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Effects of manual therapy on oral opening, swallow function and upper quarter mobility in Chilean survivors of head and neck cancer: a study protocol for a controlled, randomised study (MAnual ThErapy for Oral Opening (MATEO) study)

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ABSTRACT

Introduction Head and neck cancer (HNC) accounts for over 4% of global cancer incidence, yet the oncological treatment induces several sequelae such as oral dysfunction, cervical and shoulder impairments or pain that are not well addressed. Thus, survivors of HNC (sHNC) perceive a decrease in their quality of life (QoL). This study protocol aims to investigate the effects of manual therapy (MT) to determine the effectiveness and safety on oral opening, swallow function and upper quarter mobility, cervical muscle strength, pain, functionality and QoL of sHNC.

Methods and analysis A randomised controlled trial will include 70 sHNC over 18 years of age and will be divided into two groups. Intervention will last for 6 weeks with a total of 18 sessions, including MT targeting mastication and head and neck muscles. The control group will receive motor control exercises. The main outcomes will be oral opening and swallow function. An intention-to-treat analysis will be performed to evaluate the effectiveness of the intervention, which will be further determined with the calculation of effect sizes expressed in Cohen's d.

Ethics and dissemination The study was approved by the Ethics Committee of the Universidad de La Frontera (File 001_24) according to the Helsinki Declaration for Biomedical Research. All participants will provide informed consent. Study results will be published in open access peer-reviewed journals and may be shared at relevant meetings and research meetings.

Trial registration number This trial was registered with ClinicalTrials.gov on 28 November 2023 (code: NCT06148077).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The interventions in this protocol are clearly defined in this manuscript and are based on previously published protocols, enhancing their reliability. This provides a standardised framework that enables other physical therapists to implement the interventions consistently and compare findings in future research.

⇒ This study builds on widely used physiotherapy techniques, making it practical for various healthcare settings, from hospitals to rehabilitation centres and outpatient clinics. Its standardised approach ensures consistency while allowing flexibility to adapt to other patient populations with similar needs. Additionally, it provides a clear framework that supports meaningful research comparisons across different healthcare systems and communities.

⇒ This prospective work as a randomised controlled trial will track homogeneous mid-term follow-up.

⇒ This study has methodological limitations: (1) the single-blinded design may introduce bias, as only evaluators are blinded, while therapists and participants are aware of treatment allocation. (2) The heterogeneous participant population, with varying cancer types, treatments and timelines, increases response variability, making it harder to identify specific subgroups that benefit most.

INTRODUCTION

Head and neck cancer (HNC) involves the upper aerodigestive tract, including the oral cavity, pharynx, larynx, nasal cavity, paranasal sinuses and salivary glands.[1] Generally, it arises in the squamous cells of epithelial surfaces, commonly known as squamous cell carcinoma of the head and neck.[2] In 2020, it accounted for over 4% of global cancer incidence, ranking among the top 10 most prevalent types.[3] It predominantly affects individuals over 50 years old. In terms of

gender distribution, male predominance is present at a ratio of 3:1.[4]

Currently, there is an epidemiological transition due to an increased incidence of HNC associated with Human Papillomavirus infection in younger males, who are generally diagnosed at earlier stages with a better prognosis.[5] Considering the above and in response to improvements in early detection strategies and oncological treatments, it is estimated that survival rates in stage I are 80% or higher, while in advanced stages (III–IV), reach 40%.[6]

The standard treatment for these patients includes surgery, radiotherapy and chemotherapy or combined treatments like chemoradiotherapy (CRT), which are associated with a wide variety of side effects.[7] For example, surgery is required for tumour resection. This procedure can be related to the resection or injury of the spinal accessory nerve, which is the principal motor nerve of the trapezius and sternocleidomastoid muscles, affecting movements like elevation of the shoulder, rotation and flexion of the neck.[8] For its part, radiotherapy could lead to fibrotic changes in the tissues, causing a reduction of the maximum mouth opening (MMO) and the cervical and shoulder range of motion (ROM), in addition to loss of salivary gland functions and osteoradionecrosis.[9] Finally, CRT is related to nutritional symptoms such as trismus, dysphagia and oral pain and is one of the treatments that generates the greatest disability in survivors of HNC (sHNC).[10]

Together, all these impairments could significantly affect these patients' quality of life (QoL).[10 11] Among all of those, trismus—defined as MMO <35 mm[12] has been reported as the second most common comorbidity in sHNC.[13] It is mainly associated with postradiotherapy subcutaneous fibrosis, muscle atrophy, damage to neck neurological structures, or a combination of these factors affecting the masticatory muscles.[14] Thus, physical capacity, feeding and communication abilities are affected, leading to a decrease in the overall QoL perception in sHNC[14 15] and may even impact the ability to return to work.[16] In addition, loss of shoulder flexibility and strength is related to deficits in functionality and QoL in this population.[17]

Among the physiotherapeutic tools commonly used to address these dysfunctions are therapeutic exercise (known as motor control)[18] and manual therapy (MT). The latter, a general term for manipulation of soft tissue, such as petrissage, effleurage and myofascial release, has effects on improving circulation, reducing local ischaemia, stimulating proprioception and synovial fluid production, decreasing muscle spasm, and breaking fibrous adhesions[19 20] could have promising effects on the sequelae presented by sHNC. This is similar to breast cancer patients, where published meta-analyses support the utility of MT.[21]

