# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 May 2026

## Effects of face and body acupuncture on glabellar frown lines in women aged 30-59 years referred to the dermatology or acupuncture clinics of Mashhad University of Medical Sciences

## Protocol summary


**Study aim**

Determining the effects of facial and body acupuncture on the frown line in women aged 30-59 referring to dermatology or acupuncture clinics of Mashhad University of Medical Sciences.

**Design**

A Two-arm parallel (36 patients in each arm), randomized trial with blinded assessors and data analysts

**Settings and conduct**

Intervention group: The acupuncture points of the body and face, as well as the depth of the frown line, are needled. Needling is done twice a week for 6 weeks and the needles last for twenty minutes in each session. Patients are subjected to imaging of the glabella area three times including at the time of the first visit, one week and six weeks after the end of the last treatment session under standard conditions in two states of rest and maximum frown. Control group: These patients are subjected to imaging of the glabella region three times including at the time of the first visit, seven and twelve weeks after the first visit under standard conditions in two states of rest and maximum frown without any intervention.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: 72 women aged 30-59 suffered from frown lines with informed consent. Exclusion criteria: performing facial rejuvenation procedures in the glabella and forehead area in the last six months or during treatment; skin diseases, diabetes, and tuberculosis; anticoagulant or thrombolytic use; pregnancy or breastfeeding; history of herpes.

**Intervention groups**

Intervention group: face and body acupuncture and Control group: no treatment

**Main outcome variables**

The three images of each patient, in two states of rest and maximum frown, are scored and compared independently by three trained physicians (outside of the research team) using the Glabellar Line Scale (GLS) and by one of the researchers using the Global Aesthetic Improvement Scale (GAIS).


## General information

**Reason for update**

Adding the item #10 to the exclusion criteria (which is already recorded in the Pajuhan's proposal and implemented in the study)

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20230204057316N1**
Registration date: **2023-04-21, 1402/02/01**
Registration timing: **prospective**

Last update: **2025-04-13, 1404/01/24**
Update count: **4**

**Registration date**

2023-04-21, 1402/02/01


**Registrant information**

**Name**

Hossein Haghir

**Name of organization / entity**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-07-02, 1402/04/11

**Expected recruitment end date**

2024-03-17, 1402/12/27

**Actual recruitment start date**

2023-07-02, 1402/04/11

**Actual recruitment end date**

2024-06-16, 1403/03/27

**Trial completion date**

2024-09-15, 1403/06/25

**Scientific title**

Effects of face and body acupuncture on glabellar frown lines in women aged 30-59 years referred to the dermatology or acupuncture clinics of Mashhad University of Medical Sciences

**Public title**

Effects of face and body acupuncture on frown lines in women aged 30-59 years

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

30-59-year-old females Suffered from frown lines Having informed consent to participate in the study

**Exclusion criteria:**

Patients who have undergone one of the dermabrasion methods, deep skin peeling, laser peeling (ablative or nonablative), botulinum toxin injection, filler injection, or topical steroid treatment in the glabella and forehead area within six months prior to referral Patients with obvious skin disease or a history of chronic skin disease Pregnant or lactating patients Patients with a history of herpes Patients with a history of skin allergy and needle or metal allergy Patients with diabetes and tuberculosis Patients receiving anticoagulant or thrombolytic therapy Patients with serious systemic diseases (heart, lung, kidney...) Using any other facial rejuvenation treatment during the course of acupuncture treatment Not participating in more than two sessions or creating an interval of more than one week between acupuncture sessions

**Age**

From **30 years** old to **59 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **72**

Actual sample size reached: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization will be performed using the sealedenvelope website (www.sealedenvelope.com) to generate a randomization sequence. Using permuted block randomization method with block size of 4, the methodologist will generate the randomization sequence. Then the codes will be placed in sequentially numbered, opaque, sealed envelopes to ensure allocation concealment.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In the present study, it is not possible to mask the patients, however, the outcome assessors who are outside the research team are unaware of the group assigned to the participants. The data analyzer will be blinded to the assigned group of each patient using A and B codes in the datasheet.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

The research team conducted an extensive search based on existing studies that show the superiority of "waiting list" over "sham control" in this research field; It has been decided to use the waiting list model in the present study. (Liu J, Li L, Luo X, Qin X, Zhao L, Zhao J, Zhou X, Liu Y, Deng K, Ma Y, Zou K. Specification of Interventions and Selection of Control in Acupuncture Randomized Controlled Trials: A Cross-Sectional Study.)

