is uncertain whether there is any difference between yoga and other exercise for back-related function or pain, or whether yoga added to exercise is more effective than exercise alone.

Yoga is associated with more adverse events than non-exercise controls, but may have the same risk of adverse events as other back-focused exercise.

Yoga is not associated with serious adverse events.

There is a need for additional high-quality research to improve confidence in estimates of effect, to evaluate long-term outcomes, and to provide additional information on comparisons between yoga and other exercise for chronic non-specific low back pain."

D. THE WHO TRIAL REGISTRATION DATA SET

The WHO has defined a Trial Registration Data Set (TRDS) that must be registered for any clinical trial before the study recruitment starts, and later updated with the trial results. It is composed of 24 items (53):

- **Primary Registry and Trial Identifying Number**
- **Date of Registration in Primary Registry**
- **Secondary Identifying Numbers**
- **Source(s) of Monetary or Material Support**
- **Primary Sponsor**
- **Secondary Sponsor(s)**
- **Contact for Public Queries**
- **Contact for Scientific Queries**
- **Public Title**
- **Scientific Title**
- **Countries of Recruitment**
- **Health Condition(s) or Problem(s) Studied**
- **Intervention(s)**

  For each arm of the trial record, a brief intervention name and description.

  For controlled trials, the identity of the control arm should be clear.
- **Key Inclusion and Exclusion Criteria**
- **Study Type, Design & Phase**
- **Date of First Enrollment**
- **Sample Size**
- **Recruitment Status**
- **Primary Outcome(s)**

  For each primary outcome provide:
  - The name of the outcome (do not use abbreviations)
  - The metric or method of measurement used (be as specific as possible)
  - The timepoint(s) of primary interest
- **Key Secondary Outcomes**

  Provide the same information than for primary outcomes
- **Ethics Review**

  Status, date of approval, name and contact details
- **Study Completion date**

- **Summary Results**

  It consists of:

  - Date of posting of results summaries
  - Date of the first journal publication of results
  - URL hyperlink(s) related to results and publications
  - Baseline Characteristics: Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. These data include demographics, such as age and sex, and study-specific measures.
  - Participant flow: Information to document the progress and numbers of research participants through each stage of a study in a flow diagram or tabular format.
  - Adverse events: An unfavorable change in the health of a participant, including abnormal laboratory findings, and all serious adverse events and deaths that happen during a clinical study or within a certain time period after the study has ended. This change may or may not be caused by the intervention being studied.
  - Outcome measures: A table of data for each primary and secondary outcome measure and their respective measurement of precision (eg a 95% confidence interval) by arm (that is, initial assignment of participants to arms or groups) or comparison group (that is, analysis groups), including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any.
  - URL link to protocol file(s) with version and date
  - Brief summary

- **IPD sharing statement**

  Statement regarding the intended sharing of deidentified individual clinical trial participant-level data (IPD). Should indicate whether or not IPD will be shared, what IPD will be shared, when, by what mechanism, with whom and for what types of analyses. It consists of:

  - Plan to share IPD (Yes, No)
  - Plan description

E. OSWESTRY DISABILITY INDEX

The information below on the questionnaire is extracted from the SRA-Lab ODI page (56).

0% to 20%: minimal disability:	The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting sitting and exercise.
21%-40%: moderate disability:	The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means.
41%-60%: severe disability:	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation.
61%-80%: crippled:	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
81%-100%:	These patients are either bed-bound or exaggerating their symptoms.

Instructions

"This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes your problem."

Section 1 – Pain intensity

- ☐ I have no pain at the moment
- ☐ The pain is very mild at the moment
- ☐ The pain is moderate at the moment
- ☐ The pain is fairly severe at the moment
- ☐ The pain is very severe at the moment
- ☐ The pain is the worst imaginable at the moment

Section 2 – Personal care (washing, dressing etc)

- ☐ I can look after myself normally without causing extra pain
- ☐ I can look after myself normally but it causes extra pain
- ☐ It is painful to look after myself and I am slow and careful
- ☐ I need some help but manage most of my personal care
- ☐ I need help every day in most aspects of self-care
- ☐ I do not get dressed, I wash with difficulty and stay in bed

Section 3 – Lifting

- ☐ I can lift heavy weights without extra pain
- ☐ I can lift heavy weights but it gives extra pain
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eg. on a table
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- ☐ I can lift very light weights
- ☐ I cannot lift or carry anything at all

Section 4 – Walking*

- ☐ Pain does not prevent me walking any distance
- ☐ Pain prevents me from walking more than 1 mile
- ☐ Pain prevents me from walking more than 1/2 mile
- ☐ Pain prevents me from walking more than 100 yards
- ☐ I can only walk using a stick or crutches
- ☐ I am in bed most of the time

Section 5 – Sitting

- ☐ I can sit in any chair as long as I like
- ☐ I can only sit in my favourite chair as long as I like
- ☐ Pain prevents me sitting more than one hour
- ☐ Pain prevents me from sitting more than 30 minutes
- ☐ Pain prevents me from sitting more than 10 minutes
- ☐ Pain prevents me from sitting at all

