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EFFECTS OF COMPLEX NECK THERAPY – KINESIOTHERAPY AND INTERSPINAL MUSCLES MASSAGE – ON TINNITUS

Contributions:
A Study design/planning
B Data collection/entry
C Data analysis/statistics
D Data interpretation
E Preparation of manuscript
F Literature analysis/search
G Funds collection

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Abstract

Introduction: Past studies have shown connections between the somatosensory system (the neck and temporomandibular joint region) and the auditory system. It is therefore likely that tinnitus patients might benefit from neck therapy. The aim of this study was to investigate the effects of physiotherapy of the neck, comprising cervical spine kinesiotherapy and interspinal muscles massage, on subjective tinnitus. We also investigated the effects of the therapy on the range of cervical spine motion and cervical muscles tension.

Material and methods: This was a non-randomised controlled trial. Adult patients with chronic subjective tinnitus ($n = 118$) were enrolled in an intervention group and received 10 sessions, over 2 weeks, of neck therapy comprising active exercises, massage of the cervical interspinal muscles, and post-isometric relaxation exercises. There was also a control group (waiting list). The effects of the therapy on tinnitus were assessed at baseline, immediate post-treatment, and follow-up (2 weeks after the end of therapy) using the Polish Tinnitus Functional Index (TFI-Pl, primary outcome measure), a visual analogue scale (VAS) of tinnitus loudness, and the Polish Tinnitus Handicap Inventory (THI-Pl). Effects of therapy on neck were assessed using two measures: the range of cervical spine movement (cervical flexion, cervical rotation, and cervical side bending measured in cm using a tape measure); and muscle tension – assessed by palpation and graded using a scale of either 0 (normal) or 1 (increased).

Results: In the intervention group, the mean TFI score was reduced significantly from baseline (mean = 52.6, SD = 20.4) to post treatment (mean = 40.9, SD = 19.0, $p < 0.001$) and at follow-up (mean = 40.4, SD = 21.1, linear mixed model). In the control group, mean TFI score did not change significantly from baseline (mean = 46.8, SD = 20.1) to post treatment (mean = 45.8, SD = 40.9) and follow-up (mean = 45.2, SD = 26.2, linear mixed model). Improvement in tinnitus in the intervention group was accompanied by a reduction in cervical muscles tension and improvement in the range of cervical spine motion.

Conclusions: Complex neck therapy of the neck appears to be a promising intervention for tinnitus treatment. Further randomised studies are needed to confirm the positive effects of the therapy on tinnitus and explore the mechanisms leading to improvement.

Key words: tinnitus • treatment • complex neck therapy • kinesiotherapy • massage • cervical spine

WPŁYW KOMPLEKSOWEJ TERAPII SZYI – KINEZYTERAPII I MASAŻU MIĘŚNI MIĘDZYKOLCOWYCH – NA SZUMY USZNE

Streszczenie

Wstęp: Prowadzone w przeszłości badania wykazały istnienie powiązań między układem somatosensorycznym (szyi i okolicy stawu skroniowo-żuchwowego) a drogą słuchową. Dlatego możliwe jest, że kompleksowa terapia szyi może przynieść dobre efekty u pacjentów z szumami usznymi.

Podstawowym celem pracy było zbadanie wpływu fizjoterapii szyi, obejmującej kinezyterapię szyjnego odcinka kręgosłupa i masaż mięśni międzykolcowych, na subiektywne szumy uszne. Zbadaliśmy także wpływ terapii na zakres ruchu kręgosłupa szyjnego i napięcie mięśni szyi.

Materiał i metody: Badanie nierandomizowane z grupą kontrolną. Grupa badana składała się z dorosłych pacjentów z przewlekłymi szumami usznymi ($n = 118$) – w czasie 2 tygodni uczestniczyli oni w 10 sesjach kompleksowej terapii szyi obejmującej: aktywne ćwiczenia, masaż mięśni międzykolcowych szyi i ćwiczenia relaksacji poizometrycznej. Uwzględniono także grupę kontrolną (lista oczekujących). Szumy uszne oceniano przed leczeniem, po zakończeniu terapii oraz podczas badania kontrolnego (2 tygodnie po zakończeniu terapii), z użyciem polskiej wersji Tinnitus Functional Index (TFI-Pl), wizualnej skali analogowej (VAS) głośności szumów usznych oraz polskiej wersji Tinnitus Handicap Inventory (THI-Pl). Wpływ terapii na kręgosłup szyjny oceniono na podstawie zakresu ruchomości szyjnego odcinka kręgosłupa (zgięcia oraz skręt i skłon do boku mierzone w cm za pomocą taśmy krawieckiej) i napięcia mięśni szyi ocenianego palpacyjnie w skali dwuwartościowej: 0 (normalne) i 1 (wzmożone).

Wyniki: W grupie badanej średni wynik TFI zmalał znacząco w kolejnych pomiarach: przed leczeniem (średnia = 52,6; SD = 20,4), po zakończeniu terapii (średnia = 40,9; SD = 19,0; $p < 0.001$) i w okresie kontrolnym (średnia = 40,4; SD = 21,1; liniowy model mieszany). W grupie kontrolnej średni wynik TFI nie zmienił się znacząco w czasie od okresu przed leczeniem (średnia = 46,8; SD = 20,1) do czasu po zakończeniu terapii (średnia = 45,8; SD = 40,9) i badania kontrolnego (średnia = 45,2; SD = 26,2; liniowy model mieszany). Poprawie szumów usznych towarzyszyła redukcja napięcia mięśni szyi i zwiększenie zakresu ruchomości odcinka szyjnego kręgosłupa w grupie badanej.