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics commitee of Mashhad University of Medical Sciences

**Street address**

Research chancellor of Mashhad University of Medical Sciences, 2nd floor, Ghoreishi Building, Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

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**Approval date**

2023-04-07, 1402/01/18

**Ethics committee reference number**

IR.MUMS.REC.1402.011

## Health conditions studied

### 1

**Description of health condition studied**

Wrinkles and aging of the facial skin

**ICD-10 code**

L57.9

**ICD-10 code description**

Skin changes due to chronic exposure to nonionizing radiation, unspecified

## Primary outcomes

### 1

**Description**

The frown line depth score on "Glabellar Line Scale (GLS)"

**Timepoint**

Images will be taken from the patients and evaluated in three sessions. The first appointment will be at the first visit (in both groups), the second appointment will be one week after the end of the last treatment session in the intervention group and seven weeks after the first appointment in the control group, and the third appointment will be six weeks after the second appointment in both groups.

**Method of measurement**

Photographs of patients' foreheads are performed using a Canon 5D Mark III (Japan) digital camera mounted on a tripod. The photography room has no windows (no outside light). The patient's chin is placed on a support. Light conditions are standardized using two photographic lamps that were placed at an angle of 45 degrees to each other and at 45 degrees above the patient's forehead. By choosing the center of the image as a point just above the glabellar region, the entire forehead is shown on the image. The side margins of the photos were set 2 cm lateral to the lateral corner of the eye. All patients were photographed without makeup at rest and during function (maximum frown). The frown line depth score is evaluated by three physicians (outside the research executive team) independently and the average score of these three evaluators will be calculated for each case. To ensure the validity of results, clinicians performing GLS assessments will receive GLS training. The frown line depth score on a 4-degree "Glabellar Line Scale (GLS)": 0 = no line, There is no frown line at rest and maximum frown. 1 = mild, There is no frown line at rest, but a subtle frown line can be seen at the maximum frown state. 2 = moderate, At rest there is a subtle frown line that becomes more pronounced at maximum frown. 3 = severe, At rest there is a clear frown line that deepens in maximum frown.

### 2

**Description**

Aesthetic improvement score on "Global Aesthetic Improvement Scale (GAIS)"

**Timepoint**

This evaluation will be done in two stages. In the first stage, the score of aesthetic improvement between the images of the second appointment compared to the images of the first appointment, and in the second stage the score of aesthetic improvement between the images of the third appointment compared to the second and first appointments will be evaluated in each patient.

**Method of measurement**

Evaluation by a research team member, blinded to the patients, is performed based on the difference in the frown line depth score between three times of photography (at rest and maximum frown) for each patient according to the Glabellar Line Scale (GLS). The Global Aesthetic Improvement score on a 5-point "Global Aesthetic Improvement Scale (GAIS)": (+2) much improved = improving at least two degrees or reaching the zero degree (no frown line). (+1) improved = one degree of improvement without reaching the zero degree. (0) no change = no change. (-1) worse = a degree of worsening. (-2) much worse = two degrees worse.

## Secondary outcomes

### 1

**Description**

The general level score of satisfaction in participants

**Timepoint**

This assessment is done by the patient herself one week after the end of the last treatment session in the intervention group and seven weeks after the first visit in the control group.

**Method of measurement**

Self-evaluation using "Subject Satisfaction Scale" (A five-point scale: 2=very satisfied, 1=satisfied, 0=no difference, -1=unsatisfied, -2=very unsatisfied)

### 2

**Description**

The Score of the Quality of Life

**Timepoint**

This evaluation is done at the first visit and then one week after the end of the last treatment session in the intervention group and seven weeks after the first visit in the control group and compared with the results at the time of first visit.

**Method of measurement**

Using the 36-Item Short Form Survey (SF-36) questionnaire.

## Intervention groups

### 1

**Description**

Intervention group: The acupuncture treatment protocol for the intervention group is reported according to the criteria for reporting interventions in clinical trials of acupuncture (STRICTA). Points used in body acupuncture: A) Calming points of the mind that relax and relax the muscles and thus reduce frown lines: DU 20, LIV 3, PC 6, and ST 36 B) Effective points in regulating skin moisture: SP 9, LI 4, and LU 7 C) Effective points in helping to blood supply of the skin, anti-itching and anti-dryness of the skin: LI 11 and SP 10. These points are bilaterally needled (except for DU 20 which is located in the midline) by needles with 25mm (length) × 0.25mm (thickness) size. The depth of the needle