However, the existing evidence in HNC is limited but emerging, including a retrospective case series, in which improvement in MMO was observed in patients with radiation-associated trismus after one session of MT.[14] Moreover, other prospective experimental studies on sHNC focus on a kind of MT known as myofascial induction therapy (MIT), showing promising results over MMO, pain and cervical function.[9 11] Additionally, a systematic review highlighted the benefits of MT on sHNC, but without MMO as an outcome of interest.[20] Finally, a scoping review focused on the use of MT and jaw mobilisation devices over MMO on sHNC, describing the paucity of studies led by physical therapists and, therefore, MT as a therapeutic tool for this population.[12]

Well-designed prospective experimental studies with explicit protocols regarding the modality of techniques, duration, frequency and following period are required. First, this study aims to evaluate the reliability and reproducibility of previously described protocols by applying them within a standardised and clearly defined framework. Second, MAnual ThErapy for Oral Opening (MATEO) is designed to differentiate the effects of hands-on MT from those of active motor control exercises, allowing us to assess the individual and combined efficacy of these two well-established interventions. By incorporating both objective measures and patient-reported outcomes, this trial seeks to contribute robust evidence that can guide clinical decision-making and support the integration of these approaches into routine care for sHNC. Moreover, this study aims to determine the effectiveness and safety of MT on oral opening, swallow function and upper quarter mobility, cervical muscle strength, pain, functionality and QoL perception in sHNC.

METHODS AND ANALYSIS

Study design

This protocol for a randomised controlled trial (RCT) study aligns with the recommendations of the Standard Protocol Items: Recommendation for Interventional Trials (SPIRIT) (online supplemental material 1),[22] the Consolidated Standards of Reporting Trials Statement,[23] and the Template for Intervention Description and Replication checklist (online supplemental material 2).[24] The MATEO trial was registered with ClinicalTrials.gov on 28 November 2023 (code: NCT06148077), and the stage it relates to is Pre-results.[25]

An effectiveness study will be performed based on a RCT design of 2 parallel groups, including an experimental group and a control group, to examine the effects of the MATEO programme. The entire protocol of the present study will be performed at the MovInRehab Laboratory at the University of La Frontera, Temuco, Chile. The study population will be sHNC diagnosed with at least one of the following symptoms: trismus/temporomandibular disorders (TMD) or signs of cervical and/or shoulder dysfunction. Individuals will be recruited from Complejo Asistencial Padre Las Casas and Hernán Henríquez Aravena Hospital in Temuco, Chile (figure 1).

The sampling design for both groups will be non-probabilistic convenience sampling using a snowball sampling strategy. Individuals who express interest in

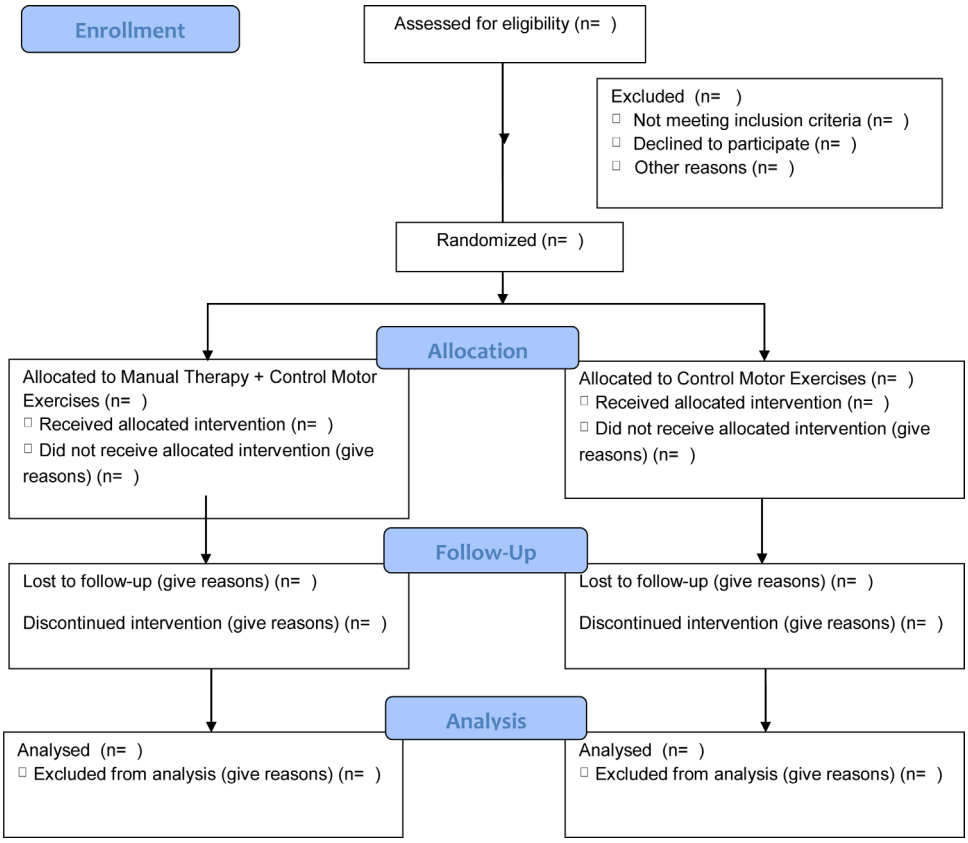

Figure 1 The proposed Consolidated Standards of Reporting Trials diagram of enrolment, allocation, follow-up and analysis throughout the study for each arm.

