Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Acupressure on Anxiety, Nausea, and Vomiting in Patients Undergoing Upper Gastrointestinal Endoscopy: A randomized clinical trial

Protocol summary

Study aim

The effect of acupressure on preoperative anxiety and postoperative nausea and vomiting in patients undergoing upper gastrointestinal endoscopy.

Design

A single-blind, parallel-group, randomized controlled clinical trial with two intervention groups and one control group.Total sample size was 70 participants.

Settings and conduct

The study was conducted in 2019 in the endoscopy unit of Vali-e-Asr Specialized Teaching Hospital, affiliated with Fasa University of Medical Sciences, Fars Province, Iran. A trained researcher performed acupressure on the intervention groups. The control group received sham acupressure (anxiety assessment) and routine care (nausea/vomiting assessment). Participants in the control group were blinded to the sham intervention's non-therapeutic nature. The outcome assessor and data analyst were also blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 18-65 years; stable hemodynamic status; no skin lesions at acupressure sites,... Exclusion Criteria: Unwillingness to continue participation; cancellation of EGD procedure during the study; gastrointestinal obstruction, ...

Intervention groups

Intervention Group 1 (Anxiety): Acupressure at Yintang (5 min, thumb pressure) and HE-7 (20 min, wristband) points, 30 minutes before EGD. Intervention Group 2 (Nausea/Vomiting): Acupressure at ST-36 and PC-6 points (45 min, ankle bands and thumb pressure) from the start of EGD. Control Group: Received routine care and sham acupressure (non-specific point) for anxiety assessment; routine care only for nausea/vomiting assessment. Participants were blinded to sham intervention.

Main outcome variables

(1) Mean anxiety score measured by Spielberger State-Trait Anxiety Inventory (STAI), (2) Nausea severity measured by Visual Analog Scale (VAS), (3) Vomiting frequency and volume measured by counting episodes and graduated container.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260630070019N1**
Registration date: **2026-07-20, 1405/04/29**
Registration timing: **retrospective**

Last update: **2026-07-20, 1405/04/29**
Update count: **0**

Registration date

2026-07-20, 1405/04/29

Registrant information

Name

Faezeh Abadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5335 0994

Email address

faeze.abadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2021-06-06, 1400/03/16

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2021-06-06, 1400/03/16

Trial completion date
2021-06-06, 1400/03/16

Scientific title
Effect of Acupressure on Anxiety, Nausea, and Vomiting in Patients Undergoing Upper Gastrointestinal Endoscopy: A randomized clinical trial

Public title
Acupressure on Anxiety, Nausea, and Vomiting in Patients Undergoing Upper Gastrointestinal Endoscopy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Iranian nationality Age between 18 and 65 years No specific local problem at the acupressure application site (e.g., wound, bleeding, burn, cyst, abscess, bruising) No use of anxiolytic or antiemetic medications before the procedure by the patient or ward staff Patient is conscious and alert Not pregnant Stable hemodynamic status before endoscopy No history of psychiatric problems No history of using acupressure before an invasive procedure No history of drug or alcohol addiction No physical limitations (visual, auditory, or mental impairment) Receiving a standard and equal dose of sedative medication (2.5 mg IV Midazolam) during the procedure Undergoing a similar duration of endoscopy

Exclusion criteria:
Patient's unwillingness to continue participation Cancellation of the EGD procedure during the study Gastrointestinal or intestinal obstruction Receiving sedative medication before the procedure by the patient or ward staff out of routine care Receiving antiemetic medication immediately after endoscopy upon admission to the recovery room

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **70**
Actual sample size reached: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
This study employed a block randomization method with a block size of four to allocate participants to either the intervention or control group. The unit of randomization was the individual participant. To ensure comparability between groups, participants were stratified and matched based on two key baseline characteristics: history of previous endoscopy (yes/no) and age category (below 30 years or 30 years and above). The randomization sequence was generated using a computer random number generator by an independent statistician who was not involved in participant recruitment, intervention delivery, or outcome assessment. Allocation concealment was rigorously maintained using sequentially numbered, opaque, sealed envelopes. The envelopes were prepared by the independent statistician and were opened sequentially only immediately before the intervention by the researcher who administered the acupressure, ensuring that neither the participants nor the outcome assessor were aware of the group assignments until the moment of intervention. In cases where participants were excluded from the study after randomization, new eligible participants were recruited and allocated to the appropriate groups using the same block randomization method to maintain the intended sample size and balance between groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
This was a single-blind study. The outcome assessor was blinded to the group allocation of participants throughout the study. Participants in the intervention group received active acupressure at specific acupoints (Yintang and HE-7 for anxiety; ST-36 and PC-6 for nausea and vomiting), while participants in the control group received acupressure at a sham (placebo) point that had no therapeutic effect. The control group participants were not informed that they were receiving a sham intervention and were unaware of its non-therapeutic nature, thus ensuring blinding of the participants. The researcher who performed the acupressure and the clinical staff were aware of the group assignments due to the nature of the intervention; however, all outcome measurements were collected by a trained research assistant who was blinded to the group allocation. Additionally, the statistical analysis was performed by an independent statistician who was not involved in the intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Fasa University of Medical Sciences

Street address
Ebn sina square

City
Fasa

Province
Fars

Postal code

7461686688

Approval date

2019-05-23, 1398/03/02

Ethics committee reference number

IR.FUMS.REC.1398.066

Health conditions studied

1

Description of health condition studied

This study examines preoperative anxiety and postoperative nausea and vomiting (PONV) in patients undergoing Esophagogastroduodenoscopy (EGD), and evaluates the effectiveness of acupressure in managing these complications.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean anxiety score measured by the Spielberger State-Trait Anxiety Inventory (STAI) - State Anxiety subscale. This is the primary outcome variable based on which the sample size was calculated. The score ranges from 20 to 80, with higher scores indicating greater anxiety.

Timepoint

First measurement: 30 minutes before endoscopy (baseline, before intervention); Second measurement: 5 minutes after completion of acupressure intervention (post-intervention). Both measurements were taken before sedation and in the endoscopy waiting room.

Method of measurement

Spielberger State-Trait Anxiety Inventory (STAI) - State Anxiety subscale, a standardized 20-item self-report questionnaire. Scores range from 20 to 80, with higher scores indicating greater anxiety. The questionnaire has a reported reliability of 79%.

2

Description

Severity of nausea measured by the Visual Analog Scale (VAS) following endoscopy. Nausea is defined as an unpleasant feeling of wanting to vomit.

Timepoint

One hour after wearing the acupressure ankle bands and stabilization of vital signs following the endoscopy procedure.

Method of measurement

Visual Analog Scale (VAS), a 10-point ruler where: 0 = no nausea, 1-3 = mild nausea, 4-6 = moderate nausea, 7-9 = severe nausea, and 10 = unbearable nausea. Patients were asked to rate their nausea on this scale.

3

Description

Frequency and volume of vomiting measured by counting episodes and using a graduated container. Vomiting is defined as the expulsion of gastric contents.

Timepoint

One hour after wearing the acupressure ankle bands and stabilization of vital signs following the endoscopy procedure.

Method of measurement

Counting the number of vomiting episodes and measuring the volume of emesis using a graduated container. Severity was categorized based on frequency: mild = less than 3 episodes, moderate = 3-5 episodes, severe = more than 5 episodes.

Secondary outcomes

empty

Intervention groups

1

Description

Acupressure for preoperative anxiety. Patients in this group received acupressure approximately 30 minutes before the EGD procedure in the waiting room. The Yintang point was stimulated using gentle thumb pressure applied by a trained researcher for 5 minutes. Simultaneously, the HE-7 point was stimulated using a specialized acupressure wristband secured on the patient's wrist for 20 minutes. The synergistic effect of these two points on reducing preoperative anxiety was evaluated . All interventions were performed on the right side of the body. No other interventions were provided before the procedure.Acupressure for postoperative nausea and vomiting. Following the EGD procedure, patients in this group received acupressure at the ST-36 and PC-6 points for 45 minutes. Specialized acupressure wristbands and ankle bands were secured on the right side of the body at the specified points from the beginning of the EGD procedure. The synergistic effect of these two points on reducing postoperative nausea and vomiting was evaluated . All interventions were performed on the right side of the body.

