# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Learning Effects Mindfulness Knowledge on Life Expectancy in Dialysis Patients

### Protocol summary

**Study aim**

Determining the Effect of Mindfulness Education on Life expectancy in hemodialysis patients

**Design**

A clinical trial with a control group in the waiting list and one month follow up of the intervention and control group

**Settings and conduct**

After sampling and assigning 45 patients in each intervention and control group, the study was conducted as Mental awareness training in 8 sessions of 90 minutes for the intervention group at Imam Hossein Hospital in Shahid Beheshti Hospital in Babol. At this time, no intervention was performed for the control group Failed. The training was done by a psychologist and with the help of a psychologist, as well as providing a manual for each patient. The intervention group was re-tested one month after the training (with follow-up by the researcher for exercises within a month). The questionnaires used in this study were Omid Schneider's questionnaire, Spielberg's anxiety, and Philips social suppo

**Participants/Inclusion and exclusion criteria**

Inclusion criteria 1-a willingness to participate in the study2-Being treated with dialysis3-Age up to age 65-184-History of at least three months hemodialysis5-Lack of well-known psychological illness, psychosis, stroke- ،Exclusion criteria Include 1-Mental disorders require immediate treatment2- Anxiety treatment with an officer3- Use of psychotics4-Late or absent in three sessions of training sessions5-No adherence to the assignment related to training intervention

**Intervention groups**

A total of 45 hemodialysis patients undergoing training on Mindfulness in 8 sessions of 90 minutes.The control group had 45 hemodialysis patients who did not receive any training.

**Main outcome variables**

Age, sex, anxiety, social support, duration of hemodialysis, underlying illness, mindfulness,Hope for life

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20171203037723N3**
Registration date: **2019-01-23, 1397/11/03**
Registration timing: **retrospective**

Last update: **2019-01-23, 1397/11/03**
Update count: **0**

**Registration date**

2019-01-23, 1397/11/03

**Registrant information**

**Name**

Hamideh Azimi Lolaty

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2018-04-17, 1397/01/28

**Expected recruitment end date**

2018-04-23, 1397/02/03

**Actual recruitment start date**

2018-06-28, 1397/04/07

**Actual recruitment end date**

2018-07-01, 1397/04/10

**Trial completion date**
2018-10-02, 1397/07/10

**Scientific title**
Learning Effects Mindfulness Knowledge on Life Expectancy in Dialysis Patients

**Public title**
Train the minds of patients with dialysis

**Purpose**
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Includes a willingness to participate in the study Being treated with dialysis Age up to age 65-18 Lack of well-known psychological illness, psychosis, stroke History of hemodialysis at least three months

**Exclusion criteria:**
Psychological disorders require immediate treatment Treated with anti-anxiety and anti-depressant drugs Use of psychotics Delay or absence in three sessions of training sessions A lack of adherence to the assignments related to training intervention

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

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **70**
Actual sample size reached: **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**
First, according to the criteria of entry from 2 hospitals, eligible patients were enrolled in the study, and according to the draw, one of the hospitals in the intervention group (45) and one in control group (45) were selected and then intervention was performed

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
IR.MAZUMS..REC.1397.159

**Street address**
Sari Street Teacher, Student Research Deputy

**City**
Sari

**Province**
Mazandaran

**Postal code**
48157-33971

**Approval date**
2018-06-25, 1397/04/04

**Ethics committee reference number**
IR.MAZUMS.REC.1397.159

## Health conditions studied

### 1

**Description of health condition studied**
hemodialsis

**ICD-10 code**
I13.2

**ICD-10 code description**
Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease

## Primary outcomes

### 1

**Description**
Life expectancy

**Timepoint**
Measurement ofLife expectancy after 8 sessions of mindfulness intervention

**Method of measurement**
Schneider's Life Expectancy Questionnaire

## Secondary outcomes

### 1

**Description**
Anxiety - Social Support

**Timepoint**
Before and after 8 sessions of mindfulness intervention

**Method of measurement**
Philip Social Support Questionnaire - Spielberg's Anxiety Inventory

## Intervention groups

### 1

**Description**
Intervention Row: Intervention will be provided in 8 sessions of 90 minutes. There is also a booklet prepared on the basis of these sources and has been reviewed by psychiatrist, psychiatric nurse and doctorate in clinical psychology and has undergone and is subject to corrections. Available to each patient in the intervention

group. Mental awareness training was carried out by a student and clinical education psychologist. Familiarity with the technique of teaching attention, familiarity with the technique of automatic guidance, familiarity with the training of tone, familiarity with the technique of respiratory mediation, familiarity with the examination technique of the body.

**Category**
Other

**2**

**Description**
Control group: Control group: Includes people with homo-dialysis disease that there is no intervention in them.

**Category**
Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Feraidonkenar Imam Khomeini hemodylysis Center-Babol Shahid Beheshti Hospital

**Full name of responsible person**
Hamideh Azimi lolaty

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## Sponsors / Funding sources

**1**

**Sponsor**

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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**
Sari University of Medical Sciences

**Proportion provided by this source**
50

**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**
Mazandaran University of Medical Sciences

**Full name of responsible person**
Hamideh Azimi lolaty

**Position**
ssistant professor

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Ph.D.

**Other areas of specialty/work**
Psychiatric nursing

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## Person responsible for updating data

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## 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**
No - There is not 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