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Title: Pain Education and Virtual Reality improves pain, pain-related fear of movement, and trunk kinematics in individuals with persistent low back pain.

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Abstract

Objectives: To evaluate the effect of combining pain education and virtual reality exposure therapy using a cognitive behavioural therapy-informed approach (VR-CBT) on pain intensity, fear of movement, and trunk movement, in individuals with persistent low back pain.

Methods: Thirty-seven participants were recruited in a single cohort repeated measures study, attending three sessions one week apart. The VR-CBT intervention included standardised pain education (Session 1), and virtual reality exposure therapy (Session 2) incorporating gameplay with mixed reality video capture and reflective feedback of performance. Outcome measures (Pain intensity, pain-related fear of movement (Tampa Scale of Kinesiophobia), and trunk kinematics during functional movements (maximum amplitude, peak velocity) were collected at baseline (Session1), and one week following education (Session 2) and virtual reality exposure therapy (Session 3). One-way repeated measures ANOVAs evaluated change in outcomes from baseline to completion. Post-hoc contrasts evaluated effect sizes for the education and virtual reality components of VR-CBT.

Results: Thirty-four participants completed all sessions. Significant ($p<0.001$) reductions were observed in Mean(SD) pain (baseline 5.9(1.5); completion 4.3(2.1)) and fear of movement (baseline 42.6(6.4); completion 34.3(7.4)). Large effect sizes (Cohen's *d*) were observed for education (pain intensity 0.85; fear of movement 1.28) while the addition of virtual reality exposure therapy demonstrated very small insignificant effect sizes, (pain intensity 0.10; fear of movement 0.18). Peak trunk velocity, but not amplitude, increased significantly ($p<0.05$) across trunk movement tasks.

Discussion: A VR-CBT intervention improved pain, pain-related fear of movement, and trunk kinematics. Further research should explore increased VR-CBT dosage and mechanisms underlying improvement.

Keywords: Low back pain; Virtual Reality; pain science education; kinesiophobia; kinematics

Introduction

Persistent low back pain (LBP) is the greatest contributor to disability[1] and the leading cause of Australian injury burden.[2] $4.8B is spent annually managing LBP in Australia alone.[3] Forty-three percent of individuals with acute low back pain transition to persistent LBP and nearly one third do not recover by 12 months.[4]

Management of persistent LBP is challenging and multifactorial. Current evidence recommends incorporating therapeutic exercise (aimed at restoring optimal movement) with Pain Science Education (PSE).[5] Appropriate PSE steers individuals away from traditionally held biological understandings of pain to acknowledge social, environmental, and psychological contributions, in addition to the physiological changes to the nervous system. PSE assists individuals to scrutinise and re-conceptualise unhelpful illness beliefs and maladaptive pain cognitions, enabling individuals to take positive steps towards active self-management. Combining therapeutic exercise and PSE provides greater improvements in pain and disability compared to usual care[6,7] and facilitates graded movement exposure using a cognitive behavioural approach.[7]

Immersive Virtual Reality (VR) is increasingly being used in pain rehabilitation[8,9] with demonstrated effectiveness in decreasing pain[10-16], pain-related fear of movement[17,18,16] and kinematics[19] in individuals with persistent LBP. Benefits of VR include simulating engaging environments in game-like scenarios[20,21], and reducing pain-related fear through graded exposure to activity[22,14,19]. Purported mechanisms for VR interventions in persistent pain populations include immersive distraction, positive interactivity, and embodiment of a virtual avatar[21]. VR interventions for persistent LBP have utilised both behavioural therapy interventions (incorporating pain education and behavioural approaches)[12,13], and

interventions stimulating movement[22,14,19] including performance feedback.[23] However, only one study by Eccleston et al has been identified whereby both PSE and interventions specifically targeting trunk movement were combined.[18] Individuals underwent a 6 to 8-week program (total 30 sessions) incorporating PSE delivered by a virtual mentor, in addition to a graded movement-based activity that involved picking and stacking fruit. Significant improvements in pain-related fear of movement and pain were demonstrated, however, there was no specific feedback of movement performance apart from a visual metaphor in the form of a growing plant indicating progress in the "fruit picking" activity.

Given that increased lumbar movement during VR has been previously demonstrated in individuals with persistent LBP[19], an interventional approach combining PSE, VR gameplay encouraging graded increases in lumbar movement, and movement performance feedback during VR is indicated. This approach could facilitate stronger engagement with PSE principles, whereby pain and movement are discussed in relation to the purported mechanisms of VR that impact them (including context, distraction, immersion, and emotion). Positive reinforcement of desirable movement patterns (i.e., decreased trunk stiffness, increased lumbar bending) achieved during VR gameplay and guided reflection on pain experienced throughout these movements using a cognitive behavioural therapy-informed approach could augment the effectiveness of VR to improve pain, pain-related fear of movement, and movement. This study therefore aimed to evaluate the short-term effects of a physiotherapist-led Virtual Reality-based Cognitive Behavioural Therapy (VR-CBT) intervention on pain, pain-related fear of movement, trunk kinematics, and activity levels, in individuals with persistent LBP.

Materials and Methods

Study Design: This study was a single cohort repeated measures study conducted between July 2021 and February 2023. It was prospectively registered as a clinical trial at ANZCTR (Trial ID: ACTRN12621000455864) on 19/04/2021 and received ethics approval through the administering Human Research Ethics Committee (HREC/2021/QRBW/73003). This paper was prepared in accordance with The Strengthening the Reporting of Observational studies in Epidemiology (STROBE) Guidelines.[24]

Participants: A single cohort of 37 individuals (18-65 years) were recruited through 1) attendance at physiotherapy clinics at the Royal Brisbane and Women's Hospital (RBWH) Physiotherapy Department or clinical appointments at the Tess Cramond Pain and Research Centre; and 2) through response to staff or social media advertising. Participants with LBP (≥3 months duration) were eligible for inclusion if they demonstrated evidence of at least medium pain-related fear of movement (≥35 on Tampa Scale of Kinesiophobia)[25], at least moderate LBP-related disability (≥22% on Oswestry Disability Index)[26], and minimum average pain in the preceding seven days of 3/10 on a numerical rating scale (anchored by 0: no pain, and 10: pain as bad as it could be). Exclusion criteria included current pregnancy, medical disorders contra-indicating physical exercise, specific back muscle training or pain education within the last 6 months, or non-English speaking requiring an interpreter. Individuals assessed via clinical examination or medical history as having specific diagnoses impacting forward bending (e.g., unstable spondylolisthesis, disc herniation), back pain of a non-musculoskeletal origin, or severe neurological deficit or symptoms (e.g., cauda equina syndrome, myelopathy, or evidence of nerve root compromise) were also excluded. A sample size of 34 was calculated to detect significant reduction in pain-related fear of movement (between baseline alone and post-VR-CBT time points) with a power of 0.80, alpha of 0.05, and large effect size (d=0.8), assuming a conservative correlation between repeated measures

of r=0.5. An effect size of d=0.8 was considered reasonable given that larger effect sizes (d=1.49-1.72) for pain-related fear of movement have been demonstrated in longer (8-week) cognitive behavioural rehabilitation interventions for persistent LBP.[27,28]

Outcomes Measures:

Primary Outcomes:

Pain Intensity: Average pain level (over the preceding 7 days) was recorded on an 11-point numeric rating scale (0-10), anchored by 'no pain' (0) and 'pain as bad as it could be' (10). A reduction of 2.0 points on the numeric rating scale or a reduction of at least 30% is considered a Minimum Clinically Important Difference (MCID) in low back pain populations.[29]

Pain-related Fear of Movement: Beliefs around fear of movement were assessed using the Tampa Scale of Kinesiophobia (TSK). It has been used extensively in the LBP population and has demonstrated excellent reliability.[30] An MCID in fear of movement of 4.0 points[30] or a reduction of at least 18%[27] has been established for improvement in the low back population following non-surgical rehabilitation.

Secondary Outcomes:

Kinematics: Peak 3-dimensional trunk amplitude and velocity was quantified using an 8-camera OptiTrack motion analysis system (NaturalPoint Inc, Oregon USA). The OptiTrack system has demonstrated measurement accuracy of within ±0.2mm in most applications.[31] Fifteen spherical retroreflective markers of 9 mm diameter were placed on anatomical landmarks according to the Rizzoli markerset[32] (Figure 1). The pelvis segment and orientation was defined by markers placed on the left and right Anterior superior iliac spine (LASIS, RASIS) and the left and right Posterior superior iliac spine (LPSIS, RPSIS). The trunk is represented by a 5-link segment model from the Fifth lumbar vertebrae (L5), Third

lumbar vertebrae (L3), First lumbar vertebrae (L1), the midpoint between left and right scapular apex, near the T10 vertebrae, and C7. Time-position data was collected at 120hz during the following self-paced standardised movement tasks:

[INSERT FIGURE 1 ABOUT HERE]

Static reference position. Participants stood with feet shoulder width apart, arms in 30° shoulder abduction. This served as the reference position from which change in trunk amplitude was calculated for all tasks to minimise the impact of measurement error due to marker placement between sessions, which can be as much as ±8.4mm.[33]

Trunk Flexion. Participants commenced from the reference position and were asked to bend forwards as far as they felt they could comfortably without bending their knees, before returning to the reference position (Figure 2a). The lumbar range of motion during this task has established excellent within-[34] and between-session[35] reliability in the persistent LBP population, with a calculated between-session Standard Error of Measurement (SEM) of 7.5°.[34]

Trunk Extension. Participants commenced from the reference position and were asked to bend backwards as far as they felt they could comfortably without bending their knees, before returning to the reference position (Figure 2b). The lumbar range of motion during this has demonstrated excellent between-session reliability with a calculated SEM of 5.0°.[35]

Lifting a box from the floor to hip height ('Box Lift'): Participants commenced from the reference position with feet behind a line 15cm from a shelf. They then lifted a box (dimensions 40 x 30 x 23.5cm, weight 4kg) with handles from a lower shelf (with height set such that the top of the box was 10cm below the apex of the patella) to an upright standing position for approximately one second, before lowering it to the shelf again (Figure 2c). The

lumbar range of motion during this task has established excellent within- and between-session reliability, and an SEM of 1.9°.[36]

Lowering a 4kg box from shoulder height to floor ('Box Lower'). Participants commenced from the reference position with feet behind a line 30cm from a shelf. They then lifted the box from an upper shelf (with height set such that top of the box was at the participant's shoulder height), lowered it to the lower shelf for approximately one second, before returning the box to the upper shelf (Figure 2d). A similar task requiring greater shoulder elevation has demonstrated moderate within- and between-session reliability of lumbar range of motion with an SEM of 1.1°[36]

For all movement tasks, participants were instructed to move at a speed and range that they were comfortable and were given opportunity to stop the task if required. No behavioural data (e.g. pain level, perceived effort) were collected during or following the tasks.

[INSERT FIGURE 2 ABOUT HERE]

Daily Physical Activity: A wireless physical activity monitor (ActivPAL™, Glasgow UK) was attached to the participant's thigh to measure average daily step count and time spent in moderate-vigorous physical activity (MVPA) over the 7-day periods following Session one and Session two. The ActivPAL monitor has established reliability measuring physical activity levels[37,38] and has previously been used in a persistent LBP population.[39]

Participant clinical presentation and demographics: Demographic information was collected to provide a descriptive profile of the participant population. Information collected included Date of Birth, Sex, Height, Weight, Occupation, Symptoms (duration, location, and nature),

current pain medications, direction of aggravating movement, and level of back-related disability (Oswestry Disability Index).[26]

Study Procedure:

Participant Recruitment: Participants were recruited through social media advertisement and through staff notices and patients at a tertiary hospital in Brisbane, Australia. Eligible patients were recruited through i) an advanced-practice physiotherapist-led musculoskeletal screening clinic where individuals referred for neurosurgical or orthopaedic consideration are assessed to determine suitability for a trial of conservative management for their low back pain; and ii) the persistent pain service, where individuals initially undertake an assessment by clinical staff to determine Allied Health input needs. In both instances recruitment and data collection took place following an initial assessment, but prior to commencement of conservative management which was typically booked 3-4 weeks following initial assessment. Eligibility was confirmed by a 10-minute phone screening interview. Written consent was obtained at the initial session, and participants completing all three sessions received a $40 gift card in recognition of their time.

Data Collection: Participants attended three sessions (baseline, week 1, week 2). Pain education was considered part of the VR-CBT intervention and a necessary primer for engagement in Session 2. That is, engaging in the VR exposure therapy would likely only make sense to a participant in light of a modern understanding of pain. Therefore, participants underwent sessions in the same linear order, with PSE always delivered first (see Figure 3):

Session 1 (Baseline, total 90 minutes) Baseline Measures and Intervention component A (Pain Science Education). Self-reported outcome measures were collected including average pain intensity and pain-related fear of movement beliefs. Following this, retroreflective markers were placed on anatomical landmarks and time-position data was

recorded as participants undertook three repetitions of the Standardised Movement Tasks. Participants were able to practice the tasks prior to task commencement and were given numerous opportunities to rest or to delay further assessment if the symptoms increased beyond the participant's expectations.

Following collection of outcome measures, participants underwent a standardised 30-minute PSE session based on 'Explain Pain'.[40] The session was delivered by physiotherapists with substantial experience in persistent pain management (PW or MMu) and covered topics including:

Pain physiology. This included an overview of how the nervous system works and its role in persistent pain, outlining contrasts between acute and persistent pain, and identifying and addressing unhelpful structural-pathological and biomechanical beliefs. The educational content also covered the multiple factors that can influence the pain experience, such as attention/distraction, context, expectation, and mood. The overarching aim of this intervention was to provide an alternative rationale to the participant's pain experience that would support a reduction in the perceived threat associated with pain and movement to facilitate engagement in graduated activity strategies. This intervention has established evidence in reducing pain intensity and improving quality of life.[41]

Graduated activity. Graduated activity was not a specific intervention per se, but education relating to pacing and graduated activity was provided as part of the pain science education. Participants were not directed to establish baseline activities or provided with a plan to increase activity levels, but rather were given principles around establishing a baseline, and then increasing at increments that did not induce a flare up of symptoms. While the overall education content was standardised, participants were given the opportunity to ask specific questions relating to the session content, and effort was made to make case examples relevant to the individual participant's presenting condition. A handout

summarizing the presentation content was provided and participants were encouraged to revisit the content in the ensuing week.

[INSERT FIGURE 3 ABOUT HERE]

The ActivPAL monitor was then attached to the front of the thigh using a waterproof dressing and worn for seven continuous days to assess physical activity levels during their normal daily life.

Session 2 (Week 1, total 90 minutes) Post-PSE measures (45 minutes) and Intervention component B (VR Exposure Therapy (VRET), (45 minutes). Participants repeated self-reported outcome measures (pain intensity, Tampa Scale of Kinesiophobia) and collection of kinematic data during standardised movement tasks.

Intervention component B (VRET): Following self-reported outcome measures and standardised movement tasks, participants were familiarized with the VR system (HTC VIVE Pro, HTC Corporation, New Taipei City, Taiwan) by means of a short introductory video. They then underwent 20 minutes of VR gameplay including four, five-minute sessions with small breaks. Participants played PierHead Arcade 2 (Mechabit, Liverpool UK) through the SteamVR™ application (Valve Corporation, Washington USA). PierHead Arcade 2 presents a virtual environment where users can select from a variety of arcade-style games. Three games were played in the following order: basketball hoops, ice curling, and 10-pin bowling (Figure 4). Games were chosen to provide an immersive, self-paced gaming experience with increasing range of movement requirements (i.e., predominantly upright/slight trunk extension – basketball hoops; slight trunk flexion – ice curling; and moderate trunk flexion – 10-pin bowling). The game environments were navigated through hand-held controllers, while the position of the controllers and headset relative to the virtual game environment was

determined from the system's infra-red sensors. Participants continued playing 10-pin bowling for the final component, during which video footage was simultaneously collected through the LIV® Mixed Reality Capture tool (LIV, San Francisco USA) utilising a green screen which overlaid footage of the participant into the virtual game environment. Video footage was recorded using OBS Studio software (http://obsproject.com). Following gameplay, participants underwent a short (approximately 20 minutes), structured feedback session utilising a cognitive behavioural therapy-informed approach. The feedback session explored participant perceptions of the VR intervention, and their experience with pain and fear of movement during the gameplay. Video footage of participants taken during VR gameplay was then replayed to the participant in which positive movement strategies were highlighted, with an emphasis on consolidating links between content covered during pain education (e.g., impact of distraction, task context, expectation of pain during tasks) and the participant's experience during VR gameplay. Participants were prompted to reflect on their movement performance and consider changes to their approach to movement and activity as a result of viewing the footage.

[INSERT FIGURE 4 ABOUT HERE]

The ActivPAL monitor was again attached to the participant's thigh and worn for seven continuous days.

Session 3 (Week 2, Post-VRET, total 45 minutes). Participants completed self-reported outcome measures and kinematic measures, i.e., post-VRET changes to baseline and post-PSE measures.

Data Management and Analysis: Optitrack (NaturalPoint Inc, Oregon USA) software tools were used to label, construct, interpolate and filter (Butterworth 4th order; 6Hz cutoff frequency) the marker trajectories during the movement tasks. Visual 3D™ (C-motion Inc, Germantown, Maryland USA) was used to build the Rizzoli model from the processed marker trajectories. Data was exported to MATLAB (version R2020b) for analysis. The average data of three trials was used for each task. Peak trunk amplitude (i.e., maximum angle achieved (°)) and peak trunk velocity (i.e., maximum angular velocity achieved (°/sec)) were determined for the trunk segment relative to the pelvis from the reference position in the sagittal plane during each task. Peak trunk flexion velocity was recorded as positive, and extension velocity as negative. ActivPAL data was batch processed and analysed using the ActivPAL™ software PALanalysis (v8.11.8.75; CREA algorithm v1.3). Data was extracted in 15-second epochs and further analysed using MATLAB to provide daily step count and intensity of physical activity (specifically moderate-vigorous physical activity (MVPA)). A minimum of three days recording was considered adequate to compute a weekly average, with 24-hour periods analysed from midnight to midnight.

