Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

Phone
+98 51 3852 8511

Email address
sadeghie971@mums.ac.ir

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 then 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

City
Mashhad

Province
Razavi Khorasan

Postal code
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 acupressure 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
Street address
The beginning of Parstar Ave,Ahmadabad Ave,Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
91766-99199
Phone
+98 51 3801 2484
Email
b.ghaem@mums.ac.ir
Web page address
https://quaem.mums.ac.ir/index.php/clinics

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen tafaghodi
Street address
Deputy of Research and Technology,next to Hoveyzeh Cinema, Ghorashi Building,Daneshgah Ave,Mashhad, Khorasan Razavi
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Fax
+98 51 3843 0249
Email
tafaghodim@mums.ac.ir
Web page address
https://v-research.mums.ac.ir/
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
Street address
Bahonar Blvd,Dormitory campus Mashhad university of Medical science
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3852 8511
Fax
Email
sadeghie971@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
maryam salehian
Position
Consultant
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Ibnsina Ave, Nursing and Midwifery school
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3852 8511
Fax
Email
SalehianMR@mums.ac.ir

Person responsible for updating data

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
Street address
Bahonar Blvd,Dormitory campus Mashhad university of Medical science
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3852 8511
Fax
Email
sadeghie971@mums.ac.ir

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