Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effectiveness of dialectical behavior therapy on the intensity of suicidal thoughts and psychological well-being of people who attempt suicide: A human intervention study (randomized clinical trial)

Protocol summary

Study aim
To determine the effect of dialectical behavior therapy on the suicidal thoughts and psychological well-being in individuals with a history of suicide attemots.

Design
A randomized controlled clinical trial with parallel groups, will be conducted on 60 patients. The block randomization method will be used.

Settings and conduct
First, a list of individuals with a history of suicide attempts will be prepared. After contacting them and explaining the purpose of the study, they will be asked to complete the informed consent form, along with study questionnaires measuring the severity of suicidal thoughts and psychological well-being. A total of 60 eligible participants will be selected using convenience sampling and will be randomly assigned to either the intervention or control group. The intervention group will receive 8 to 11 weekly two-hour sessions of Dialectical Behavior Therapy techniques, while no intervention will be provided to the control group. After the completion of the therapy sessions, participants from both groups will be asked to complete the study questionnaires again. The interventions will be conducted at the educational hall of Shahid Rajaei Hospital in Yasuj.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1. written informed consent. 2. Literacy (ability to read/write). 3. Age >18 years. 4. History of suicide attempt(s). 5. Moderate scores on the Beck Scale for Suicidal Ideation (6–19) and Ryff Psychological Well-Being Scale (42–63). Exclusion Criteria: 1. Electroconvulsive therapy (ECT) in the past six months. 2. Psychotherapy sessions in the past six months. 3. Cognitive impairments affecting sessions comprehension.

Intervention groups
Intervention Group: will receive Dialectical Behavior Therapy. Control Group: will receive no intervention.

Main outcome variables
Intensity of suicidal thoughts Psychological well-being

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241222064125N1**
Registration date: **2025-01-21, 1403/11/02**
Registration timing: **registered_while_recruiting**

Last update: **2025-01-21, 1403/11/02**
Update count: **0**

Registration date
2025-01-21, 1403/11/02

Registrant information

Name
Negar Dehghani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4222 2873

Email address
negar.dehghani1372@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-20, 1403/11/01

Expected recruitment end date
2025-03-19, 1403/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness of dialectical behavior therapy on the intensity of suicidal thoughts and psychological well-being of people who attempt suicide: A human intervention study (randomized clinical trial)

Public title
The effectiveness of dialectical behavior therapy on the intensity of suicidal thoughts and psychological well-being of people who attempt suicide
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study. Ability to read and write. Age above 18 years. History of a suicide attempt. Insight into their condition, meaning they are aware of their current state. If they have a mental illness, they must acknowledge and accept it. Ability to communicate effectively. Concurrently scoring within the moderate range on both the Beck Scale for Suicidal Ideation (BSSI) (score between 6-19) and the Ryff's Psychological Well-Being Scale (score between 42-63).
Exclusion criteria:
Undergoing electroconvulsive therapy (ECT) at least 6 months prior to the study. Attending psychotherapy sessions at least 6 months before the the study. Presence of extensive cognitive impairments that hinder the understanding of sessions content.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
A block randomization method will be employed to allocate participants into the intervention and control groups. Utilizing the online tool introduced by Sealed Envelope (2022), block randomization will be performed with the code number 70759167262320. Given the total sample size of 60 participants and the two study groups, block sizes of 2 and 4 were considered. As a result, 19 blocks were generated, and participants will be assigned to either the intervention group (A) or the control group (B) based on the obtained sequence and defined code.
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 Yasuj University of Medical Sciences
Street address
Fars province, Kazeroon city, Ershad street, 8-Maqam alley
City
Kazeroon
Province
Fars
Postal code
7319664433
Approval date
2024-12-21, 1403/10/01
Ethics committee reference number
IR.YUMS.REC.1403.122

Health conditions studied

1

Description of health condition studied
Investigating the effect of dialectical behavior therapy on the intensity of suicidal thoughts and psychological well-being of people attempting suicide: a human intervention study (randomized clinical trial)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
intensity of suicidal thoughts
Timepoint
One session per week for up to 2 months
Method of measurement
Beck Suicidal Ideation Questionnaire (BSSI)

2

Description
Psychological well-being
Timepoint
One session per week for up to 2 months
Method of measurement
Ryff psychological well-being questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For this group, 8 psychotherapy sessions (DBT) will be held, one two-hour session per week.
Category
Treatment - Other

2

Description
Control group: Will not receive any intervention.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei Hospital
Full name of responsible person
Negar Dehghani
Street address
Kohkiloyeh and Boyer Ahmed, Yasuj, Imam Hussein Square, Shahid Rajaei Hospital
City
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Province
Kohgilouyeh-va-Boyrahmad
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Phone
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Email
rajaeey@yums.ac.ir
Web page address
https://rajaeey.yums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Seyed Amin Hosseini
Street address
Shahid Motahari Blvd., Yasouj, Kohgiluyeh and Boyer Ahmad Provinces
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Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Phone
+98 74 3333 7230
Email
info@yums.ac.ir
Web page address
https://edu.yums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Dr. Mohammad Malekzadeh
Position
Associate Professor
Latest degree
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Other areas of specialty/work
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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
After the study results are published in the form of a paper, each of the data will be sent upon request by individuals and by contacting the corresponding author.
When the data will become available and for how long
Up to 3 years after publication of the paper.
To whom data/document is available
All individuals who request access to the study data by email to the corresponding author, stating the reason.
Under which criteria data/document could be used
The documentation of this research, as well as the use of research results and treatment protocols, can be useful for researchers related to this field, as well as healthcare professionals.
From where data/document is obtainable
Email to the corresponding author
negar.dehghani1372@gmail.com
What processes are involved for a request to access data/document
After publishing the paper, email to the corresponding author and send documents to the requester.
Comments