participating will be informed about the procedures, risks and benefits, so they can voluntarily and freely decide to participate. It will be emphasised that non-participation or withdrawal will have no consequences once accepted into the study. Additionally, they must read the informed consent document and address any potential questions before signing it. All procedures will be conducted under the Declaration of Helsinki.[26]

Randomisation and blinding

Once the recruitment process is complete, participants will be randomised (1:1 ratio) into each group using a random number generation programme (EPIDAT V.4.2, Xunta de Galicia, Spain). Even numbers will allocate participants to the intervention group, and odd numbers will allocate participants to the control group.

An external researcher will perform the randomisation process after the baseline assessment and inform the physical therapist of the intervention about each participant's allocation. Moreover, outcome assessors and data analysers will be blinded to the randomisation of the participants.

Calculation of the sample size

The estimation of the sample size and statistical power for the trial was determined based on the effect size (Cohen's d ≥0.8) with a power of 95% and a significance level alpha (α) of 0.05. A minimum of a 5 mm difference in the MMO between groups was established to calculate our sample size, based on previous studies.[11 27] This will require a sample of 35 participants per group, which will result in a total of 70 participants. Therefore, a maximum monitoring loss of 10% will be allowed. The G*Power V.3.1.9.7 software (Düsseldorf, Germany) is used to carry out this sample calculation.

Eligibility criteria

The inclusion criteria will be (1) individuals with HNC, (2) individuals over 18 years of age, (3) individuals who have undergone oncological surgery of the head and neck and/or radiotherapy, (4) having finished oncological medical treatment between 3 and 36 months before inclusion, (5) at least one of the following: trismus, TMD or signs of cervical and/or shoulder dysfunction and (6) Spanish native speakers. The exclusion criteria will be (1) sequelae of stroke previous, (2) structural instability and/or osteoporosis of the cervical spine, spondylosis, cervical herniated discs, (3) active osteoradionecrosis or open wounds (fistulas, soft tissue necrosis) in the anatomical treatment area, (4) tracheostomised individuals, (5) metastasis or active cancer and (6) refusal to participate.

Intervention

The MATEO programme consists of 18 sessions over 6 weeks (three sessions per week). The length of this programme is based on the previous work of Ortiz-Comino *et al*.[11] It will be a physical therapist-led programme that applies MT and motor control exercises.