Wnioski: Fizjoterapia szyi wydaje się obiecującą metodą leczenia szumów usznych. Potrzebne są dalsze, randomizowane badania w celu potwierdzenia pozytywnego wpływu tej terapii na szumy uszne i zbadania mechanizmów prowadzących do ich poprawy.

Słowa kluczowe: szumy uszne • leczenie • kompleksowa terapia szyi • kinezjoterapia • masaż • szyjny odcinek kręgosłupa

Introduction

According to a revised definition, tinnitus is the conscious awareness of a tonal or composite noise for which there is no identifiable corresponding external acoustic source [1]. Patients often describe tinnitus as a ringing, buzzing, humming, or hissing sound [2,3]. It is a symptom rather than a disease [4]. A systematic review and metanalysis by Jarach et al. [5] found that 740 million adults suffer from tinnitus worldwide and about 120 million adults consider it a major complaint [5]. While many patients habituate to it, others report a major impact on the quality-of-life, psychological disorders such as anxiety and depression [6] and debilitating difficulties in the activities of daily living [7].

Tinnitus can be either subjective or objective. The latter usually results from abnormal muscle contractions or blood flow, while subjective tinnitus is thought to be pathological neural activity somewhere along the auditory pathway. The underlying pathology of subjective tinnitus is still not understood [4,8].

In some patients, tinnitus can be triggered or modulated by a change in the input from the somatosensory system of the cervical spine or temporomandibular joint. This type of tinnitus is a subtype of subjective tinnitus known as somatosensory tinnitus [9,10]. Some of the symptoms associated with somatosensory tinnitus are pain in the neck, jaw, and increased muscle tension in suboccipital muscles and extensor muscles of the cervical spine [10–12].

Animal studies have shown the effect of the somatosensory system on the auditory system and tinnitus [13–17]. Shore et al. [18] described anatomical, functional, and physiological properties and interactions between the somatosensory input (via dorsal root ganglion, spinal trigeminal ganglion) and the auditory system (dorsal cochlear nuclei) which may result in tinnitus [18]. Human studies have reported that tinnitus can result from complex interactions between sensorimotor, somatomotor, visual-motor, and neurocognitive systems [9,12,19].

Several studies have demonstrated that tinnitus can be modulated or elicited by head and neck muscle contractions, demonstrating somatosensory effects on the hearing system [20,21]. Importantly, Michiels et al. reported a higher prevalence of neck symptoms in the general tinnitus population (neck pain was present in 69% of participants), compared to the general population (48.5%) [22]. Moreover, a high prevalence of cervicogenic somatic tinnitus in the general tinnitus population (37 of 87 participants; 43%) has also been reported [11]. Moreover, a significant improvement in tinnitus symptom severity, as measured with Tinnitus Functional Index (TFI), following multimodal cervical spine physiotherapy has been reported in a group of patients with cervical spine dysfunctions (CSD) [23]. Some literature reviews have shown that, for neck disorders, the therapeutic potential of combined (multimodal) treatments – manual therapy techniques like manipulation and/or mobilization of cervical spine, stabilization exercises, and muscle relaxation exercises – is more beneficial than application of a single treatment method [24,25].

In the literature, there is no established or standardized physiotherapeutic protocol available for the management of neck symptoms in individuals with tinnitus. Active exercises are common techniques used to increase muscle length, thereby improving the mobility and flexibility of the muscle and joint [26]. They involve muscular activity of the patient and lead to stretching and lengthening of the muscles. The exercises are usually performed by the patients themselves [26]. Massage, however, can be helpful for treating increased muscle tension [27] and chronic neck pain [28–30]. Apart from reducing pathological muscle tension, it improves blood circulation, reducing pain and inducing muscle relaxation [31]. Post-isometric relaxation (PIR) is a subtype of muscle energy technique (MET) involving osteopathic manipulations. MET is used to improve musculoskeletal function by reducing pathological tension and improving extensibility, together with better circulation and lymphatic flow [32,33]. Thus, MET leads to mobilization of joints, increases in range of motion [34], stretching of muscles [34], and reduction of neck pain [35].

