

## Efficacy of manual therapy on somatic tinnitus dual modulatory factors: a study protocol

## Eficácia da terapia manual nos fatores modulatórios duais do zumbido somático: um protocolo de estudo

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**ABSTRACT | BACKGROUND AND PURPOSE:** The literature has shown promising effect of manual therapy in improving the severity of somatic tinnitus. However, no previous study which has demonstrated the effect of manual therapy on dual modulatory factors (Temporomandibular disorders and cervical spine muscles). The purpose of the study is to evaluate the efficacy of manual therapy on somatic tinnitus dual modulatory factors (TMD and cervical spine). **METHODS/DESIGN:** Thirty nine patients with somatic tinnitus will be randomly assigned to one of the three groups i.e., A(Cervicogenic somatic tinnitus),B(TMD induced somatic tinnitus) and C(Dual modulatory factors induced somatic tinnitus) respectively. This multi group, parallel arms, pre-test post-test, single centre, randomized clinical trial with three parallel groups will receive six treatment sessions of integrated manual therapy on alternate days for two weeks. Postural re-education exercises will be advised to the patients as home exercises. The primary outcome measure will be Tinnitus Handicap Inventory (THI) and secondary outcome measures include Visual Analogue Scale (VAS) and Digitalized Calibrated Algometer (DCA) to measure pre and post intervention effect of the treatments. **DISCUSSION:** The efficacy of manual therapy in patients with somatic tinnitus in each group will be established with this study.

**TRIAL REGISTRATION:** Clinical Trials Registry - India. (CTRI/2020/03/024394)  
Universal trial number- U1111-1248-3141

**KEYWORDS:** Exercise therapy. Musculoskeletal manipulations. Quality of life. Temporomandibular joint. Tinnitus.

**RESUMO | O JUSTIFICATIVA E OBJETIVO:** A literatura tem demonstrado efeito promissor da terapia manual na melhora da gravidade do zumbido somático. No entanto, não há nenhum estudo anterior que tenha demonstrado o efeito da terapia manual nos fatores modulatórios duplos (disfunções temporomandibulares e músculos da coluna cervical). O objetivo do estudo é avaliar a eficácia da terapia manual nos fatores modulatórios duais do zumbido somático (TMD e coluna cervical). **MÉTODOS / PROJETO:** Trinta e nove pacientes com zumbido somático serão aleatoriamente designados para um dos três grupos, ou seja, A (zumbido somático cervicogênico), B (zumbido somático induzido pela TMD) e C (fatores modulatórios duplos induzidos ao zumbido somático), respectivamente. Este ensaio clínico randomizado de vários grupos, braços paralelos, pré-teste pós-teste, centro único, com três grupos paralelos receberá seis sessões de tratamento de terapia manual integrada em dias alternados durante duas semanas. Os exercícios de reeducação postural serão aconselhados aos pacientes como exercícios em casa. O desfecho primário será o Tinnitus Handicap Inventory (THI) e os desfechos secundários incluem Escala Visual Analógica (VAS) e Algômetro Calibrado Digitalizado (DCA) para medir pré e pós efeito de intervenção dos tratamentos. **DISCUSSÃO:** A eficácia da terapia manual em pacientes com zumbido somático em cada grupo será estabelecida com este estudo.

**REGISTRO DE ENSAIO:** Registro de Ensaio Clínicos - Índia. (CTRI / 2020/03/024394)  
Número universal de teste - U1111-1248-3141

**PALAVRAS-CHAVE:** Terapia por exercício. Manipulações musculoesqueléticas. Qualidade de vida. Articulação temporomandibular. Zumbido.

## Introduction

Tinnitus is referred as a characteristic sound that is falsely perceived in the absence of any external auditory stimuli<sup>1</sup>. Tinnitus affects 20.7% to 24.2% of the general population and 10% to 15% of the adult population which hinders the quality of life of the patient<sup>2-4</sup>. Somatic or somato-sensory tinnitus attributed to the disorders of cervical spine or temporo-mandibular region<sup>2</sup> which can modulate the pitch and loudness in tinnitus patients<sup>5</sup>. Its prevalence is 36% to 43% of the Belgian population along with subjective tinnitus patients<sup>2</sup>. Somatogenic disorders turn out to be highly prevalent in tinnitus patients<sup>5</sup>. Prevalence of cervicogenic somatic tinnitus is 43%<sup>3</sup> and Temporomandibular Disorders TMD is 64% in patients with chronic tinnitus<sup>2</sup>. which is more common in patients with dental pulpagia<sup>5</sup>.

