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Comparing a custom dental splint with standard headache medicines for tension-type headache and migraine

Submission date
23/07/2026

Recruitment status
No longer recruiting

Registration date
27/07/2026

Overall study status
Completed

Last Edited
27/07/2026

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Tension-type headache and migraine are common conditions that can affect daily life, work and wellbeing. Some people with headaches also have problems with their jaw joints, jaw muscles or teeth grinding during sleep. This study compared two different treatment approaches. One treatment used a custom-made dental splint worn at night. The other used standard headache medicines prescribed by a neurologist. The aim was to find out whether dental splint treatment could reduce headache pain and headache-related disability compared with standard drug treatment.

Who can participate?
People could take part if they:
- Were aged 18 to 65 years
- Had a diagnosis of tension-type headache or migraine confirmed by a neurologist
- Had experienced headaches for at least 3 months
- Had at least 4 headache days per month

People could not take part if they had a headache caused by another medical condition, had used a dental splint within the previous 12 months, had certain active inflammatory or infectious diseases, had severe jaw joint inflammation needing urgent surgery, were pregnant, or did not give informed consent.

What does the study involve?
Participants were assigned to one of two groups through the normal clinical referral process. The first group received a custom-made hard acrylic dental splint. Before receiving the splint, participants had an assessment of their jaw function, jaw pain and possible teeth grinding during sleep. The splint was adjusted after 1 week and then worn at night for 12 weeks.
The second group received standard medical treatment from a neurologist. Treatment could include medicines used to stop headaches when they occur and medicines used to help prevent future headaches.
Both groups were followed for 12 weeks. Participants attended assessments at the start of the

study and after 2, 6 and 12 weeks. Researchers collected information about headache pain, headache frequency, daily functioning, anxiety, depression, pain location and use of headache medicines.

What are the possible benefits and risks of participating?
Participants may have experienced an improvement in their headache symptoms and may have benefited from regular monitoring by healthcare professionals. The study may also help improve future treatment options for people with tension-type headache or migraine.
Possible risks in the dental splint group may have included discomfort when wearing the splint or temporary changes in how the teeth or jaw felt. Participants receiving medication may have experienced side effects associated with their prescribed medicines. As with any clinical study, there may also have been inconvenience from attending study visits and completing questionnaires.

Where is the study run from?
The study is run from the Medical University of Warsaw in Warsaw, Poland.

When is the study starting and how long is it expected to run for?
April 2024 to July 2026

Who is funding the study?
The study is funded by the Minister of Education and Science of the Republic of Poland.

Who is the main contact?
Dr Katarzyna Kępczyńska, katarzyna.kepczynska@wum.edu.pl

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title

Occlusal splint therapy versus standard pharmacotherapy in patients with tension-type headache and migraine: an interdisciplinary dental–neurological comparative study

Study objectives
To evaluate whether occlusal splint therapy, delivered following structured DC/TMD-based prosthodontic assessment, reduces headache pain intensity and headache-related disability compared with standard neurological pharmacotherapy in patients with tension-type headache and migraine.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/01/2024, Bioethics Committee of the Medical University of Warsaw (Żwirki i Wigury Street 61, warsaw, 02-091, Poland; +48 22 5720303; komisja.bioetyczna@wum.edu.pl), ref: KB/9/2024

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Tension-type headache and migraine (ICHD-3 criteria), with comorbid assessment of temporomandibular disorder and nocturnal bruxism

Interventions
Patients in the splint group (n=60) received an individually fabricated hard-acrylic stabilisation occlusal splint, with vertical thickness determined by cephalometric analysis, following structured prosthodontic assessment including the DC/TMD-based TMD Pain Screener and nocturnal bruxism assessment per International Consensus criteria. The splint was adjusted at a 1-week review appointment and worn nocturnally throughout the 12-week observation period, with compliance monitored by patient diary and clinical inspection at each follow-up visit. Patients in the control group (n=29) received standard neurological pharmacotherapy individualised by the treating neurologist according to European Headache Federation guidelines, comprising acute medications (triptans, NSAIDs, gepants) and preventive agents

selected according to headache diagnosis, attack frequency, and patient profile.
Both groups were followed for 12 weeks with assessments at baseline, 2, 6, and 12 weeks. Group allocation followed the interdisciplinary clinical referral pathway rather than randomisation.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Custom hard-acrylic stabilisation occlusal splint

Primary outcome(s)
1. Headache pain intensity measured using Numerical Rating Scale (NRS, 0–10) at Baseline, 2 weeks, 6 weeks, and 12 weeks

Key secondary outcome(s)
1. Headache-related disability measured using Migraine Disability Assessment (MIDAS) score at Baseline, 2 weeks, 6 weeks, and 12 weeks

2. eadache frequency measured using Self-reported number of headache days per month at Baseline, 2 weeks, 6 weeks, and 12 weeks

3. Depression and anxiety symptoms measured using Patient Health Questionnaire-4 (PHQ-4) at Baseline, 2 weeks, 6 weeks, and 12 weeks

4. Generalised anxiety symptoms measured using Generalised Anxiety Disorder-7 (GAD-7) at Baseline, 2 weeks, 6 weeks, and 12 weeks

5. Pain localisation measured using Pain drawing (body/facial pain map) at Baseline, 2 weeks, 6 weeks, and 12 weeks

6. Pharmacological consumption measured using Self-reported analgesic and triptan use at Baseline, 2 weeks, 6 weeks, and 12 weeks

Completion date
06/07/2026

Eligibility

Key inclusion criteria
1. Aged 18–65 years
2. Neurologist-confirmed primary headache diagnosis of tension-type headache or migraine according to ICHD-3 criteria
3. Minimum 3 months of active headache history
4. At least 4 headache days per month

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
89

Key exclusion criteria
1. Secondary headache aetiology
2. Prior occlusal splint use within 12 months
3. Active inflammatory or infectious disease
4. Acute temporomandibular joint inflammation requiring immediate surgical intervention
5. Pregnancy
6. Refusal of informed consent

Date of first enrolment
30/04/2024

Date of final enrolment
13/04/2026

Locations

Countries of recruitment
Poland

Sponsor information

Organisation
Medical University of Warsaw

ROR
https://ror.org/04p2y4s44

Funder(s)

Funder type

Funder Name
Government, Minister of Education and Science of the Republic of Poland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request