Continuous clinical characteristics and demographic variables were assessed for normality and presented as either mean (SD) or Median (IQR). Categorical variables were presented as n (%). The Shapiro-Wilk test and box plots were used to assess for normality and potential outliers for measures of pain and pain-related fear of movement, kinematics, and activity levels. Where data were approximately normally distributed, separate Repeated Measures one-way ANOVAs with Timepoint (Baseline, Post-intervention component A (PSE), post-intervention component B (VRET) as an independent factor and pain, TSK and kinematics (trunk amplitude, velocity) outcomes were performed to assess within-group differences across timepoints. Sensitivity analyses were conducted where significant outliers were

present. If Mauchly's assumption of sphericity was violated, the Greenhouse-Geisser correction was used. Where significant main interactions were demonstrated, post-hoc testing with Bonferroni corrections were used to determine effect sizes (partial η^2) for individual intervention components across the separate timepoints. Partial η^2 values were converted to Cohen's *d* using the formula $f = \sqrt{\frac{\eta 2}{1-\eta 2}}$. For main effects, *d* was calculated as $d = 2 \times f \times \sqrt{3 \times (k-1) \div (k+1)}$, where k is the number of means, and for individual comparisons *d* was calculated as $d = 2 \times f$.[42] Effect sizes <0.2 were considered very small, $0.2 \leq d < 0.5$ small, $0.5 \leq d < 0.8$ moderate, and ≥0.8 large.[42] Further exploratory analysis of kinematic variables demonstrating a significant main effect was undertaken to evaluate if change in kinematics between baseline and follow up were correlated with change in primary outcome scores (i.e., change in TSK scores, change in pain intensity), using Pearson's r or Spearman's rho. Correlation coefficients (+/-) $0<r<0.3$ were considered weak, $0.3<r<0.7$ moderate, and $0.7<r<1$ strong[43]. Post hoc analyses were used to examine the proportion of participants meeting MCID for the primary outcome measures (pain intensity (2.0 points or achieving at least 30% reduction in pain intensity,[29] and TSK (4.0 points[30] or achieving 18% reduction)[27] across individual and combined timepoints. Paired t-tests were used to compare differences in average activity levels (daily step count, daily time spent in moderate-vigorous physical activity) following Intervention components A and B. Missing values were not imputed. Alpha was set to 0.05 and all analyses were conducted using SPSS v28.00 software.

Results

Thirty-seven participants were recruited to the study. Two participants withdrew following Session 1 (Baseline measures and PSE intervention), and one participant was lost to follow up following Session 2 (Post-PSE measures and VRET), as seen in Figure 3. Thirty-four

participants completed outcome measures for all timepoints, with participant demographics and clinical characteristics presented in Table 1. Participants included a slightly higher proportion of females (58.8%), with half of participants having their symptoms for five or more years. Over three-quarters (76.5%) of participants reported a continuous episode of pain, and 76.5% of participants also reported that their most provocative direction of movement was in the sagittal plane (i.e., flexion (55.9%) or extension (20.6%) related movements).

[INSERT TABLE 1 ABOUT HERE]

Primary Outcomes:

Outcomes are presented in Table 2.

Pain intensity: Shapiro-Wilk tests demonstrated that pain intensity scores for Session 1 and Session 3 were not normally distributed (Session 1 $p<0.01$; Session 2 $p=0.33$; Session 3 $p=0.02$) however box plots revealed an approximate normal distribution with no outliers. A one-way repeated measures ANOVA demonstrated a significant main effect for average pain intensity in the preceding seven days across the three timepoints ($F(2,66) =19.31$, $p<0.001$). Pain decreased significantly from baseline to completion (Session 3) (mean (SD) 5.9(1.5) to 4.3(2.1); mean difference -1.5(1.6)), with a large effect size (Cohen's $d = 0.98$). Post Hoc contrasts demonstrated a large effect size between baseline and post-PSE (Cohen's $d = 0.85$, $p<0.001$) and a very small effect size between post-PSE and post-VRET (Cohen's $d = 0.10$, $p=0.22$), timepoints.

Pain-related fear of movement: TSK scores for Session 1 were not normally distributed (Session 1 $p=0.01$; Session 2 $p=0.78$; Session 3 $p=0.20$) however box plots revealed an approximate normal distribution with no outliers. A significant main effect was demonstrated

for TSK scores (F(2,66) =41.99, p<0.001). Average TSK scores decreased from baseline to completion (Session 3) (Mean (SD) 42.6(6.4) to 34.3(7.4); Mean difference -8.3(5.5)). Post Hoc contrasts demonstrated a large effect size between baseline and post-PSE (Cohen's *d* = 1.96, p<0.001 and a very small effect size between post-PSE and post-VRET (Cohen's *d* = 0.18, p=0.08).

[INSERT TABLE 2 ABOUT HERE]

Participants achieving clinically important improvements for pain intensity or pain-related fear of movement, are presented in Table 3. Following completion of both intervention components, fifteen participants (44.1%) achieved an MCID for pain intensity, while over one-third (35.3%, n=12) had at least 30% reduction in their pain intensity. Over three-quarters of participants (79.4%, n=27) achieved an MCID for pain-related fear of movement following completion of both intervention components.

[INSERT TABLE 3 ABOUT HERE]

Secondary outcomes:

Kinematics:

Data were available for 33 participants, with one unable to be calculated due to issues with marker visualisation.

Trunk amplitude: Peak Trunk flexion and extension amplitude remained unchanged across timepoints for all standardised movement tasks with no significant main effect (Trunk Flexion F(2,64) =0.18, p=0.84; Trunk extension F(2,64) =2.09, p=0.13; Box lift F(2,60)

=0.59, p=0.56; Box lower F(2,62) =0.74, p=0.48). Box plots revealed between 1-4 outliers for each task however sensitivity analyses revealed similar findings.

Trunk peak velocity: Peak trunk flexion and peak extension velocity demonstrated 1-4 outliers across all tasks. During the Trunk Flexion task, a significant main effect was observed for both peak flexion (absolute mean difference 8.2°/s, p<0.001) and peak extension (absolute mean difference: 9.0°/s, p<0.01), indicating that individuals moved faster in both the flexion and extension phases of the task. The Trunk Extension task demonstrated a significant increase in peak trunk flexion velocity (i.e., during return to upright from extension, absolute mean difference 3.9°/s, p<0.01) and peak extension velocity (i.e.,, during extension movement, absolute mean difference 1.8°/s, p=0.03). No significant main effect was observed for the Box Lift task for either peak flexion velocity (F(2,62) =1.64, p=0.20) or peak extension velocity (F(2,62) =0.62, p=0.54). The Box Lower task revealed significant main effects for both peak trunk flexion velocity (absolute mean difference 6.5°/s, p<0.05) and peak trunk extension velocity (absolute mean difference 6.2°/s, p<0.05). Post hoc contrasts revealed small effect sizes between baseline and post-PSE during trunk flexion (peak trunk flexion velocity Cohen's *d* = 0.39, p=0.01) and trunk extension (peak trunk extension velocity Cohen's *d* = 0.30, p=0.02) and between post-PSE and post-VRET during the Box Lower task (Cohen's *d* = 0.37, p<0.05). Sensitivity analyses demonstrated no changes to significance or effect size. Further exploratory analysis of kinematic variables demonstrating significant main effects showed weak, insignificant correlations between change in peak velocities (i.e., Follow up minus Baseline measures) and change in primary outcome scores, with the exception of change in peak flexion velocity during the Trunk Flexion task, which showed a moderate, negative correlation with change in TSK (Pearson's r -.35 (p=.046, 95% CI -.62 to -.01). This indicates that with reduction in TSK scores, peak flexion velocity increased across timepoints. Full results are shown in Appendix 1.

Physical Activity: Paired comparisons of data were available for 28 participants, with two files lost due to corrupted data and four recordings not reaching the minimum three days of data collection due to low battery. Paired t-tests showed the proportion of time spent in MVPA increased by an average of 3.5 minutes/day (9.8%) between the two intervention components (post-PSE Mean (SD) minutes 35.4(20.2), post-VRET Mean (SD) 38.9(22.5)), however this was not statistically significant (p=0.11). Similarly, average daily step count increased across the two sessions by 450 steps/day (6.2%) (post-PSE Mean (SD) steps/day 7256(3092), post-VRET Mean (SD) 7706(3401), p=0.20). Sixteen of the 28 participants (57.1%) increased physical activity between the two timepoints, in both MVPA and daily step count.

Adverse Events: No significant adverse events were reported. One participant experienced mild headache symptoms following completion of the VRET component that resolved within 30 minutes.

Discussion

This study appeared to show that PSE combined with VRET utilising a cognitive behavioural therapy-informed approach can reduce pain intensity and pain-related fear of movement at least in the short-term. Improvements were also demonstrated in some kinematic parameters across timepoints, however with the exception of peak flexion velocity during Trunk Flexion, improvements in these kinematic parameters during functional movements were weakly correlated with changes in pain-related fear of movement or pain intensity. These changes were observed together with modest, insignificant increases in physical activity, suggesting improvements were related to a change in attitudes and beliefs towards pain and fear of

movement, rather than altered activity levels. These findings, together with the large overall effect sizes observed for both primary outcomes, highlight the potential of VR-CBT as a combined intervention for individuals with persistent LBP and pain-related fear of movement.

