

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### The effect of acupressure on the severity of functional constipation in elderly women referring to the medical clinic Hospital of Social Security in Bojnourd 1397

#### Protocol summary

##### Study aim

Determining the effect of acupressure on the severity of constipation in women aged 50-70 years who referred to the Social Security Clinic of the City of Bojnordar 1398-1397

##### Design

It has two groups of control and intervention - targeting based sampling Randomization Based on 2-Blocks and 2-Blind (Assisted Researcher and Data Analyzer)

##### Settings and conduct

In the clinic of Social Security Hospital based on purpose-based sampling

##### Participants/Inclusion and exclusion criteria

Equivalent to the study: Patients are in the age group of 70-70, mentally conscious and capable of answering questions, postmenopausal, having constipation according to Roman III criteria, lack of history of the diseases listed in the study, non-addiction Drugs and alcohol, absence from the nursing home (due to the lack of control and intervention of the control group and easy access to the samples), exclusion criteria: incidence of emergency and side effects during the intervention, diet change Elimination of constipation during the intervention period, failure to implement acupressure program more than 3 consecutive times per week, mental, psychological, Varian, divorce, travel, the patient died.

##### Intervention groups

The intervention group is a routine therapeutic approach, as well as acupressure training at designated points for 4 weeks, and the control group has a common therapeutic approach.

##### Main outcome variables

Severity of constipation, acupressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190117042393N1**

Registration date: **2019-02-03, 1397/11/14**

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

Last update: **2019-05-29, 1398/03/08**

Update count: **1**

##### Registration date

2019-02-03, 1397/11/14

##### Registrant information

##### Name

Zohreh Nazari Koushki

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 58 3241 8382

##### Email address

z.nazari@nkums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-20, 1397/10/30

##### Expected recruitment end date

2019-03-01, 1397/12/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The effect of acupressure on the severity of functional constipation in elderly women referring to the medical clinic Hospital of Social Security in Bojnourd 1397

**Public title**

acupressure on the severity of functional constipation in elderly women

**Purpose**

Basic science

**Inclusion/Exclusion criteria****Inclusion criteria:**

1-Patients in the age range of 50-70 years 2- Mentally minded and able to answer questions. 3 - Have a chance 4 - Constipation according to Rome III. 5. Lack of history of diseases, spinal cord injuries, inflammatory digestive diseases, gastrointestinal obstructive diseases, gastrointestinal bleeding, lupus erythematosus, Parkinson's disease, hypothyroidism, hyperparathyroidism, advanced leg legs, thrombophlebitis, bone marrow, non-use of anti-Parkinson drugs, Psychiatric disorders according to medical records, acute stress disorder, pituitary gland palsy, sympathomimetics, lack of history of anti diarrhea drugs, psychotropic drugs and no history of injury in the abdomen and legs and arms during the last two years and lack of medication Constipation causes iron, if necessary, tests Laboratory Rmal like TSH, lack of blood in the stool, normal liver enzyme alkaline phosphatase, and normal WBC, and pelvic floor problems, no history of serious illness. 6. Non-drug and alcohol addiction 7. Absence in the nursing home (due to the lack of control and intervention and the easy access to samples)

**Exclusion criteria:**

1- Emergency and side effects during the intervention 2- Diet change to relieve constipation during the intervention period. 3. Failure to perform acupressure program more than 3 times a week. 4. Critical psychological, psychological, mourning, divorce, travel, patient death.

**Age**

From **50 years** old to **70 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

70 people aged 50-70 years attending a social welfare clinic who suffer from constipation or other complaints, but at the same time suffering from constipation, are selected based on objective sampling and each person has a proprietary code given by A statistic consultant is provided in blocks 2 and unaware of which code belongs to which group is placed in the envelope (with random

allocation based on the referral of patients) and the subjects are randomly assigned to two groups of control and intervention Get it The intervention group carries out a routine treatment approach plus acupressure at the designated points for 4 weeks, and the control group also has a common therapeutic approach. And questionnaires are completed before and after the intervention by a researcher who is unaware of the intervention and control group. Constipation is the main variable in this studyp also performs the usual treatment.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

1-The researcher's assistance completes the questionnaires before intervention and 4 weeks after the intervention and unaware of the control and intervention group. 2-The data analyzer also analyzes the data without knowing the control group and interfering them with the code given to them

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of North Khorasan University of Medical Sciences

**Street address**

Central building of North Khorasan University of Medical Sciences, Government boulevard, Bojnourd

**City**

Bojnord

**Province**

North Khorasan

**Postal code**

74877-94149

**Approval date**

2018-09-26, 1397/07/04

**Ethics committee reference number**

IR.NKUMS.REC.1397.041

**Health conditions studied****1****Description of health condition studied**

Constipation

**ICD-10 code**

k90-k93

**ICD-10 code description**

Other diseases of the digestive system

## Primary outcomes

1

### Description

Score the severity of the constipation

### Timepoint

At the beginning of the study (before the start of the study) and 4 weeks after the start of the intervention

### Method of measurement

Million and Williams constipation severity questionnaire

## Secondary outcomes

empty

## Intervention groups

1

### Description

The intervention group receives the usual therapeutic approach and 4 weeks of acupressure twice a day by the individual.

### Category

Treatment - Other

2

### Description

Control group: The control group continues their usual treatment and does not receive an intervention.

### Category

Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Clinic of Samen Alaemah Hospital (Social Security)

#### Full name of responsible person

Zohreh Nazari Kushaki

#### Street address

Samen Alaemah Hospital (Social Security), Chamran Street

#### City

Bojnord

#### Province

North Khorasan

#### Postal code

74877-94149

#### Phone

+98 58 3223 1852

#### Email

z.nazari1126@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Bojnourd University of Medical Sciences

#### Full name of responsible person

Dr. Seyed Kaveh Hojjat

#### Street address

Central building of North Khorasan University of Medical Sciences, Government boulevard, Bojnourd

#### City

Bojnord

#### Province

North Khorasan

#### Postal code

74877-94149

#### Phone

+98 58 3229 7156

#### Email

k.hojjat@nkums.AC.IR

#### Web page address

http://research.nkums.ac.ir

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Bojnourd 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

Bojnourd University of Medical Sciences

#### Full name of responsible person

Zohreh Nazari Kushaki

#### Position

Student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

#### Street address

Central building of North Khorasan University of Medical Sciences, Government boulevard, Bojnourd

#### City

Bojnord

#### Province

North Khorasan

#### Postal code

74877-94149

**Phone**

+98 58 3229 7156

**Email**

z.nazari1126@gmail.com

**Web page address**

<http://nkums.ac.ir/category/22227>

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

Mahboubeh Tabatabaei chehr

**Position**

Academic staff

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

**Street address**

Central building of North Khorasan University of Medical Sciences, Government boulevard, Bojnourd

**City**

Bojnord

**Province**

North Khorasan

**Postal code**

74877-94149

**Phone**

+98 58 3229 7097

**Email**

chehr192@gmail.com

**Web page address**

<http://nkums.ac.ir/category/22227>

**Person responsible for updating data****Contact****Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

Zohreh Nazari Kushaki

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Central building of North Khorasan University of Medical Sciences, Government boulevard, Bojnourd

**City**

Bojnord

**Province**

North Khorasan

**Postal code**

74877-94149

**Phone**

+98 58 3241 8382

**Email**

z.nazari1126@gmail.com

**Web page address**

<http://nkums.ac.ir/category/22227>

**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