ISRCTN59420095 https://doi.org/10.1186/ISRCTN59420095

Trunk bending improvement in people with low back pain through a virtual reality experience

Submission date
01/03/2022

Recruitment status
No longer recruiting

Registration date
29/03/2022

Overall study status
Completed

Last Edited
04/10/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Expectations of either pain relief or worsening, previous experiences, beliefs and contextual cues affect the perception of pain. Negative expectations can lead to behavioural and physiological responses which worsen motor performance (movement) and reinforce pain endurance.
For instance, chronic low back pain involves abnormal activity of the erector spinal muscle. This muscle contraction results in a reduction of lumbar (lower spine) mobility during trunk flexions (bending).
This phenomenon is useful to protect the body from any further injuries during the acute inflammatory phase, but if it is maintained when the symptoms disappear it can cause the person to avoid certain activities such as trunk flexions. This initial protective mechanism could keep the pain process in the chronic phase resulting in reduced mobility.
Expectations play a major role in pain perception and can be affected by the presence or absence of contextual cues such as positive self-beliefs, personal and clinical good relations or pleasant care environments. Immersive virtual reality (IVR) can be used to manipulate contextual cues and experience by placing the individual in a virtual environment. The 'real feel' of the IVR is a powerful element that is likely to help change expectations beyond the state-of-the-art of clinical solutions for the management of pain.
This study is focused on using IVR to change the contextual cues and experiences in people with chronic low back pain. The aim is to shift their expectations from negative to positive, improving pain perception.

Who can participate?
Participants aged between 18 and 75 years affected by chronic low back pain for at least 3 months

What does the study involve?
Participants will be randomly divided into three groups: the neutral expectation group, the positive expectation group and the ositive expectation group + visual-haptic illusion group. All participants in every group will perform a series of trunk flexions pointing toward the floor while immersed inside a virtual reality application. The three groups will be manipulated with different verbal stimuli (neutral or positive) and different perceptive experiences in IVR (e.g., the

sensation of touching the floor) related to their trunk mobility. The distance reached from the floor by the hand will be measured through a digital meter. Individuals' expectations of their movement capacity will be also measured.

What are the possible benefits and risks of participating?
This study poses no potential health risks for the participants as it involves a simple physical exercise in a controlled virtual reality environment. Should the participants experience feelings of nausea or muscle pain, they will be free to withdraw from the experiment.

Where is the study run from?
University of Genova (Italy)

When is the study starting and how long is it expected to run for?
March 2020 to November 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Marco Testa PT, PhD
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
REHELAB.VR.0001

Study information

Scientific Title
Trunk flexion improvement in people with low back pain through visual-haptic illusion: a randomised controlled trial

Study objectives
Positive expectations of trunk flexion capacity, driven by positive verbal statements and reinforced by perceptive experience, can improve and augment the amplitude of trunk flexion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/11/2020, Ethics Committee for University Research (CERA: Comitato Etico per la Ricerca di Ateneo, University of Genova, Via Balbi, 5, 16126 Genova, Italy; +39 (0)10/209 51841; presidente.cera@unige.it), ref: CERA2020.23

Study design
Single-centre interventional triple-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Low back pain

Interventions
Sixty participants with chronic low back pain will be randomly divided by simple randomisation using a random sequence generator into three groups of equal numbers before beginning the selection process. Group allocations will be sealed in consecutively numbered opaque envelopes by a member of the research team not involved in the recruitment, assessment, or treatment of participants. Furthermore, the statistician will be blinded to the assigned groups.

After the initial screening (inclusion criteria), a fictitious clarification of the study will be provided to all participants once they arrive at the laboratory:

"The goal of this study is to evaluate whether virtual reality can be used as a tool to measure in real-time changes in the mobility of the spinal column. We will take the measurements both with a digital laser meter and with the virtual reality system to see how much difference there is between the accuracy of these two assessments."