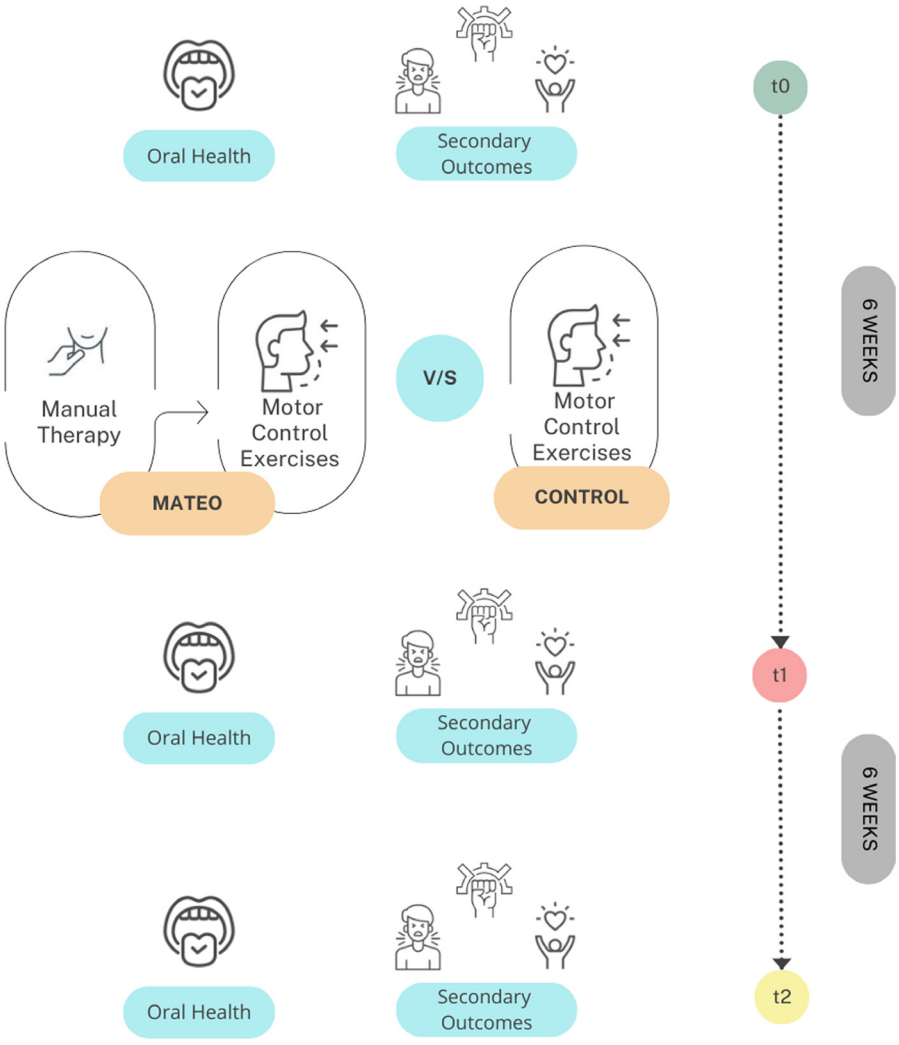

Figure 2 Overview of the MAnual ThErapy for Oral Opening (MATEO) trial intervention group session.

All the procedures will be realised at the MovInRehab laboratory by a physical therapist with experience in MT (figure 2). Programme adherence will be reported by registering assistance on each day of the study intervention; only participants with 75% or more of attendance will be included in the following statistical analysis.[28]

After the initial assessment, all the intervention group participants will be treated with MT and motor control exercises similar to the intervention performed by McMillan *et al*[14]; the control group will be treated only with motor control exercises, based on the Manual Therapy for Fibrosis-Related Late Effect Dysphagia (MANTLE) trial described by Hutcheson K *et al*.[29] The sessions will be performed individually and face-to-face on alternate days, with a minimum rest period of 40 hours between sessions.[11] The potential adverse effects, such as pain, dizziness or faintness, will be registered during the intervention programme.

The MT session will be held with the patient in a supine position or sitting in a chair (in case the patient cannot reach this position) to receive the treatment. The selected manoeuvres will focus on cervical, masticatory and shoulder regions. Besides, intraoral manoeuvres will be made using latex gloves for the masseter, medial and lateral pterygoid muscles. Subsequently, motor control exercises will be performed, which will focus on strengthening and stretching exercises for the cervical, masticatory and shoulder muscles. Patients should not experience pain exceeding a level of two on the EVA scale (0–10)[30] (figure 3).

Participants will be notified of their assessment and treatment appointments by phone or e-mail according to their preferences. Moreover, to enhance the retention of treatment groups, participants will be constantly informed about how many weeks and sessions remain.

While the timeline and overall treatment approach align with established protocols (Ortiz-Comino *et al*'s and McMillan *et al*'s).[11 14] The MATEO programme introduces several distinctive elements. A key innovation is the integration of specific MT techniques that target the fascial connections between the cervical, masticatory and shoulder regions, differing from conventional treatments that typically address these areas in isolation. Additionally, the programme follows a progressive treatment algorithm that systematically addresses movement restrictions in a cranial–caudal sequence, starting in the

GROUP	PROCEDURE	TECHNIQUES	FREQUENCY	TIME	DETENTION CRITERIA
Intervention	Manual Therapy+Motor Control Exercises	1. Extraoral maneuvers such as petrissage, effleurage and myofascial release over cervical, masticatory, and shoulder regions. 2. Intraoral maneuvers for masseter, medial and lateral pterygoid. 3. Motor control exercises described for control group.	Three times per week (alternate days)	15 minutes for MT 35 minutes for motor control exercises	VAS>2 (0-10)
Control	Motor Control Exercises	1. Stretching: • Upper cervical anterior and posterior glide, lateral glide. • Upper+lower cervical flexion/extension, lateral tilt, cervical rotation. • Buccal opening. • Protrusion, retraction, and lateral sliding. 2. Isometric exercises: • Cervical retraction glide+extension, slip+flexion. • Mouth opening. • Mandibular protrusion and retraction. • Lateral slippage of the mandible (to both sides). • Bite. • Scapular retraction.	Three times per week (alternate days)	Stretching: 3 times holding for 20 seconds. 15 minutes total Isometric exercises:3 sets of 10 repetitions held for 3-5 seconds. 20 minutes total	VAS>2 (0-10)

Figure 3 Overview of the intervention procedures. Based on Ortiz-Comino *et al*'s and McMillan *et al*'s[11 14] previous work. MT, manual therapy; VAS, visual analogue scale.

oral region, then prioritising cervical mobility before advancing to shoulder function. This sequence relates to the anatomical, functional and pathophysiological relationship between the cervical spine and TMD, suggesting that treating these regions in this order leads to improved functional outcomes.[30–32]

Outcome measurements

Demographic (age, sex, alcohol consumption and tobacco habits) and clinical (time since diagnosis, time since last oncological treatment, tumour location, tumour stage and oncological treatment received) data will be recorded at the first appointment with the participants.

sHNC will be assessed at three different times: baseline (T0), at the end of the 6-week intervention (T1) and 6 weeks after the end of the intervention (mid-term) (T2), following the recommendations of the SPIRIT diagram (figure 4). Assessments will be performed in one session of approximately 1 hour by an assessor blinded to the aims of the study and to each patient's assigned group.

