ISRCTN96737564 https://doi.org/10.1186/ISRCTN96737564

Can jaw exercises with wooden tongue depressors prevent restricted mouth opening after radiotherapy for head and neck cancer?

Submission date
25/08/2026

Recruitment status
No longer recruiting

Registration date
26/08/2026

Overall study status
Completed

Last Edited
09/11/2026

Condition category
Cancer

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator

Contact name
Prof Syed Nabil Syed Omar

Contact details
Universiti Kebangsaan Malaysia, Jalan Raja Muda Abdul Aziz
Kuala Lumpur
Malaysia
50300
+60 (0)3-92897742
syednabil@ukm.edu.my

Type(s)
Public, Scientific

Contact name
Dr Tharmentheran Pitchaimuthu

Contact details
No 18 Jalan Palma 1E, Bukit Palma Kemensah
Hulu Klang
Malaysia
53100

+60 (0)123006273
P138663@siswa.ukm.edu.my

Additional identifiers

Study information

Scientific Title
A randomized controlled trial of structured jaw exercises using wooden tongue depressors versus basic jaw exercises for preventing radiotherapy-induced trismus and preserving mouth opening and mandibular function in adults with head and neck cancer

Study objectives
1. To determine maximum mouth opening (MMO) and maximum interincisal distance (MID) measurements before, during, and after radiotherapy
2. To determine the effectiveness of the wooden tongue depressor exercise program in reducing radiotherapy-induced trismus (RIT) severity by comparing between intervention and control groups
3. To assess the relationship between RIT severity and quality of life using validated questionnaires
4. To explore how demographic and clinical variables affect the intervention’s success

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/11/2023, National University of Malaysia Research Ethics Committee (Hospital Canselor Tuanku Muhriz Jalan Yaacob Latif Kuala lumpur, Bandar Tun Razak, Cheras, 56000, Malaysia; +60 (0)3-91455046/5048; sepukm@ukm.edu.my), ref: UKM PPI/111/8/JEP-2023-524

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility, Prevention

Study type(s)

Health condition(s) or problem(s) studied
Adults with head and neck cancer receiving radiotherapy

Interventions
Current interventions as of 10/09/2026:

This single-centre, parallel-group randomised controlled trial recruited adults with head and neck cancer who were receiving radiotherapy at Hospital Canselor Tuanku Muhriz, Universiti Kebangsaan Malaysia. Participants were randomised in a 1:1 ratio using block randomisation generated by Random Allocation Software version 1.0 by a departmental statistician. The allocation sequence was concealed in sequentially numbered, opaque, sealed envelopes. The enrolling investigator opened the relevant envelope after completion of the baseline assessment. Stratified randomisation was not used.

Active control group:
Participants were taught basic jaw-opening, closing, and side-to-side exercises. They performed the exercises twice daily for 30 seconds for 20 weeks.

Intervention group:
Participants completed a structured 20-week programme using wooden tongue depressors. The 5-5-30 protocol consisted of five sessions each day, with five cycles per session and a 30-second stretch in each cycle. Each session began with 10 repetitions of jaw opening and small lateral movements, followed by chin movements to the left, right, and forward held for 3 seconds each and maximal mouth opening held for 10 seconds. For passive stretching, participants inserted a tolerable stack of wooden tongue depressors, added one further depressor, and held the stretch for 30 seconds. The number of depressors was progressively increased as tolerated.

Mouth opening was measured at baseline before radiotherapy and at 10 and 20 weeks after initiation of radiotherapy. Mandibular function was assessed at the same three timepoints, and health-related quality of life was assessed at 20 weeks after initiation of radiotherapy. Standard oncological treatment, including radiotherapy, chemotherapy, and surgery where applicable, was determined by the treating team and was not allocated by the study.

