

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Comparison of The Effect of Six Weeks of Self-Massage and Nerve Gliding Exercise on Wrist Pain and Functional Disability of Piano Players with Carpal Tunnel Syndrome

#### Protocol summary

##### Study aim

A comparison of the effects of six weeks of self-massage and nerve stretching exercises on pain and functional disability in the wrists of pianists with carpal tunnel syndrome.

##### Design

A controlled, parallel-group, single-blind, randomized clinical trial on 30 musicians. Simple randomization.

##### Settings and conduct

3 days before the start of the training, 30 subjects will be invited to complete a written consent form, as well as a form containing anthropometric characteristics and medical history, and to perform the Fallen and Tinel test, which has been developed according to the research input indicators. During a briefing session, the participants will be given the necessary explanations. The subjects will be randomly divided into two control groups and an experimental group. This means that the subjects in the experimental group will receive massage and nerve stretching exercises, and the control group will not receive any specific activity. The number of treatment sessions will be 6 weeks, 3 sessions per week, and at the end, a post-test will be administered to both groups.

##### Participants/Inclusion and exclusion criteria

Having at least 1 year of playing experience, moderate wrist pain (VAS score 4-7); Having mild to moderate symptom severity and functional status; 20-40 years of age; No medical problems contraindicated for massage

##### Intervention groups

Nerve stretching exercises and self-massage

##### Main outcome variables

Wrist pain; Wrist strength; Wrist flexibility

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20251118068043N1**

Registration date: **2025-11-22, 1404/09/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2025-11-22, 1404/09/01**

Update count: **0**

##### Registration date

2025-11-22, 1404/09/01

##### Registrant information

###### Name

Sara Ghorbani

###### Name of organization / entity

Shahid beheshti university

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 9990

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sara.gh7699@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-11-22, 1404/09/01

##### Expected recruitment end date

2026-01-05, 1404/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of The Effect of Six Weeks of Self-Massage and Nerve Gliding Exercise on Wrist Pain and Functional Disability of Piano Players with Carpal Tunnel Syndrome

## **Public title**

Comparing the effects of massage and nerve stretching exercises on symptoms of pianists with carpal tunnel syndrome

## **Purpose**

Education/Guidance

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Have at least 1 year of experience playing the piano  
Having moderate pain in the wrist (VAS score 4 to 7)  
Having mild to moderate symptom severity and functional status Age range 20-40 years Positive at least one of the Fallen and Tinel physical examination tests  
Absence of predisposing factors such as diabetes, hypothyroidism, hyperthyroidism, acute trauma, pregnancy  
Not participating in a physical therapy program in the previous month  
Absence of medical conditions that would contraindicate massage therapy

### **Exclusion criteria:**

Unwillingness to continue cooperation  
Having three absentee sessions in the entire protocol  
Failure to submit self-massage report  
Failure to participate in the post-test

## **Age**

From **20 years** old to **60 years** old

## **Gender**

Both

## **Phase**

N/A

## **Groups that have been masked**

- Participant

## **Sample size**

Target sample size: **30**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

1. Randomization method and explanation: Main method: Simple Randomization, which will be performed using a random number table. - Reason for choosing this method: No need to control the intervening variables in the study and ease of implementation. - Quasi-random method: Quasi-random methods will not be used in this study. 2. Randomization unit: Individual randomization: Each participant will be randomized independently and without grouping (such as cluster or block). 3. Randomization tool: - Random Number Table: - After assigning unique numbers to the participants( In the base of Randomization method), corresponding numbers are selected from the table. - Even numbers are assigned to the intervention group and odd numbers to the control group. 4. How to create a random sequence: - Step-by-step steps: 1. A complete list of the statistical population (based on the study entry criteria) will be prepared. 2. Each person will be assigned a unique numerical code. 3. By referring to the random number table, numbers corresponding to the codes will be selected and assigned to the group. 5. Allocation Concealment: - Method: Use of sealed envelopes and use of a third party. - Process

Description: - After determining the random sequence, the names of the groups (intervention/control) will be placed in opaque envelopes. - The envelopes will be kept and opened by an independent person who will not play a role in the study. - Objective: To prevent selection bias by the researcher. - 6. Stratification: - Stratified randomization will not be used in this study. - 7. Supplementary Notes: - Transparency of the lottery process: - With respect to the traditional method (taking paper from the container), it is worth noting: - The container will be shaken homogeneously. - The papers will be the same in size and shape. - The process will be recorded by an independent observer. It is also worth noting that this method was designed in accordance with CONSORT guidelines for simple randomization and allocation concealment (REF)

