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Research Paper

Effects of Dry Needling on Clinical Parameters of Migraine Patients: A Randomized Clinical Trial Protocol

Neda Najafi[1], Amin Momenzadeh[1], Mandana Rezaei[1], Hakimeh Adigozali[1*], Bahram Amirshakeri[1], Mohammad Yazdchi[2]

1. Department of Physical therapy, Faculty of Rehabilitation Sciences, Tabriz University of Medical Sciences, Tabriz, Iran.
2. Neurosciences Research Center, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran.

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ABSTRACT

Background and Objectives: Migraine headache is one of the most common health complaints among adults. Myofascial trigger points (MTrPs) in the cranial or cervical region may stimulate migraine symptoms and aggravate migraine pain. Physiotherapy interventions, such as trigger point dry needling (DN), can deactivate these points and may have positive effects on alleviating migraine symptoms. Therefore, this trial aims to investigate the impact of upper trapezius (UT) muscle DN in addition to medication drug therapy (pharmacotherapy) on headache characteristics in patients with migraine headaches.

Methods: A parallel randomized controlled trial with single-blinded outcome assessors was conducted. Forty patients were randomly assigned to two groups. The participants in the control group received pharmacotherapy, and those in the intervention group received three sessions of trigger point DN of the UT muscle with an inter-session interval of one week as an additional treatment to pharmacotherapy.

Results: The primary outcome measure was headache intensity measured by a daily headache diary form, and the secondary outcome measures were the headache duration, drug consumption, frequency of headache recorded by the daily headache diary form, pain pressure threshold, and pain intensity of the MTrPs in the UT muscle measured by an algometer and visual analog scale (VAS), respectively.

Conclusion: Introducing a dry needling protocol has implications in designing clinical trials to manage migraine headache symptoms.

Keywords: Dry needling (DN), Headache disorders, Migraine disorders, Physical therapy, Trigger point

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*** Corresponding Author:**
Hakimeh Adigozali, Associate Professor.
Address: *Department of Physical Therapy, Faculty of Rehabilitation Sciences, Tabriz University of Medical Sciences, Tabriz, Iran.*
Tel: *+98 (41) 33375359*
E-mail: *adigozalih@tbzmed.ac.ir, adigozalih@gmail.com*

Function & Disability Journal

What is "already known" in this topic:

Dry needling technique is an effective method in reducing headache symptoms.

What this article adds:

The effects of the upper trapezius muscle myofascial trigger points dry needling to manage headache characteristics in patients with migraine headache are unknown.

Introduction

Migraine is a benign headache affecting nearly 12% of the adult population worldwide [1]. As a diagnostical and differential marker, a person with migraine headache should experience at least five attacks that cause unilateral, pulsating headaches of moderate to severe intensity that last between 4 to 72 hours. Additional symptoms, such as vomiting, photophobia, or nausea accompany this condition. The intensity of the headache increases with routine activities or while walking up or down stairs, reducing the ability to perform routine daily tasks [1, 2]. The origin of migraine as a neurovascular condition can be related to vascular, central nervous system, and peripheral contributors that can sensitize the peripheral nervous system [2]. Risk factors, such as hypertension, smoking [3], and the consumption of medication drugs for other problems can initiate or aggravate symptoms [4].

Pharmacotherapy as a primary treatment for migraine may be curative or prophylactic. However, only about half of the patients with this disorder have a clinically significant response to preventive pharmacotherapy treatments, and more than 10% of patients refuse to continue the treatment process due to interactions with other medications or long-term side effects [5].

Considering that migraine is a multifactorial problem, patients may have musculoskeletal system dysfunction [6]. Many of the migraineurs have cervical muscle dysfunction. Disorders, such as forward head posture, reduced range of motion of the neck, and increased sensitivity of the neck muscles may be observed [7]. Some of these changes are also called myofascial trigger points (MTrPs) [8]. MTrPs are irritable points in the taut band that develop in skeletal muscles or fascia and can cause local sensitivity and referral pain when compressed [9]. These points can contribute to muscular impairment, such as lower strength and endurance, altered recruitment patterns, motor control, and a limited range of motion of the involved joint [10, 11]. MTrPs in specific muscles, such as the sternocleidomastoid (SCM), suboccipital, and upper trapezius (UT), could initiate or at least aggravate the characteristics of migraine headaches [12, 13]. Additionally, the referred pain zone of active MTrPs in these muscles is similar to the areas affected by migraine headaches [13]. As one of the major muscles in the cervical region, the UT plays a role in cervical movement and has high potency in developing MTrPs. Referral pain of MTrPs in the UT feels unilateral upward along the posterolateral aspect of the neck and extends to the temple and the back of the orbit [13]. A positive correlation is observed between the number of MTrPs in temporal and suboccipital areas and the frequency and duration of migraine attacks [7]. Furthermore, UT-induced irritation of MTrPs in migraineurs may initiate migraine headache symptoms [14].