Category

Prevention

2

Description

Control group: Patients in this group received routine care and sham (placebo) acupressure. For the anxiety assessment, a sham point with no recognized therapeutic effect (located at the beginning of the middle three fingers) was stimulated using the same gentle thumb pressure applied by the same trained researcher and the same wristband for the same duration as the intervention group.For the nausea and vomiting assessment, the control group received routine postoperative nursing care without any acupressure.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali asr hospital
Full name of responsible person
Maryam Akbari
Street address
Ebn sina sqiare
City
fasa
Province
Fars
Postal code
۷۴۶۱۶-۸۶۶۸۸
Phone
+98 71 5335 0994
Email
info@fums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Zhila Fereidouni
Street address
Ebn sina, square
City
fasa
Province
Fars
Postal code
۷۴۶۱۶-۸۶۶۸۸
Phone
+98 71 5335 0994
Email
faeze.abadi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Fasa university of medical science

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
Fasa University of Medical Sciences
Full name of responsible person
zhila ferydoni
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Ebn sina square
City
fasa
Province
Fars
Postal code
۷۴۶۱۶-۸۶۶۸۸
Phone
+98 71 5335 0994
Email
faeze.abadi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Faezeh Abadi
Position
Assistance Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Ebn sina square
City
fasa
Province
Fars
Postal code
۷۴۶۱۶-۸۶۶۸۸
Phone
+98 71 5335 0994
Email
faeze.abadi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Maryam Akbari
Position
student

Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Ebn sina square
City
Fasa
Province
Fars
Postal code
۷۴۶۱۶-۸۶۶۸۸
Phone
+98 71 5335 0994
Email
faeze.abadi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All collected de-identified individual participant data (IPD) for the outcome measures, including anxiety scores (STAI), nausea severity (VAS), vomiting frequency and volume, and demographic information (age, gender, education, history of endoscopy, BMI, vital signs), as well as the study protocol and statistical analysis plan.
When the data will become available and for how long
The data will be available after the main study findings are published.
To whom data/document is available
De-identified IPD and supporting documents will be available to researchers working in academic and scientific institutions (universities, research centers, and hospitals) who submit a valid research proposal. Researchers from commercial organizations (industry) may also apply, but their requests will be reviewed on a case-by-case basis for scientific validity and potential conflicts of interest.
Under which criteria data/document could be used
Requests for data access will be reviewed by the corresponding authors (Dr. Zhila Fereidouni and Faezeh Abadi). Criteria for approval include: (1) submission of a methodologically sound research proposal with clear objectives, (2) approval from the applicant's institutional ethics committee, (3) agreement to use the data solely for the proposed analyses, (4) commitment to not attempt to re-identify participants, (5) acknowledgment of the original study in any publications, and (6) agreement to share any resulting publications with the study team. Data will only be shared for non-commercial, scientific research purposes. The review process typically takes 2-4 weeks.
From where data/document is obtainable
Applicants should contact the corresponding authors via email to request access to the data and documents.
What processes are involved for a request to access data/document
The process for requesting data access involves the following steps: Submission (Week 1): The applicant submits a formal request via email to the corresponding authors, including their institutional affiliation, research proposal with clear objectives, and proof of ethics approval. Review (Weeks 1-3): The corresponding authors review the request for scientific validity, methodological soundness, and absence of conflicts of interest. They may request additional information or clarification during this period. Decision (Week 3-4): The applicant is notified of the decision. If approved, a Data Sharing Agreement (DSA) is provided for signature, outlining terms of use, confidentiality, and publication requirements. Data Preparation and Transfer (Week 4-5): Once the signed DSA is returned, the de-identified dataset and supporting documents (study protocol, statistical analysis plan, data dictionary) are prepared and shared via a secure file transfer method (e.g., encrypted email, institutional data repository). The entire process from initial request to data receipt is estimated to take 4-6 weeks, depending on the completeness of the initial application and the responsiveness of the applicant.
Comments