Section 6 – Standing

- ☐ I can stand as long as I want without extra pain
- ☐ I can stand as long as I want but it gives me extra pain
- ☐ Pain prevents me from standing for more than 1 hour
- ☐ Pain prevents me from standing for more than 30 minutes
- ☐ Pain prevents me from standing for more than 10 minutes
- ☐ Pain prevents me from standing at all

Section 7 – Sleeping

- ☐ My sleep is never disturbed by pain
- ☐ My sleep is occasionally disturbed by pain
- ☐ Because of pain I have less than 6 hours sleep
- ☐ Because of pain I have less than 4 hours sleep
- ☐ Because of pain I have less than 2 hours sleep
- ☐ Pain prevents me from sleeping at all

Section 8 – Sex life (if applicable)

- ☐ My sex life is normal and causes no extra pain
- ☐ My sex life is normal but causes some extra pain
- ☐ My sex life is nearly normal but is very painful
- ☐ My sex life is severely restricted by pain
- ☐ My sex life is nearly absent because of pain
- ☐ Pain prevents any sex life at all

Section 9 – Social life

- ☐ My social life is normal and gives me no extra pain
- ☐ My social life is normal but increases the degree of pain
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests eg, sport
- ☐ Pain has restricted my social life and I do not go out as often
- ☐ Pain has restricted my social life to my home
- ☐ I have no social life because of pain

Section 10 – Travelling

- ☐ I can travel anywhere without pain
- ☐ I can travel anywhere but it gives me extra pain
- ☐ Pain is bad but I manage journeys over two hours
- ☐ Pain restricts me to journeys of less than one hour
- ☐ Pain restricts me to short necessary journeys under 30 minutes
- ☐ Pain prevents me from travelling except to receive treatment

F. ROLAND MORRIS DISABILITY QUESTIONNAIRE

The information below on the questionnaire is extracted from the SRA-Lab RMDQ page (57). The score is given by the total number of items checked, ranging from 0 (no disability) to 24 (severe disability). Stratford et al cautioned in 1996 that assessing improvements in patients with an initial score lower than 4 or greater than 20 points could not be reliably detected (60).

Instructions

"When your back hurts, you may find it difficult to do some of the things you normally do. This list contains sentences that people have used to describe themselves when they have back pain. As you read the list, think of yourself today. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Only tick the sentence if it describes you today."

1. I stay at home most of the time because of my back.
2. I change position frequently to try and get my back comfortable.
3. I walk more slowly than usual because of my back.
4. Because of my back I am not doing any of the jobs that I usually do around the house.
5. Because of my back, I use a handrail to get upstairs.
6. Because of my back, I lie down to rest more often.
7. Because of my back, I have to hold on to something to get out of an easy chair.
8. Because of my back, I try to get other people to do things for me.
9. I get dressed more slowly then usual because of my back.
10. I only stand for short periods of time because of my back.
11. Because of my back, I try not to bend or kneel down.
12. I find it difficult to get out of a chair because of my back.
13. My back is painful almost all the time.
14. I find it difficult to turn over in bed because of my back.
15. My appetite is not very good because of my back pain.
16. I have trouble putting on my socks (or stockings) because of the pain in my back.
17. I only walk short distances because of my back.
18. I sleep less well because of my back.
19. Because of my back pain, I get dressed with help from someone else.
20. I sit down for most of the day because of my back.
21. I avoid heavy jobs around the house because of my back.
22. Because of my back pain, I am more irritable and bad tempered with people than usual.
23. Because of my back, I go upstairs more slowly than usual.
24. I stay in bed most of the time because of my back.

G. PAIN SELF-EFFICACY QUESTIONNAIRE

The Pain Self-Efficacy Questionnaire (PSEQ) (63) is a 10-item self-reported questionnaire that evaluates the strength with which patients with chronic pain believe in their ability to accomplish some activities despite their pain. Each item scores from 0 (not at all confident) to 6 (completely confident) on a 7-point Likert scale. SEQ scores range from 0 to 60, a higher score indicating stronger self-efficacy beliefs (87).

No MCID value is yet available for the PSEQ, despite its confirmed internal consistency and construct validity (90).

PSEQ Minimal Important Change (MIC), corresponding to the smallest change in score that patients perceive as important, has been estimated as 5.5 (9%) of the PSEQ score by Chiarotto et al 2016 study, with a 2.5 change for high PSEQ baseline scores, while a previous study had evaluated 9 points (90). Further research is needed to confirm MIC values.

PSEQ-2 & -4 are shorter versions of the PSEQ, used in time-pressured clinical settings and ranging from 0 to 12 or 24 respectively. Their MIC have been evaluated by Chiarotto et al as 1.5 for both, what represents a change of 13% and 6% respectively (90).