Dry needling (DN), a known physiotherapy intervention used to deactivate MTrPs, is defined as the penetration of a fine needle into the skin, subcutaneous tissues, and muscle to release MTrPs [15]. DN may have beneficial effects on reducing pain perception, improving blood circulation, and promoting the secretion of endogenous opioids, such as β-endorphin, which affects the nervous system and may impact headache characteristics during pharmacotherapy [9, 16]. However, evidence on releasing MTrPs and their impact on headache characteristics in patients with migraine headaches are limited. To the best of our knowledge, only one study has investigated the impact of releasing MTrPs with the DN technique in patients with migraine headaches. In this study, the DN technique was performed on MTrPs of SCM, and as the results showed, SCM-DN can have positive effects on the clinical parameters of headache (intensity, duration, and frequency); therefore, this technique can

be considered a cost-effective complementary treatment to improve the quality of life (QoL) of patients with migraine headaches [6]. Although this study has provided valuable results regarding the effectiveness of the DN technique in the treatment of migraine patients, the impact of the DN on SCM-MTrPs cannot be generalized to other muscles [6], especially UT-MTrPs, whose referral pain can mimic and cause migraine headaches [13].

Although releasing MTrPs of the UT muscle seems to have positive effects on headache characteristics [13, 17], more studies need to be conducted about the effectiveness of MTrP-DN of UT in migraineurs. Therefore, this randomized controlled trial aims to investigate the impact of the MTrP-DN of the UT on migraine headaches and evaluate its possible effects on migraine headache characteristics, such as frequency, duration, medication drug consumption, and intensity, along with MTrP characteristics, such as the pressure pain threshold (PPT) and pain intensity at the MTrP.

The primary objective is to determine the effects of DN on UT-MTrP plus pharmacotherapy compared to pharmacotherapy alone on headache intensity in patients with migraine headaches, reported by the daily headache diary form. This study secondarily aims to determine the impact of DN on the UT-MTrP plus pharmacotherapy compared to pharmacotherapy alone on headache frequency, duration, and drug consumption, all of which will be assessed by the daily headache diary form. MTrPs sensitivity or the PPT will be evaluated by algometer, and the pain intensity of UT-MTrPs while applying pressure by algometer will be assessed by the visual analog scale (VAS).

Materials and Methods

Study design

This protocol is a single-blinded, randomized control trial with parallel groups of 40 patients. The study protocol was created following SPIRIT guidelines [18] and registered under IRCT20200215046499N2, with the registration on 2021-12-06. It received approval from the Research Ethics Committee of Tabriz University of Medical Sciences, with the registration code IR.TBZMED.REC.1400.430, which was approved on 2021-08-02. Patient recruitment, assessment, and treatment will be performed at a public hospital (Table 1). The Physiotherapy Department is liable for monitoring the study process from its initial to its final stage. The study team considered no interim analysis for this study. No auditing trial has been predicted in this study. After considering any changes in the protocol, the recent approach will be edited at Iranian Registry of Clinical Trials (IRCT).

Participants

The subjects in this study included adults who suffered from migraine headaches and had MTrP (according to Travell and Simons' definition of MTrP) in the UT muscle of the affected side [13]. These patients were diagnosed according to the International Classification of Headache Disorders (ICHD-3) [19] and referred by a neurologist to the physiotherapy clinic of a public hospital under the supervision of an expert physiotherapist with 15 years of clinical experience in treating headaches. Using G*Power software, version 3.1.2 with the parameters of effect size: 0.8, α error probability: 0.05, and power: 0.80, 40 patients were determined for two groups (20 patients for each group). The effect size of the present study was determined according to the study of Ghanbari et al., and the mean and standard deviation of the headache intensity variable were determined [20].