Average pain intensity reduced by 1.5 points following VR-CBT, with 44.1% of individuals achieving an MCID and 35.3% reporting at least 30% reduction in pain intensity symptoms. A key feature of the intervention was a cognitive behavioural-informed approach incorporating a post-VR interview to positively reinforce PSE concepts through reflective questioning and video feedback of movement. While previous studies investigating VR interventions in persistent LBP have used cognitive behavioural-informed approaches, these have either not incorporated specific feedback of movement performance,[18] or did not target movement as part of the intervention.[12,13] Eccleston et al[18] found an average 1.9-point reduction in pain intensity following 30 sessions over 6-8 weeks, combining PSE with a fruit picking game designed to elicit movements at gradually increasing frequency and location. However, feedback of progress was limited to a visual metaphor represented through a growing plant. Other VR interventions underpinned by a cognitive behavioural approach have demonstrated mixed results. Garcia et al[12] found significant reductions in pain (mean 2.2-points following daily VR use over 8 weeks) and a significant treatment by time effect compared to a sham VR intervention, whereas another study using VR gameplay (10 minutes daily over four weeks) to introduce PSE concepts demonstrated significant main treatment effects for daily worst and least pain scores compared to standard care, but without significant time effects or treatment-time interactions.[13] In both studies, graded exposure to trunk movement was not an intervention target. Where immersive VR interventions have been limited to gameplay only, smaller reductions in pain have been observed. Thomas et al[19]

observed a mean 6.7-point reduction (/100) over three sessions with a dodgeball intervention designed to elicit progressive increases in trunk flexion, while an estimated 1.0-point reduction in pain intensity was demonstrated using VR gameplay encouraging forward bending across 6-9 sessions.[14] These findings together with our results, suggest that VR treatment effects for pain intensity involving graded exposure to movement may be enhanced by incorporating PSE using a cognitive behavioural-informed approach, particularly over interventions of longer duration.

Larger reductions were observed for pain-related fear of movement. Nearly 80% of participants reported an MCID in fear of movement with an average 8.3-point reduction in TSK. This is despite the intervention consisting of only two sessions, with traditional graded exposure interventions undertaken over 8-10 sessions.[44,45] Similar improvements in fear of movement were demonstrated by Eccleston et al.[18] In contrast, Macintyre et al[14] found no effect on fear of movement over 6-9 sessions of VR gameplay incorporating a graded exposure approach. Baseline TSK scores were lower in that study which may indicate a floor effect; however, it may indicate the need to specifically address unhelpful beliefs potentially contributing to fear of movement, rather than graded exposure to movement alone. This is potentially highlighted in a study by De Jong et al that combined a single education session with traditional (i.e., non-VR) exposure therapy (total 24 hours over 6 weeks), and in contrast to findings from Macintyre et al demonstrated similar reductions in fear of movement following each modality.[46] We sought to integrate education principles with VR gameplay by providing constructive reinforcement of helpful cognitions through reflective interviewing and highlighting positive movement through video feedback. Previous studies have demonstrated greater reductions in TSK scores compared to other interventions when exercise or graded exposure is combined with a cognitive behavioural approach[47] or pain

education intervention.[48] However, other studies evaluating education or exercise alone compared to a combined approach have found no differences in pain-related fear of movement.[49,50] In these studies, no specific efforts were made to consolidate links between PSE and the pain experience during exercise, potentially highlighting the need for reflective learning as a core component of an exposure therapy approach. Interestingly, an inhibitory learning approach for exposure therapy is enhanced when the mismatch between expectation (i.e., movement will cause pain) and experience (i.e., pain did not increase) is greater, and education delivered prior to exposure therapy may therefore limit the impact of the intervention.[51] In our study we did not specifically address pain-related fear of movement in the PSE, but rather established a platform upon which the post-VRET feedback could highlight and reinforce the veracity of the PSE content.

Reductions in pain intensity and pain-related fear of movement were accompanied by changes in some kinematic parameters, together with small insignificant increases in daily physical activity levels. Trunk amplitude did not change across timepoints for any tasks, mirroring the results of Thomas et al[19] who found that although lumbar flexion increased within and across three gameplay sessions during a VR dodgeball intervention, lumbar flexion amplitude during a reaching task was unchanged. Traditional rehabilitation approaches have similarly found no change in maximum lumbar amplitude during bending over a two-week intervention period,[52] potentially indicating the need for interventions over longer duration to affect trunk range of movement that may be impacted by physical limitations (e.g., joint stiffness, reduced flexibility) in addition to psychological or behavioural factors. As the games were navigated using hand controllers, participants could have used movement strategies that minimised trunk flexion in favour of greater upper limb movement, which may have contributed to the lack of trunk amplitude change during the

movement tasks. In contrast peak trunk flexion and extension velocities increased during Trunk Flexion, Trunk Extension, and the Box Lower tasks, although it is noted that reliability and SEM for these tasks were available for amplitude only (not peak velocity). Increased peak velocities may reflect reduced pain-related fear of movement and a preparedness to move with less guarding, with slower trunk movements during reaching tasks having been identified in individuals with high pain-related fear of movement despite resolution of LBP.[53] However only change in peak trunk flexion velocity demonstrated a moderate relationship with change in TSK scores between Baseline and Follow up. Flexion was nominated as the most provocative movement direction in over half (55.9%) of our cohort, and the VRET component of the intervention was focused on increased bending requirements, which may partly explain these findings. Interestingly, our study did not identify changes in trunk velocity during the Box Lift task. Other research has identified reduced peak extension velocity during a lifting task in individuals with persistent LBP, that was mediated by fear of movement.[54] The box weight in that study was set to 37.5% of the participant's weight (4kg in our study) which may have contributed to higher apprehension and subsequent slower task performance. Further, trunk angle was calculated relative to the vertical axis whereas our study considered the trunk relative to the pelvis. This potentially limited relative changes in angular velocity of the trunk if a predominantly hip strategy was employed in the lifting tasks, even if the movement itself was performed at a faster rate. Individuals with LBP perform a lifting task with primary contribution from the hip relative to the lumbar spine when instructed to maintain a neutral lumbar spine.[36] Participants in our study were not instructed on how to perform the movement tasks, however despite improvements in pain and TSK scores may have elected to adopt a 'safe' movement strategy during a functional load carrying task, thereby limiting potential increases in peak velocity across timepoints.

This is the first study specifically utilising feedback of performance following VR gameplay to positively reinforce PSE principles. It recruited participants from multiple sites in addition to staff, enhancing the generalisability of the project findings, with high (91.9%) retention of participants. Participants covered a broad age range (18-64 years) and included a high proportion (58.8%) of females, known to be under-represented in VR studies.[55] The intervention utilised commercially available hardware and games, thereby broadening its applicability to clinical practice. However, the study did not utilise a control, and although the VR-CBT intervention was developed to incorporate both PSE and VRET components, it is possible that improvements observed following VRET reflected ongoing benefits from PSE rather than an additive effect. This may have been mitigated using multiple baseline testing but was not feasible due to time constraints. Multiple testing of movement tasks (that participants may have perceived as harmful) may also have affected their performance during these tests on successive occasions. As the order of intervention could not be randomised (i.e. reflective interviewing following the VRET intervention would only make sense following PSE) the study design did not enable meaningful comparison of relative effect sizes. We were also unable to control for non-specific effects such as participant expectations or therapeutic alliance. Both participants and researchers were unblinded, increasing the risk of bias. The study was limited to only a single dose of each component of the intervention and lacked longer term follow up including the post-treatment phase. This would have strengthened the study as both behavioural therapy and VR interventions have reported dose-response relationships,[56,14] and other studies have observed some increase in pain intensity following completion of VR interventions.[18] We also utilised the same VR games for each participant irrespective of their presenting condition. Although over three-quarters of participants nominated movements in the sagittal plane as most provocative and the games chosen were selected to elicit increasing range of sagittal plane trunk movement, greater improvements

may have been evident through individualised selection of games that were appropriate to presenting pain intensity, movement ability, and direction of provocative movement. Utilising an individualised patient-centred approach to address fear and avoidance behaviours has been highlighted in the literature as an important consideration,[57] and future studies investigating VR-CBT should consider the capacity for individualised interventions. We assessed pain-related fear of movement through the TSK which may underestimate task-specific fear,[58] known to influence trunk kinematics in this population.[59] Potentially a more task-specific measure of fear may have strengthened the observed associations between kinematics and pain-related fear. Trunk kinematics were evaluated to provide a global picture of movement performance and we did not assess the lumbar spine specifically, which may have provided additional insight as evidence suggests different movement strategies between the upper (L1-L3) and lower (L4-L5) lumbar segments in CLBP.[60,61] Variability in between-session marker placement is a known cause of measurement error in 3D motion capture[33] and although we attempted to control this by using a reference position this may have impacted calculated trunk amplitude between sessions. Finally, although Post Hoc testing indicated significant impacts for the PSE component of the intervention on pain-related fear of movement, we did not specifically evaluate if the pain education led to changes in participants' pain beliefs, although this has been demonstrated in other chronic pain populations utilising similar education content.[62-64]

This study demonstrated that PSE followed by VRET utilising cognitive behavioural-informed principles led to significant improvements in pain, pain-related fear of movement, and trunk velocity, in individuals with persistent low back pain. The intervention was well tolerated with no reported adverse events. Further clinical trials utilising control interventions are required to confirm efficacy and relative effect sizes and evaluate the durability of

improvements with longer intervention and follow up phases that include measures of disability and pain beliefs.