———

Previous interventions:

This single-centre, parallel-group randomised controlled trial recruited adults with head and neck cancer who were receiving radiotherapy at Hospital Canselor Tuanku Muhriz, Universiti Kebangsaan Malaysia. Participants were randomised in a 1:1 ratio using block randomisation generated by Random Allocation Software version 1.0 by a departmental statistician. The allocation sequence was concealed in sequentially numbered, opaque, sealed envelopes. The enrolling investigator opened the relevant envelope after completion of the baseline assessment. Stratified randomisation was not used.

Active control group:
Participants were taught basic jaw-opening, closing, and side-to-side exercises. They performed the exercises twice daily for 30 seconds for 20 weeks.

Intervention group:
Participants completed a structured 20-week programme using wooden tongue depressors. The 5-5-30 protocol consisted of five sessions each day, with five cycles per session and a 30-second

stretch in each cycle. Each session began with 10 repetitions of jaw opening and small lateral movements, followed by chin movements to the left, right, and forward held for 3 seconds each and maximal mouth opening held for 10 seconds. For passive stretching, participants inserted a tolerable stack of wooden tongue depressors, added one further depressor, and held the stretch for 30 seconds. The number of depressors was progressively increased as tolerated.

Mouth opening was measured at baseline before radiotherapy and at 10 and 20 weeks after radiotherapy. Mandibular function was assessed at the same three timepoints, and health-related quality of life was assessed at 20 weeks after radiotherapy. Standard oncological treatment, including radiotherapy, chemotherapy, and surgery where applicable, was determined by the treating team and was not allocated by the study.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Wooden tongue depressors (non-commercial exercise aid)

Primary outcome(s)
1. Mouth opening measured using maximal interincisal distance (dentulous participants) or maximal mouth opening between the maxillary and mandibular alveolar ridges (edentulous participants), measured in millimetres using a calibrated WIHA digital calliper at baseline before radiotherapy, 10 weeks after initiation of radiotherapy, and 20 weeks after initiation of radiotherapy

Previous primary outcome(s):

1. Mouth opening measured using maximal interincisal distance (dentulous participants) or maximal mouth opening between the maxillary and mandibular alveolar ridges (edentulous participants), measured in millimetres using a calibrated WIHA digital calliper at baseline before radiotherapy, 10 weeks after radiotherapy, and 20 weeks after radiotherapy

Key secondary outcome(s)
1. Mandibular function measured using the 17-item Mandibular Function Impairment Questionnaire (MFIQ) at baseline before radiotherapy, 10 weeks after initiation of radiotherapy, and 20 weeks after initiation of radiotherapy

Previous key secondary outcome(s):

1. Mandibular function measured using the 17-item Mandibular Function Impairment Questionnaire (MFIQ) at baseline before radiotherapy, 10 weeks after radiotherapy, and 20 weeks after radiotherapy

Completion date
13/11/2026

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Coherent: demonstrates the capacity to perform mouth opening exercises independently and effectively
3. Able to communicate in English, Bahasa Malaysia, or Mandarin
4. Patients diagnosed with head and neck cancer with documented tumour staging and histopathological examination
5. Having any head and neck cancer, excluding larynx
6. Underwent radiotherapy treatment either exclusively or combined with chemotherapy and/or surgical treatment

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
38

Key exclusion criteria
1. Poor general health with need of assistance or care
2. Patient is unable to perform mouth exercises independently
3. Patient refused/declined or passed away between follow-up reviews
4. Patient whose radiotherapy treatment was interrupted or placed on hold

Date of first enrolment
05/12/2023

Date of final enrolment
10/01/2026

Locations

Countries of recruitment
Malaysia

Study participating centre
Tuanku Muhriz Chancellor Hospital
Jalan Yaacob Latif Kuala lumpur, Bandar Tun Razak

Cheras
Malaysia
56000

Sponsor information

Organisation
National University of Malaysia

ROR
https://ror.org/00bw8d226

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/10/2026	09/11/2026	Yes	No
Other files			26/08/2026	No	No
Participant information sheet			26/08/2026	No	Yes