insertion will depend on the thickness of the skin and subcutaneous fat tissue at the needle insertion site and according to the acupuncture reference texts. All the above points are used for all patients, regardless of other signs and symptoms. The needling will be the same in all points and with the even method. First, the points on the lower limb, including LIV 3, ST 36, SP 9, and SP 10 are needled from the distal to the proximal end of the limb, respectively (first the on the right and then on the left lower limb). Then the points on the upper limb including LI 4, LU 7, PC6, and LI 11 are needled, respectively from the distal to the proximal end of the limb (first the on the right and then on the left upper limb). Finally, DU 20 will be needled in the vertex. The total number of needles used in the body is 17. Points used in the face: BL 2, Ex-HN4 (Yuyao), TB 23, and Ex-HN3 (Yintang) are bilaterally used (except Ex-HN3 which is in the midline) by needles with 13mm (length) x 0.18mm (thickness) size. The depth of the needle insertion will depend on the thickness of the skin and subcutaneous fat tissue at the needle insertion site and according to acupuncture references. All the above points are used for all patients, regardless of other signs and symptoms. The needling will be the same in all points and with the even method. First, Ex-HN3 is needled in the middle of the glabella and between the two eyebrows. Then, BL 2, Ex-HN4, and TB 23 are needled from the medial end toward the lateral end of the eyebrow (first on the right and then on the left side). The total number of needles used in the face is 7. Points used in the depth of the frown line: Finally, intradermal needles with a size of 5 mm (length) x 0.22 mm (thickness) are used in the depth of the frown line and with a distance of 2 mm from each other. These needles are inserted at an angle of 45 degrees to the skin in the depth of the groove. The direction of entering the needles is upwards. By inserting the needles intradermally in the area of the frown line, very small damage is caused to the skin. Then the body tries to repair this damage by producing collagen, and in this way, the frown line is gradually filled. The patient is lying on the bed in the supine position and a small pillow is placed under her head during the entire period of acupuncture. All the needles used in the body, face, and frown line are made by Huanqiu (China), which remain in the patient's body for twenty minutes in each treatment session and are then removed. If there is bleeding and possible bruising after removing the needle, Arnica ointment and an ice pack are used. The total number of acupuncture sessions will be 12 sessions and acupuncture will be done twice a week for 6 weeks by an experienced therapist (14 years of experience).

**Category**

Treatment - Other

**2**

**Description**

Control group: The control group will be monitored for six weeks without any intervention and on a waiting list. At the end of the research (after the third appointment of imaging) and as a reward, the people of this group will also undergo acupuncture treatment according to the protocol of the intervention group.

**Category**

Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Acupuncture Clinic of Mashhad University of Medical Sciences

**Full name of responsible person**

Hoda Azizi

**Street address**

Acupuncture clinic, 2nd floor, Imam Reza Hospital-west side, Ḏaneshgah street (against Kafai street)

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**2**

**Recruitment center**

**Name of recruitment center**

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**Full name of responsible person**

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## Sponsors / Funding sources

**1**

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**Full name of responsible person**

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**Grant name**

**Grant code / Reference number**
4011855

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Mashhad University of Medical Sciences

**Proportion provided by this source**
100

**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**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

## Trial results

**Please tick if results have been published**

Yes

**Summary result posting date**

2025-04-13, 1404/01/24

**Table of baseline comparison**

**Participant flow diagram**

**Table of variable outcomes' results**

**Table of adverse events**

**First publication date**

2025-04-08, 1404/01/19

**Abstract of published paper**

ABSTRACT Background: As life expectancy rises, facial rejuvenation has gained significance. Aims: This study aimed to evaluate the effects of body and facial acupuncture on reducing frown lines in women aged 30–59 in Mashhad, Iran. Patients/Methods: In this double-arm randomized wait-list controlled trial, 72 participants were randomly assigned to either an intervention group, receiving facial and body acupuncture twice weekly for 6weeks, or a control group with no treatment. The primary outcome was assessed using the Global Aesthetic Improvement Scale (GAIS) based on standardized photographs. Secondary outcomes included the Subject Satisfaction Scale (SSS) and Quality of Life (QOL) scores. Measurements were taken at three time points: week 0 (pre-treatment), week 7 (post-treatment), and week 12 (follow-up). Results: At week 7, 63% of the intervention group showed reduced frown lines at rest, and 72% during maximum frowning, significantly outperforming the control group. The improvements observed in the intervention group persisted at week 12 with 68.6% at rest and 57.2% at maximum frown. The SSS indicated that 72.2% and 62.9% of the intervention group were satisfied with their frown lines at weeks 7 and 12, respectively. Notable QOL improvements in social functioning were observed in the inter□vention group compared to the control group at both weeks 7 and 12. No serious adverse effects were reported; minor bleeding occurred in 4.86% of treatment sessions, resulting in bruising in 0.69%. Conclusion: This study demonstrates that facial and body acupuncture is an effective and safe method for reducing frown lines. Trial Registration: IRCT20230204057316N1 (https://irct.behdasht.gov.ir/trial/68408)