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Figure Legends:

Figure 1. Trunk and pelvis marker placement showing anterior (L) and posterior (R) views. RA: Right acromio-clavicular joint. LA Left acromio-clavicular joint. IJ: Jugular notch. PX: Xiphoid process. RASIS: Right Anterior Superior Iliac Spine. LASIS: Left Anterior Superior Iliac Spine. C7: Seventh Cervical Vertebrae. T2: Second Thoracic Vertebrae. RBAK: Right Back. MAI: Midpoint between left and right scapular apex. L1: First lumbar vertebrae. L3: Third lumbar vertebrae. L5: Fifth lumbar vertebrae. LPSIS: Left Posterior Superior Iliac Spine. RPSIS: Right Posterior Superior Iliac Spine.

Figure 2. Sagittal trunk amplitude (left) and peak angular velocity (right) during the standardised movement tasks: Trunk Flexion (A), Trunk Extension (B), Box Lift (C), and Box Lower (D).

Figure 3. CONSORT Flow Diagram.

Figure 4. Virtual reality gameplay (Left to Right: Basketball hoops, ice curling, 10-pin bowling).

Figure 1

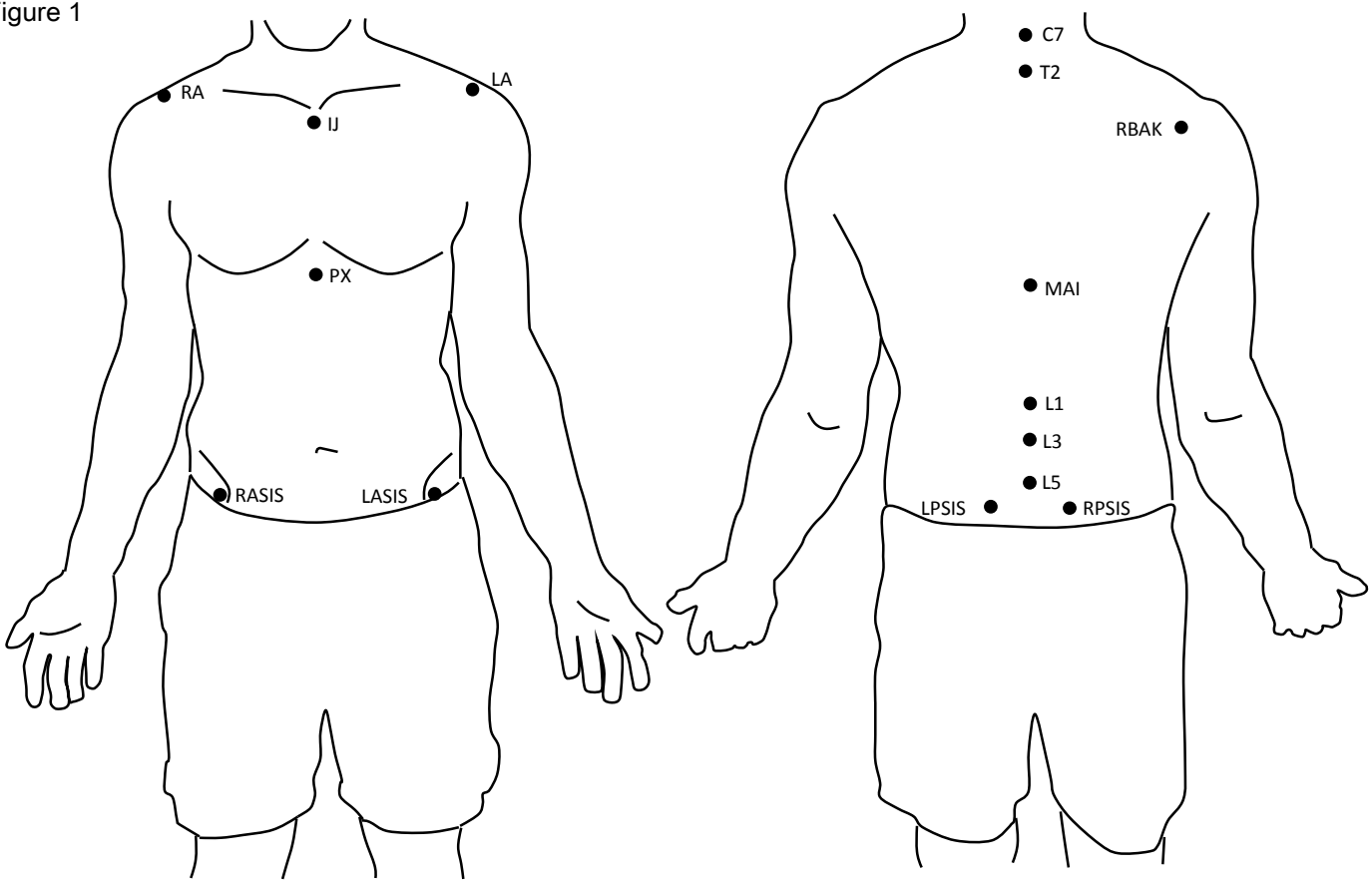
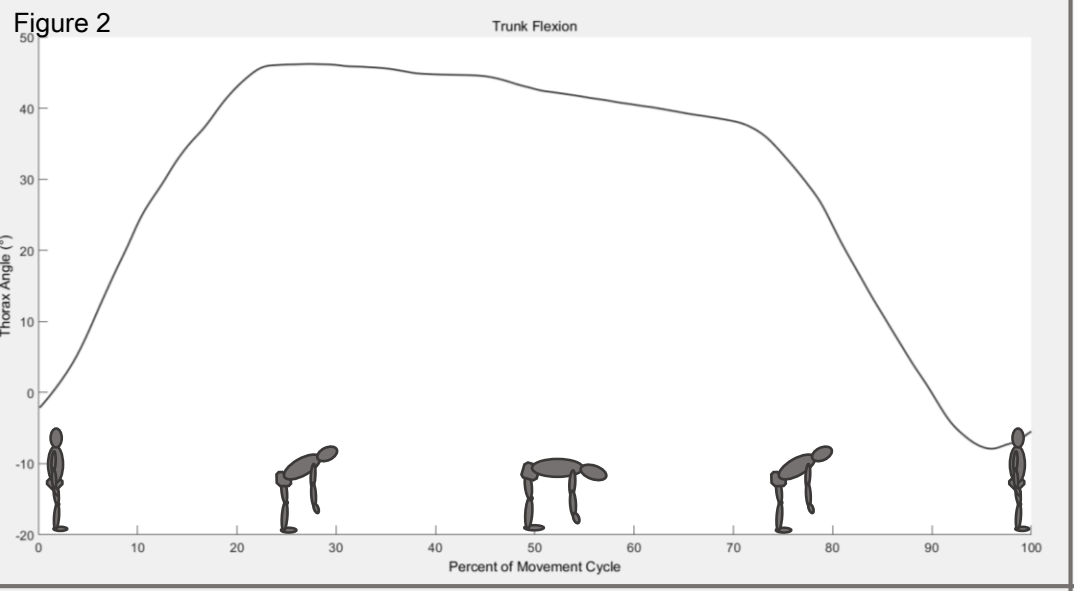
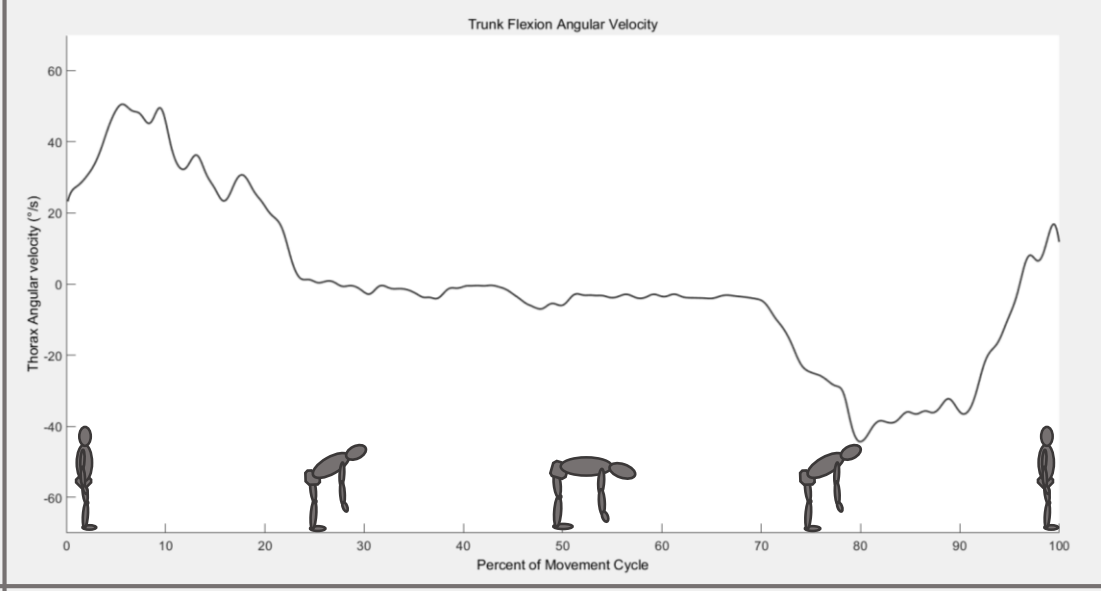
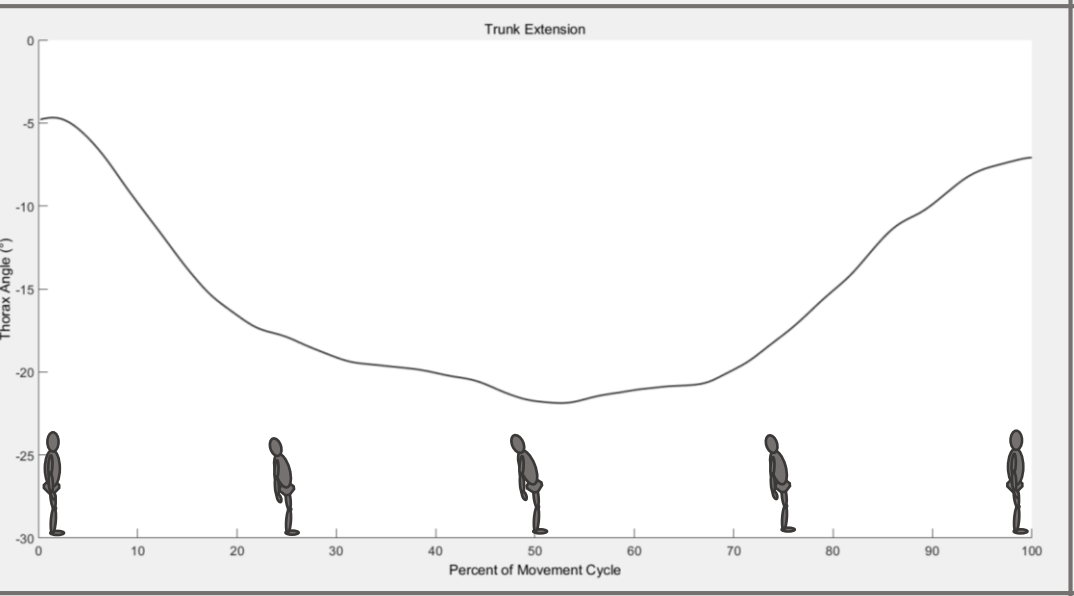
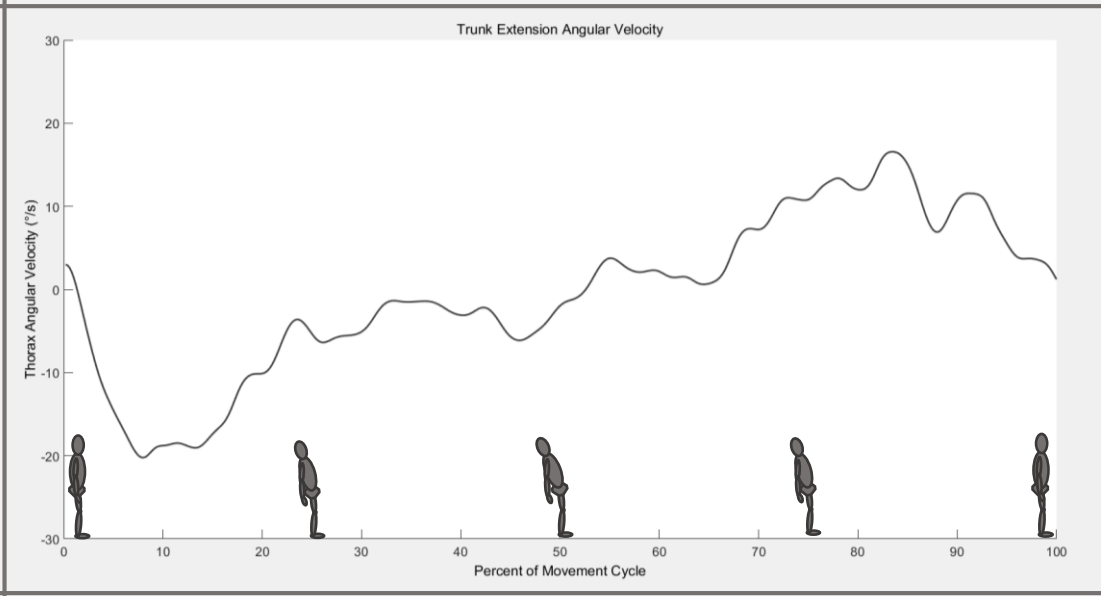