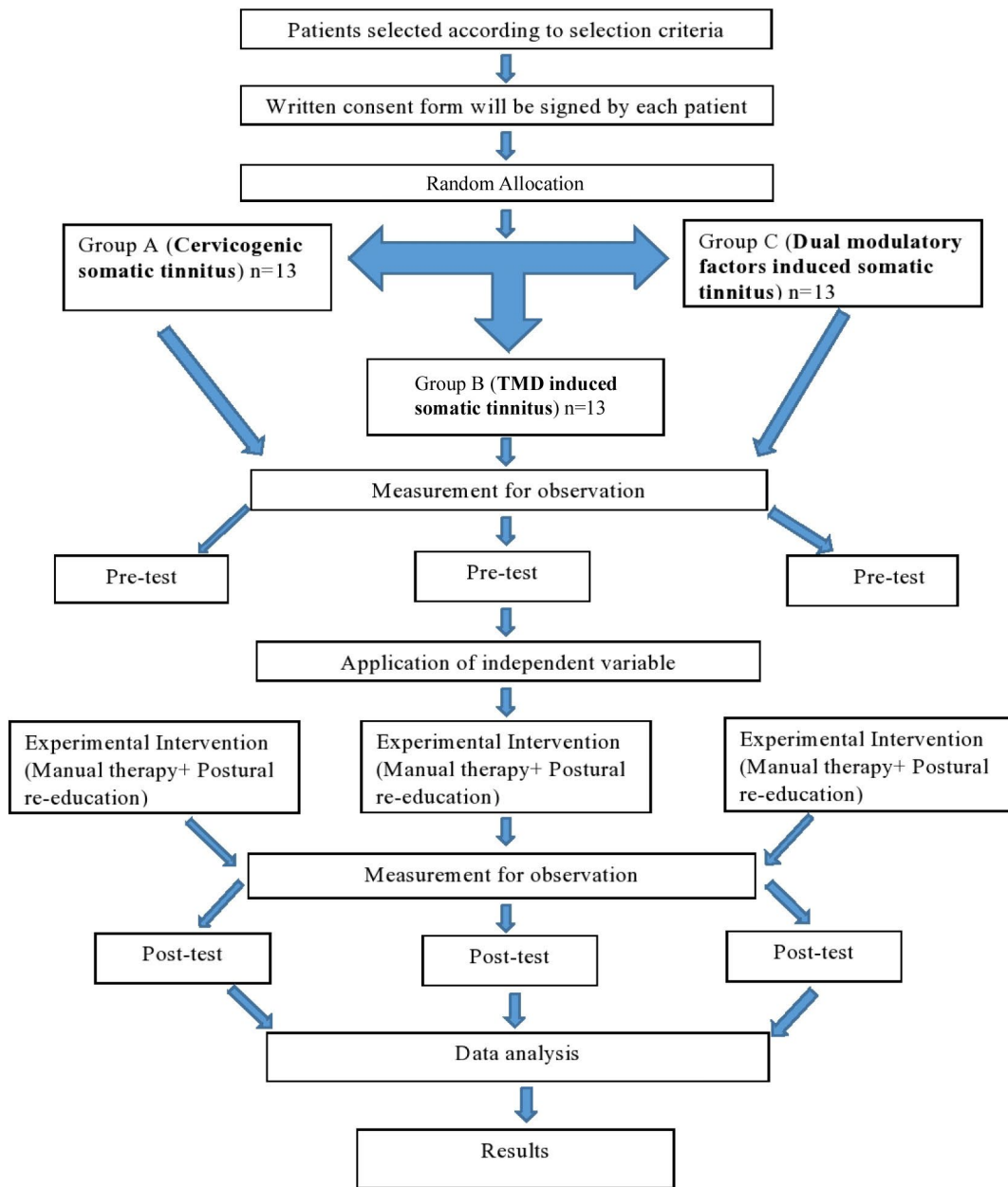
There is a link present between the somatic structures of the cervical spine and temporomandibular region with the Cochlear Nuclei (CN)<sup>6</sup>. The somatosensory information of cervical and temporomandibular area is transferred to the brain by afferent fibers. These fibers are located in the dorsal root ganglia<sup>2</sup>, out of which some are projected towards central auditory system particularly to the dorsal cochlear nuclei (CN)<sup>2</sup>.