-10	-4	-2	PSEQ Statement
✓			I can enjoy things, despite the pain.
✓			I can do most of the household chores (e.g., tidying-up, washing dishes, etc.), despite the pain.
✓			I can socialise with my friends or family members as often as I used to do, despite the pain.
✓	✓		I can cope with my pain in most situations.
✓		✓	I can do some form of work, despite the pain. (“work” includes housework, paid and unpaid work).
✓	✓		I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite pain.
✓			I can cope with my pain without medication.
✓	✓		I can still accomplish most of my goals in life, despite the pain.
✓	✓	✓	I can live a normal lifestyle, despite the pain.
✓			I can gradually become more active, despite the pain.

H. PHYSICAL ACTIVITY READINESS QUESTIONNAIRE

The 2020 PAR-Q+ questionnaire (65) is available online http://eparmedx.com/ (66).

Please refer to the full online questionnaire for more details on the pages 2 & 3.

GENERAL HEALTH QUESTIONS

Please read the 7 questions below carefully and answer each one honestly: check YES or NO.	YES	NO
1) Has your doctor ever said that you have a heart condition ☐ **OR** high blood pressure ☐?	☐	☐
2) Do you feel pain in your chest at rest, during your daily activities of living, **OR** when you do physical activity?	☐	☐
3) Do you lose balance because of dizziness **OR** have you lost consciousness in the last 12 months? Please answer **NO** if your dizziness was associated with over-breathing (including during vigorous exercise).	☐	☐
4) Have you ever been diagnosed with another chronic medical condition (other than heart disease or high blood pressure)? **PLEASE LIST CONDITION(S) HERE:** _____	☐	☐
5) Are you currently taking prescribed medications for a chronic medical condition? **PLEASE LIST CONDITION(S) AND MEDICATIONS HERE:** _____	☐	☐
6) Do you currently have (or have had within the past 12 months) a bone, joint, or soft tissue (muscle, ligament, or tendon) problem that could be made worse by becoming more physically active? Please answer **NO** if you had a problem in the past, but it **does not limit your current ability** to be physically active. **PLEASE LIST CONDITION(S) HERE:** _____	☐	☐
7) Has your doctor ever said that you should only do medically supervised physical activity?	☐	☐

If you answered NO to all of the questions above, you are cleared for physical activity.
Please sign the PARTICIPANT DECLARATION. You do not need to complete Pages 2 and 3.

- Start becoming much more physically active – start slowly and build up gradually.
- Follow Global Physical Activity Guidelines for your age (https://apps.who.int/iris/handle/10665/44399).
- You may take part in a health and fitness appraisal.
- If you are over the age of 45 yr and NOT accustomed to regular vigorous to maximal effort exercise, consult a qualified exercise professional before engaging in this intensity of exercise.
- If you have any further questions, contact a qualified exercise professional.

PARTICIPANT DECLARATION
If you are less than the legal age required for consent or require the assent of a care provider, your parent, guardian or care provider must also sign this form.

I, the undersigned, have read, understood to my full satisfaction and completed this questionnaire. I acknowledge that this physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if my condition changes. I also acknowledge that the community/fitness center may retain a copy of this form for its records. In these instances, it will maintain the confidentiality of the same, complying with applicable law.

NAME _____ DATE _____

SIGNATURE _____ WITNESS _____

SIGNATURE OF PARENT/GUARDIAN/CARE PROVIDER _____

If you answered YES to one or more of the questions above, COMPLETE PAGES 2 AND 3.

Delay becoming more active if:

- You have a temporary illness such as a cold or fever; it is best to wait until you feel better.
- You are pregnant - talk to your health care practitioner, your physician, a qualified exercise professional, and/or complete the ePARmed-X+ at www.eparmedx.com before becoming more physically active.
- Your health changes - answer the questions on Pages 2 and 3 of this document and/or talk to your doctor or a qualified exercise professional before continuing with any physical activity program.

I. PATIENT HEALTH QUESTIONNAIRE - 9

The PHQ-9 questionnaire is a multipurpose instrument for screening, diagnosing, monitoring and measuring the severity of depression, described on the SRA-Lab PHQ-9 page (67).

PHQ-9 scores interpretation

- scores of 5, 10, 15, 20 → mild, moderate, moderately severe, severe depression.
- score ≥ 10 → sensitivity of 88% and specificity of 88% for major depression.

PHQ-9 Score	Provisional Diagnosis	Treatment Recommendation *Patient Preferences should be considered*
5-9	Minimal Symptoms*	Support, educate to call if worse, return in one month
10-14	Minor depression ++ Dysthymia* Major Depression, mild	Support, watchful waiting Antidepressant or psychotherapy Antidepressant or psychotherapy
15-19	Major depression, moderately severe	Antidepressant or psychotherapy
>20	Major Depression, severe	Antidepressant and psychotherapy (especially if not improved on monotherapy)

Over the past 2 weeks, how often have you been bothered by any of the following problems?	Not At all	Several Days	More Than Half the Days	Nearly Every Day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3
3. Trouble falling asleep, staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you're a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or, the opposite - being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
Column Totals	_____	+ _____	+ _____	
Add Totals Together	_____			

10. If you checked off any problems, how difficult have those problems made it for you to Do your work, take care of things at home, or get along with other people?