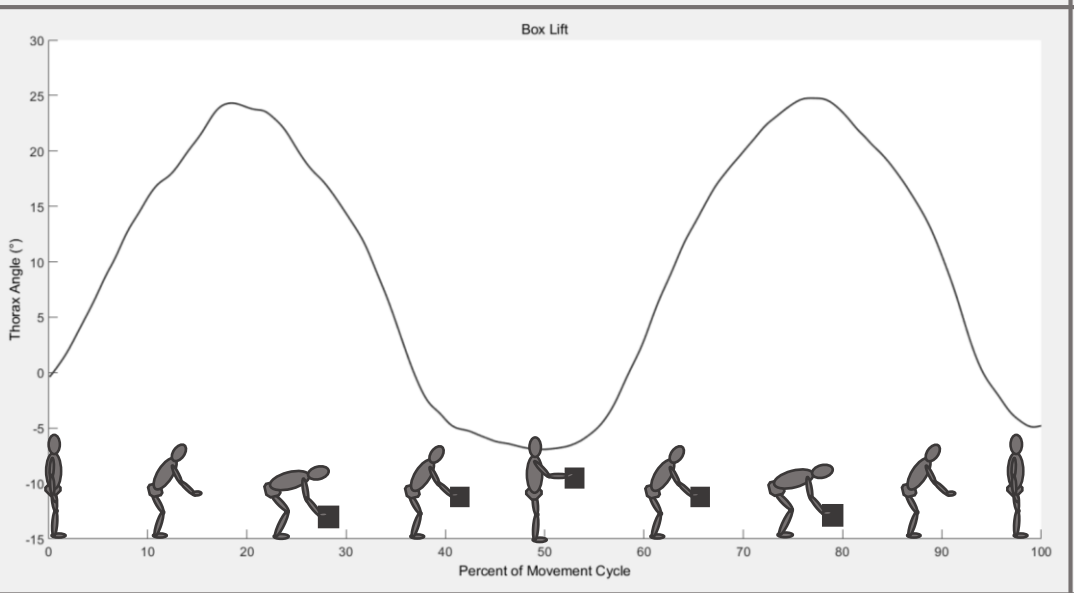
Figure 2

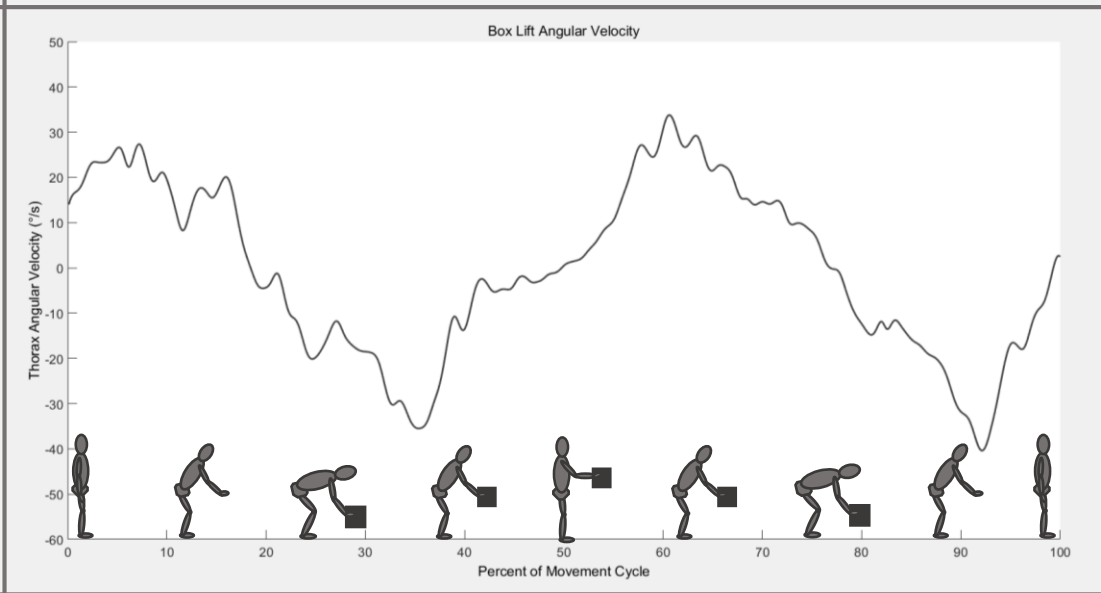

Trunk Flexion
Thorax Angle (°)
Percent of Movement Cycle

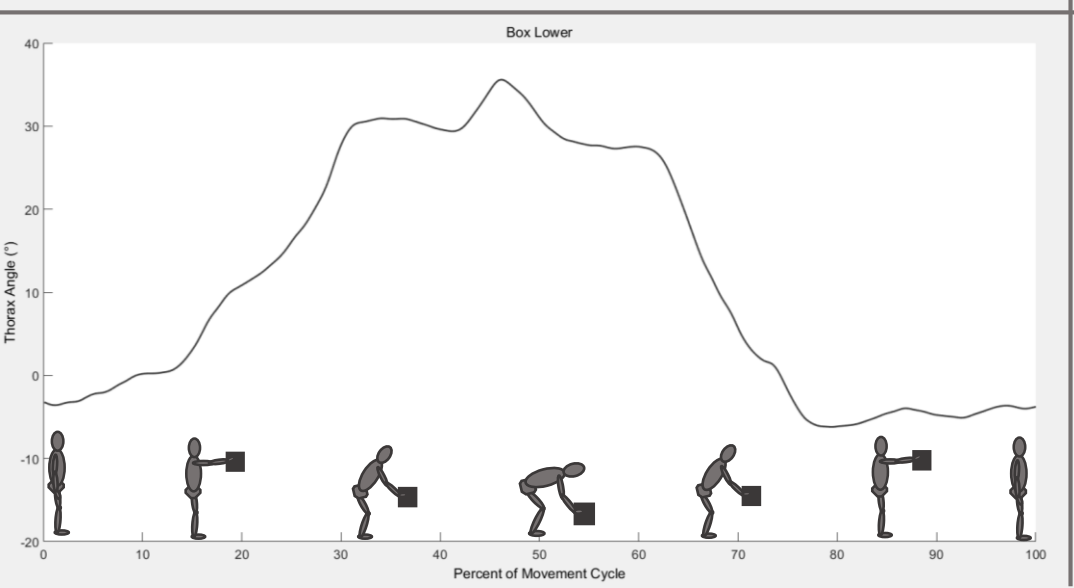

Trunk Flexion Angular Velocity
Thorax Angular velocity (°/s)
Percent of Movement Cycle


Trunk Extension
Thorax Angle (°)
Percent of Movement Cycle


Trunk Extension Angular Velocity
Thorax Angular Velocity (°/s)
Percent of Movement Cycle


Box Lift
Thorax Angle (°)
Percent of Movement Cycle


Box Lift Angular Velocity
Thorax Angular Velocity (°/s)
Percent of Movement Cycle


Box Lower
Thorax Angle (°)
Percent of Movement Cycle

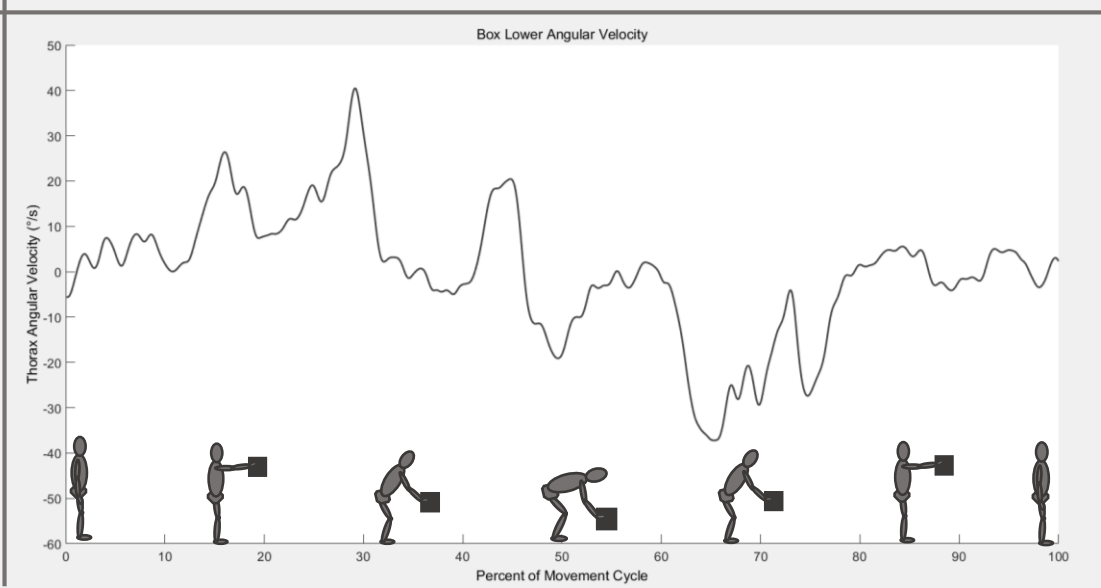

Box Lower Angular Velocity
Thorax Angular Velocity (°/s)