In previous animal studies also it has been found that there is a connection between the dorsal column of the spinal cord and the cochlear nuclei (CN). The cells in the cochlear nuclei generate responses by the stimulation of specifically C2 dorsal root ganglion<sup>6</sup>. Therefore, the symptoms could be aggravated or improved by somatic system such as by forceful muscle contractions of neck or jaw muscles, pressure on myofascial trigger points or due to tensor tympani muscles increased muscular tension<sup>1</sup>.

Previous researches<sup>7,8</sup> used manual therapy as a treatment in patients with TMD and cervical spine induced somatic tinnitus and concluded its effectiveness in improving the quality of life and pain pressure threshold. To best of authors' knowledge the research gap identified in the previous published literature is that they didn't discuss about the combined effect of TMD and Cervical spine muscles treatment in somatic tinnitus patients and the previous studies only targeted the superficial muscles but this current study will focus on deep as well as superficial muscles. Therefore, objective of this randomized clinical trial will be to evaluate the efficacy of manual therapy on muscle dysfunction induced due to dual modulatory factors (TMD and cervical spine) on pain pressure threshold and quality of life in patients with somatic tinnitus.

## Material and methods

Figure 1. Flow chart of study protocol



This protocol was written according to the SPIRIT (Standard Protocol Items: Recommendations for Interventional trials) to improve the quality of trial<sup>9</sup>.

## Trial registration

The proposed study has been approved by the Institutional Research Ethics Committee. This study is registered at Clinical Trials Registry-India. (CTRI/2020/03/024394) on 31/03/2020 and Universal Trial Number is U1111-1248-3141. Trial will be conducted in the Physiotherapy Outpatient Department of a medical college.

## Study design

The proposed study is single centred, multi-group, parallel armed, pre-test post-test design. Fig. 1 demonstrates an overview of protocol. Written consent form for the voluntary participation of the patients will be taken. Every patient will be assured that there will be no harm, the information obtained from them will be used for research purpose and their privacy will be maintained. Primary outcome measure will be tinnitus handicap inventory to assess quality of life in somatic tinnitus patients. Secondary outcome measures are visual analogue scale which will be used to assess the severity of loudness and Digitalized Calibrated Algometer will be used to evaluate pain pressure threshold respectively.

## Participants recruitment

Thirty nine patients with somatic tinnitus will be recruited in the study according to the selection criteria as mentioned in Table 1. Patients will be referred by Otolaryngologist and Dental outpatient department. Demographic data such as the name, age, gender, occupation, address of each patient will be documented in a pre-designed Performa for the eligible patients. Detailed information about the participants is given in the Table 1.

Table 1. Selection Criteria for participants

Inclusion criteria	Exclusion Criteria
<ul style="list-style-type: none"><li>Somatic tinnitus patients as per diagnostic criteria which should be stable for past three months.<sup>21</sup></li><li>Tinnitus can be unilateral or bilateral with normal hearing.</li><li>Age group between 18 to 35 years.</li><li>Tinnitus which is associated by teeth or jaw manipulation.</li><li>Increase in the severity of tinnitus during poor posture while rest, working, walking or sleeping.</li><li>Trigger points located on masseters, temporalis, sternocleidomastoid and upper trapezius, lateral pterygoid, splenius capitis, infraspinatus, levator scapulae, scalenus medius and digastric muscle.</li></ul>	<ul style="list-style-type: none"><li>Underlying cause of tinnitus is Ear, nose and throat pathology.</li><li>Severe depression.</li><li>Neurological abnormalities.</li><li>Patients who are unable to fill the questionnaire due to language problem or blindness.</li><li>Patients who cannot follow commands.</li><li>Intracranial pathology.</li><li>Trauma of cervical spine or temporomandibular joint in past six months.</li><li>Suffering from fibromyalgia.</li><li>Had gone for head and neck physical therapy in past twelve months.</li></ul>