Primary outcome: oral opening and swallow function

This outcome is composed of:

A. *MMO*: this will be assessed using a sliding calliper, with the patient sitting in a chair. sHNC will be asked to open their mouth as wide as possible, and then the evaluator will measure the distance (mm) between the upper and lower incisors.[33] Edentulous sHNC patients who wear a dental prosthesis will be asked to wear them during assessments.[34] In the case of edentulous participants without dental prostheses, the distance (mm) between the corresponding location of the upper and lower gums will be registered.[14] The reliability of the MMO assessment is excellent, with an intraclass correlation coefficient (ICC) of 0.95–0.96.[35]

B. *TMD*: the Fonseca Anamnestic Index will be used to assess TMD.[36] This self-administered questionnaire has 10 items, with three possible answers: 'yes' (10 points), 'sometimes' (five points) or 'no' (0 points). The total score is classified according to the following categories: no TMD, medium dysfunction, moderate dysfunction and severe dysfunction. The reliability of this tool in its Spanish version is excellent, with an ICC of 0.93.[37]

C. *Swallowing function and difficulty*: the Eating Assessment Tool-10 will be used, which consists of 10 items with a scoring range from 0 (absence of a problem) to 4 (severe problem), where a higher total score indicates greater difficulty in swallowing. The reliability of this questionnaire is quite high, with a Cronbach's alpha of 0.88.[38] Plus, the visual analogue scale (VAS) will be used to measure difficulty in swallowing, employing a horizontal line of 10 cm in length with the phrases 'no difficulty' at its left end and 'impossible' at its right end. Additionally, subjects will be asked in which phase of swallowing they perceive the greatest difficulty: (0) no problem; (1) preoral phase (ie, impairments when opening the mouth); (2) oral phase (ie, difficulty to move the mandible and the tongue to push the bolus through the oral cavity); (3) pharyngeal phase (ie, impairment to move the bolus through

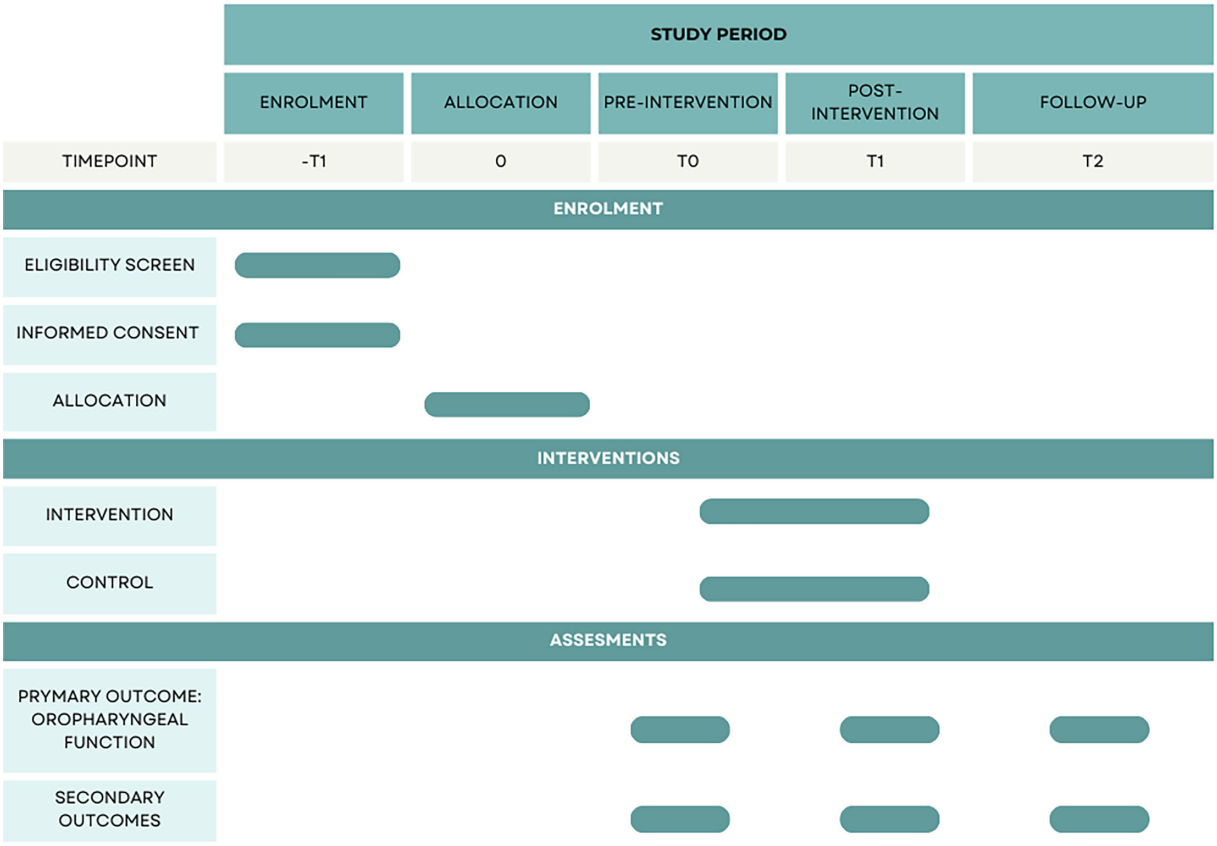

Figure 4 Example template of recommended content for the schedule of enrolment, interventions and assessments.