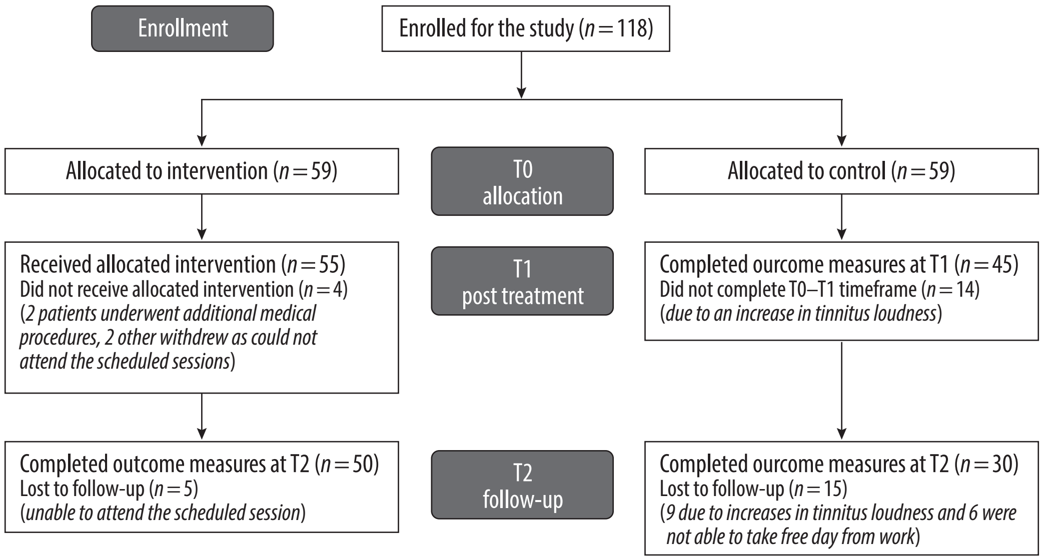

Figure 1. Flow chart of recruitment and testing

We consider that the use of complex neck therapy – comprising active exercises, PIR, and massage – to target a wide range of pathological neck somatic effects that might contribute to tinnitus generation and modulation, could be an effective multimodal approach in subjective tinnitus. Taking into account the data from the animal and human studies describing the somatosensory influences in tinnitus generation and modulation together with the studies showing the high prevalence of neck symptoms in general tinnitus population, there is a rationale for the use of combined physiotherapeutic methods targeting neck region to alleviate tinnitus. This therapy may be effective not only for those diagnosed with CSD but also for the wider population of people with tinnitus [36].

The primary aim of this study was to investigate the effects of complex neck therapy comprising cervical spine kinesiotherapy and interspinal muscles massage on subjective tinnitus. We have investigated the effects of the therapy on the range of motion of the cervical spine and on cervical muscles tension.

Material and methods

Recruitment

Ethical approval for this study (number RNN/157/19/KE) was granted by the Bioethics Committee of the Medical University of Lodz (Poland). Participants gave their written informed consent to take part in the study in accordance with the approval granted.

Adult patients with subjective tinnitus ($n = 118$) were recruited from the Department of Otolaryngology, Laryngological Oncology, Audiology and Phoniatrics, Teaching Hospital of Medical University of Lodz, Poland. **Figure 1** is a flow chart of the recruitment process. Patients were enrolled into an intervention group or a control group according to the order in which they registered for treatment at our clinic. Patients were offered the therapy on a first come, first served basis. Patients were enrolled in the intervention group if they were willing to undergo the therapy and able to attend multiple daily treatment sessions. The control group comprised patients who were willing to take part in the study but could not commit time to undergo intervention. We included adult patients with chronic subjective tinnitus, intermittent or constant, and irrespective of sensorineural hearing loss. Exclusion criteria were: i) other tinnitus treatment in the last 6 months; ii) objective tinnitus; iii) external or middle ear pathology; iv) conductive or mixed hearing loss; and v) general contraindications for kinesiotherapy and massage (i.e., acute infection, fever, risk of bleeding, severe respiratory or circulatory insufficiency, vascular pathology, periarticular soft tissue inflammation in the cervical region, severe pain, advanced osteoporosis, cervical spine instability, disc herniation, or radiculopathy). Participants with clinically significant depression (Beck's Depression Inventory score ≥ 15) or anxiety (Beck's Anxiety Inventory score ≥ 19) were also excluded from the study and were referred for psychiatric consultation [37,38].

Medical history, otolaryngological examination, audiological assessment (pure tone audiometry, speech audiometry, impedance audiometry, auditory brainstem responses, otoacoustic emission) for hearing loss and tinnitus were performed. Tinnitus type (noise, pure tone, or multiple sounds) was determined based on the patient's report. To assess the condition of the cervical spine, radiological diagnostics (X-ray, CT, or MRI, depending on indications) was performed. Demographic data (e.g., age and sex) were also collected. Radiological diagnostics of the central nervous system (CT or MRI) was done if needed.

Study design

The study was a non-randomized controlled trial. Adult patients with chronic (> 1 year duration) subjective tinnitus were enrolled. The otolaryngologist, who was blinded to the group allocation, conducted patient recruitment.

The control group comprised patients registered at the clinic in a waiting list for other tinnitus treatment. Patients in the intervention group received complex neck therapy, while those in the control group received no intervention.

Power and sample size

The study was designed to have a power of 80%. To achieve this, a minimum of 48 participants in each group were required. We added 22 extra patients in order to account for the risk of patient drop out, although as it happened the drop out rate was higher than expected. The standard deviation required for sample size calculation was extracted from the study of Wrzosek et al. [39]. Sample size calculations were based on wanting to detect a clinically relevant change of 13 points in the total TFI score (a value taken from the study of Meikle et al. [40]). A two-tailed two-sample unpaired Z-test with a significance level of 0.05 was applied. With a sample size of 118 tinnitus patients in total ($n = 59$ participants in each group), our study had a power of 88%.

Complex neck therapy

A qualified physiotherapist performed the therapy. The treatment was performed for 10 consecutive working days over a period of 2 weeks (the standard protocol for physiotherapy that is recommended and refunded by the Polish National Health Fund).

