Official Title:

Interactive and Adapted Physical Exercise for the Remote Management of Chronic Low Back Pain

NCT number: Not Available

Unique Protocol ID: CLBPEO

Date: April 24th, 2023

Project Protocol

Experimental design

The study is an interventional proof-of-concept pilot study. Participants will be 45 people with CLBP aged 18 to 80 years who are able to consent, have no contraindication to physical activity, and can communicate, read, and understand French. Participants will be randomly divided into 3 groups: an interactive physical activity group, a video physical activity group, and a control group. Recruitment will be done from participant pools of multiple locations across Montréal and the province of Québec. The intervention will last 12 weeks and consist of 3 physical activity sessions per week for the intervention groups. The interactive group sessions will be interactive (and live) via Zoom and the video sessions will consist of be pre-recorded videos. The control group will be instructed to continue their lifestyle habits throughout the study.

Patient sample

For this study, participants will be adults between 18 years and 80 years of age, presenting with chronic low back pain (CLBP) for more than 6 months. Patients selected will need to respond to the criteria established by the Canadian minimum dataset for CLBP (Lacasse et al., 2017). Other inclusion criteria will include having an internet connection and access to a computer with webcam or tablet and be able to follow a physical activity program, which will be assessed with the Questionnaire sur l'Aptitude à l'Activité Physique (QAAP questionnaire). Individuals with a history of psychiatric or neurological illness will be excluded. Participants will not be eligible for the study if they have neuropathic signs (radiating pain that spreads to the knee and leg (http://www.physio-pedia.com/Red_Flags_in_Spinal_Conditions).

Participants will be recruited from: 1) the Quebec Pain Research Network (QPRN) participant pool (>3000 CLBP patients), 2) the *Centre de Recherche de l'Institut Universitaire de Gériatrie de Montréal* (CRIUGM) participant pool (>1000 seniors), 3) the Quebec Chronic Pain Association (QCPA) low back pain participant pool, 4) former participants of the laboratory's research projects who have agreed to be recontacted, 5) the pool of people with low back pain attending the *Institut universitaire sur la réadaptation en déficience physique de Montréal* and the *Clinique d'adaptation à la douleur chronique du Centre de réadaptation Lucie-Bruneau*. Participants will be randomly assigned to one of 3 groups.

Dependent variables

In addition to the inclusion criteria, assessments will be performed at weeks 0 (pre) and 12 (post-intervention) following a videoconference or telephone format and using lime-survey©. This mode of evaluation is done to make long-term implantation feasible and flexible for any geographical location, and also in case of restrictions, including due to weather or the current pandemic.

These assessments will measure:

1) CLBP intensity using the national Institutes of Health minimum (NIH) dataset. The primary outcome will be pain intensity perceived on average for the previous 7 days, reported in an 11-point numerical rating scale from 0 (no pain) to 10 (maximum imaginable pain)
2) CLBP outcomes from the NIH minimum dataset, including: 5 dimensions of pain history, 4 dimensions of medical interventions for CLBP, 4 dimensions of pain interference, 4 dimensions of physical function, 4 dimensions of depressive symptoms, 4 dimensions of sleep, 2 items on absenteeism due to

CLBP, Kinesiophobia, Pain catastrophizing, 2 items on substance abuse, 1 item on smoking and the patient's height and weight to calculate their body-mass index

3) Physical health (functional capacity: SPPB, unipodal balance, Timed Up and Go (TUG); physical performance: lower extremity power (10 repetition chair test, 30sec chair test), gait speed (4 minutes fastest possible gait). Patients will rate pain intensity before and after each of these tests in an 11-point numerical rating scale from 0 (no pain) to 10 (maximum imaginable pain)
4) Pain intensity before and after each session attended. Participants will be asked to rate in an 11-point numerical rating scale from 0 (no pain) to 10 (maximum imaginable pain), the low back pain intensity perceived while standing, lying down and walking, before and after each training session
5) Finally, the adherence (number of sessions; minimum threshold of 75% to be considered complete, and 66% or 4/6 sessions in the last two weeks) to both remote interventions will be assessed.