Study procedure

MTrP diagnosis and DN treatment were performed by a physiotherapist who is a professional in MTrP treatment and certified in releasing MTrPs with the DN technique. According to Travel and Simon's criteria, an active MTrP is determined by the existence of a taut band in the muscle, an irritable tender point in the taut band, spontaneous pain, local twitch response (LTR) with compression, and familiar referral pain, which is reproduced by irritating the point [13]. Recruitment began by interviewing patients referred by neurologists with a diagnosis of migraine. The assessor of the study completed the assessment process in terms of the eligibility criteria if subjects were eligible to participate in the study considering the inclusion and exclusion criteria (Table 2) and having MTrP in the UT muscle, they were informed about possible benefits, harms, and objectives; if they were interested in participating, they would sign the written informed consent form. After the participants were included in the study, their demographic data were collected, including the following items: Age, gender, weight, height, medication history, drug usage, and side of headache. Then, the participants were randomly allocated into intervention and control groups via sealed envelopes. The participants in the intervention group received three sessions of DN treatment with an inter-session interval of 1 week plus pharmacotherapy, and those in the control group received only pharmacotherapy. The duration of the study program for the intervention and

control groups was the same (Figures 1 and 2). Someone outside the study team randomized participants with a simple randomization method by sealed envelopes. Two envelopes were prepared with A & B titles. Each participant randomly selected one envelope, and the letters of the envelopes were recorded for that participant. Then, envelopes were set beside each other, and the next participant repeated the same procedure until all participants were randomly divided into two groups. It was conducted by someone outside the research team with a 1:1 parallel allocation method that used a computerized randomization program to assign participants to groups, using blocks of four and six. After that, the allocation of groups was enclosed and hidden in opaque envelopes sealed with prelabeled letters A and B. Someone outside the study team performed the recruiting procedure. The outcome assessor was blinded to the intervention type and should be blinded during the study without any excuses. Unmasking events were recorded while the participants were performing the study. After completing the recruiting and treatment procedure for all participants, the outcome assessor could be informed about the group allocation if they were willing to.

Therapeutic interventions

The intervention group received routine pharmacotherapy plus three sessions of DN on the most irritable

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT**	$-t_1$	0	t_1	t_2	t_3	t_4
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
[List other procedures]	X					
Allocation		X				
INTERVENTIONS:						
Study groups			←	—	→	X
[Intervention Group]			X	X	X	X
[Control Group]						X
ASSESSMENTS:						
Headache intensity	X		X	X	X	X
frequency	X		X	X	X	X
Duration of headache	X		X	X	X	X
Drug consumption	X		X	X	X	X
PPT	X		X	X	X	
Pain intensity of MTrP	X		X	X	X	

PPT: Pain Pressure threshold, MTrP: Myofascial Trigger Point, t: therapeutic session

Figure 1. Trial schedule of the protocol study

Abbrevitions: PPT: Pain pressure threshold; MTrPs: Myofascial trigger points; T: Therapeutic session.

