

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The effect of Swedish massage on vital signs and mental toughness of elderly

#### Protocol summary

##### Study aim

Determining The effect of Swedish massage on vital signs and mental toughness of elderly in nursing home in Dezful

##### Design

Quasi Experimental clinical trial, before-after design with an intervention group. The sample size includes 80 elderly people who were selected by census method.

##### Settings and conduct

Dezful nursing home.the study begins After selecting the samples and obtaining informed consent . Before the intervention, the demographic information questionnaire is filled out by the samples. In the first 4 weeks, once a week in the morning, the Mental toughness Questionnaire is filled out by the samples and vital signs are measured in three positions: lying down, sitting and standing. In the second 4 weeks, once a week in the morning, a 30-minute massage is performed for the elderly. Once before the intervention and once after the intervention, data on mental toughness and vital signs such as the first 4 weeks are collected. Finally, the data will be analyzed using SPSS software.

##### Participants/Inclusion and exclusion criteria

The elder must be at least 65 years old. The elder is hospitalized in the nursing home, conscious and has mental stability

##### Intervention groups

The study is performed in 8 weeks, but no intervention is performed in the first 4 weeks. The intervention is performed in the second 4 weeks and one day every week. In this way, a massage therapist goes to the elderly bedside and gives Swedish massage for the elderly for 30 minutes (15 minutes back, 5 minutes neck, 5 minutes hands, 5 minutes legs).

##### Main outcome variables

vital signs, mental toughness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170607034381N7**

Registration date: **2022-06-02, 1401/03/12**

Registration timing: **prospective**

Last update: **2022-06-02, 1401/03/12**

Update count: **0**

##### Registration date

2022-06-02, 1401/03/12

##### Registrant information

##### Name

Ferdos Pelarak

##### Name of organization / entity

Dezful Azad University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 916 941 7091

##### Email address

pelarak.f@dums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-05, 1401/03/15

##### Expected recruitment end date

2022-08-06, 1401/05/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of Swedish massage on vital signs and mental toughness of elderly

## Public title

The effect of Swedish massage on vital signs and mental toughness of elderly

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

The elder must be at least 65 years old The elder is hospitalized in the nursing home The elder is conscious and has mental stability

### Exclusion criteria:

## Age

From **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Gachsaran Islamic Azad University

##### Street address

کوی مدرس مجتمع دانشگاه

##### City

Gachsaran

##### Province

Kohgiluyeh-va-Boyerahmad

##### Postal code

7581863876

#### Approval date

2021-12-15, 1400/09/24

#### Ethics committee reference number

IR.IAU.IAUG.REC.1400.005

## Health conditions studied

### 1

#### Description of health condition studied

Vital signs

#### ICD-10 code

#### ICD-10 code description

### 2

#### Description of health condition studied

Mental toughness

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Vital signs

#### Timepoint

The first 4 weeks: once a week in the morning and the second 4 weeks: once a week in the morning, before and after the intervention

#### Method of measurement

Mercury sphygmomanometer, thermometer, pulse and respiration rate count by the researcher

### 2

#### Description

Mental toughness

#### Timepoint

Mercury sphygmomanometer, thermometer, pulse and respiration rate count by the researcher

#### Method of measurement

Clough Mental Toughness Questionnaire (MTQ48)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: During 4 weeks (1 session per week) Swedish massage is performed for 30 minutes by a specialist for the elderly (15 minutes back, 5 minutes neck, 5 minutes hands and 5 minutes legs).

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Masoum nursing home  
**Full name of responsible person**  
Lale Sadeghian Pour  
**Street address**  
Shams Abad Road, Madar Alley  
**City**  
Dezful  
**Province**  
Khouzestan  
**Postal code**  
6133768342  
**Phone**  
+98 61 4237 9262  
**Email**  
info@behzisty-khz.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
معاونت پژوهشی دانشگاه آزاد اسلامی دزفول  
**Street address**  
Islamic Azad University of Dezful  
**City**  
Dezful  
**Province**  
Khouzestan  
**Postal code**  
6461645169  
**Phone**  
+98 61 4242 0606  
**Email**  
info@iaud.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Islamic Azad University  
**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**  
Islamic Azad University  
**Full name of responsible person**

Seyede Fateme Zakipour  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Islamic Azad University of Dezful  
**City**  
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**Province**  
Khouzestan  
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6461645169  
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**Email**  
Fatemezakupour80@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Islamic Azad University  
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## Person responsible for updating data

#### Contact

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Islamic Azad University  
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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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data is potentially shareable after unidentifiable individuals

**When the data will become available and for how long**

En 12 months after the results are published

**To whom data/document is available**

Researchers working in scientific and academic institutions

**Under which criteria data/document could be used**

According to the terms and conditions of Dezful Azad University, the data can be used

**From where data/document is obtainable**

Email:fatemezakupour80@gmail.com

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

Written request and consent of the Executor of the project and colleagues

**Comments**