ISRCTN16093248 https://doi.org/10.1186/ISRCTN16093248

Sleep changes from exercise in chronic pain patients

Submission date
18/07/2023

Recruitment status
No longer recruiting

Registration date
07/08/2023

Overall study status
Completed

Last Edited
07/08/2023

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Exercise could potentially improve chronic pain related outcomes including sleep disturbances, and chronic pain severity and mood. However, the underlying biological pathways are still unknown. This study aims to address the biological changes associated with an orofacial exercise which is designed for the chronic pain population suffering from temporomandibular disorders. Temporomandibular disorders (TMD) are disorders of the jaw muscles, temporomandibular joints, and the nerves associated with chronic facial pain. This study aims to explore the effects of exercise on OMICS, which are biological factors that may predetermine how we cope with pain.

Who can participate?
Adult participants with temporomandibular disorders for more than 3 months.

What does the study involve?
Enrolled participants undergo blood draws at the baseline and at the end of the 4 weeks monitoring. At the first visit, participants will be provided with study equipment and information, with instructions for use during a four-week study period, and then participants will be randomly assigned to one of two groups that will be asked to do different activities as part of the study. At the end of the study timeframe, participants will come to a second lab visit similar to the first day's visit. Each visit will take approximately one hour. Participants will be in the study for
a total of four weeks.

What are the possible benefits and risks of participating?
Benefit: Participants may or may not benefit by taking part in this study. There is no guarantee that participants will receive direct benefit from your participation on this study. Exercises may help relieve the TMD pain. Findings from this study could add to research on how relief of TMD pain affects OMICS
The risks involved in this study are about the same as the risks involved in normal daily life.
1. Risks Associated with Blood Draw: participants may have some discomfort and bruising where the needle entered through the skin. There is also a very small risk of fainting. Infection in the area of needle entry is rare.

2. Risks Associated with Filling Forms and Questionnaires: Participants may experience some emotional discomfort, such as sadness or happiness, while answering questions on the forms or questionnaires.
3. Risks Associated with the Motionwatch 8: There is also the slight chance that the participants will experience some mild irritation or discomfort where the Motionwatch 8 is placed. If this occurs, participants may take off the device.
4. Risks Associated with the Exercises: There may be risks of some mild discomfort or muscle fatigue that feels like a light workout activity. These issues usually resolve in a day or two as participants continue to do the exercises.

Where is the study run from?
University of Maryland School of Nursing (USA)

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

Who is funding the study?
1. National Institute of Nursing Research P30 (AD) (USA)
2. University of Maryland School of nursing start-ups (LC) (USA)

Who is the main contact?
Luana Colloca, MD, PhD, colloca@umaryland.edu

Contact information

Type(s)
Principal investigator

Contact name
Dr Luana Colloca

ORCID ID
https://orcid.org/0000-0002-6503-4709

Contact details
University of Maryland School of Nursing
655 W Lombard Street
Baltimore City
United States of America
21201
+1 410-706-8244
colloca@umaryland.edu

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HP-00085798

Study information

Scientific Title
Exercise improves sleep in chronic pain patients: A feasibility interventional study with ecological momentary assessment to capture long-term sleep patterns

Acronym
EMASLEEPEXERCISETMD

Study objectives
Exercise improves total sleep time, sleep efficiency, sleep latency, and sleep fragmentation in chronic pain patients compared to non-exercise group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/01/2020, University of Maryland Institutional Review Board (620 West Lexington Street, Baltimore, 21201, United States of America; +1 410-706-5037; hrpo@umaryland.edu), ref: HP-00085798

Study design
This study is a single center interventional randomized parallel design clinical trial where participants are randomly assigned to either 1) exercise group where they perform a set of orofacial exercise for 4 weeks, or 2) natural history group where they will keep their usual care for the chronic pain.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic temporomandibular pain disorder

Interventions
Each day, participants in exercise group will complete the following: chin tucks 10x/hour holding for 5 seconds, 30-60 seconds of closure-muscle stretching exercise 6x/day, 15 seconds of chest stretch 3x/day with 2 reps each, 15 seconds of wall stretch 3x/day with 2 reps each, 10 repetitions of on-your-back neck stretch before bed, 1x/day of face-down arm lifts for 5 days /week.

Participants in the natural history group will keep their daily usual care and daily exercise if applicable.

The randomization is conducted by an independent statistician where half of the participants are assigned to the exercise group while the other half are assigned to no exercise group.

Intervention Type
Behavioural

Primary outcome(s)
1. Sleep quality is measured using Patient-Reported Outcomes Measurement Information System (PROMIS) sleep disturbances, and an actigraph watch continuously for the 4 weeks of the study. PROMIS-sleep disturbance is measured at baseline, week 1 to week 4. Actigraphy is obtained continuously over the 4 weeks.
2. Chronic pain related outcomes including chronic pain interference, pain behavior, depression and anxiety were assessed weekly using PROMIS pain interference, pain behavior, depression and anxiety scales. Pain related outcomes are measured at baseline, week 1 to week 4.

Key secondary outcome(s))
Peripheral blood mononuclear cells RNA changes. Peripheral blood is withdrawn at the baseline enrollment visit and at the end of the intervention period for both exercise and no exercise groups.

Completion date
15/07/2022

Eligibility

Key inclusion criteria
1. Aged 18 - 65 years
2. Can speak and write in English
3. Myogenous chronic non-neuropathic pain equal to at least 2 on a scale of 1-10 for orofacial pain
4. Pain duration longer than 3 months
5. Type of pain is in the jaw, temple, in ear, or in front of the ears
6. Pain is modified with jaw movement, function, or parafunction
7. Exam positive for confirmation of pain location(s) in the temporalis or masseter muscle(s) and reports familiar pain in the temporalis or masseter muscle(s) with at least one of the following provocation tests: Palpation of the temporalis or masseter muscle(s) or maximum unassisted or assisted opening movement(s).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Aged over 65 years
2. History of local or general trauma, degenerative neuromuscular diseases, cervical pain (ie. stenosis, radiculopathy)
3. Removable full dental prostheses
4. Neuropathic temporomandibular pain
5. Major neurological or psychiatric disorders (ie. schizophrenia, bipolar disorders, autism).

Date of first enrolment
02/02/2021

Date of final enrolment
15/06/2022

Locations

Countries of recruitment
United States of America

Study participating centre
University of Maryland School of Nursing
655 W Lombard St
Baltimore
United States of America
21201

Sponsor information

Organisation
National Institute of Nursing Research

ROR
https://ror.org/01y3zfr79

Organisation
University of Maryland, Baltimore

ROR
https://ror.org/04rq5mt64

Funder(s)

Funder type
Government

Funder Name
National Institute of Nursing Research

Alternative Name(s)
National Institute of Nursing Research National Institutes of Health, NINR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
University of Maryland School of Nursing

Alternative Name(s)
University of Maryland, College Park, The University of Maryland, College Park, Maryland Agricultural College, Maryland State College, UMD

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr. 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?
Participant information sheet			20/07/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes