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Effectiveness of immersive Virtual Reality in patients with neck pain after traffic accident

Submission date
06/03/2024

Recruitment status
No longer recruiting

Registration date
03/04/2024

Overall study status
Completed

Last Edited
03/04/2024

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
A scientific study will be conducted to compare two different treatments (traditional physiotherapy treatment or traditional physiotherapy along with virtual reality therapy) for individuals diagnosed with whiplash, which is a type of neck injury commonly associated with car accidents.
The primary objective is to evaluate the effectiveness of virtual reality in increasing range of motion and patient satisfaction and reducing pain intensity, fear of movement, perceived disability, and days off work.

Who can participate?
Patients with neck pain associated with whiplash, aged 18 - 65 years.

What does the study involve?
The study will involve two groups of participants: one group will receive traditional physiotherapy treatment, while the other group will receive traditional physiotherapy along with virtual reality therapy using specific software. Each participant will attend a total of 20 treatment sessions, which will take place daily from Monday to Friday over a period of 4 weeks. Each treatment session will last for 90 minutes. Additionally, there will be a control group that will receive a simulated treatment through immersive virtual reality, which serves as a placebo. The participants for this study will be recruited from individuals covered by work accident insurance.

What are the possible benefits and risks of participating?
Possible benefits are improvement in pain, range of motion and disability. The only risk of participating is experiencing cybersickness, but participants are warned before starting and are asked to stop if it happens to them, making it a minor controlled risk.

Where is the study run from?
Umivale Activa (Spain)

When is the study starting and how long is it expected to run for?
March 2023 to April 2025

Who is funding the study?
Umivale Activa (Spain)

Who is the main contact?
Vicent Pontes-Forner, vpontes@umivaleactiva.es

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Effectiveness of a specific program of immersive Virtual Reality in patients with neck pain after traffic accident

Study objectives
Virtual reality is effective in increasing range of motion and patient satisfaction, and reducing pain intensity, fear of movement, perceived disability, and days off work.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/03/2023, Comite de Etica de Investigacion Clinica en Fisioterapia Col Fisioterapia Comunidad Valenciana (San Vicent Màrtir nº 61 piso 2º, pta 2ª, Valencia, 46002, Spain; +34 963 533 968; administracion@colfisiocv.com), ref: CE.ICOFCV 0001

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with neck pain diagnosed with whiplash after a car accident

Interventions
A comparative randomized clinical trial of two interventions will be carried out: conventional physiotherapy vs conventional physiotherapy + virtual reality (specific software). A total of 20 sessions will be held, scheduled daily from Monday to Friday, with a total duration of 4 weeks. The duration of the treatment session is 90 minutes. The control group will receive a placebo through immersive virtual reality. The study subjects are diagnosed with whiplash and are recruited in the setting of a work accident insurance company.

The treatment consists of 20 daily sessions, each lasting 90 minutes for 4 consecutive weeks. Subjects will be evaluated prior to treatment (T0), in session 15 (T1) and in session 30 (T2). The total duration of participation in the study for the participant will be 6 weeks, including evaluation at T0, treatment and evaluation at T1 and T2.

Control group
They will do it in the following order:
-Diathermy 20 min (capacitive 15 min automatic musc/ 5 min manual resistive on C1-C5 sticklebacks) – Thermal effect
-Free active mobility 10 min (without pain) in front of a mirror
-Isometrics resisted by the physiotherapist (2 sets of 10 repetitions) in flexion, extension, lateralization and rotation movements (without pain) and in the Supine position
-Stabilizer (3 x 15 reps – Intensity 20 mmHg)
-Placebo immersive VR: at the end of the session, 2D video with the same duration as the intervention group.

Intervention Group:
Same treatment as Control Group, but with the use of specific VR software with the following:
Day 1: Position: sitting. Duration: 3'. Software: relaxation, free mode (3')
Day 2: Position: sitting. Duration: 5'. Software: relaxation, guided breathing (3'); cervical: flexion+extension, slow, easy difficulty (2').
Day 3: Position: sitting. Duration: 5'. Software: relaxation, free mode (3'); cervical: rotation, slow, easy difficulty (2').
Day 4: Position: sitting. Duration: 7': Software: relaxation, guided breathing (3'); cervical: flexion+extension, slow speed, easy difficulty (2') + rotation, slow speed, easy difficulty (2')
Day 5: Position: sitting. Duration: 10': Software: relaxation, free mode (3'); cervical: flexion+extension, slow speed, medium difficulty (2') + rotation, slow speed, medium difficulty (2') + flexion+extension+rotation, slow speed, easy difficulty (2').
Day 6: Position: standing. Duration: 10'. Software: relaxation, free mode (3'); reaction speed: game mode: one color; response time: 2''; movement on obstacles: no; game time: 2' (2') + game mode: two colors; response time: 2''; movement on obstacles: no; game time: 2' (2') + game mode: one color; response time: 1.5''; movement on obstacles: no; playing time: 2' (2').
Day 7: Position: standing. Duration: 10': Software: relaxation, guided breathing (3'); cervical: flexion+extension, slow speed, medium difficulty (2') + rotation, slow speed, medium difficulty (2') + flexion+extension+rotation, slow speed, medium difficulty (2').
Day 8: Position: standing. Duration: 10'. Software: relaxation, free mode (3'); reaction speed: game mode: one color; response time: 1.5''; movement on obstacles: no; game time: 2' (2') +