Each treatment session took about 30 minutes. The neck therapy comprised:

1. Active exercises of the neck (5 minutes) which were first demonstrated by the physiotherapist and then performed by the patient under supervision. They comprised: i) cervical flexion (neck forwards); ii) cervical rotation (neck turned to the left and right); iii) cervical side bending to the left and to the right. All exercises were performed in a sitting position and repeated 5 times.
2. Massage of the interspinal muscles in the neck region performed by the physiotherapist for 3 minutes. During the massage patient was lying in a supine position on the couch, with head held by the therapist sitting behind the patient's head.
3. Post isometric relaxation (PIR) exercises in a sitting position for 15 minutes following the method of Lewit and Simons [41]. They were performed by the physiotherapist as follows: i) cervical flexion; ii) cervical rotation to the left and right; iii) cervical side bending to the left and to the right; iv) cervical torsion to the left and right. The starting position for all exercises was the most comfortable position for the patient. The therapist placed hand on the patient's head on the side opposite to the movement. The patient was asked to push against the therapist's hand at half strength for 7 seconds (by counting from 1 to 7). After 7 seconds the patient took a breath in and out, and while they were exhaling the therapist extended muscles towards the direction of the head movement. Instructions given to the patient were that the therapist would stretch the neck muscles, the patient should not resist, and should allow the stretch and breathe.
4. Active exercises of the neck were repeated as described in point 1.

Outcome measures

Outcome measures were assessed at three time points: time point 0 – baseline (T0), time point 1 – post treatment (T1) and time point 2 – follow up (T2). For the intervention group: T0 was the first session (first day, before the therapy); T1 was session nr 10 (after the last intervention and 12 days from session 1); and T2 was 2 weeks after the last day of intervention. For the control group, the time points were: T0 – the day of registration on the waiting list, T1 – 2 weeks from the day of registration, and T2 – 4 weeks from the day of registration.

Primary outcome measure

The Polish validated version of the TFI (TFI-Pl; Wrzosek et al. [39]) was the primary outcome measure. TFI is a 25-item questionnaire with ratings made on an 11-point (0 to 10) scale. It assesses tinnitus experiences over the past week, and asks questions on eight functional domains (intrusiveness, sense of control, cognitive interference, sleep disturbance attributed to tinnitus, auditory difficulties attributed to tinnitus, interference with relaxation, quality of life, and emotional distress). TFI was developed to both quantify the severity of tinnitus and as an outcome measure [40]. A change in the total TFI score (increase or decrease) by at least 13 points is considered a clinically relevant improvement or clinically relevant deterioration in tinnitus [40]. TFI-Pl has high internal consistency (Cronbach's $\alpha = 0.96$) with a reliability ranging from 0.82 to 0.95 for the different subscales [39].

Secondary outcome measures

The Polish validated version of the Tinnitus Handicap Inventory (THI-Pl [39]) comprises 25 items assessing the impact of tinnitus on daily living [42]. Each of the 25 items is rated on a 3-point scale: "yes" (4 points), "sometimes" (2 points), and "no" (0 points). A score of 100 indicates the greatest impact on everyday living. THI-Pl shows high internal consistency (Cronbach's $\alpha = 0.93$) [39]. The minimally clinically important difference (MCID) for THI is a change of at least 20 points [43].

Visual analogue scale for loudness (VAS loudness): at the time of testing tinnitus loudness was measured on a 10 cm visual analogue scale. The left end of the line was marked with zero (0) representing no audible tinnitus and the right end was marked with 10 representing extremely loud tinnitus. Minimally clinically identifiable difference (MCID) estimates cluster between 1 and 1.5 points [44].

Physiotherapeutic measures

The range of motion (ROM) of the cervical spine was measured by the same physiotherapist who administered the intervention, using a tape measure [45,46]. The following range of movements (in centimeters) was assessed: cervical flexion, cervical rotation to the left and right, and cervical side bending tilting to the left and right. For measuring the range of motion, the distance between the following bony landmarks was measured (a) cervical flexion: distance between occipital protuberance and spine of seventh cervical vertebrae was measured, first in neutral and

Table 1. Demographic data of subjects with tinnitus, divided into intervention and control groups

Data	Intervention group *n* = 59	Control group *n* = 59
Age, years		
Mean (SD)	51.8 (14.5)	49.6 (15.8)
Gender		
Male	36 (61%)	29 (49%)
Female	23 (39%)	30 (51%)
Degree of hearing loss in dB*		
Mean (SD)	41.2 (17.3)	39.2 (13.4)
Severity of tinnitus (Tinnitus Functional Index score) at baseline		
Mean (SD)	52.6 (20.4)	46.8 (20.1)
Location of tinnitus		
Bilateral		
Equally in both ears	16 (27%)	17 (29%)
LE louder	12 (20%)	9 (15%)
RE louder	6 (10%)	8 (14%)
Unilateral		
LE	10 (17%)	8 (14%)
RE	10 (17%)	7 (12%)
Inside the head	2 (3.5%)	5 (9%)
Difficult to tell	2 (3.5%)	2 (4%)
Not reported	1 (2%)	3 (5%)
Sounds of tinnitus		
Tonal	15 (26%)	12 (20%)
Noise	25 (43%)	28 (48%)
Music-like	1 (2%)	0 (0%)
Cricket-like	7 (12%)	5 (9%)
Multiple sounds	7 (12%)	9 (15%)
Difficult to tell	2 (3%)	2 (3%)
Not reported	2 (3%)	3 (5%)
Pain complaints		
Headache	5 (9%)	10 (17%)
Neck pain	14 (24%)	11 (18%)
Earache	2 (3%)	1 (2%)
Neck pain accompanied by headache, earache, face pain, or jaw pain	22 (36%)	23 (39%)
Headache accompanied by earache or face pain	3 (5%)	2 (4%)
No pain	12 (21%)	11 (18%)
Not reported	1 (2%)	1 (2%)

* Calculated as the average of hearing thresholds at 0.5, 1, 2, 4, 6, and 8 kHz

then in flexion position, (b) cervical side bending to right and left side: distance between mastoid process of temporal bone and acromion process of the scapula was first measured in neutral position and then in side bending position, (c) cervical rotation to right and left: distance between the tip of the chin and acromion of scapula was first measured in neutral position and then in rotated position [47].