Percent of Movement Cycle

Figure 3

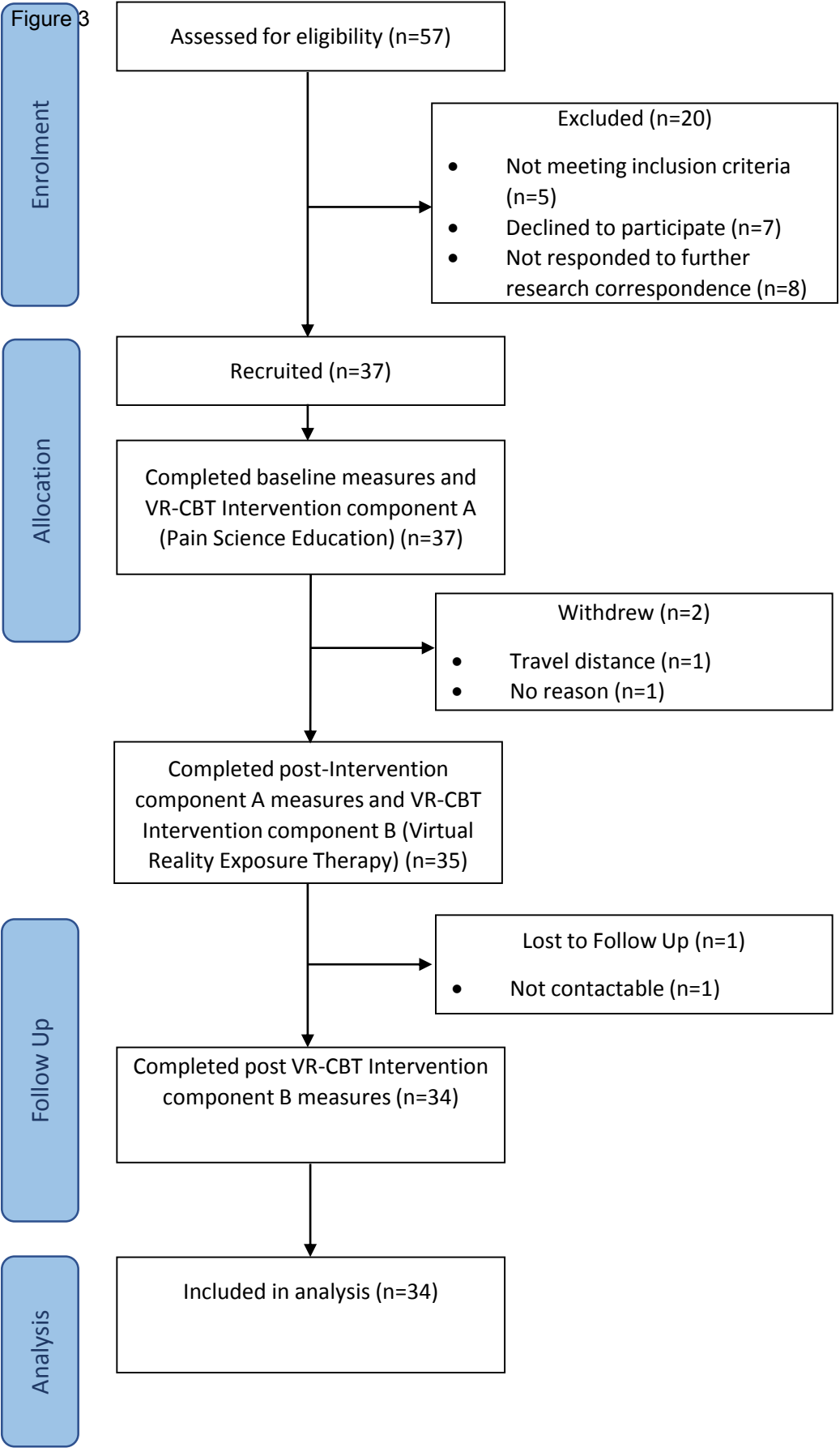

Enrolment
Assessed for eligibility (n=57)
Excluded (n=20)
Not meeting inclusion criteria (n=5)
Declined to participate (n=7)
Not responded to further research correspondence (n=8)
Allocation
Recruited (n=37)
Completed baseline measures and VR-CBT Intervention component A (Pain Science Education) (n=37)
Withdrew (n=2)
Travel distance (n=1)
No reason (n=1)
Completed post-Intervention component A measures and VR-CBT Intervention component B (Virtual Reality Exposure Therapy) (n=35)
Follow Up
Lost to Follow Up (n=1)
Not contactable (n=1)
Completed post VR-CBT Intervention component B measures (n=34)
Analysis
Included in analysis (n=34)