This explanation will be provided to cover the real purpose of this study, involving the administering of positive expectations induced by verbal and visual haptic stimuli to improve trunk flexion through immersive virtual reality manipulation. The real aim of the study will be disclosed to each participant only at the end of the experiment. Informed consent will be presented in written form to all participants before the experiment.

The following scales and questionnaires will be administrated to the participants:
1. Visual Analogue Scale (VAS)
2. Roland and Morris Disability Questionnaire (RMDQ)
3. Fear-Avoidance Belief Questionnaire (FABQ)
4. General Self-Efficacy Scale (GSE)
5. Pain Catastrophising Scale (PCS)
6. The 27 Item Coping Strategies Questionnaire-Revised (CSQ-R-I)
7. Acceptance and Action Questionnaire – II (AAQ-II)
8. Hospital Anxiety and Depression Scale (HADS)
9. Five-point Likert scale about the expectation to improve their trunk flexion after (sham) physiotherapeutic treatment

Subsequently, participants will receive a detailed explanation of the main experimental task performed in an immersive virtual reality (IVR) environment consisting of a sequential series of trunk flexions. The trunk flexions will be executed by maintaining the knees, the elbows and the fingers extended, reaching a target represented by a black "X" mark located to a distance of 20 cm from the tip of the toes, positioned in parallel along a straight line on the floor. The distance from the floor reached by the participant in every repetition will be measured using a digital laser meter held between their hands, precisely the top of it will be positioned under the distal phalanx of the middle fingers.
The virtual environment will be composed by two scenarios with a lounge background music: (S1) a realistic 1:1 scale virtual reconstruction of the laboratory where the experimental trial will be held, with the possibility to modify the vertical point of view of the user to give the impression of a deeper movement; (S2) a neutral scenario characterised by a black loading screen and a higher volume of the music to hide the actions of the experimenter during the perceptive manipulation in virtual reality.
After the initial explanation, in the familiarisation phase, participants will be immersed in the IVR scenario. They will execute a series of trunk flexions to adjust for the eventual mobility gain related to the continuous repetitions of the task. This initial warm-up will be performed according to the subsequent protocol:
1. Fifteen trunk flexions, of which the last five are used to calculate the interquartile range (IQR) of the distances reached from the floor
2. Ten-second pause
3. Five trunk flexions, from which an average value is calculated
4. If the average value is inside the calculated interquartile range (IQR), the familiarisation phase finishes as the participants have reached their maximal trunk flexion capacity (if the average value is outside the calculated IQR, the familiarisation phase continues, a new IQR is calculated from the lastest five repetitions and a new series of trunk flexions is performed until the stop criteria are met).

After a 1-minute pause (without the IVR system on), participants will be randomly allocated to one of three possible groups to execute the main experimental task across four sequential phases (baseline, intervention, after-effect and follow-up) as described below. The groups will be the neutral group (called G0), the positive expectation group (called G+) and the positive expectation + visual-haptic illusion group (called G++). All groups will receive a sham physiotherapy treatment, but this manoeuvre will be accompanied by a neutral statement about its effectiveness in the G0 group, by a positive statement about its efficacy in the G+ group, and by a positive statement about its efficacy to increase the trunk flexion and a visual-haptic illusion created through the virtual reality system in the G++ group.

Four experimenters will be present in the laboratory where the study will occur. For the sake of clarity, they will be called A, B, C and D. Two of them (A and B) will be aware of which group

participants belong to only when they enter the laboratory. Experimenter A will guide the experimental trial and execute the sham physiotherapeutic manoeuvre. Experimenter B will control the virtual scenario from the PC workstation. The third trialist (C) will take the participant's personal data and transcribe the distance reached from the floor in each condition. The fourth experimenter (D) will always read the laser meter display. During each condition in which the participants execute the trunk flexions, trialist D will communicate to trialist C the distance from the floor reached per each trunk flexion. The distance reached will be communicated by writing them on paper not to influence the participants.