An increase in ROM (meaning an increase in motion compared to baseline) after treatment, and at follow up, was considered an improvement. The adopted measurement error for ROM was 0.5 cm, following the recommendation of Zembaty [47].

Cervical muscles tension (MST) was assessed by the same physiotherapist who administered the intervention via the palpation method [48]. Upper fibers of the trapezius muscles were palpated to check for increased muscle tension. Muscle tension was graded as increased 0 and 1, where 0 means normal and 1 means elevated muscle tension.

Statistical analysis

Means and standard deviation were reported for continuous variables that were normally distributed. Medians and interquartile ranges (IQRs) were reported for variables that were not normally distributed. Frequencies and proportions were reported for categorical variables. Statistical analyses on outcome measures were performed using Statistical Package for the Social Sciences (IBM SPSS version 26) and STATA version 14. Intention to treat analysis was applied for the primary outcome measure (i.e. TFI) only. The data was assessed for normal distribution by a Shapiro–Wilk's test.

Effect of intervention on reduction of tinnitus severity (TFI). The effect of the intervention was assessed using an intention-to-treat approach. We included the baseline TFI score in the imputation model as a covariate. The number of imputations was set to 100, which is recommended as a minimum for critical inferences [49]. We imputed missing scores at T1 and T2 making a missing-at-random assumption. We conducted a sensitivity analysis to compare the results of the model without imputation and the one with imputation.

Table 2. Changes in primary and secondary outcome measures in the intervention and control groups from T0 (baseline), to T1 (post treatment), and to T2 (follow up). MST = pathological cervical muscles tension. The models used to predict the outcome measures are listed and were applied to the entire data set. The *p*-values correspond to the interaction between group and time

Outcome measure	Intervention group	Control group	Analysis	*p*-value	
				Intervention group	Control group
TFI	**Mean (SD)**	**Mean (SD)**	Linear mixed model	$p < 0.001$	$p = 0.56$
T0	52.6 (20.4)	46.8 (20.1)			
T1	40.9 (19.0)	45.8 (40.9)			
T2	40.4 (21.1)	45.2 (26.2)			
THI	**Median (IOR)**	**Median (IQR)**	Friedman test	T0 to T1 $p < 0.001$; T0 to T2 $p = 0.01$	$p = 0.766$
T0	48 (29.63)	36 (28.54)			
T1	28 (17.56)	38 (30.60)			
T2	28 (16.62)	37 (20.60)			
VAS	**Mean (SD)**	**Mean (SD)**	Linear mixed model	$p < 0.001$	$p = 0.461$
T0	6.24 (1.65)	6.07 (1.73)			
T1	5.11 (1.77)	6.13 (1.84)			
T2	5.02 (2.01)	5.93 (1.86)			
MST	**%***	**%***	Random effects logistic regression	$p = 0.003$	$p = 0.64$
T0	80%	50%			
T1	30%	45%			
T2	35%	47%			

* Percentage of patients with increased (pathological) cervical muscles tension

The primary analysis was a linear mixed model which was used to investigate the effect of the intervention on the reduction of tinnitus severity. Patients were included in the model as a random effect, while the baseline TFI score, intervention, and time were included as fixed effects. From this model, we tested for interaction (between-group) effects.

Impact of tinnitus on daily living (THI). A Friedman test was conducted to evaluate the differences in THI measurements across the three time points in the control and intervention groups. Pairwise comparisons were performed with a Bonferroni correction for multiple comparisons. This model allowed us to test within-group effects.

Effect of intervention on tinnitus loudness. Of the total 118 participants, 68% ($n = 80$) had complete data. The missing data was due to loss to follow up, meaning that our target power of 80% was not achieved. To assess the effect of the intervention on tinnitus loudness as measured by VAS, a linear mixed model was applied. Patients were included in the models as random effects. From this model, we tested for within-group and between-group effects.

Effect of intervention on muscle tension (MST). From 118 participants in the sample 67% ($n = 79$ patients) had complete data at all three time points. There were 20 people who missed the last time point (T2). To evaluate the effect of the intervention on muscle tension in the cervical spine muscles, a random effects logistic regression was conducted. The binary outcome was the presence or absence of pathological elevated muscle tension. From this model, we tested for within-group and between-group effects.

Analysis for neck ROM. Of the 118 participants, 67.8% ($n = 80$ patients) had complete data. The missing data was due to loss to follow up. A linear mixed model was conducted to investigate the change over time of the intervention in neck range of motion. Patients were included in the models as random effects. From this model, we tested for between-group effects.

Results

There were 23 females and 36 males (mean age 51.8 years, SD = 14.5) in the intervention group and 30 females and 29 males (mean age 49.6 years, SD = 15.8) in the control group. The demographic characteristics of the groups are presented in **Table 1**. The groups were balanced and did not differ significantly in terms of the degree of hearing loss (degree of hearing loss was calculated as the average of 6 pure-tone hearing thresholds at 0.5, 1, 2, 4, 6, and 8 kHz). In both groups the average hearing threshold showed mild sensorineural hearing loss in the range 3–8 kHz (WHO hearing classification). In the range 0.5–2 kHz the average hearing thresholds in both groups were within normal limits (**Table 1**).