☐ Not difficult at all ☐ Somewhat difficult ☐ Very difficult ☐ Extremely difficult

J. WII FIT U YOGA EXERCISES

The Nintendo Wii Fit U console proposes a set of yoga exercises in the Wii U game (95), and the use of the Wii Balance Board is required to allow interactivity and motivational feedback.

The picture below presents the Wii Fit U yoga program, with the corresponding name of each exercise listed in the table below it. More information on each exercise is easily available on internet, via websites (96) or Youtube videos (97) (98) (99), especially the “Nintendo Thumb” Youtube channel that provides a short video for each Yoga Exercise (100).

Wii Fit U Yoga Exercises				
Deep Breathing	Half Moon	Warrior	Tree	Sun Salutation
Standing Knee	Palm Tree	Chair	Triangle	Downward Facing Dog
Dance	Cobra	Bridge	Spinal Twist	Shoulderstand
-	Spinal Extension	Gate	Grounded V	-

The last 4 exercises being harder to perform without guidance, they are excluded from the Wii Fit U home yoga program (shoulderstand, spinal extension, gate, and grounded V).

K. THERAPEUTIC EXERCISES

The therapeutic exercise program is composed of 9 exercises, all of which belong to the usual chronic LBP exercise program of the Bellvitge University Hospital rehabilitation service (75):

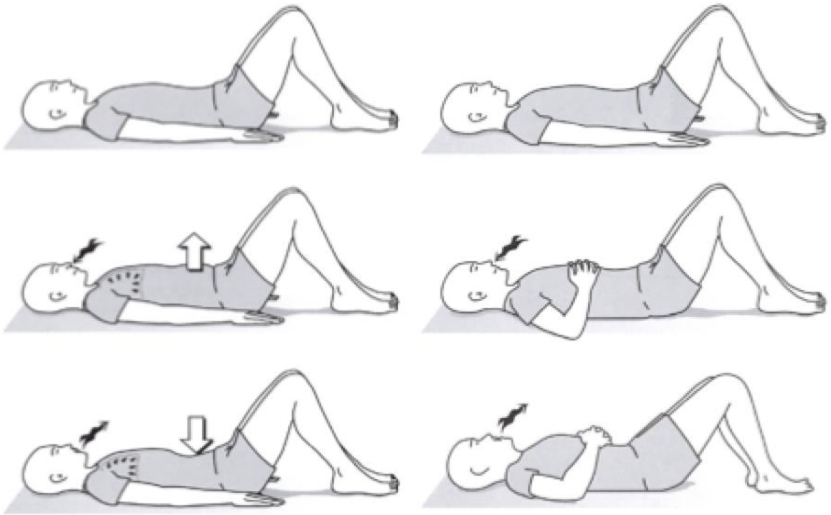
1) diaphragmatic breathing; 2) pelvic girdle; 3) supine spinal twist; 4) abdominal curl ups; 5) back extensors strengthening; 6) quadruped “cat camel” exercise; 7) quadruped opposite arm & leg lift; 7) front plank; 8) supine spinal; 9) glute bridge..

DIAPHRAGMATIC BREATHING

At inspiration, the subject breathes in slowly with the nose, until complete filling up of the lungs, trying to inflate through the belly. At expiration, he/she breathes out slowly with the mouth until having no air left in the lungs, trying to dig the belly in (“absorbing the ombilicus”).

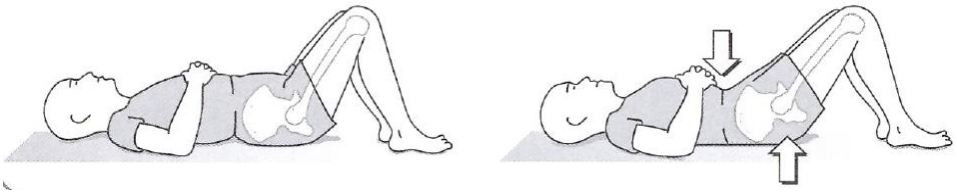
The participant is asked to try to extend the duration of the inhalation and exhalation so that they each last about 5 seconds, targeting an equal flow of air throughout the breathing cycle. The arms can stay relaxed on the floor, or the hands can be put on the thorax or belly to better feel the air coming in and out, the rib cage and belly up and down, with inflation and deflation.

This exercise should be done 15 times, what represents 2 to 3 minutes.



PELVIC GIRDLE

The subject should alternate in tilting the pelvis from neutral to retroversion by slightly lifting up the lower glutes from the floor while “rotating” the pubis toward the upper body. This position should be held for 5 seconds, then rest for 5 seconds. This should be repeated 5 times.



SUPINE SPINAL TWIST

Starting supine with flexed knees, and extended arms spread on each side of the body, the patient should slowly rotate the knees down to a side, keeping them joined, as far as his/her lumbar spine allows. The upper trunk and shoulders should remain grounded on the floor.

This position must be maintained for 10 seconds, then rest. It must be done 2 times.