Independent variables

A computer application (random-number generator) will be used to generate a randomization sequence and thus assign each patient to one of the three groups. The intervention will last 12 weeks. Physical activity sessions for both intervention groups will take place 3 times per week (Monday, Wednesday, Friday) providing a total of approximately 180 min/week. The intensity of each session is categorized by levels 1, 2 or 3 and the allocation to this level is decided according to a decision tree taking into account the mobility profile of each participant (balance and cardiomuscular health).

Interactive physical activity group (IPA, n=15): The sessions will be provided to groups of about 10 people and will be interactive via the Zoom conference medium (the link will be sent to them by email). They will last 1h30 min and will consist of 60 min of physical activity, preceded and followed by 15 optional minutes of virtual social interaction with the kinesiologist and the other members of the group. This training mode will allow the kinesiologist to correct the participants in real time during the sessions while creating a sense of belonging. Finally, if the participants are unable to attend the group session, a video of the course given will be available for them to follow afterwards via a website.

Virtual physical activity group (VPA, n=15): The sessions will be conducted individually without interaction via pre-recorded videos. The videos are identical to those of courses given by the kinesiologist to the IPA group. Participants will be able to contact the kinesiologist by phone or email to ask questions about the sessions.

The control group (CTL, n=15) will be instructed to continue their lifestyle habits throughout the study. The interactive physical training program will be offered after the 12-week wait. Participants in the control group will follow the training regimen of the IPA group.

Procedures

The study will have a total estimated duration of two years, during which each patient will participate in 36 sessions divided into 3 weekly sessions for 12 weeks. The research protocol consists of several stages. Initially, participants are contacted via telephone and administered a questionnaire. If they are deemed eligible for the study, they proceed to the next stage, otherwise, their participation is terminated at this stage. Participants who are eligible for the study are then given access to LimeSurvey, an online

survey platform to provide questionnaire data. Eligible participants undergo an online physical evaluation via the Zoom platform, which also serves to confirm their recruitment. Only participants who successfully meet the inclusion criteria after completing the physical evaluation proceed to the next stage.

At this point, participants are randomly allocated to either be placed on a waiting list, given access to receive videos (group VPA), or assigned to participate in the interactive Zoom classes (group IPA). Those on the waiting list are contacted for a final online evaluation at a later date. Participants in the VPA group are given access to a video platform and contacted for a final evaluation at a later date. Participants assigned to the IPA group are managed by Neuromotrix, a team of kinesiologists specialized in adapted physical activity. Neuromotrix provides them with three Zoom meetings per week and a reminder email on Sundays prior to every week. These participants are also contacted for an online final evaluation at a later date. All participants undergo a final physical assessment on the date of the final evaluation, after which they complete a final questionnaire on LimeSurvey.

Statistical analysis plan

Homoscedasticity will be verified using the Levene test. Descriptive statistics will be employed to define the sample characteristics. The main outcome variable (average pain intensity due to CLBP) will be compared between groups (IPA, VPA and CTL) over time at the primary endpoint (baseline and week 12) using a mixed analysis of variance (ANOVA). Other secondary outcomes will be similarly examined by using mixed ANOVAs to compare groups and effects. Age, gender and baseline pain intensity will be used as covariates. For exploratory purposes, changes in pain intensity (delta = post – pre)

before and after each session will be averaged across sessions and the means compared within and between groups to evaluate acute changes in pain intensity (positive or negative) immediately after the exercise session. In addition, the mean rate of attendance to sessions in the IPA and VPA groups will be compared by means of a non-paired t-test to interpret adherence data.

References

Lacasse A, Roy JS, Parent AJ, Noushi N, Odenigbo C, Page G, Beaudet N, Choiniere M, et al. (2017), The Canadian minimum dataset for chronic low back pain research: a cross-cultural adaptation of the National Institutes of Health Task Force Research Standards. CMAJ Open 5:E237-E248.