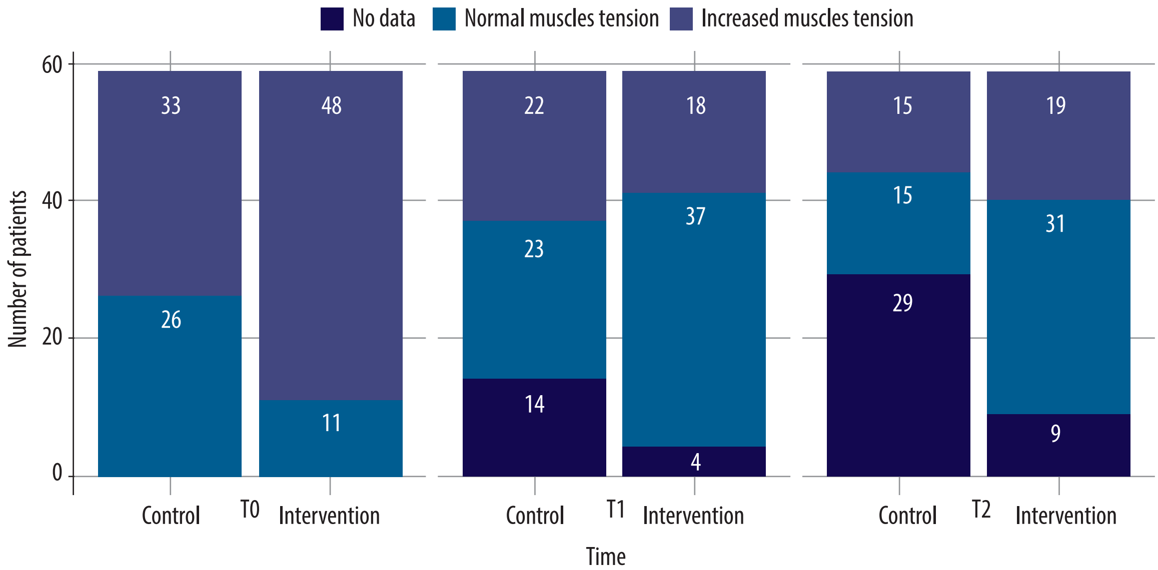

Figure 2. Cervical muscles tension (MST) in the intervention and control groups at the three time points (T0, T1, and T2)

Table 3. Effect on neck mobility (cervical spine range-of-movement, ROM) in the intervention group analyzed by linear mixed models applied to the entire data set. The *p*-values and CIs are interactions between time and intervention

Cervical spine ROM (in cm)	Mean (SD) at T0	Mean (SD) at T1	Mean (SD) at T2	Estimated effect – increase per time point (95% CI)	*p*-value of the estimated effect
Cervical flexion	4.77 (1.77)	5.33 (1.98)	5.45 (2.12)	0.42 (0.23 to 0.61)	$p < 0.001$
Cervical right-side bending	3.35 (2.03)	4.42 (1.65)	4.34 (1.67)	0.74 (0.42 to 1.07)	$p < 0.001$
Cervical left-side bending	3.59 (1.73)	4.57 (1.76)	4.73 (1.95)	0.64 (0.28 to 1.00)	$p < 0.001$
Cervical rotation to right	6.74 (2.16)	7.97 (1.82)	8.04 (2.05)	0.80 (0.42 to 1.18)	$p < 0.001$
Cervical rotation to left	6.53 (2.44)	8.25 (2.16)	7.81 (2.45)	0.78 (0.33 to 1.23)	$p < 0.001$

Patient dropout

In the intervention group ($n = 59$), 4 of 59 patients dropped out at post treatment (T1) and a further 5 did not complete the full treatment (T2). The reasons for drop out at T1 were undergoing additional medical procedures ($n = 2$) and not being able to take extra time off work to attend treatment ($n = 2$). The reason for drop out at T2 was not being able to take time off work ($n = 5$). In the control group ($n = 59$), 14 participants dropped out at T1. These patients reported that they experienced an increase in their tinnitus loudness because they were paying more attention to it. At T2, 15 additional participants dropped out (9 due to an increase in tinnitus loudness and 6 who were unable to take a free day from work). Patient dropout is shown in **Figure 1**.

Tinnitus severity as assessed by TFI

The intention-to-treat analysis yielded a statistically significant result in the intervention group. TFI decreased by 10.65 points (95% CI 14.87 to 6.44) in the intervention group compared to the control. The observed effect is similar to the model without imputation (10.22; 95% CI 14.72 to 5.72). Therefore, in the intervention group we obtained a reduction of 10.65 points on the TFI scale, which is not a minimum clinically identifiable difference (which is 13 points for TFI), although it is close [40].

Changes in the mean TFI score from baseline to follow up in the intervention and control groups are shown in **Table 2**.

We used secondary outcome measures to evaluate the effect of intervention on the impact of tinnitus on daily living (THI), the mobility of the neck (using cervical spine range of motion, ROM), tinnitus loudness (using VAS), and cervical muscles tension (by palpation, grading muscle tension as 0 and 1 (where 0 is normal and 1 is increased). All 118 patients were analyzed to evaluate the effect of the therapy. The results showed that patients who received the therapy (the intervention group) had significant changes in secondary outcome measures (see **Table 2**). Details are as follows.