## **Blinding (investigator's opinion)**

Single blinded

## **Blinding description**

1. Overall Blinding Design: - This study will be designed as a single-blind study, meaning that: Participants will not be aware of their group allocation (intervention or control). 2. Implementation methods for blinding participants: a) For the intervention group: - In addition, the intervention will be carried out at the house of the individuals, so the intervention is designed to be similar in appearance to the daily activities of the individuals in this group and its implementation will not interfere with daily activities. - Neutral terms will be used to describe the intervention (instead of "new program", "activity program" will be used). b) For the control group: - Participants will be told that they are participating in a "daily activity pattern study" and will not do heavy exercise during this period. - They will be asked to continue their usual activities without change. - Both groups will be monitored from the same time and under the same conditions. 3. Standardization of conditions for both groups: - Research calls: The number and duration of follow-up calls will be the same for both groups. The content of the conversations is standardized in advance. - Measurement instruments: \* The same instruments will be used for both groups. \* The instructions for the tests and measurement instruments will be the same. 4. Control of confounding factors: - Time separation: \* Assessment sessions for the two groups will be held at different times. \* Interaction between members of the two groups will be prevented. - Trained personnel: \* Researchers involved in the study are trained to prevent unwanted disclosure of information. 5. Evaluation of blinding success: - At the end of the study, participants will be asked: \* "Which group do you think you were in?" \* "How sure are you of this?" 6. Documentation and appendices: - Standardized blinding instructions will be attached as an appendix to the study protocol. It is important to note that the above section and the methods mentioned are designed in accordance with Section 11b of the CONSORT 2010 guidelines. Finally: These arrangements will ensure that: 1. Participants will not be able to tell whether they are in the intervention or control group. 2. This lack of awareness of group allocation will prevent participants from biasing their reporting of results.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

research Ethics Committee of Shahid Beheshti University

##### Street address

Shahid Shahryari Square, Evin,

##### City

Tehran

##### Province

Tehran

##### Postal code

1983969411

#### Approval date

2025-04-12, 1404/01/23

#### Ethics committee reference number

IR.SBU.REC.1404.011

## Health conditions studied

### 1

#### Description of health condition studied

Carpal tunnel syndrome

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Wrist pain

#### Timepoint

Pre-test & post-test

#### Method of measurement

Visual Analogue Scale

### 2

#### Description

Wrist strength

#### Timepoint

Pre-test & post-test

#### Method of measurement

Hand dynamometer

### 3

#### Description

Wrist flexibility

#### Timepoint

Pre-test & post-test

#### Method of measurement

Goniometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Nerve stretching and massage exercise group

#### Category

Rehabilitation

### 2

#### Description

Control group

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tanin Mandegar Music School

##### Full name of responsible person

محمد رضا عباسی

##### Street address

3rd Floor- Unit 6 - Mehregan Building- South Kargar Street, Labafinejad Intersection- Enghelab Square

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

shahid beheshti university of Tehran

##### Full name of responsible person

seii deh mehri hamidi sangdahi

##### Street address

shahid beheshti university- shahid shahriari Sq- Evin

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**Grant name**

shahid beheshti university

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

shahid beheshti university of Tehran

**Proportion provided by this source**

30

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact****Name of organization / entity**

shahid beheshti University of Tehran

**Full name of responsible person**

Fariborz Howanloo

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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شهید بهشتی تهران

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The data file without names and personal information, the raw sample of the informed consent form, and the clinical study report are included in the text of the final research report.

**When the data will become available and for how long**

After completing the research project, up to six months thereafter

**To whom data/document is available**

Everyone

**Under which criteria data/document could be used**

Any manipulation of data, misuse, or plagiarism of it without citing the source is not permitted.

**From where data/document is obtainable**

Fariborz Hovanloo, Contact Number: 29905847

University Address: Shahid Shahryari Square, Evin,

Tehran, Email: F\_Hovanloo @sbu.ac.ir

**What processes are involved for a request to access data/document**

After applying in person or electronically and in case of verification, a maximum of 1 week

**Comments**