

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of acupressure and foot reflexology on fatigue in Elderly with Parkinson's disease

Protocol summary

Study aim

comparing the effect of acupressure and foot reflexology on fatigue of elderly with Parkinson disease

Design

Randomized Clinical trial ,three parallel groups design of 90 patients, was done using the time block.

Settings and conduct

Researcher By attending the clinic and doctor's office,examines the elderly with Parkinson's disease if they are satisfied check for fatigue , and if they have inclusion criteria criteria (elderly and caregiver) , they enter the study. Then, at the end of the first session, the tools for the elderly and caregiver are completed. in the Next time visit session ,researcher provides the necessary training to the caregivers of the intervention groups. The training is done individually and practically in the clinic and doctor's office then asked to perform the procedure 3 times a week for a month at home for her/his elderly.The training points for acupressure (ST36, HT7 and yin tang) and the reflexology areas are solar plexus ,spinal cord and kidney area, which is massaged for 18 minutes in each interval.Fatigue is examined immediately after the intervention and one month after the end of the last intervention session by the researcher and with the multidimensional fatigue assessment questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: elderly person has Parkinson's disease and his/her fatigue score (Smets) is more than 48 and her/his cognitive test(AMTS) score is more than 6
exclusion criteria: Injuries, fractures and lesion at the site of the intervention

Intervention groups

In two intervention groups, in addition to medication and routine self-care counseling to reduce fatigue, reflexology or acupressure are performed by the caregiver, and the control group receives only self-care medications and routine self-care counseling to reduce fatigue.

Main outcome variables

□primary out come is score of fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200505047313N1**

Registration date: **2020-06-06, 1399/03/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-06, 1399/03/17**

Update count: **0**

Registration date

2020-06-06, 1399/03/17

Registrant information

Name

Elnaz sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3852 8511

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-04, 1399/03/15

Expected recruitment end date

2020-08-05, 1399/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of acupressure and foot reflexology on fatigue in Elderly with Parkinson's disease

Public title

Comparing the effect of acupressure and foot reflexology on fatigue in Parkinson's disease

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The elder is 60 to 85 years old Be able to speak and understand Persian language He or she get Score more than 6 AMTS test Having a caregiver with inclusion criteria for entering the study to perform the intervention. Elderly fatigue is greater than 48 according to multidimensional measurements Have the health of the limb at the site of the intervention (foot, hand and between the two eyebrows) The elderly, have given written consent Caregiver, lives with the elderly Caregiver should have the ability to move their hands for reflexology and acupressure Caregiver, has a level of education higher than fifth grade Caregiver, is able to speak and understand Persian language Caregiver, have access to mobile phone The caregiver, have given written consent

Exclusion criteria:

Injuries, fractures, or lesion occur at the site of the intervention The elder is reluctant to participate in the study The caregiver is reluctant to participate in the stud

Age

From **60 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The time block method is such that from the beginning a block is considered for each week (one week of intervention block 1, one week of intervention block 2 and one week of control block). Lottery is also used to select the intervention(1,2) and control block.

Secondary Ids

empty

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

Ethics committee of Mashhad university of Medical Science

Street address

Deputy of Research and Technology,next to Hoveyzeh Cinema, Ghorashi Building,Daneshgah Ave,Mashhad, Khorasan Razavi

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9138813944

Approval date

2020-04-28, 1399/02/09

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.003

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

Parkinson disease

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes**1****Description**

Fatigue score in the multi-dimensional fatigue questionnaire(Smets)

Timepoint

immediately before the intervention, immediately after the intervention and one month after the last intervention session

Method of measurement

Multidimensional fatigue inventory of Smets

Secondary outcomes**1****Description**

Depression score geriatric depression questionnaire

Timepoint

before the intervention begins,Immediately after the intervention, one month after the first intervention session

Method of measurement

geriatric Depression Questionnaire: This questionnaire contains 15 questions

2

Description

daily drowsiness Epworth questionnaire

Timepoint

before the intervention begins, Immediately after the intervention, one month after the first intervention session

Method of measurement

The 7-question daily drowsiness Epworth questionnaire

Intervention groups

1

Description

Control group receives common pharmacological treatments for fatigue (levodopa, dopaminergic agonists, central nervous system stimulants, and depression) and common self-care recommendations to reduce fatigue (Do your favorite activities and meetings when they have the most energy, first do the things that matter most to them, if they don't have the energy to meet friends and relatives in person, by phone or the Internet. Communicate, when they have more energy to eat

Category

Rehabilitation

2

Description

In the intervention group 1, the caregiver performs foot reflexology three times a week for one month for 18 minutes per session, in the areas of solar plexus, kidney area, spinal cord, sole of the foot for the elderly. The duration of massage in each area is 3 minutes.

Category

Rehabilitation

3

Description

In the intervention group 2, the caregiver performs acupuncture three times a week for one month for 18 minutes per session, in points of ST36 both feet, HT7 both hands, Yin tang which is located between the two eyebrows, for his/her elderly. The duration of massage in each area is 3 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

ghaem Specialized clinic

Full name of responsible person

Dr.farzanehfar

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The beginning of Parstar Ave, Ahmadabad Ave, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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**

Mashhad University of Medical Sciences

Full name of responsible person

Elnaz Sadeghi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

All potential data can be shared after people have not been identified

When the data will become available and for how long

The access period is 6 months after the results are printed

To whom data/document is available

Data will only be available to researchers working at academic and scientific institutions

Under which criteria data/document could be used

The prerequisite for submitting a request for access to data and documents is its use in the clinic and comparison with the results of the research

From where data/document is obtainable

To send a request to receive data, please refer to Elnaz Sadeghi with phone number 09196122557 and e-mail address sadeghie971@mums.ac.ir or sadeghielnaz130@gmail.com

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

After sending the request by phone or email and mentioning the scientific position and the reason for

accessing the data In case of discretion, the data will be sent within one day after

Comments