NEUTRAL EXPECTATION GROUP (G0)
Baseline:
Experimenter D will enter the laboratory, and participants will execute five forward flexions in the S1 scenario. The level of the virtual floor will be maintained at the same level as the real one. At every flexion performed by the participant, the distance from the floor is registered using the digital meter and annotated by experimenter D. Subsequently, experimenter D will leave the laboratory.

Intervention
Immediately after the Baseline, the S2 scenario will be displayed. A movable floor panel will be raised by 10 cm from the floor during this period. Note that this action is performed to remove any possible indication to experimenter D about the participant group. Thereafter, in the S1 scenario, participants will receive a sham physiotherapy manoeuvre by experimenter A, accompanied by the following neutral verbal statement: “I am going to apply pressure on four different points of your back, after which we will resume the measurement.”
The pressure will be standardised through a digital algesimeter as 40 N for ten sec. in four specific bones sites not directly involved in the back movement:
1. Left and right summit of the iliac crest (laterally)
2. Left and right medial margin of the spine scapulae
Subsequently, participants will execute five forward flexions. The level of the virtual floor will be maintained at the same level as the real one, and the exercise will be performed toward a not raised floor panel.

After-effect
Immediately after the intervention, the S2 scenario will be displayed for 10 seconds. Thereafter, experimenter D will enter the laboratory, and in the S1 scenario, participants will perform five forward flexions. The level of the virtual floor will be maintained at the same level as the real one, and the exercise will be performed toward a not raised floor panel. Subsequently, experimenter D will leave the laboratory.

Follow-Up
Subsequently to the After-Effect, the S2 scenario will be displayed for 5 minutes. During this period, after lowering the movable floor panel, the participants will be allowed to remove the IVR system momentarily. Thereafter, experimenter D will enter the laboratory, and in the S1 scenario, participants will perform five forward flexions. The level of the virtual floor will be maintained at the same level as the real one, and the exercise will be performed toward a not raised floor panel. Subsequently, experimenter D will leave the laboratory.

POSITIVE EXPECTATION GROUP (G+)
Baseline:
Experimenter D will enter the laboratory, and participants will execute five forward flexions in the S1 scenario. The level of the virtual floor will be maintained at the same level as the real one. At every flexion performed by the participant, the distance from the floor is registered using the

digital meter and annotated by experimenter D. Subsequently, experimenter D will leave the laboratory.

Intervention
Immediately after the baseline, the S2 scenario will be displayed. A movable floor panel will be raised by 10 cm from the floor during this period. Note that this action is performed to remove any possible indication to experimenter D about the participant group. Thereafter, in the S1 scenario, participants will receive a sham physiotherapy manoeuvre by experimenter A, accompanied by the following positive verbal statement: “Through this manoeuvre, I will treat the main trigger points that could reduce the flexibility of the spine, and by stimulating them, your mobility will increase, and you will be able to bend forward more.” The pressure will be standardised through a digital algesimeter as 40 N for ten sec. in four specific bones sites not involved in the back movement:
1. Left and right summit of the iliac crest (laterally)
2. Left and right medial margin of the spinal scapulae
Participants will be asked to express their prior expectations towards the upcoming task concerning the received manoeuvre using a 5-point Likert-type scale:
Q - “The treatment performed will affect the mobility of my back.”
A - “0 Completely disagree / 1 More in disagreement than in agreement / 2 I do not know / 3 More in agreement than in disagreement / 4 Completely agree”
Subsequently, participants will execute five forward flexions. The level of the virtual floor will be maintained at the same level as the real one, and the exercise will be performed toward a not raised floor panel.

After-effect
Immediately after the intervention, the S2 scenario will be displayed for 10 seconds. Thereafter, in the S1 scenario, participants will be asked to express their prior expectation toward the upcoming task about the received manoeuvre using a 5-point Likert-type scale:
Q - “The treatment performed will affect the mobility of my back.”
A - “0 Completely disagree / 1 More in disagreement than in agreement / 2 I do not know / 3 More in agreement than in disagreement / 4 Completely agree”
Subsequently, experimenter D will enter the laboratory, and in the S1 scenario, participants will perform five forward flexions. The level of the virtual floor will be maintained at the same level as the real one, and the exercise will be performed toward a not raised floor panel.
Subsequently, experimenter D will leave the laboratory.

