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Using virtual reality at home to treat chronic temporomandibular joint disorders

Submission date
30/06/2023

Recruitment status
No longer recruiting

Registration date
18/07/2023

Overall study status
Completed

Last Edited
08/04/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The purpose of this research study is to better understand pain perception and how it can be influenced by using virtual reality tools in a home setting. In this study, we will investigate the effect of pain-specific virtual reality (VR) modules on the physical and psychological responses to pain, as compared to an audio intervention and no-intervention. This study can provide valuable information for a long-term study in the future.

Who can participate?
Adult participants with ongoing chronic orofacial pain primarily diagnosed with temporomandibular disorder (TMD).

What does the study involve?
This study will be completed over one month. During week one, the study team will educate the participants on how to daily record their pain via an online link. From week 2-4, we will assign them several different interventions: virtual reality, audio, or no-intervention. The participants will take part in the study in the comfort of their homes. Through the mail, they will receive a virtual reality headset and audio player. The participants will use the VR device continuously for 5 days with a 20 minutes session each day. In a randomized order, participants will also complete MP3/4 intervention for another 5 days.

What are the possible benefits and risks of participating?
Participants may or may not benefit from participating in this study. The risks of participating include loss of confidentiality, breaching of privacy, the risk associated with psychological questionnaires, the risk associated with immersive VR, and unknown risks.

Where is the study run from?
University of Maryland, Baltimore (USA)

When is the study starting and how long is it expected to run for?
July 2020 to May 2021

Who is funding the study?
MPowering the State grant (USA)

Who is the main contact?
Luana Colloca, MD, PhD, MS
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
HP-00069094

Study information

Scientific Title
At-home virtual reality as a therapeutic approach for individuals with chronic temporomandibular joint disorders

Study objectives
The purpose of this study is to investigate the effect of virtual reality educational modules on pain experiences at home, as compared to an audio intervention and no-intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/07/2020, Institutional Review Board at the University of Maryland Baltimore (620 W Lexington Street, Baltimore City, 21201, United States of America; +1 410-706-5037; hrpo@umaryland.edu), ref: HP-00069094

Primary study design
Interventional

Study design
Randomized controlled cross-over study

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Treatment of chronic pain in patients with temporomandibular joint disorders

Interventions
All participants will receive a 5-day virtual reality treatment, and a 5-day audio treatment with identical contents. The sequence of receiving the treatment will be randomized according to a 1: 1 ratio. These 5-day intervention periods will be preceded and followed by a 5-day run-in period to stabilize the medication and familiarize the daily monitoring method. There will also be a 5-day washout period with no intervention between the intervention periods.

Virtual reality (VR) intervention: Participants will be mailed an AppliedVR headset and controller that can run pre-installed programs with immersive, calming environments and audio. They will complete daily 20-minute sessions for five days.

Audio (MP3/4) intervention: Participants will be mailed an MP3/4 player with pre-installed programs to play soothing audio with identical content to VR (without immersion). They will complete daily 20-minute sessions for five days.

No intervention: No experimental interventions will be introduced to the participants. Participants are allowed to keep their usual care regimen.

Intervention Type
Behavioural

Primary outcome(s)
Daily pain intensity levels will be measured using visual analogue scale (VAS) from 0=no pain at all to 100=maximum tolerable pain.

Key secondary outcome(s)
1. Daily pain unpleasantness, anxiety, mood will be measured using VAS from 0=no pain unpleasantness/no anxiety at all/extremely bad to 100=maximum pain unpleasantness /maximum tolerable anxiety/extremely good.
2. Weekly pain behavior, pain interference, anxiety, and sleep disturbances will be measured using Patient Reported Outcome Measurement Information Systems (PROMIS) tools.

Completion date
11/05/2021

Eligibility

Key inclusion criteria

1. Age (18-75 years old)
2. English speaker (written and spoken)
3. Temporal Mandibular Disorder (TMD) for at least 3 months
4. TMD Grade Chronic Pain Scale (GCPS) ≥1
5. TMD Screening from HP-00068315 2016 and after

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
54

Key exclusion criteria
1. Present or past degenerative neuromuscular disease
2. Cardiovascular, neurological diseases, pulmonary abnormalities, kidney disease, liver disease, history of cancer within past 3 years
3. Any personal (or family first degree) history of mania, schizophrenia, or other psychoses
4. Severe psychiatric condition (e.g. schizophrenia, bipolar disorders, autism) leading to hospitalization within the last 3 years.
5. Lifetime alcohol/drug dependence or alcohol/drug abuse in past 3 months
6. Pregnancy or breast feeding
7. Color-blindness
8. Impaired or uncorrected hearing
9. Any facial trauma that has occurred in the last 6 weeks
10. History of a severe facial trauma in the last 2-3 months
11. Conditions that would interfere with the VR mask placement (e.g. trauma, burn, infection)
12. Known history of severe motion sickness

Date of first enrolment
23/11/2020

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
United States of America

Study participating centre
University of Maryland School of Nursing
655 W.Lombard Street
Baltimore
United States of America
21210

Sponsor information

Organisation
University of Maryland, Baltimore

ROR
https://ror.org/04rq5mt64

Funder(s)

Funder type
Government

Funder Name
MPower State grant

Funder Name
National Center for Complementary and Integrative Health

Alternative Name(s)
Office of Alternative Medicine, National Center for Complementary and Alternative Medicine, NCCIH, OAM, NCCAM

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from the principal investigator Dr. Luana Colloca at colloca@umaryland.edu.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/04/2025	08/04/2025	Yes	No
Participant information sheet			04/07/2023	No	Yes