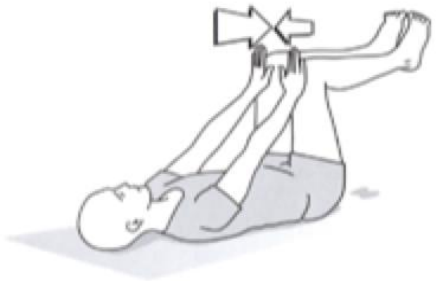
ABDOMINAL CURL UPS

A) The subject should raise the 90° flexed knees to a 90° hip flexion position, then gently push with extended arms both hands on knees, maintaining the position for 5 seconds (isometric), before resting for 5 seconds. This should be repeated 10 times.

B) The subject should raise the upper trunk from the floor, bringing the hands toward the knees, without flexing or putting too much tension on the cervical spine. This position should be held for 5 seconds, before resting 5 seconds, repeated 10 times.

C) The subject should place the hands behaind the head, arms open as widely as possible on the sides. He/she should bring one elbow toward the opposite knee, lifting the corresponding foot from the floor to bring the knee toward the elbow simultaneously. The other elbow and foot should remain stable on the floor. The subject should then slowly go back to the starting position, controlling the moving down to the floor, and alternate with the other elbow/knee side. This should be performed 10 times on each side.

A



B

C

EXTENSORS STRENGTHENING

A) The starting position is prone with a pillow under the belly to avoid lumbar hyperlordosis, arms extended above the head, legs extended and roughly joined. The pelvis should be kept slightly posteriorly tilted to reduce lumbar lordosis and put the abdominals in slight tension.

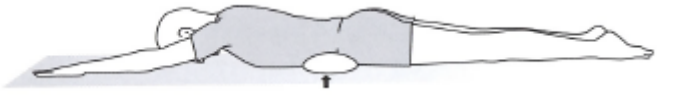
B) The subject should raise one arm and maintain the position for 5 seconds, before slowly putting it down, alternating with the other arm. This should be repeated 10 times for each arm.

C) The subject should raise one leg and maintain the position for 5 seconds, before slowly putting it down, alternating with the other leg. This should be repeated 10 times for each arm.

D) The subject should raise one arm and the opposite leg simultaneously, maintain them for 5 seconds, then alternating with the contralateral arm and leg. This should be repeated 10 times for each side.

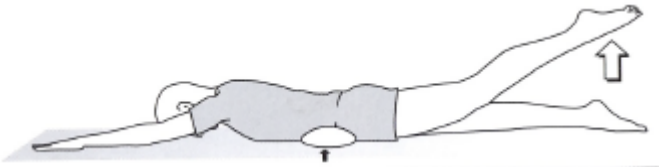
E) The hands should be joined on the forehead, the elbows spread out as widely as possible. The subject should slowly raise the upper trunk, keeping the legs firmly on the floor, maintain the position for 5 seconds, before slowly going back down. This should be repeated 5 times.

A)

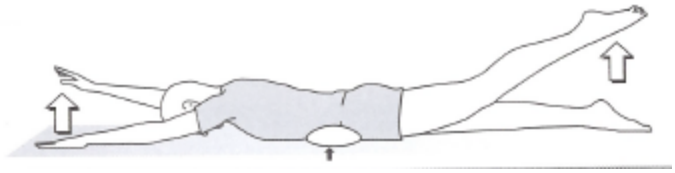


B)

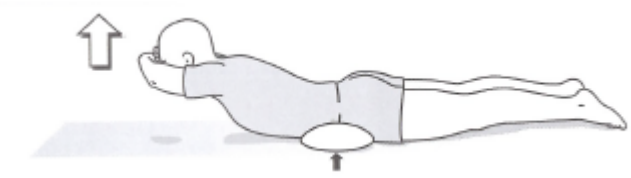
C)



D)



E)



QUADRUPED "CAT & CAMEL"

Starting from four point kneeling (on hands and knees, gaze down), the patient should alternate between a flat spine ("camel") to a pronounced lumbar kyphosis ("cat"), the cervical spine staying in a relatively relaxed and neutral position, and the lumbar spine never in lordosis. This should be repeated 20 times.

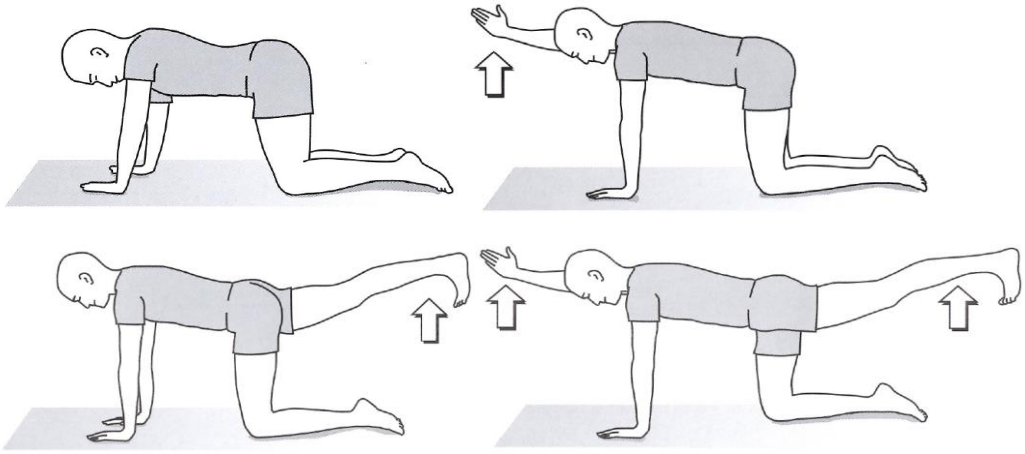
QUADRUPED OPPOSITE ARM & LEG LIFT

The starting position is in four point kneeling (on handls and knees, gaze down).