## Randomization

Criterion based purposive sampling will be used to randomly assign the patients into three groups with thirteen patients in each group, according to their typical clinical feature SNOSE method (randomization sequence, the use of sequentially numbered, opaque sealed envelopes). Patients with somatic tinnitus induced by cervicogenic factors (trigger points present on cervical muscles) will be assigned to Group A, patients with somatic tinnitus induced by TMD factors (trigger points present on masticators or at TMJ area) will be assigned to Group B and patients with somatic tinnitus induced by dual modulatory factors (trigger points present on cervical muscles as well as on TMJ area) will be assigned to Group C.

## Interventions

Physical examination will be done by the therapist and treatment will be given according to the majorly involved area. Interventions will be given to all the three groups i.e. Group A(cervicogenic somatic tinnitus), Group B (TMD induced somatic tinnitus) and Group C(Dual modulatory factors induced somatic tinnitus) with same designed dosage as shown in figure(1). Each group will receive six sessions of soft tissue manual therapy for 30 minutes/ day on alternative days for two consecutive weeks.Integrated Soft tissue manual therapy will be given to the muscles of mastication except medial pterygoid muscle and also to the muscles of the cervical region including sternocleidomastoid, upper trapezius, splenius capitis, levator scapulae, scalenus medius muscles respectively. Postural re-education will be advised to the patient as a home exercise programme. Primary aim of the treatment is to relax the jaw and neck muscles which can be achieved by myofascial release of the neck and jaw muscles<sup>10</sup>. Summary of interventions is shown in table 2. Dosage of the intervention will be modified according to the severity of the pain. Repetitions will be inversely proportional to the severity of the pain. More number of repetitions in the pain will worsen the condition.

**Table 2.** Summary of interventions to be given to the patients (to be continued)

Technique	Procedure
<b>Myofascial trigger point(MTP) Release</b>	<p><b>Patient position-</b> Siting position</p> <p><b>Therapist position-</b> Standing behind the patient.</p> <p><b>Procedure-</b> In the proposed study, pressure release technique/ischemic compression technique of MFR will be used to release MTP. Therapist will place the thumb over the diagnosed MTP and apply the pressure sufficient enough to release the trigger point. The procedure will be repeated for 5 times applying pressure for 30 seconds each time along with 10 sec interval in between each repetition .<sup>11</sup></p>
<b>Sternocleidomastoid stretching</b>	<p><b>Patient position-</b> Supine lying with shoulders at the periphery of the treatment couch and head out of the treatment couch supported by therapist hand at the base of occiput.</p> <p><b>Therapist position-</b> Standing at the head end of the couch holding head of the patient at the base of the occiput to provide it support.</p> <p><b>Procedure-</b> Therapist will rotate the patient's head towards non-affected side and laterally flex the head toward the affected side.</p> <p>This a prolonged stretch from 5 to 45 seconds will be maintained according to the tolerance of the patient.<sup>12</sup></p>