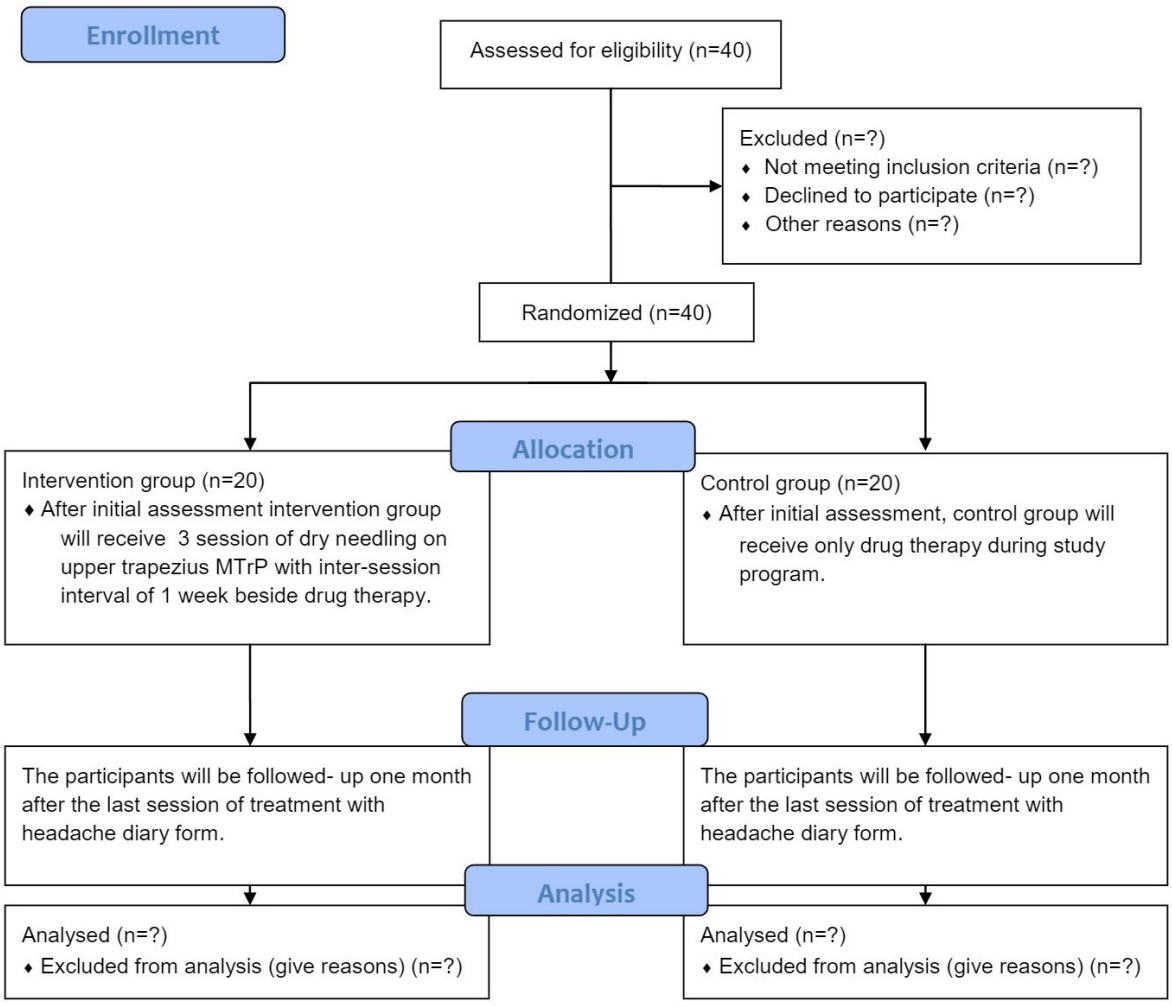

Figure 2. CONSORT flowchart of the study

MTrP of UT at one-week inter-session intervals. The patient should lie in prone to perform the DN technique on the UT. The taut band is taken with the thumb and index finger of the nondominant hand, and the needle is directly inserted into the MTrP of the muscle with the dominant hand. The needle should move back and forth to elicit LTR until the LRT is not visible by moving the needle ten times. The MTrP location is marked with a waterproof marker so that the location of this point remains constant during the three sessions of the DN. If more than one painful point is observed, the point with the most pain will be selected. In addition, participants in the intervention group received migraine pharmacotherapy so that they were not deprived of their routine treatment. As the neurological doctor neurologist prescribes, the participants in both groups take drugs like propanol, which has a prophylactic effect. Sodium valproate and topiramate act as anticonvulsants: Amitriptyline, nortriptyline, and other tricyclic antidepressants (TCAs). The prescription of drugs and their dosage depends on the intensity of their headache daily drug usage and their possible interactions. Participants in the control group only received pharmacotherapy.