A) The subject should raise one arm and maintain the position for 5 seconds, then put it back down slowly and alternate with the other arm, with 10 repetitions for each arm.

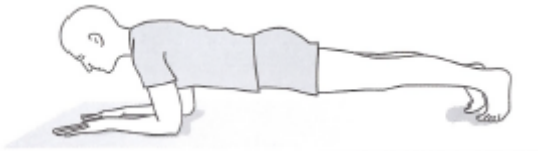
B) The subject should raise one leg, with the foot in full dorsiflexion, maintain the position for 5 seconds, then alternate with the other leg, with 10 repetitions for each leg.

C) The subject should raise one arm and the opposite leg simultaneously, maintain the position 5 seconds, then alternate with the other arm and leg, with 10 repetitions for each side.



FRONT PLANK

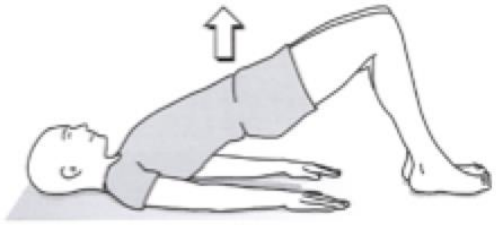
Starting from a prone position, with fully flexed elbows and dorsiflexed ankles, the patient lifts the entire body up to a plank position, the body weight supported by forearms and feet, keeping the gaze down between the hands. This exercise should be performed 3 times 30 seconds.



GLUTE BRIDGE

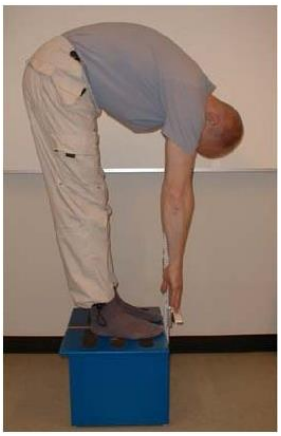
From a supine position with flexed knees, the subject should slowly raise the pelvis, with both extended arms resting firmly on the floor, the body weight distributed on the shoulders to avoid any excessive tension on the cervical spine.

This position should be held for 5 to 10 seconds, before going down very slowly, vertebra by vertebra, ending with the buttocks, with then a 5 seconds rest. Ideally, the subject should breath in while raising, and out while going down. This exercise should be repeated 5 times.



L. BACK FUNCTION TESTS: FINGERTIP-TO-FLOOR, SHIRADO & BIERING-SORENSEN

FTTF test (101)



Quack et al (2007)

Eur Spine J (2007); 16:803-812

Shirado test (trunk flexors endurance) (78)

Fransoo et al (2009)

Kinestither Rev (2009); 87:39-42

Biering-Sorensen test (trunk extensors endurance) (102)

Moradi et al (2009)

Eur Spine J (2009); 18:1041–1049

M. TAMPA SCALE FOR KINESIOPHOBIA

The TSK-17 questionnaire is composed of 17 items subjectively assessing fear of movement or re-injury due to physical activity (84) (85).

Each item scores from 1 (strongly disagree) to 4 (strongly agree) with a 4-point Likert scale. The total score is calculated after inversion of the individual scores of items 4, 8, 12 & 16.

The TSK-11, most widely used, is composed of a subgroup of 11 items with items 4, 8, 9, 12,14 and 16 removed from the original 17-item questionnaire. The total score is easier to calculate since it does not require any inversion.

-17	-11	TSK Statement
✓	✓	1. I'm afraid that I might injury myself if I exercise
✓	✓	2. If I were to try to overcome it, my pain would increase
✓	✓	3. My body is telling me I have something dangerously wrong
✓		4. My pain would probably be relieved if I were to exercise
✓	✓	5. People aren't taking my medical condition seriously enough
✓	✓	6. My accident has put my body at risk for the rest of my life
✓	✓	7. Pain always means I have injured my body
✓		8. Just because something aggravates my pain does not mean it is dangerous
✓		9. I am afraid that I might injure myself accidentally
✓	✓	10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening
✓	✓	11. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body
✓		12. Although my condition is painful, I would be better off if I were physically active
✓	✓	13. Pain lets me know when to stop exercising so that I don't injure myself
✓		14. It's really not safe for a person with a condition like mine to be physically active
✓	✓	15. I can't do all the things normal people do because it's too easy for me to get injured
✓		16. Even though something is causing me a lot of pain, I don't think it's actually dangerous
✓	✓	17. No one should have to exercise when he/she is in pain

N. INFORMED CONSENT

This informed consent is for adults with chronic non-specific low back pain who are invited to participate in the research project “Comparison of the effects on disability of Wii Fit U game-based home yoga

and supervised yoga programs versus therapeutic exercise in patients with non-specific chronic low back pain: a randomized controlled trial”.