**Table 2.** Summary of interventions to be given to the patients (conclusion)

Technique		Procedure
Upper stretching	Trapezius	<p><b>Patient position-</b> Hook lying position.</p> <p><b>Therapist position-</b> Standing behind the patient.</p> <p><b>Procedure-</b>Therapist will stabilize patient’s shoulder with dominant hand simultaneously with the other hand will move patient’s head towards the opposite shoulder to stretch upper trapezius muscle.</p> <p>A prolonged stretch for 10 seconds will be maintained with 3 reps*3 sets per session for each sides along with 10 seconds rest between each set.<sup>13</sup></p>
Cranio-cervical flexion exercise in supine lying		<p><b>Patient position-</b> Supine lying.</p> <p><b>Therapist position-</b> Standing by the side of the patient towards the head end of the couch.</p> <p><b>Procedure -</b> These exercises will be performed to relax deep neck flexors muscles of the patient. Patient will be instructed to lie comfortably on the couch. Therapist will ask patient to lift his head with chin tuck in<sup>14</sup>and holding it for 10 seconds. The procedure will be repeated for 10 times with 10 seconds hold between each repetition.</p>
Cranio-cervical flexion exercise in sitting		<p><b>Patient position-</b> Sitting</p> <p><b>Therapist position-</b> Standing behind the patient.</p> <p><b>Procedure -</b> Patient will move the head forwards and therapist will resist the movement.<sup>14</sup>Therapist will hold it for up to 10 seconds and repeat it for 10 times with 10 second hold between each repetition.</p>
Lateral muscle	pterygoid	<p><b>Patient position-</b> Sitting</p> <p><b>Therapist position-</b> Sitting in front of the patient.</p> <p><b>Procedure-</b>Resistance training will be given. Patient will be instructed to open his mouth and therapist will apply resistance holding it for 10 seconds during this movement and repeat it for 10 times with 10 second rest between each repetition.</p> <p>Then, the patient will be instructed to close his mouth and therapist will apply resistance over the chin during this movement and hold it for 10 seconds and repeat it for 10 times.<sup>15</sup></p>
Masseter muscle		<p><b>Patient position-</b> Supine lying.</p> <p><b>Therapist position-</b> Standing by the side of the patient couch.</p> <p><b>Procedure-</b>Gliding technique will be performed at TMJ. Anterior translation of TMJ will be applied by the therapist at grade 3 for 3 to 6 minutes. Previous researches have showed a decrease in pain and improvement in pain pressure threshold of masseter muscle.<sup>16</sup></p>
Home program	exercise	<p>Home exercise program consists of postural re-education which will be advice to the patient after first session and exercise should be checked after each session.</p> <ul style="list-style-type: none"> <li>• Patient will be instructed to stand against the wall with posterior aspect aligned with the then gradually retract the head backwards until the head make contact with the wall. This position will be sustained for 30 seconds and will be performed for 3-5 times a day.<sup>12</sup></li> <li>• Patient will be advised to avoid habits such as nail biting or tooth clenching.<sup>12</sup></li> <li>• Night splints can be advised if the patient has habit of grinding.<sup>2</sup></li> <li>• Patient will be instructed to always keep the teeth apart except swallowing and eating and avoid excess mouth opening.<sup>17</sup></li> <li>• Patient will be instructed to place the tongue on roof of the mouth behind the front teeth while opening and closing of mouth.<sup>8</sup></li> <li>• Patient will also be advise to relax masticators.<sup>17</sup></li> </ul>

## Outcome measures

A trained physiotherapist will assess the outcome measures prior to the first treatment session and after the completion of the sixth session.

### Primary outcome measure

Tinnitus Handicap Inventory: Tinnitus Handicap Inventory scale is used to evaluate the quality of life in tinnitus patients. THI includes 25 questions, each question can be answered by yes, sometimes or no. "Yes" will be scored as four points, "sometimes" will be scored as two points and "no" will be scored as a zero. Total score will be used to categorize the tinnitus patients into four types. If the score will range from '0 to 16' points then it will be categorized as "slight tinnitus", if score will range from '18 to 36' points then it will be categorized as "mild tinnitus", if score will range from '38 to 54' points then it will be categorized as "severe tinnitus" and if score will range from '58 to 100' points, it will be categorized as "catastrophic tinnitus"<sup>18</sup>. A previous study has evaluated the reliability, validity and sensitivity of self-report tools which are used to check the severity of tinnitus such as tinnitus handicap inventory (THI), Tinnitus Questionnaire (TQ), tinnitus impairment questionnaire (TIQ) and TBF-12 (Tinnitus Beeinträchtigung Fragebogen (i.e., Tinnitus Impairment Questionnaire, TBF-12) in which they concluded that all the tools have high internal consistency, validity and sensitivity. Therefore, they proved that these tools can be applied as a suitable measure to assess the severity of tinnitus<sup>19</sup>.

### Secondary Outcome measures

Visual Analogue Scale: VAS evaluates the subjective loudness of tinnitus<sup>20</sup>. There is a 10 cm horizontal line which indicates the severity of loudness in tinnitus. On the line of tinnitus, left end denotes 'no tinnitus' and the right end denotes 'severe tinnitus'. Patient will be asked to mark a point on the scale which will indicate the loudness of the tinnitus. It has been noted that integrated visual analogue scale is used as an outcome measure to evaluate the severity of the tinnitus and it is a consistent and valid tool ( $r = 0.75$ )<sup>2</sup>.