game mode: two colors; response time: 1.5''; movement on obstacles: no; game time: 2' (2') + game mode: one color; response time: 1''; movement on obstacles: no; playing time: 2' (2').
Day 9: Position: standing. Duration: 10': Software: relaxation, guided breathing (3'); cervical: flexion+extension, medium speed, medium difficulty (2') + rotation, medium speed, medium difficulty (2') + flexion+extension+rotation, slow speed, medium difficulty (2').
Day 10: Position: standing. Duration: 8': Software: relaxation, free mode (3'); lumbar: story mode, easy difficulty, middle lane, level 1 (5').
Day 11: Position: standing. Duration: 8': Software: relaxation, free mode (3'); lumbar: story mode, easy difficulty, middle lane, level 4 (5').
Day 12: Position: standing. Duration: 10': Software: relaxation, guided breathing (3'); cervical: flexion+extension, medium speed, medium difficulty (2') + rotation, medium speed, medium difficulty (2') + flexion+extension+rotation, medium speed, medium difficulty (2').
Day 13: Position: standing. Duration: 8': Software: relaxation, free mode (3'); lumbar: story mode, easy difficulty, middle lane, level 7 (5').
Day 14: Position: standing. Duration: 10': Software: relaxation, guided breathing (3'); cervical: flexion+extension, slow speed, difficult difficulty (2') + rotation, slow speed, difficult difficulty (2') + flexion+extension+rotation, medium speed, medium difficulty (2').
Day 15: Position: standing. Duration: 10': Software: relaxation, free mode (3'); mazes: story mode, pointer: glasses, overcome the greatest number of levels in the pre-established time (5').
Day 16: Position: standing. Duration: 10': Software: relaxation, guided breathing (3'); cervical: flexion+extension, medium speed, difficult difficulty (2') + rotation, medium speed, difficult difficulty (2') + flexion+extension+rotation, medium speed, difficult difficulty (2').
Day 17: Position: standing. Duration: 8': Software: relaxation, free mode (3'); lumbar: story mode, easy difficulty, all lane, level 1 (5').
Day 18: Position: standing. Duration: 10': Software: relaxation, guided breathing (3'); cervical: flexion+extension, medium speed, difficult difficulty (2') + rotation, medium speed, difficult difficulty (2') + flexion+extension+rotation, medium speed, difficult difficulty (2').
Day 19: Position: standing. Duration: 8': Software: relaxation, free mode (3'); lumbar: story mode, easy difficulty, all lane, level 7 (5').
Day 20:Position: standing. Duration: 10': Software: relaxation, free mode (3'); mazes: story mode, pointer: glasses, overcome the greatest number of levels in the pre-established time (5').

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Dynamics VR

Primary outcome(s)
Measured before treatment (T0), in session 10 (T1) and in session 20 (T2):
1. Pain intensity measured using Numerical Rating Scale (NRS)
2. Disability Perception measured using the Neck Disability Index (NDI)

Key secondary outcome(s)
Measured before treatment (T0), in session 10 (T1) and in session 20 (T2):
1. Active cervical range of motion: measured with digital goniometer by physical therapists in all neck movements: flexion, extension, tilt and rotation
2. Patient satisfaction:

2.1. Satisfaction with Treatment Received Scale CRES-4 (validated in Spanish)
2.2. Patient Global Impression of Change (P-GIC)
3. Fear of movement measured using Tampa Scale-11
4. Days of sick leave: collected as a simple discrete quantitative variable measured using patient records at end of study
5. MVIC of the neck muscles: The positions for each movement were as follows: (1) neck flexor strength was measured in the supine position, with the knees flexed, the head and neck in a neutral position, and the arms along the body; (2) neck extensor strength was measured in the prone position, with the arms along the body; and (3) lateral flexion strength was measured in lateral recumbency, also with the arms along the body. For all test positions, two Velcro bands were used, one in the shoulder region, at T3, and another in the pelvis, at the iliac crest.

Completion date
01/04/2025

Eligibility

Key inclusion criteria
1. Adults (18-65 years)
2. Neck pain associated with whiplash
3. With normal or corrected vision (with glasses or contact lenses)
4. Who are undergoing treatment at umivale Activa Quart de Poblet
5. That signed the informed consent to take part in the study.

Participant type(s)
Patient, Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
1. Inability to participate or attend the treatment program
2. Systemic infection or metabolic/neurological degenerative disorder
3. Fracture or surgery of the cervical spine
4. Specific neck pain due to metastases, neoplasms, infectious or inflammatory. processes, fractures or traumatic history of cervical injury
5. Positive neurological signs or evidence of spinal cord compression (abnormal diffuse tenderness, hyperreflexia, or diffuse weakness)

6. Radiculopathy
7. Epilepsy

Date of first enrolment
01/04/2023

Date of final enrolment
01/10/2023

Locations

Countries of recruitment
Spain

Study participating centre
Umivale Activa
Avda. Reial Monestir de Poblet, 20
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Sponsor information

Organisation
Dynamics VR

Funder(s)

Funder type
Industry

Funder Name
Dynamics VR

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication