Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of dignity therapy on internal stigma, dignity and hope of depressed patients in the inpatient and outpatient departments of 505 Aja Hospital in 1403.

Protocol summary

Study aim

Determining the effect of dignity therapy on the internal stigma, dignity and hope of depressed patients in the inpatient and outpatient departments of Aja 505 Hospital in 1403

Design

This clinical trial will be conducted on 72 patients and in two groups of test and control, in a blinded and randomized manner in 6 blocks of 4

Settings and conduct

This study will be carried out in 505 Aja Hospital. At first, the control group will be included in the study, and then in the test group, the intervention will be carried out in the form of the implementation of the dignity therapy protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, age range from 18 to 60 years old, absence of other mental disorders at the same time as depression, ability to read and write in Farsi, definitive medical diagnosis of depression that has been diagnosed for more than three years and go to hospital 505 on an outpatient basis or for hospitalization. Exclusion criteria: two sessions of non-attendance at the training sessions, unwillingness to continue cooperation, diagnosis of another mental disorder during the study, lack of cooperation of the patient's family.

Intervention groups

Dignity therapy is a non-pharmacological psychological intervention in which the patient is guided towards the feeling of human and inner dignity with the help of an interview with the therapist and the step-by-step implementation of the dignity therapy protocol. Dignity treatment protocol is in accordance with the wishes and specific needs of patients.

Main outcome variables

Dignity therapy is effective in improving the sense of dignity in patients with depression disorders. Dignity therapy is effective in improving the quality of life of patients with bipolar disorder.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241008063298N1**
Registration date: **2025-01-11, 1403/10/22**
Registration timing: **retrospective**

Last update: **2025-01-11, 1403/10/22**
Update count: **0**

Registration date

2025-01-11, 1403/10/22

Registrant information

Name

Zahra Tat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3622 2374

Email address

zahratat98@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-16, 1403/07/25

Expected recruitment end date

2024-11-05, 1403/08/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of dignity therapy on internal stigma, dignity and hope of depressed patients in the inpatient and outpatient departments of 505 Aja Hospital in 1403.

Public title
The effect of dignity therapy on internal stigma, dignity and hope of depressed patients in the inpatient and outpatient departments of 505 Aja Hospital.
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Depressed patients in the inpatient and outpatient departments of 505 Aja Hospital.
Exclusion criteria:
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
The researcher will use the random block method (6 blocks of 4) with the aim of randomizing and allocating samples in two control and intervention groups. Depressed outpatients and inpatients will be randomly selected separately. The intervention group will consist of 60% outpatients and 40% inpatients, and the control group will be the same ratio.
Blinding (investigator's opinion)
Single blinded
Blinding description
The researcher distributes the questionnaires among the studied samples and the study participants do not know whether they are in the control or intervention group. So the study is a blind one.
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Aja University of Medical Sciences
Street address
13th floor, Block A, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Simai Iran St., between South Flamak and Zarafshan, Quds town (west), Tehran
City
Tehran
Province
Tehran
Postal code
1411718541
Approval date
2024-10-02, 1403/07/11
Ethics committee reference number
IR.AJAUMS.REC.1403.163

Health conditions studied

1

Description of health condition studied
Major Depressive Disorder
ICD-10 code
F32.2
ICD-10 code description
Major depressive disorder, single episode, severe without psychotic features

Primary outcomes

1

Description
Human dignity measurement questionnaire is a 25-item scale to measure human dignity. This questionnaire will be scored based on a 5-point Likert scale. The score of this questionnaire varies between 25 and 125, and according to the way the questionnaire is expressed, a lower score means more dignity and a higher score means less dignity.
Timepoint
Human dignity is measured at the beginning of the intervention and then 14 days after dignity treatment.
Method of measurement
Human Dignity Questionnaire

2

Description
Internalized Stigma of Mental Illness Index (ISMI) is a 29-item self-report instrument. The answers are in the form of four Likert options from completely agree to completely disagree. The way of scoring the questions is that in the first 4 sub scales, I completely agree with a score of 4, I agree with a score of 3, I disagree with a score of 2, and I completely disagree with a score of 1,

and in the last sub scale (resistance to stigma), scoring is reversed. That is, I completely agree with a score of 1, I agree with a score of 2, I disagree with a score of 3, and I completely disagree with a score of 4. Overall, a higher score indicates a more intense internal stigma.

Timepoint

The measurement of Internal Stigma is at the beginning and then 14 days after dignity therapy.

Method of measurement

Internalized Stigma Index of Mental Illness (ISMI)

3

Description

The hope questionnaire of Schneider and colleagues has 12 questions and its purpose is to measure the level of hope in people. This questionnaire is designed for people 15 years old and above. To get the score of the questionnaire, the scores of each question are added together. A higher score indicates a higher life expectancy of the respondent, and a lower score indicates a lower life expectancy.

Timepoint

Hope Measurement is done at the beginning and then 14 days after dignity therapy.

Method of measurement

The Hope Questionnaire of Schneider (ADHS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dignity therapy is a non-pharmacological psychological intervention in which the patient is guided by interviewing the therapist with questions from the Dignity Therapy protocol. The questions of the dignity treatment protocol are in accordance with the specific wishes and needs of patients. These interviews are recorded and edited within 3 to 5 days and become a coherent narrative. Editing includes removing colloquial phrases, correcting the chronological order, removing unnecessary content. Another meeting is arranged to read and correct it, and after the patient approves the final version, a printed version is given to the patient to give to her family or friends.

Category

N/A

2

Description

Control group: The pre-test including the demographic information form, questionnaires of human dignity, internal stigma and hope will be provided to the control group, and after two weeks, the post-test will be administered to the control group. And they are asked to complete the questionnaires mentioned. During this period, the control group will not receive any other intervention, apart from the treatment and routine care of the hospital. Then the data collection for the test group will also be done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

505 Aja Hospital

Full name of responsible person

Vahid Donyavi

Street address

505 Nezaja Hospital, End of Oshan Boulevard, Army Highway, End of Imam Ali (AS) highway (North)

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

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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

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Zahra Tat

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Just part of the data, such as information related to the main outcome or similar, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

All postgraduate students of medical sciences and researchers and professors of medical sciences

universities of the country

From where data/document is obtainable

Adress: Dr. Zahra Farsi- Vice President of Research- Additional Education- Faculty of Nursing- Aja University of Medical Sciences. Contact number: 02177500929 Email address: zahrafarsi@gmail.com Address: Nursing Faculty of the Islamic Republic of Iran Army- end of Kaj St- Shariati St- Tehran Postal code: 6717855379 E-mail: https://mail.ajaums.ac.ir/ Website of Aja Nursing School: https://nursing.ajaums.ac.ir/

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

It takes about 1 month to access information through the faculty

Comments