Digitalized Calibrated Algometer: In recent researches accuracy and reliability of Digitally calibrated algometer has been proved to find out the pain pressure threshold on masticators and TMJ<sup>2</sup>. The pressure pain sensitivity of Masseters, Temporalis, Sternocleidomastoid, upper Trapezius, lateral Pterygoid, Splenius Capitis, Infraspinatus, Levator Scapulae, Scalenus Medius and Digastric muscles will be investigated in terms of kilopascal (KPa). ALGO-DS-01 model of digital calibrated algometer will be used. To measure the pain pressure threshold, the pressure will be subsequently increased. Patients should inform about any change in the pressure into pain.

## Safety and adverse outcomes

Tinnitus Handicap Inventory will be used as a primary outcome measure. Visual Analogue Scale (VAS) and Digitalized Calibrated Algometer (DCA) will be used as a secondary outcome measure. All the outcome measures will be used prior and after the intervention. Therapist who will provide the intervention will also record about any adverse effect and will record the grades and severity of the same. Treatment protocol will be set in such a way that it has minimal risk. In any case if the treatment will cause side effects then it will be liable to the therapist.

According to the WHO guidelines therapist will take all the safety measures such as to wear PPE Kit, gloves and masks. Separate cabin will be used for the treatment. Before the treatment temperature monitoring will be done. Gathering will be avoided and sanitization will be done prior and after the treatment. Bedsheets will be changed after each session. Patients will be instructed for taking care of hand hygiene and to use personal protective equipment, such as face masks, etc.

## Data monitoring

An independent researcher will perform all the statistical analyses and datasets. A treating physiotherapist will monitor the treatment sessions in each group.

## Follow up

Call the patient for follow up. Follow up will be to after six sessions. Therapist will encourage the patients on phone to visit for the follow up on decided dates.

## Sample size calculations

The sample size was calculated using G\* Power 3.1.9.4 statistical software. The calculated effect size is 1.0, the significance level set is 0.05 and power set is 90%<sup>7</sup>. The minimum numbers of samples calculated for each group was 10 but considering a drop out of 10%, 13 samples in each group were calculated making the total sample size equal to 39<sup>7</sup>.

## Analysis of data

If the patient will refuse for the further treatment then we will perform intention to treat analysis. We will include the outcomes of the entire patients who will receive at least two sessions of the interventions. If the patient will unable to come or if the data will be missed then we will include the outcomes upto the last data collected.

Data will be analyzed using statistical package for social sciences (SPSS) version 20. Normality of the collected data will be established using Shapiro Wilk test. Appropriate statistical analysis will be used to achieve the aim of the study. If the data will be normally distributed then One-way ANOVA will be used and if the data will not be normally distributed then the 'Kruskal Wallis' test will be used for analysing data between the group. Between group analysis will be done by Paired t test or Wilcoxon signed rank test. Between group effect sizes will be calculated by SPSS version 20. Descriptive statistics for the baseline data will be expressed either as mean  $\pm$  standard deviation or median (interquartile range) depending upon the normality of the data.

## Discussion

Somatic tinnitus is a condition in which the patient experiences ringing in the ears due to associated domains which are cervical spine induced somatic tinnitus, TMD induced somatic tinnitus or Dual modulatory factors induced somatic tinnitus. The present research will try to find out whether integrated soft tissue manual therapy will improve pain pressure threshold and quality of life in somatic tinnitus patients. As manual therapy works on relaxation of the muscles by reversing back the length of the muscle and desensitization of the trigger points thereby reducing the severity of tinnitus in patients<sup>22</sup>. There are previous researches<sup>7,8</sup> proving that manual therapy as an effective technique to improve quality of life in somatic tinnitus patients but there is no such study which includes somatic tinnitus patients having cervical spine domain, TMD domain as well as dual modulatory domain<sup>2</sup>. The study design of the three active treatment groups will find out the effect of manual therapy in each group.

## Author contributions

Sharma P participated in designing the study methodology and writing the original draft. Goyal M participated in conceptualization, designing the study methodology and reviewing the manuscript. Kothiyal S participated in designing the study methodology, writing reviewing and editing the manuscript. All the authors approved the final version of the manuscript.

## Competing interests

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).



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