the pharynx) and (4) preoral, oral and pharyngeal phases.[39]

D. Dysphagia: the 100 mL water swallow test was performed to evaluate dysphagia.[40] During this test, participants have to drink 100 mL of water, whereas evaluators register (1) swallow volume (ie, number of swallows taken to drink 100 mL of water) and (2) swallow capacity (millilitres swallowed divided by time taken). In case the patient reported choking when drinking, this test was not performed, and the score was zero for both items. In case patients (1) cough or choke postswallow, (2) have a wet voice quality postswallow or (3) are unable to drink the whole amount of water, the test will be assessed as 'invalid'. The sensitivity and specificity of this test in the HNC population to detect swallowing impairments are >67% and >46%, respectively.[40]

Secondary outcomes

A. *Cervical and shoulder active range of motion (AROM)*: the AROM of cervical flexion, cervical extension, cervical lateral flexion (inclination) and cervical rotation will be measured in degrees by using a cervical ROM instrument, CROM device (Performance Attainment Associates, Spine Products, Roseville, MN, USA). Movements will be assessed bilaterally with the subject seated and feet resting on the floor. The ICC ranges from 0.89 to 0.98, depending on the performed movement.[41] The AROM of shoulder flexion, abduction and external and internal rotations will be evaluated bilaterally. Measurement will be conducted using a manual two-armed goniometer with a 360° ROM. During measurement, the subject will be in a supine position and will be asked to perform different movements from the initial position to the maximum possible ROM, whether limited by joint end-range, stiffness or pain. Compensatory body movements during the motion will be avoided. Joint measurement using a goniometer has an ICC of 0.94, with a 95% CI of 0.91 to 0.99[42] (online supplemental material 3).

B. *Strength and endurance*: the deep cervical flexor endurance test will be used to assess cervical muscle endurance, an outcome that may be impaired after oncological medical treatment (ie, surgery and radiotherapy). To perform this test, subjects will be supine on the examination table, with the evaluator's hands placed under their head. They will be asked to assume a double chin position to induce flexion of the upper cervical muscles and to lift their head only as much as necessary to avoid touching the evaluator's hands. Using a stopwatch, the time (s) will be recorded from when the subject lifts their head until (1) the subject is unable to maintain the position any longer, (2) the head rests on the evaluator's hands for more than 1 s during the test or (3) the subject begins to experience pain.[43] This test has demonstrated an intraclass correlation coefficient of 0.82–0.91.[44] Functional Muscle

Test by Daniels and Worthingham (D&W),[45] defined for the upper fibres of the trapezius, will be used to assess shoulder muscle strength. With the subject seated and arms at both sides of the trunk, they will be asked to push cauda-cranially against the evaluator's hand, positioned over their shoulder. The D&W functional muscle scale ranges from 0, complete absence of muscle contraction, to 5, normal muscle response. This test has shown an intraclass correlation coefficient ranging from 0.63 to 0.98.[46] Handgrip strength has been considered a marker for whole-body skeletal muscle function and, specifically, it is a predictor of survival, mortality and treatment outcomes in the cancer populations.[47–49] This outcome will be determined with a digital dynamometer (JamarPlus+). The patient will be asked to perform a grip with maximum effort while in a seated position and holding a dynamometer, with the elbow at a 90° flexion and the shoulder in a neutral position. Three attempts will be made with each hand (six total attempts), with a 1-minute rest between each one. The mean value (in kg) of the three attempts will be calculated for the data analysis. The reliability of this handgrip dynamometer is very high: its systematic error for test–retest is ≤0.3 kg.[50] This test has an intraclass correlation coefficient range of 0.89–0.97.[51]

C. *Pain intensity and pressure pain thresholds*: this will be assessed at the cervical level and the temporomandibular joint (bilaterally) using a validated VAS[52]: a horizontal line of 10 cm in length indicating 'no pain' at its left end (value 0) and 'maximum pain' at its right end (value 10).[53] sHNC will be asked, at the time they are filling out the questionnaire, to mark the intensity of the perceived pain during their day-to-day activities with a cross on the line. The pressure pain threshold (PPT) will also be assessed for a complete description of pain perception. This evaluation has been performed previously in HNC populations to evaluate the presence of myofascial pain and widespread pressure hypersensitivity, as tumour site and/or neck dissection may influence the presence of these impairments, suggesting both peripheral and central sensitisation processes.[54 55] PPTs are related to active trigger points on sHNC.[54] The temporal muscles, masseter, upper fibres of the trapezius and elevator scapular muscles; the C5–C6 zygapophyseal and sternoclavicular joints; and the anterior tibial muscle as a peripheral point will be analysed bilaterally, defined as the minimum pressure tolerated at which the sensation of pressure begins to be perceived as pain.[56] sHNC will be asked to indicate to the examiner when the sensation of pressure changes to a sensation of pain. An analogue algometer (Baseline Hydraulic Algometer) will be used for this study. Each point to be evaluated will be analysed three times with a 30-second interval between evaluations, and the arithmetic mean of the three measurements will be used for subsequent statistical analysis (kg/cm^2). Pressure algometry has demonstrated high reliability when the assessment is conducted on the same day (0.82–0.97)[56] and up to a maximum of 4 days (0.94–0.97).[57]