Follow-up
Immediately after the intervention, the S2 scenario will be displayed for 5 minutes. During this period, after lowering the movable floor panel, the participants will be allowed to remove the IVR system momentarily. Thereafter, in the S1 scenario, participants will be asked to express their prior expectation toward the upcoming task concerning the received manoeuvre using a 5-point Likert-type scale:
Q - “The treatment performed will affect the mobility of my back.”
A - “0 Completely disagree / 1 More in disagreement than in agreement / 2 I do not know / 3 More in agreement than in disagreement / 4 Completely agree”
Subsequently, experimenter D will enter the laboratory, and in the S1 scenario, participants will execute five forward flexions. The level of the virtual floor will be maintained at the same level as the real one, and the exercise will be performed toward a not raised floor panel.
Subsequently, experimenter D will leave the laboratory.

VISUAL-HAPTIC ILLUSION + POSITIVE VERBAL EXPECTATION GROUP (G++)
Baseline:

Experimenter D will enter the laboratory, and participants will execute five forward flexions in the S1 scenario. The virtual floor level will be maintained at the same level as the real one. At every flexion performed by the participant, the distance from the floor is registered using the digital meter and annotated by experimenter D. Subsequently, experimenter D will leave the laboratory.

Intervention
Immediately after the baseline, the S2 scenario will be displayed. During this period, a movable floor panel will be raised at a specific height to allow the participant to touch its surface (as measured during the baseline phase). Thereafter, in the S1 scenario, participants will receive a sham physiotherapy manoeuvre by experimenter A, accompanied by the following positive verbal statement: “Through this manoeuvre, I will treat the main trigger points that could reduce the flexibility of the spine, and by stimulating them, your mobility will increase, and you will be able to bend forward more.” The pressure was standardised through a digital algesimeter as 40 N for ten sec. in four specific bones sites not directly involved in the back movement:
1. Left and right summit of the iliac crest (laterally)
2. Left and right medial margin of the spine scapulae
Participants will be asked to express their prior expectations toward the upcoming task about the received manoeuvre using a 4-point Likert-type scale:
Q - “The treatment performed will affect the mobility of my back.”
A - “0 Completely disagree / 1 More in disagreement than in agreement / 2 I do not know / 3 More in agreement than in disagreement / 4 Completely agree”
Subsequently, participants will execute five forward flexions. The level of the virtual floor will be set at the same level as the raised floor panel, and the exercise will be performed towards the raised floor panel.

After-effect
Immediately after the intervention, the S2 scenario will be displayed for 10 seconds. Thereafter, in the S1 scenario, participants will be asked to express their prior expectation toward the upcoming task about the received manoeuvre using a 5 point Likert-type scale:
Q - “The treatment performed will affect the mobility of my back.”
A - “0 Completely disagree / 1 More in disagreement than in agreement / 2 I do not know / 3 More in agreement than in disagreement / 4 Completely agree”
Subsequently, experimenter D will enter the laboratory, and in the S1 scenario, participants will perform five forward flexions. The level of the virtual floor will be maintained at the same level as the real one, and the exercise will be performed toward a not raised floor panel. Subsequently, experimenter D will leave the laboratory.

Follow-up
Immediately after the intervention, the S2 scenario will be displayed for 5 minutes. During this period, after lowering the movable floor panel, the participants will be allowed to remove the IVR system momentarily. Thereafter, in the S1 scenario, participants will be asked to express their prior expectation toward the upcoming task concerning the received manoeuvre using a 5-point Likert-type scale:
Q - “The treatment performed will affect the mobility of my back.”
A - “0 Completely disagree / 1 More in disagreement than in agreement / 2 I do not know / 3 More in agreement than in disagreement / 4 Completely agree”
Subsequently, experimenter D will enter the laboratory, and in the S1 scenario, participants will execute five forward flexions. The level of the virtual floor will be maintained at the same level as the real one, and the exercise will be performed toward a not raised floor panel. Subsequently, experimenter D will leave the laboratory.

Intervention Type
Other

Primary outcome(s)
The distance reached from the floor measured by a digital laser meter at every trunk flexion at baseline, after-effect and follow-up

Key secondary outcome(s))
The participants' a priori expectation regarding their ability to perform the main experimental task as the consequence of the sham physiotherapy treatment, measured using a five-point Likert scale. In particular, participants will express their agreement on the following displayed statement “The treatment performed will affect the mobility of my back” and they will sign to what extent they agree through a 5 point Likert-type scale (0 – “Completely disagree” / 1 “More in disagreement than in agreement” / 2 “Neither in disagreement nor in agreement” / 3 “More in agreement than in disagreement” / 4 “Completely agree”). The Likert Scale will be presented after the sham treatment in G+ and G++ groups, and before the trunk flexions.

Completion date
30/11/2022

Eligibility

Key inclusion criteria
1. Participants must be aged between 18 and 75 years
2. Participants must be affected by low back pain at least for 3 months
3. Low back pain must represent the main musculoskeletal disease
4. Participants must report a pain comprised between 2 and 6 in the last 2 weeks on a scale of 0 to 10
5. Participants must score at least 4 on the Morris Disability Questionnaire

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 13/09/2022:
1. Participants that reach the floor during the trunk flexion
2. Participants that report to have or have had spinal pathologies (e.g., cancer, infections, fractures, systemic inflammatory disorders, etc)

3. Participants that underwent surgery on the spine, chest, pelvis or lower limbs in the last year
4. Participants that have screws or other objects implanted as a consequence of a surgery
5. Participants that report musculoskeletal damages to the lower limbs or spine in the last 3 months
6. Participants that report neurological disorders (e.g., amyotrophic lateral sclerosis, stroke, Alzheimer's, etc)
7. Participants that report psychiatric disorders (e.g., schizophrenia) or taking psychotropic drugs (e.g., antipsychotics)
8. Participants with visual impairments not correctable with lenses or spectacles
9. Participants that taken muscle relaxants in the last 30 days and anti-inflammatories in the last 5 days
10. Pregnant participants or those that have given birth in the last 6 months

Previous exclusion criteria:
1. Participants that reach the floor during the trunk flexion
2. Participants that report to have or have had spinal pathologies (e.g., cancer, infections, fractures, systemic inflammatory disorders, etc)
3. Participants that underwent surgery on the spine, chest, pelvis or lower limbs in the last year
4. Participants that have screws or other objects implanted as a consequence of a surgery
5. Participants that report musculoskeletal damages to the lower limbs or spine in the last 3 months
6. Participants that report neurological disorders (e.g., amyotrophic lateral sclerosis, stroke, Alzheimer's, etc)
7. Participants that report psychiatric disorders (e.g., schizophrenia) or taking psychotropic drugs (e.g., antipsychotics)
8. Participants with visual impairments not correctable with lenses or spectacles
9. Participants that taken muscle relaxants in the last 30 days and anti-inflammatories in the last 5 days
10. Participants that received therapy or a treatment for the low back pain in the last month
11. Pregnant participants or those that have given birth in the last 6 months

Date of first enrolment
06/07/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Italy

Study participating centre
REHELab (University of Genoa)
University Campus of Savona
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Sponsor information

Organisation
University of Genoa

ROR
https://ror.org/0107c5v14

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be anonymised and available upon request from the principal investigator Marco Testa (marco.testa@unige.it). Access to the data can be requested by qualified researchers engaging in independent scientific research and will be provided under a data sharing agreement (DSA) following review and approval of a research proposal together with a statistical analysis plan.

IPD sharing plan summary
Available on request