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

PART I - INFORMATION SHEET

INTRODUCTION

I am a researcher from the Escola Universitaria de la Salut I l’Esport (EUSES), graduating in the international inter-university physiotherapy degree of the University of Girona (UdG) and the University of Barcelona (UB).

I am involved in a study on the reduction of disability for non-specific chronic low back pain (LBP) in adults following a 2 month therapeutic exercise program.

Before deciding to participate in this study**,** please read carefully this informed consent.

Remember that you can take all the time you need. If something is not clear or requires more explanations, please do not hesitate to ask me any question about the study.

STUDY FUNDING, SPONSORS AND SETTINGS

This trial is funded by the Bellvitge University Hospital (HUB), the Catalan Health Service (CatSalut), and the Generalitat de Catalunya (GenCat). It is sponsored by the EUSES, via the inter-university physiotherapy degree from the UdG and the (UB. The study will take place at the Bellvitge Campus of the University of Barcelona, in cooperation with the rehabilitation service of the Bellvitge University Hospital (46).

PURPOSE OF THE RESEARCH

The purpose of this study is to compare the effectiveness of different modalities of therapeutic exercises on chronic non-specific low back pain. It is a very common condition, that can affect people at any age, and now represents the leading cause of disability, even though no specific

structural cause can be identified in most cases. The current best treatment is a combination of pain education, advice to remain active, and therapeutic exercise. This study will compare 3 therapeutic exercise modalities: 1) Wii Fit U game-based home yoga, 2) supervised yoga, or 3) classic supervised exercise for LBP (control group).

TYPE OF RESEARCH INTERVENTION

This study is a “randomised controlled trial”, which means that after having consented to participation, you will be randomly allocated to one of the 3 study groups. Depending on your group, the treatment will be performed slightly differently, but in every case, you will be provided with the best treatment interventions for the treatment of chronic low back pain. This study compares the effect of each treatment modality, based on several assessments of your disability, flexibility, endurance, pain intensity, pain self-efficacy, fear of movement.

PARTICIPANT SELECTION

To be included in this study, you should be an adult (18 to 65 years old) with a non-specific chronic low back pain lasting for at least 3 months. This chronic pain should be non-specific, i.e., not associated with any specific pathology (fracture, osteoporosis, disc extrusion, lumbar stenosis, radiculopathy, spondylolisthesis, cauda equina syndrome, metastatic disease).
You should not have any diagnosis of chronic pain (fibromyalgia or complex regional pain syndrome), nor uncontrolled photosensitive epilepsy, nor central or peripheral nervous system condition (stroke, multiple sclerosis…), moderate to severe depression, cardiovascular risks nor any medical condition that could significantly limit your participation (eg knee injury).
You should not have ever undergone spinal, pelvis or hip surgery, nor corticosteroids injection in the past 6 months, nor currently be involved in another physiotherapy or exercise program. If you have pain-relief medications to help you cope with pain, you may continue to take it, we will only ask you to keep track of your daily doses to report any significant increase.

We will check that your disability score is neither too high nor too low to include you in the study, since high levels could mean that physiotherapy treatment is not the best indicated, and low levels would not allow to quantify a significant improvement. You pain self-efficacy score, meaning how much effort you feel able to tolerate despite you pain, will also be checked. If too low, you would not take part in the study.

We will also check that your English skills, hearing, vision, or cognition levels are sufficient to understand instructions, and that you show no technical limitation for the study, such as the absence of high-definition multimedia interface or compatible television at home, or of a smartphone compatible with the installation of the study mobile application.

VOLUNTARY PARTICIPATION

Your participation in this research is entirely voluntary and can be withdrawn at any time without need for justification. Take your time to check everything before deciding to participate or not, this should be your personal choice. And if you later change your mind and want to stop, you have the right to do it at any time, just let us know. If you want to participate, you will have to sign this informed consent.

PROCEDURES AND PROTOCOL

You will receive a ~1h preliminary session of pain education and advice to remain active, at the Bellvitge Campus of the University of Barcelona (UB).

Then, you will be provided a 1h to 2h tutoring session corresponding to the modality of the group you have been randomly assigned to, before a 2 month intervention with 3 sessions of 40-45 minutes per week of your assigned intervention. In group 1, the intervention will take place at your home, while in groups 2 & 3, they will take place at the UB. Several assessments will be performed before and after this 2 month intervention, as well as 3, 6 and 12 months afterwards. You will also be asked to download and install a mobile application to register your pain level before and after any session. This application will also track your physical activity via the number of daily steps, and we will ask you to keep it activated for the entire duration of the study (i.e., no only the 2 months interventions but also the 12 months follow-up).