D. *Shoulder pain and disability perception*: the Spanish version of the Shoulder Pain and Disability Index (SPADI) will be used. It is a questionnaire with 13 questions divided into two sections: pain (five questions) and disability (eight questions). In each question, subjects must evaluate the pain and perceived disability in different situations during the previous week on a numerical scale from 0 (no pain or difficulty) to 10 (the worst pain imaginable or so difficult that it requires help). The score for each section is obtained by summing the total points obtained, dividing it by the total possible score and multiplying it by 100. To calculate the total score of the index, the scores obtained in each section are summed, and the obtained value is divided by the maximum possible value of the index.[58] The SPADI questionnaire has been validated in populations with shoulder pain, with an intraclass correlation coefficient greater than or equal to 0.89, and its minimal clinically important difference has been reported to range between 8 and 13.[59] It has also been previously used in HNC patients.[60]

E. *Health-related QoL*: the EORTC QLQ-C30 (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire) (only global health status item), V.3.0, will be used. It has been validated in Chile and is widely used in the oncology population. This instrument consists of 30 items scored from 0 to 100 and divided into different subscales, with higher scores indicating better overall QoL (and global health).[61] The questionnaire has a Cronbach's alpha of 0.86 for global health.[62] Additionally, its specific module for HNC, the QLQ-HN43, will be used; it consists of 43 items with a response format (4-point Likert scale) and time frame (1 week) equal to the QLQ-C30. According to the EORTC scoring manual, 18 raw scale scores were constructed by summation and transformation from 0 to 100. In all subscales, a higher score corresponds to worse symptoms. The reliability of the questionnaire in the HNC population is >0.70 for Cronbach's alpha.[63]

F. *Physical fitness perception*: the International Fitness Scale will be used. It consists of a self-administered questionnaire that considers the main physical fitness components: cardiorespiratory fitness, muscle strength, agility, speed and flexibility. Responses are based on a 5-point Likert scale (from 'very good' to 'very poor').[64] It is a reliable instrument with a 0.54–0.65 coefficient.[65] Assessing physical fitness perception in this study allows for a better understanding of its relationship with functional impairments and the potential benefits of rehabilitation interventions.[66]

G. *Satisfaction with treatment*: this will be determined through a predesigned questionnaire consisting of 6 items: one for overall satisfaction with scores from 0 to 10, and five items with dichotomous responses (yes/

no), where the patient can provide reasons for their response. This instrument has been previously used for this purpose.[67] This feedback will help to identify which aspects of the programme work well and what could be improved to enhance patient experience and adherence. Additionally, patient input will guide future treatment protocols, ensuring they are both effective and well tolerated.

H. *Adverse events*: these will be recorded in terms of adverse events, defined as any unfavourable change in health that occurs during the intervention. Each adverse event will be characterised based on severity (Grade 1 (mild) to 5 (death)), expectation (expected or unexpected), and potential relationship with study participation (not related, possibly related or related to the study), using the Common Terminology Criteria for Adverse Events (V.5.0).[68]

Patient and public involvement

Patients and the public played an integral role in shaping this research to ensure its relevance to their needs. Early consultations with sHNC informed us of the research question and the selection of key outcomes, including MMO, pain and QoL. Patient input influenced study design by addressing session duration, feasibility and potential barriers to participation. Based on their feedback, adjustments were made to improve adherence while minimising the burden. Additionally, recruitment materials and consent forms were reviewed to enhance clarity and accessibility.

To evaluate the feasibility of the intervention, patients provided insights into time commitments, leading to a structured programme that balances effectiveness with manageability. Ongoing communication will help identify and address any concerns that arise during the study. Study findings will be presented through patient-friendly summaries and educational sessions, alongside publication in open-access journals and presentations at relevant conferences.

Data collection and security

Only the researchers involved in the MATEO protocol will have physical access to all pseudo-anonymised and encrypted information, with the server located at the Universidad de La Frontera. This will ensure the safety of data management. Personal data will be handled in a way that it can no longer be attributed to study participants, following the principles of anonymity and confidentiality throughout the study.

Statistical analysis

A descriptive analysis will be performed using means±SD (95% CI) and frequencies (percentages) according to the nature of each variable. The Shapiro-Wilk/Kolmogorov-Smirnov tests will be used to test the normal distribution of the data as appropriate (p>0.05). To evaluate differences between groups at baseline (T0), the Student's t-test/U Mann-Whitney test or χ^2/Fisher test will be used, as appropriate. Moreover, a 2-way repeated measures analysis of covariance (ANCOVA) will be performed to evaluate changes between groups and time after interventions. Both approaches, intention-to-treat and per-protocol analysis, will be performed. A p value <0.05 will be considered statistically significant for the main and secondary variables.

The effectiveness of the intervention will be further determined with the calculation of effect sizes expressed in Cohen's d as insignificant (0; 0.19), small (0.2; 0.49), moderate (0.5; 0.79) and large (> 0.8)[69] with their respective 95% CI. Subgroup analysis for trismus, TMD and cervical/shoulder dysfunction, and for the type of oncological treatment (surgery/radiotherapy) will be considered depending on the characteristics of all participants. Time since diagnosis and time since last oncological treatment will be used as a covariate to adjust the ANCOVA analysis, due to its clinical interest.[11] Moreover, baseline symptom presence (ie, trismus and/or TMD and/or cervical or shoulder dysfunction) will be included as a covariate to account for variability.