The absence of two successive treatment sessions or the unwillingness to participate in the treatment procedure excludes the patient from the study, and a substitute patient replaces the excluded patient. To improve adherence to treatment protocol, all treatment costs are free for participants, and they can contact their therapist and ask questions about their clinical symptoms over the phone. The participants in the intervention group are allowed to take analgesics, such as acetaminophen or ibuprofen if tolerating pain becomes difficult [21]. On the other hand, if pain tolerance after treatment sessions is not possible for patients to perform their daily tasks, the treatment procedure must be stopped. The confidentiality principle is considered at every trial stage and re-

Table 1. SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item		Item No.	Description
Administrative Information	Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
	Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
		2b	All items from the World Health Organization Trial Registration Data Set
	Protocol version	3	Date and version identifier
	Funding	4	Sources and types of financial, material, and other support
	Roles and responsibilities	5f	Names, affiliations, and roles of protocol contributors
		5b	Name and contact information for the trial sponsor
		5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
		5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction	Background and rationale	6a	Description of research question and justification for undertaking the trial, including a summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
		6b	Explanation for choice of comparators
	Objectives	7	Specific objectives or hypotheses
	Trial design	8	Description of trial design including the type of trial (e.g. parallel-group, crossover, factorial, single group), allocation ratio, and framework (e.g. superiority, equivalence, noninferiority, exploratory)
Methods: Participants, interventions, and outcomes	Study setting	9	Description of study settings (e.g. community clinic, academic hospital) and list of countries where data will be collected. Reference to where a list of study sites can be obtained
	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (e.g. surgeons, psychotherapists)
	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g. drug dose change in response to harms, participant request, or improving/worsening disease)
		11c	Strategies to improve adherence to intervention protocols and any procedures for monitoring adherence (e.g. drug tablet return, laboratory tests)
		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g. systolic blood pressure), analysis metric (e.g. change from baseline, final value, time to event), method of aggregation (e.g. median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
	Participant timeline	13	Schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations

Section/item		Item No.	Description
Methods: Participants, interventions, and outcomes	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
	Allocation		
Methods: Assignment of interventions (for controlled trials)	Sequence generation	16a	Method of generating the allocation sequence (e.g. computer-generated random numbers) and listing any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g. blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions
	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g. central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
	Implementation	16c	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to interventions
	Blinding (masking)	17a	Who will be blinded after assignment to interventions (e.g. trial participants, care providers, outcome assessors, data analysts), and how
		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis	Data collection methods	18a	Plans for assessment and collection of the outcome, baseline, and other trial data, including any related processes to promote data quality (e.g. duplicate measurements, training of assessors) and a description of study instruments (e.g. questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
		18b	Plans to promote participant retention and complete follow-up, including a list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g. double data entry and range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
	Statistical methods	20a	Statistical methods for analyzing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
		20b	Methods for any additional analyses (e.g. subgroup and adjusted analyses) : No decision for further additional analysis has been made in this study.
		20c	Definition of analysis population relating to protocol nonadherence (e.g. as randomized analysis), and any statistical methods to handle missing data (e.g. multiple imputations) : Protocol nonadherence or loss to follow-up will be handled by intention-to-treat analysis.
Methods: Monitoring	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent of the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial : The study team considered no interim analysis for this study.
	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent of investigators and the sponsor
	Ethics and Dissemination		
	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval

Section/item	Item No.	Description
Methods: Monitoring	Protocol amendments	25	Plans for communicating important protocol modifications (e.g. changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g. investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how (see Item 32)
		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained to protect confidentiality before, during, and after the trial
	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
	Access to data	29	Statement of who will have access to the final trial dataset and disclosure of contractual agreements that limit such access for investigators
	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care and for compensation to those who suffer harm from trial participation
	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g. via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
		31b	Authorship eligibility guidelines and any intended use of professional writers
		31c	Plans, if any, for granting public access to the complete protocol, participant-level dataset, and statistical code
Appendices	Informed consent materials	32	The model consent form and other related documentation is given to participants and authorized surrogates
	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 explanation and elaboration for crucial clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT group copyrights the SPIRIT checklist under the creative commons "attribution-noncommercial-noderivs 3.0 unported" license.

mains confidential after trial results are published. If any adverse situation occurs during the trial, intentionally or unintentionally, the research team is responsible for the harm caused. The adverse effects of DNs can be divided into two categories: Minor (i.e. pain, bleeding, and bruising) and major (i.e. pneumothorax, excessive bleeding, and syncopal responses) (Table 3) [22]. Fortunately, the TP-DN technique is a relatively safe treatment [22, 23].