If you are assigned to the group 1, you will be loaned a Nintendo Wii equipment (console, remote, balance board and Wii Fit U software) for the entire duration of the study, and a research assistant will come to your home to install it for you at the first session. You will be asked to return this equipment at the end of the study. Should you have any technical issues, technicians will be at your disposal to manage them (from Monday to Friday, 9am to 9pm).

Your program will consist of 3 sessions of 40-45 minutes per week of gentle therapeutic exercise for 2 months (hence a total of 24 sessions). Remember that the objective is to reduce your low back pain & disability, and that the tutoring session will ensure that you can perform them safely and autonomously.

This study will use the following tests to assess several outcomes:

- Oswestry Disability Index (ODI) → a questionnaire about your pain & disability
- Roland Morris Disability Questionnaire (RMDQ) → a questionnaire on your disability
- Fingertip-To-Floor test → your flexibility, i.e. distance from floor when bending
- Shirado & Biering-Sorensen tests → your timed endurance (trunk flexors & extensors)
- Numeric Pain Rating Scale (NPRS) → the level of your pain intensity, from 0 to 10

- Medication use significant increase over the last week (Yes/No)
- Tampa Scale for Kinesiophobia → your eventual back pain-related fear of movement
- Pain Self-Efficacy Questionnaire → your capacity to remain active despite the pain
- Adherence → the number of sessions you perform during the 2 month intervention
- Physical Activity → your number of daily steps, during intervention and follow-up

You will be assessed before and after the 2 month intervention, and then after one 3, 6 & 12 months. Do not hesitate to ask any question about these tests. None should be painful, and you will be able to stop at any time if you feel any discomfort.

RISK AND BENEFITS OF STUDY PARTICIPATION

During this study, you should benefit from a decrease in pain & disability, eventually fear of movement too, an increase in endurance & flexibility, and hopefully pain self-efficacy and physical activity as well. You will be provided with the best physiotherapy treatment options according to the current evidence, whatever groups you are allocated to.

The therapeutic exercise programs proposed in the 3 groups are very easy to perform, will be progressive and adapted to your capacities as required. You will learn how to perform them during a preliminary tutoring session with a physiotherapist who will be at your side to ensure you always feel comfortable doing them, and that you are performing them correctly.

There is no risk of negative side effects. If at any time you would feel that your condition is worsening and wish to stop, there is absolutely no problem with this, but usually there is only improvement of the pain and disability with these therapeutic modalities. We will be available during the entire duration of the study if you have any doubt.

CONFIDENTIALITY

Your personal data will be safely stored for the entire duration of the study, with an access strictly restricted to the study personnel only, with individual authentication.

Outcomes (disability, endurance, flexibility pain intensity, fear of movement, pain self-efficacy), general health information (gender, age, weight…) and some additional information (history of family LBP, use of medications, history of use of video games) will be recorded for the study purposes. They will allow to analyse a homogeneous distribution between the intervention & control groups, and for the analysis of the study results. They will be anonymised, and not communicated to third parties.

Only the research personnel will have access to your data with a confidential duty to keep it secret. You can access your data whenever you want, and you can check and correct it if needed. It will not be kept after the study analysis is completed and it is no longer needed.

SHARING THE RESULTS

The information collected as part of this research will not distributed to other research studies. We will let you know about the results of the study once they have been analysed. Then, this study will be published to inform people interested in the subject.

RIGHT TO REFUSE OR WITHDRAW

You have no obligation whatsoever to participate in this study.

Refusal to participate will have no impact on your usual treatment.

You also can discontinue your participation in the study at any time, for any reason that you do not need to justify, this will not affect your current or future medical care either.

WHO TO CONTACT

During the study, you can contact me or other researchers to ask any questions. We will be here to answer any of your doubts, by phone, mail or any appointment you would need.

This proposition of participation has been written and approved by the research team, making sure that research participants are protected from harm.

PART II - CERTIFICATE OF CONSENT

STATEMENT BY THE PARTICIPANT

I have read the above information, or it has been read to me by a researcher. I have had the opportunity to ask questions and have been answered to my satisfaction.

I consent voluntarily to participate in this research.

Print name of participant _____

Signature of participant _____

Date _____

STATEMENT BY THE RESEARCHER/PERSON TAKING CONSENT

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

(1) The participant will meet with a research worker 5 times over 14 months to be assessed about his/her chronic non-specific low back pain (before and after the 2 month intervention, then 3, 6 and 12 months afterwards).

(2) The participant will be allocated randomly to an intervention or control group. In any case, he or she will receive a first-line intervention for the treatment of his/her chronic LBP (based on education and advice to remain active combined to a modality of therapeutic exercise).

(3) The participant commits to perform 3 therapeutic exercise sessions 40-45 min per week for 8 weeks during the intervention, and then try to maintain a weekly session over 1 year.

(3) The participant commits to install the study mobile application on his/her phone, fill in the demanded information, and to return any loaned material at the end of the study.

I confirm that the participant was given an opportunity to ask questions about the study, that have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher _____

Signature of Researcher _____

Date _____