Depending on sample size, we will also stratify our analysis to explore differential effects of the intervention, based on participants' baseline symptoms (ie, trismus, TMD or signs of cervical and/or shoulder dysfunction), cancer location (ie, oral cavity, pharynx, larynx, nasal cavity, paranasal sinuses and salivary glands) and oncological type of oncological treatment (surgery/radiotherapy). This stratification will allow us to obtain more specific results about the effects of the MATEO intervention on specific previous conditions of participants.

To reduce bias caused by adherence, participants' data will be included in the statistical analysis when a minimum of 75% attendance[28] has been accomplished, and imputation methods will be used in case of missing data.[70] All analyses will be performed with the SPSS (V.20, IBM Co, Armonk, NY, USA).

DISCUSSION

The current trial will determine the effectiveness and safety of MT on oral opening, swallow function and upper quarter mobility, cervical muscle strength, pain, functionality and QoL perception in sHNC.

Previous studies[9 11] have demonstrated the benefits of one kind of MT, MIT, on outcomes such as MMO, TMD and upper quarter mobility in sHNC. Moreover, a retrospective case series study[14] suggests that MT improves MMO with a medium to large effect size in sHNC with radiation-associated trismus. However, despite these benefits, these studies have limitations, such as no mid- or long-term follow-up,[9 11] and in their design, such as retrospective case series.[14] Nevertheless, more retrospective studies, such as the one performed by McMillan *et al*[14] are needed, as they help research by generating hypotheses and by identifying risk factors to be studied further in prospective studies, such as the present study. Compared with these studies, the present study will

provide information about the MT effects not only on the short term (ie, once the intervention is finished), but also on the mid-term (ie, 6 weeks after finishing the intervention).

In the case of TMD, more evidence tailored to this issue is shown with a systematic review of RCTs,[71] the results of which describe a varied amount of evidence supporting the use of MT to improve MMO and TMD signs and symptoms. Again, these findings are limited because they do not consider sHNC to be the population of interest. In light of the above, it is necessary to design and implement programmes for this population that consider the difficulties they face, especially in their survival stage.

In recent years, the literature has highlighted the prevalence of trismus in sHNC[72] and the use of exercise therapy as a treatment approach.[73] These interventions are widely prescribed and accepted by clinicians, primarily due to the effects of muscle balance, alignment and coordination movements.[74] Due to the nature of the oral problems and limitations of sHNC (scar tissue, soft tissue tension and fibrosis), MT could be a better intervention than motor control exercise for these impairments.

Due to the myriad of impacts that the limitation of mouth opening has not only for eating, but also for social interaction,[75] this outcome has been chosen as the main outcome of this study. Together with TMD and dysphagia, these symptoms may lead to social isolation, and consequently, the patient may experience feelings such as depression or anxiety, affecting their QoL.

The heterogeneity of our participant population is an important factor to consider when interpreting our findings. While this diversity enhances the study's real-world applicability, it also introduces methodological challenges. Participants with no baseline impairments in certain domains may exhibit ceiling effects, potentially limiting the ability to detect improvements in those areas. Additionally, the variation in tumour types, treatments and postdiagnosis timeframes may contribute to response variability. To address these challenges, our analysis includes stratification based on baseline symptom presentation and incorporates baseline characteristics as covariates in the statistical models. These steps aim to ensure a more accurate assessment of the intervention's effectiveness across different patient subgroups.

Given the mentioned heterogeneity of participant population, this study protocol does not include home-based exercise for carryover, maintenance of therapy gains and overall generalisation. Home-based exercise can have limitations in terms of equipment or motivation, and variability between participants when performing home-based exercise would be another challenge to address. However, future studies may include this type of intervention to investigate their effects combined with face-to-face interventions.

The secondary outcomes included in this protocol (ie, mobility, pain, strength, QoL, functionality or fitness perception) have also been susceptible to change when MT or motor control exercises have been applied to different populations.[21 76 77] Given the similarities between populations, it is hypothesised that these outcomes may also improve with our intervention protocol in sHNC.

It is believed that the MATEO trial could offer an assessment of the reliability of prior work in sHNC,[14 29] as well as tease out the effects between two established therapy options, with the use of numerous patient-reported outcomes and objective methods. This work will provide an understanding of the use of motor control exercise with or without MT and conceptually implicate their use as a standard of care in sHNC.

Ethics and dissemination

The study was approved by the Ethics Committee of the Universidad de La Frontera (File 001_24) according to the Helsinki Declaration for Biomedical Research. All participants will provide informed consent (online supplemental material 4).

This protocol might offer a manual for implementation in diverse clinical and healthcare settings when treating sHNC with symptoms such as trismus, shoulder and/or cervical dysfunction. Thus, physical therapists will be empowered to apply these techniques in their clinical settings to treat these dysfunctions. Finally, results from the MATEO trial will be disseminated in peer-reviewed journals and national and international conferences focused on oncology and rehabilitation.

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