Effect of the intervention on tinnitus loudness

A linear mixed model was used to analyse the effect of the intervention on tinnitus loudness. The regression slope in the control group was $\beta = 0.063$, 95% CI [−0.104 to 0.23], $p = 0.461$. In the intervention group the regression slope was $\beta = -0.66$, 95% CI [−0.877 to −0.45], $p < 0.001$. This can be interpreted as a reduction of VAS scores by 0.66 points for those in the intervention group per time point. The changes in the mean VAS score in the intervention and control groups from T0 to T1 and T2 are shown in **Table 2**.

Effect on tinnitus (THI)

THI was used to evaluate the impact of tinnitus on daily living. Since THI data was not normally distributed, median scores were used for the analysis. For this purpose, a Friedman test was conducted. It showed that in the control group, there was no statistical difference in THI scores across the three time points ($\chi^2(2) = 0.533$, $p = 0.766$). In the intervention group, the same analysis was applied (Friedman test). Pairwise comparisons were performed with a Bonferroni correction for multiple comparisons. In the intervention group, THI scores significantly differed at the different time points ($\chi^2(2) = 15.486$, $p < 0.001$). Although there was a statistically significant improvement in THI, this was below the MCID of 20 points.

Effect on muscle tension

The results of random effect logistic regression showed a significant reduction in cervical muscles tension in the intervention group ($p = 0.003$) per time point. The odds of muscle tension decreased by 13% in the control group and by 74% in the intervention group per time point. **Figure 2** shows the number of patients with normal and abnormal (increased) cervical muscles tension at T0 and how it changed at T1 and T2 in the intervention and control groups.

Effect of intervention on neck ROM

Analysis showed that the intervention had a positive effect on neck mobility (improved cervical flexion, cervical side bending to left and right, cervical rotation to left and right), although, in the case of cervical flexion, the increase in ROM (0.42 cm) was within the measurement error (0.5 cm following Zembaty [47]). Changes in the neck ROM measures from T0 (baseline) to T2 (follow up) for intervention group are presented in **Table 3**.

Discussion

In our study, we used a novel approach of delivering complex neck therapy (kinesiotherapy together with massage) to treat subjective tinnitus in the general tinnitus population. To our knowledge this is the first study that has used the three physiotherapeutic techniques together (active exercises, PIR, and interspinal muscle massage) to treat tinnitus.

There was a statistically significant reduction in the tinnitus symptom severity as measured with TFI and THI (12.2 and 15.7 points, respectively, from baseline (T0) to follow-up (T2)) in the intervention group, while there were no significant changes in the control group. According to Meikle et al. [40] a clinically relevant change in tinnitus is considered to be when TFI changes by at least 13 points. Thus, having obtained 12.2 points, we were close to obtaining this value. Furthermore, considering TFI assesses tinnitus over the past week, the tinnitus improvement measured at T1 might have been achieved earlier, namely during the second week of therapy and maintained at follow up. Similarly, when we consider minimum clinically identifiable difference (MCID) for THI (20 points, [43]) we did not reach this value [43]. At the same time, we observed a significant reduction in tinnitus loudness in the intervention group (from 6.24 points at T0 to 5.02 points at T2), while tinnitus loudness remained stable in the control group. Following Adamchic et al. [44] the change in VAS score from T0 to T2 was within the cluster of minimally clinically identifiable difference [44]. Moreover, in the intervention group the improvement in tinnitus was accompanied by a reduction in cervical muscles tension and an improvement in the range of motion of the cervical spine (although cervical flexion was within measurement error).

In the current study, it was not possible to directly explore the causal link between improvement in tinnitus symptom severity and physiotherapeutic measures. Nevertheless, our results suggest that improvement in the range of motion and reduction in increased muscles tension might have caused the improvement in tinnitus (severity and loudness). This should be further investigated in future studies.

The neck therapy which we employed targets diverse neck functions like muscle tension and range of motion by combining two kinesiotherapeutic methods (active exercises and post isometric relaxation exercises) with interspinal muscles massage. In this way, we addressed a wide spectrum of neck dysfunction like pathological muscle tension, limited cervical spine ROM, and some other symptoms (e.g. pain). Decrease in pain could be one of the possible mechanisms that might have led to the reduction in tinnitus symptom severity. Studies in the past have reported an association between pain and tinnitus [50–52]. The therapeutic benefits of our intervention – such as normalisation of neck muscle tension (by massage, PIR, and exercises) and removal of pain metabolites by massage (which improves local blood flow, removes pain metabolites, and induces muscle relaxation [53,54]) – might have positively affected the nociceptive pathways involved in pain perception and generation [55].

The improvement (increase) in the ROM together with the muscle relaxation are likely to result from therapeutic effect of massages and PIR which were two (out of three) components of our intervention. However the third component – active exercises – might have improved joint mobility by increasing muscle length and improving the alignment of joints in the cervical spine. The cumulative effect could have corrected cervical spine dysfunction, which might have been a factor in tinnitus generation. Furthermore, improvement in the ROM of cervical spine has been reported as one of the therapeutic effects of PIR (which is a muscle energy technique) [32,33,56]. Jeong et al. [57] evaluated the efficacy of passive stretching, massage, and muscle energy techniques on ROM, strength, and pressure pain underlying the musculoskeletal neck pain of young adults [57]. The authors applied these techniques on the upper trapezius, and each of the techniques was used alone in three different groups. The results showed that passive stretching, massage, and MET were effective in treating neck pain. MET as a treatment intervention resulted in a significant improvement in neck ROM, mainly rotation ($p < 0.05$) and muscle strength ($p < 0.05$). Massage had a positive effect on neck mobility and ROM but not on muscle strength. Some other studies [58–60] have shown a good effect of MET (including PIR) in reducing increased muscle tension. In contrast to Jeong et al. [57], who applied the physiotherapeutic methods singly, in our study we targeted all of the pathological symptoms (muscle tension, limited cervical spine ROM, and pain) simultaneously. Used together, we call PIR, massage, and active neck exercises as complex therapy. An additive effect of these methods might have occurred.