Outcomes measures

Headache parameters

The headache intensity, as well as its frequency, medication drug consumption, and duration, are evaluated by the daily headache diary. Scoring based on the headache diary varies from 0 to 4. Score 0 indicates the absence of a headache, score 1 indicates a headache only when the person pays attention to it, score 2 indicates that the occurrence of headache does not interfere with the person's daily activities, score 3 indicates a headache, tasks that require concentration cannot be performed, and score 4 indicates that the headache interferes with many daily tasks and only essential tasks can be performed [24]. In the intervention group, the daily headache diary form is completed by participants at baseline, before the DN technique in sessions 2 and 3. In the control group, the daily headache diary form is conducted at the first and second sessions (14 days after the first session, which equals the third treatment session in the intervention group). Participants in the control and intervention groups are evaluated by completing the daily headache diary form 30 days after the last session (follow-up session). The form is delivered to the therapist in person after being completed by the participants.

The patient reported headache frequency based on headache attacks per week with the daily headache diary form in both the intervention and control groups [21]. The procedure used to report the frequency of headaches in the intervention and control groups is similar to the headache intensity.

Table 2. Inclusion and exclusion criteria for participants in the study

Inclusion Criteria	Exclusion Criteria
The diagnosis of migraine headache by a neurologist Unilateral throbbing headache worsens with physical activity History of migraine headaches for more than 3 months Moderate to severe headache lasting between 4 and 72 hours History of having nausea, photophobia, or sound aversion during migraine attacks	History of neck trauma The presence of other types of headaches, like tension-type headaches and cluster headaches History of cervical radiculopathy History of neck or shoulder surgery Presence of facial nerve neuralgia, rheumatoid arthritis, rheumatic diseases, inflammation Presence of neck myopathy, neuropathy, myelopathy, and torticollis History of injection into MTrP of UT or acupuncture History of physiotherapy in the neck area in the last six months Fear of needles or contraindications for using dry needles Drug addiction or use of corticosteroid usage Pregnancy Presence of non-typical migraine, such as hemiplegic migraine, basal migraine, migraine with long-term aura and migraine infarcts

The headache duration represents the duration of the headache from its onset to its end and is assessed by the headache diary form in both the intervention and control groups [24]. The procedure for reporting the headache duration for the intervention and control groups is similar to that for headache intensity.

Drug consumption is reported in headache diary form in both the intervention and control groups. The procedure of reporting the drug consumption in the intervention and control groups is similar to those used to assess headache intensity.

PPT

PPT is evaluated by a digital algometer in the intervention group, before the initiation of the intervention, immediately after the intervention, and in every treatment session; in the control group, PPT is assessed once at the first session and once at the second session (equal to the third treatment session in the intervention group). This outcome is not measured in the follow-up session. A digital algometer (FPX 25 Algometer Wagner Instruments, Greenwich, USA) assesses PPT. The procedure is explained verbally to the patient to introduce the patient to how the PPT is assessed. Once the patient understands the assessor's explanations, the algometer is placed vertically on the MTrP of the UT muscle, and the pressure is increased at a constant rate (an increase of one kilogram per square centimeter of pressure per second). When the patient says "this," the assessor should stop increasing pressure, and the value displayed on the screen of the algometer is recorded. For reproducibility, the exact location of MTrPs is marked with permanent ink. This process is repeated thrice with intervals of 10 s, and the average value is used in data analysis. The reliability of

Table 3. Potential adverse events

Adverse Events Categories		Clinical Manifestations
Adverse events	Minor	Bruising Bleeding Feeling faint Initiation or aggravating of headache Nausea Drowsiness Aggravated symptoms Pain during DN performance Pain after DN performance
	Major	Pneumothorax Excessive bleeding Syncopal responses Infection Forgotten needle Fainting Numbness Flu-like symptoms Prolonged symptoms aggravation

DN: Dry needling.

the assessment using the pressure algometer device is reported to be good to excellent (interclass correlation coefficient [ICC]=0.75–0.89).

Pain intensity of the MTrP

The VAS evaluates the pain intensity of the UT-MTrP. In the intervention group, the VAS is assessed before the intervention and immediately after the intervention in every treatment session. In the control group, the VAS is assessed first and once during the second session.