Figure 4





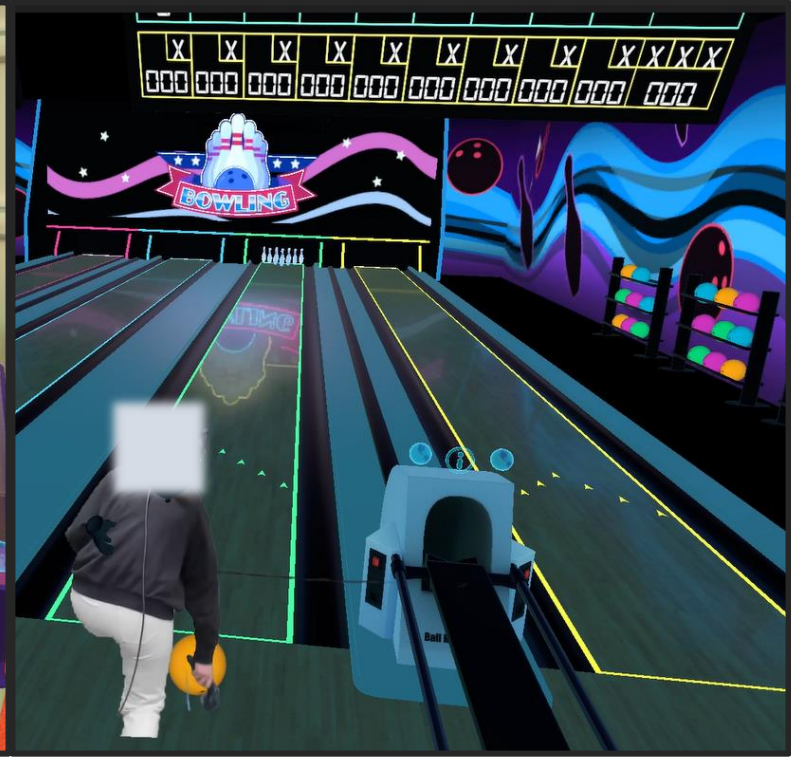


Table 1

Table 1. Participant demographics and clinical characteristics	**Median (IQR) or n (%)**
Demographics	
Age (Years)	43 (31.5, 58.0)
Sex (n, % female)	20 (58.8%)
BMI (Mean, SD)	27.7 (6.6)
Clinical Characteristics	
Duration of symptoms (months)	60 (30, 126)
Baseline ODI	32.0 (25.5, 43.0)
Baseline ODI Category	
Moderate	25 (73.5%)
Severe	9 (26.5%)
Baseline Pain Numerical Rating Scale (Mean, SD)	5.9 (1.5)
Baseline TSK (Mean, SD)	42.6 (6.4)
Onset of Symptoms	
Traumatic	18 (52.9%)
Idiopathic/postural	16 (47.1%)
Highest Analgesia usage	
None	14 (41.2%)
Complementary Medicine	1 (2.9%)
Simple Analgesia (e.g., Paracetamol, NSAIDS)	9 (26.5%)
Adjuvant Analgesia (e.g., Palexia, Amitriptyline)	5 (14.7%)
Opioids	5 (14.7%)
History	
First episode	2 (5.9%)
Recurrent episodes	6 (17.6%)
Continuous	26 (76.5%)
Occupation Demands	
Screen based	11 (32.4%)
Sedentary	8 (23.5%)
Physical	15 (44.1%)
Direction of most provocative movement	
Flexion	19 (55.9%)
Extension	7 (20.6%)
Rotation	6 (17.6%)
Side bending	2 (5.9%)

BMI: Body Mass Index. ODI: Oswestry Disability Index. TSK: Tampa Scale of Kinesiophobia. NSAIDS: Non-steroidal anti-inflammatory drug

Table 2

Table 2. Repeated Measures ANOVAs and Post Hoc contrasts for Primary (Pain intensity, Tampa Scale of Kinesiophobia) and secondary (trunk kinematics) outcomes

Outcome	Treatment Timepoint (Mean, SD)			Repeated Measures ANOVA	Post hoc contrasts with Bonferroni adjustments (Mean, SD)		
Primary Outcomes	**Baseline**	**Post-PSE**	**Post-VR-CBT (PSE and VRET)**		**Baseline vs Post-VRCBT**	**Baseline vs Post-PSE**	**Post-PSE vs Post-VRET**
Pain intensity NPRS (0-10)	5.9(1.5)	4.6(1.9)	4.3(2.1)	F(2,66)=19.31[b] Cohen's d = 0.98[e]	-1.5[b] Cohen's d = 2.27[e]	-1.3[b] Cohen's d = 0.85[e]	-0.3 Cohen's d = 0.10
Kinesiophobia TSK (17-68)	42.6(6.4)	35.8(7.7)	34.3(7.4)	F(2,66) =41.987[b] Cohen's d = 1.66[e]	-8.3[b] Cohen's d = 1.96[e]	-6.8[b] Cohen's d = 1.28[e]	-1.5 Cohen's d = 0.18
Secondary Outcomes							
Trunk Kinematics							
Trunk Flexion							
Maximum trunk flexion amplitude	39.7(14.9)°	38.6(14.0)°	39.7(16.4)°	F(2,64)=.18 Cohen's d = 0.02	-	-	-
Peak trunk flexion velocity	37.9(19.5)°/s	43.0(21.1)°/s	46.1(23.8)°/s	F(1.45,46.41)=5.50[b] Cohen's d = 0.37[c]	-8.2°/s[a] Cohen's d = 0.37[d]	-5.0°/s[a] Cohen's d = 0.39[d]	-3.2°/s Cohen's d = 0.12
Peak trunk extension velocity	-38.8(20.2)°/s	-43.6(21.4)°/s	-47.8(22.4)°/s	F(2,64)=5.09[b] Cohen's d = 0.35[c]	9.0°/s[b] Cohen's d = 0.45[c]	4.8°/s Cohen's d = 0.18	4.2°/s Cohen's d = 0.14
Trunk Extension							
Maximum trunk extension amplitude	17.0(6.5)°	18.8(6.9)°	17.8(7.5)°	F(2,64)=2.09 Cohen's d = 0.15	-	-	-
Peak trunk flexion velocity	20.7(11.4)°/s	22.6(11.0)°/s	24.6(11.1)°/s	F(2,64)=4.07[a] Cohen's d = 0.30[c]	-3.9°/s[b] Cohen's d = 0.47[c]	-1.9°/s Cohen's d = 0.12	-2.0°/s Cohen's d = 0.12
Peak trunk extension velocity	-15.7(7.2)°/s	-17.6(8.6)°/s	-17.5(7.8)°/s	F(2,64)=3.83[a] Cohen's d = 0.27	1.8°/s[a] Cohen's d = 0.39[c]	1.9°/s[a] Cohen's d = 0.30[c]	-0.1°/s Cohen's d = 0.00
Box lift							
Maximum trunk flexion amplitude	33.1(11.4)°	34.8(12.5)°	33.9(11.1)°	F(2,60)=.59 Cohen's d = 0.05	-	-	-
Peak trunk flexion velocity	45.8(18.3)°/s	50.6(22.1)°/s	51.3(21.1)°/s	F(2,62)=1.64 Cohen's d = 0.12	-	-	-
Peak trunk extension velocity	-46.3(21.7)°/s	-49.7(21.9)°/s	-46.5(16.9)°/s	F(2,62)=.62 Cohen's d = 0.05	-	-	-
Box Lower							
Maximum trunk flexion amplitude	37.3(12.5)°	38.4(11.9)°	39.2(12.6)°	F(2,62)=0.74 Cohen's d = 0.05	-	-	-
Peak trunk flexion velocity	38.1(17.6)°/s	38.1(16.8)°/s	44.7(19.3)°/s	F(2,62)=3.75[a] Cohen's d = 0.27	-6.5°/s[a] Cohen's d = 0.26	0.0°/s Cohen's d = 0.00	-6.6°/s[a] Cohen's d = 0.37[c]
Peak trunk extension velocity	-37.2(14.7)°/s	-43.1(18.3)°/s	-43.5(18.2)°/s	F(2,62)=3.36[a] Cohen's d = 0.25	6.2°/s[a] Cohen's d = 0.30[c]	5.8°/s Cohen's d = 0.24	0.4°/s Cohen's d = 0.00

[a]p<0.05 [b]p<0.01 [c]small effect size [d]medium effect size [e]large effect size

NPRS – Numerical Pain Rating Scale. TSK – Tampa Scale of Kinesiophobia

Table 3

Table 3. Proportion achieving clinically meaningful changes in primary outcomes	**Timepoint (n, %)**	
	Post-PSE	**Post-VRET**
Pain intensity		
Minimum 30% reduction in pain intensity	7 (20.5%)	12 (35.3%)
Minimum change 2.0 points	10 (29.4%)	15 (44.1%)
Tampa Scale of Kinesiophobia		
Minimum 18% reduction in fear of movement	15 (44.1%)	22 (64.7%)
Minimum change 4.0 points	22 (64.7%)	27 (79.4%)

PSE: Pain Science Education. VRET: Virtual Reality Exposure Therapy

Supplemental Data File (doc, pdf, etc.)

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Supplemental Data File (doc, pdf, etc.)
Supplemental Appendix.docx