Another complex approach to the treatment of non-specific neck pain was presented by Hidalgo et al. [61]. Based on a systematic review of 23 randomised control trials they concluded that combined therapy (manual therapy joint with neck exercises) was better than manual therapy alone [61].

The co-occurrence of neck pain and modulation of somatic tinnitus strongly suggest somatic tinnitus [10,62]. Michiels et al. [23] conducted a study comprising multimodal cervical physiotherapy in patients with cervicogenic somatic tinnitus. The authors reported a significant reduction in tinnitus in 53% ($n = 38$) of the patients immediately after treatment. These positive effects were maintained at 6 weeks follow up in 24% of the patients. Our study appears similar to that of Michiels et al. [23] in terms of using combined approaches, but the components of our interventions are different. We incorporated kinesiotherapy methods (i.e., massage, active exercises, and PIR), which works on different physiological principles than the techniques (mobilization, manual therapy technique in kinesiotherapy) used by Michiels et al. [23].

Our study also differs in terms of participants. We recruited adults suffering from subjective tinnitus whereas Michiels et al. [23] studied a specific population (i.e. patients suffering from cervicogenic somatic tinnitus). In our study, patients had no home exercises, whereas they were part of the therapy in the former study.

Some years later Michiels et al. [22] conducted another study and reported that neck pain was present in 69% of respondents among 6,115 tinnitus participants [22]. In our study, some forms of neck pain (alone or accompanied by headache, earache, or face pain) were present in 60% of the intervention group participants and 57% of the control group. In this context, Levine et al. [63] reported that "somatic testing" led to tinnitus modulation in around 80% of tinnitus individuals, and evoked tinnitus in around 50% of people who did not have it (independently of hearing/cochlea status) [63]. Thus the somatic co-factor of tinnitus probably remains underappreciated, which may lead to a lack of efficient therapy. A routine testing for somatic modulation of tinnitus would help to select tinnitus subtype for which treatment influencing somatosensory system is beneficial.

Taking into account that tinnitus results from the multi-neural system interactions (e.g. auditory and somatic), a multimodal approach (involving e.g. neck therapy) seems to account for tinnitus treatment when the cervical spine may be involved.

Future directions

In our study we used a physiotherapeutic approach (we addressed the somatic tinnitus component) and obtained significant tinnitus improvement (in TFI, THI and in VAS for tinnitus loudness) as well as the improvement in the physiotherapeutic parameters (like ROM or muscle tension). However, in the current study we can only postulate the link between improvement in tinnitus and improvement in these parameters. Future studies should investigate whether there is a causal relationship between improvement in physiotherapeutic parameters and improvement in tinnitus symptoms.

Applying the protocol among purely somatic tinnitus individuals (thus with normal hearing) might help indicate the most appropriate population of tinnitus patients for this kind of therapy. On the other hand, more individualised neck therapy targeting specific neck disorders in tinnitus patients could be another approach. This individualised approach or therapy with longer, repeated sessions may increase the clinical effect on tinnitus. Moreover, randomised controlled trial with longer follow up is needed to confirm the results.

In contrast to our results, where improvement in tinnitus was maintained at the follow up (2 weeks after the end of therapy), the study by Michiels et al. [23] showed that for longer follow up (6 weeks) the therapeutic effect of neck therapy (applied as a treatment for tinnitus) was not maintained. Therefore, future studies should include a longer follow up period. It is also possible that repeated sessions of the therapy or continuation of exercises at home will be needed to maintain the improvement.

Study limitations

The major limitation of our study was lack of randomization, which was not possible due to the limited pool of patients being able to commit time to the intensive, daily, 2-week therapy. There was a relatively high number of patients who dropped out (especially in the control group), which reduced the power of our study. Thus, the results should be interpreted with caution. The high drop out ratio could be improved by introducing an active control or incentives to keep the control arm engaged with the study.

The short follow up period might be considered another limitation, especially given that the clinical effects of neck physical therapy for tinnitus have been shown to decrease with time [23]. The high prevalence of increased MST in the intervention group is another limitation. However, the groups were balanced in terms of neck pain, so this difference is random and it is unlikely to have influenced the decision to volunteer for the study.

Conclusions

Complex neck therapy seems to have potential for treating tinnitus. It provided a statistically significant reduction in tinnitus symptom severity and loudness, reduced muscle tension, and increased cervical spine range of motion. The results show the feasibility of designing a future randomised controlled trial in this area. Further studies are needed to explore the exact mechanisms of how particular cervical spine conditions affect tinnitus.

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Data availability statement

The datasets for this study can be found in the repository of the Department of Otolaryngology, Laryngological Oncology, Audiology and Phoniatrics, Medical University of Lodz, Lodz, Poland. Enquiries to the corresponding author.

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