Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the effectiveness of selective stoic teachings on psychological distress and self□efficacy in hemodialysis patients

Protocol summary

Study aim

Evaluating the effect of selected Stoic teachings on psychological distress and self-efficacy in hemodialysis patients

Design

This study will have two intervention and control groups, with a sample size of 50 randomly assigned to the two groups. Random assignment will be done using the permutation blocking method of letters A and B. The size of each block will be 4. All possible balanced combinations will be written with 2 controls and 2 intervention cases. (6 combinations) Blocks will be randomly selected for participant allocation.

Settings and conduct

The study will be conducted at the Birjand Center for Special Diseases. A selection of Stoic teachings will be presented in the form of eight in-person and virtual sessions (podcast and film). The study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria include informed consent, age between 18 and 65 years, awareness of time and place and understanding, no drug addiction, no use of psychotic drugs, at least 6 months since the start of dialysis, being Persian-speaking, and being literate. Exclusion criteria include absence of more than two sessions, withdrawal from continuing to participate in the study, worsening of the disease that prevents cooperation in the study, and death of the patient.

Intervention groups

In the intervention group, a selection of Stoic teachings will be presented in eight in-person and virtual sessions with the aim of assessing their effect on psychological distress and self-efficacy. In-person sessions will be in the form of face-to-face training and virtual sessions will be in the form of films and podcasts. In the control group, no specific intervention will be carried out.

Main outcome variables

Psychological distress; self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241229064210N4**
Registration date: **2025-03-25, 1404/01/05**
Registration timing: **prospective**

Last update: **2025-03-25, 1404/01/05**
Update count: **0**

Registration date

2025-03-25, 1404/01/05

Registrant information

Name

Amirhossein Boostani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3275 3138

Email address

amir.boostani198100@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-03, 1404/01/14

Expected recruitment end date

2025-04-21, 1404/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of selective stoic teachings on psychological distress and self□efficacy in hemodialysis patients

Public title
Evaluating the effectiveness of selective stoic teachings on psychological distress and self□efficacy in hemodialysis patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent Age between 18 and 65 years Awareness of time, place, and person At least 6 months have passed since the start of dialysis. Being a Persian speaker Reading and writing literacy
Exclusion criteria:
Drug addiction Taking psychotic medications
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: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The random block design will be as follows: The size of each block will be four. All possible balanced combinations of the letters A and B will be written for the two control and two intervention cases. (6 combinations) The blocks will be randomly selected for the allocation of participants.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences
Street address
Ghafari street
City
Birjand
Province
South Khorasan
Postal code
9717853076
Approval date
2024-10-30, 1403/08/09
Ethics committee reference number
IR.BUMS.REC.1403.275

Health conditions studied

1

Description of health condition studied
Psychological distress
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Self_efficacy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Psychological distress
Timepoint
One month after
Method of measurement
Kessler questionnaire

2

Description
Self-efficacy
Timepoint
One month after
Method of measurement
Chronic disease self_efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, a selection of Stoic teachings will be provided to the subjects in person and virtually (podcast and film of about 30 minutes). The first session will be an introduction and the final session will be a summary of the topics presented. Related scenarios and exercises will be presented to the subjects. There will be more focus on the three central teachings of Trichotomy of control, premeditation, and mindfulness.

Category
Behavior

2

Description
Control group: In this group will not perform any intervention.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Center for Specific Diseases
Full name of responsible person
Amirhossein Boostani
Street address
Beheshti street
City
Birjand
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South Khorasan
Postal code
9719873839
Phone
+98 56 3238 1301
Email
amirhossein198100@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Masoud yousefi
Street address
Ghafari street
City
Birjand
Province
South Khorasan
Postal code
9717853076
Phone
+98 56 3239 5000
Email
Masoud.yousefi@bums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Amirhossein Boostani
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Amirhossein Boostani

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Master student

Latest degree
Bachelor

Other areas of specialty/work
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Email
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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
Yes - There is a plan to make this available

Title and more details about the data/document
Upon reasonable request, information will be made available to researchers while maintaining the privacy of the subjects.

When the data will become available and for how long
One month after results are published

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
Upon reasonable request, information will be made available to researchers while maintaining the privacy of the subjects.

From where data/document is obtainable
Amirhossein Boostani amirhossein198100@gmail.com

What processes are involved for a request to access data/document
At most within one week

Comments