Statistical analysis

The blinded outcome assessor records participants' personal information, baseline, and outcome measures on the assessor's laptop. The outcome data is saved in an Excel file for analysis. No decision for further analysis has been made in this study. Protocol nonadherence or loss to follow-up is handled by intention-to-treat analysis. Descriptive statistics, including the Mean±SD for quantitative variables, is performed for the dependent variables by SPSS software, version 26. Examining the conformity of the frequency distribution of quantitative variables with the theoretical normal distribution is conducted through the Shapiro–Wilk test and skewness. The data transformation method is used if the data distribution is not normal. To compare the variables between the first and the follow-up session in the control and intervention groups, a paired t-test is used, or to compare the variables between the two groups in the first session and the follow-up session, an independent t-test is used. Repeated measures compare the variable changes between therapeutic sessions in the intervention group. The acceptable P=0.05 in this study.

Results

After completing the study procedure, the results are ready for publication in an international peer-reviewed journal and will be presented at prominent national or international conferences.

Discussion

Although migraine headache is a benign type of headache, it can be debilitating and affect different aspects of a person's QoL during the attack [25]. Drugs from pharmaceutical families, such as beta-blockers, anticonvulsants, and TCAs, are usually prescribed to treat and reduce the negative parameters of migraine headaches [26-28]. Despite the effectiveness of such drugs, half of the patients reported dissatisfaction with their conventional pharmacotherapy. On the other hand, the tolerance and side effects of currently available medication drugs often limit their use [28].

Due to the multifactorial nature of this issue, impairments in different systems, such as the blood circulation, central nervous system, and peripheral nervous system, can be considered as aggravators of its symptoms [2]. Considering this feature, a compound treatment program that targets different perspectives on this issue may have a more positive effect than pharmacotherapy alone. On the other hand, nociceptive inputs of the myofascial system (MTrP) in muscles, such as the UT, SCM, and suboccipital muscles, can be considered an influential factor in aggravating migraine symptoms, and their release may improve the migraine headache characteristics [6, 7, 12, 29].

DN, as an effective treatment in releasing MTrPs, may have positive effects on the nervous system (central and peripheral) by activating neuron fibers, such as Aβ fibers, Aδ fibers, and C fibers, and the secretion of substances, such as endogenous opioids [30-32], by releasing substance P and calcitonin-generated peptide, DN can improve blood circulation [33-36] and regulate spontaneous electrical activity by causing LTR. Although DN seems to be an effective method to release MTrPs, evidence supporting this therapeutic method and investigating its effects in patients with migraine headaches is scarce [6].

This is the first study to determine the impact of releasing the MTrP of UT muscle in addition to pharmacotherapy and to explore whether the DN of UT as a complementary treatment can benefit routine pharmacotherapy in patients with migraine headaches.

Conclusion

The final data of the study will be published after the completion of the study procedure.

Ethical Considerations

Compliance with ethical guidelines

The trial is recognized and registered in the Ethics Committee of Tabriz University of Medical Sciences with the Ethics Committee (Code: IR.TBZMED.REC.1400.430, approved on August 2, 2021). Based on the Declaration of Helsinki, the following ethical principles will be considered during the trial: 1) The study's goal, characteristics,

and duration were informed to the participants, who signed an informed consent form to enter the study. 2) Collected information, including personal and study-related data, was protected, maintained confidentially, and used only for statistical analysis. 3) Participants were free to withdraw from the research at any stage and for any reason, or even without providing a specific reason. 4) The researcher committed to compensating any potential costs incurred by the participants due to their involvement in this study. 5) The possibility of allocation into each group was explained to participants before their assignment to the study. This trial was registered prospectively in the Iranian Registry of Clinical Trials (IRCT) (No.: IRCT20200215046499N2; registered on December 6, 2021).

Funding

Although this study is conducted under the supervision of the Rehabilitation Sciences Faculty at Tabriz University of Medical Sciences, the study team has not received any funding from the University or any other organization for any study stage.

Authors' contributions

Conceptualization: Neda Najafi, Amin Momenzadeh, Hakimeh Adigozali, and Mandana Rezaei; Methodology, and supervision: Hakimeh Adigozali, and Mandana Rezaei; Investigations, and writing the original draft: Neda Najafi and Amin Momenzadeh; Review and editing: Bahram Amirshakeri, and Mohammad Yazdchi; Final approval: All authors.

Conflict of interest

The authors declared no conflict of interest.

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