

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effectiveness of gratitude program on psychological well-being and quality of life among substance abuse patients

Protocol summary

Study aim

A gratitude program based on research findings will be used to improve the quality of life and psychological well-being of substance dependent patients in order to improve the quality of life and psychological well-being of drug dependent patients by using an appropriate and accessible method.

Design

For randomization, two small red (test) and blue (control) balls in a bag were used and the subjects were tested and controlled without knowledge. The randomization unit was simple and none of the participants and nurses of the team were familiar with the test and control groups. The study is a blind and parallel strain.

Settings and conduct

The research was conducted on 64 addicted patient which had been referred to the addiction rehabilitation center (Modarres hospital) of Isfahan city, that divided to two groups that each one included 32 patients. GQ-6, WHOQOL, and WHO-6 questionnaires used for estimate of gratitude, QoL, and well-being scores respectively. The SPSS 16 software was used for analyzing the collected data. The study is a blind and only participants and nurses and researcher were unaware of the test and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Literacy, lack of psychological services, No mental disorders, Have not any disability Exclusion criteria: unwillingness to intervention, absences during meetings, the occurrence of abnormal stress during and the six months prior to the study

Intervention groups

In order to evaluate the gratitude program on the well-being and quality of life on hospitalized substance abuse dependent, two groups of 32 patients (test and control) were selected and studied.

Main outcome variables

Gratitude program, Well-being, Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180124038495N1**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **retrospective**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Maryam Jamshidian Ghalesefidi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-12-22, 1395/10/02

Expected recruitment end date

2017-04-25, 1396/02/05

Actual recruitment start date

2016-12-22, 1395/10/02

Actual recruitment end date

2017-04-25, 1396/02/05

Trial completion date

empty

Scientific title

Effectiveness of gratitude program on psychological well-being and quality of life among substance abuse patients

Public title

The role of gratitude on psychological well-being and quality of life in patients with substance abuse dependence

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to read and write No mental disorder that is characterized reviewing patient records. No received a recent psychology treatment support (behavioral or recognition therapy) during the intervention stages Not any disability

Exclusion criteria:

An unwillingness to continue the intervention. Absence in meetings for 2 sessions The occurrence of abnormal stresses of "life crisis" during and six months before the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **64**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: Simple Randomization unit: Individual Randomization Tool: Use two small red balls (test group) and blue (control group) inside a bag

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants were aware of the study, but in which group (test or control) they were completely unaware. Also, collaborative nurses and researcher were unaware of this trend.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Department of Psychiatric Nursing, Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jarib, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۶۵

Approval date

2016-12-21, 1395/10/01

Ethics committee reference number

395606

Health conditions studied

1

Description of health condition studied

Addiction

ICD-10 code

F-11.2

ICD-10 code description

F10 Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

The percentage of participants whose gratitude score is high.

Timepoint

At the start of the study and one month after the start of the study

Method of measurement

GQ-6 used for estimate of gratitude scores.

Secondary outcomes

1

Description

Quality of life

Timepoint

At the start of the study and one month after the intervention

Method of measurement

WHOQOL questionnaire

2

Description

Well being

Timepoint

At the start of the study and one month after the intervention

Method of measurement

WHO-6 questionnaire

Intervention groups

1

Description

The intervention group (test) was evaluated using a questionnaire at the beginning of the examination of the test. The quality of life and well-being of these individuals were evaluated by WHOQOL-BREF and WHO-6 standard questionnaires. During a month, four counseling sessions and a presentation of gratitude program were completed and at the end of a month using standard questionnaires WHOQOL-BREF and WHO-6, the quality of life and well-being of these individuals were re-evaluated and compared with the initial stage of the study. The GQ-6 questionnaire was used at the end of the month to determine the effect of gratitude program. Intervention results were collected, analyzed and compared with control group during 1 month.

Category

Behavior

2

Description

Control group: The control group was evaluated using a questionnaire at the beginning of the examination of the test. The quality of life and well-being of these individuals were evaluated by WHOQOL-BREF and WHO-6 standard questionnaires. During a month, four counseling sessions and a presentation of gratitude program were completed and at the end of a month using standard questionnaires WHOQOL-BREF and WHO-6, the quality of life and well-being of these individuals were re-evaluated and compared with the initial stage of the study. The GQ-6 questionnaire was used at the end of the month to determine the effect of gratitude program. Intervention results were collected, analyzed and compared with Intervention group during 1 month.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Psychiatric Hospital

Full name of responsible person

Hamid Mohammad Beighi

Street address

Modarres hospital, Emam street, Gholdasht

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gholdasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shahnaz Kohan

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Jamshidian Ghalesefidi

Position

MSc. student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Jamshidian Ghalesefidi

Position

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Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person**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

By publishing the data and the items mentioned in the
dissertation, we will apply the valid scientific articles to
the publication of the data.

When the data will become available and for how long

Start accessing data is two months after printing results

To whom data/document is available

All interested persons

Under which criteria data/document could be used

The use of study data for the purpose of scientific
development in all fields is permissible.

From where data/document is obtainable

Department of Psychiatric Nursing, Faculty of Nursing
and Midwifery, Isfahan University of Medical Sciences,
Isfahan, Iran Maryam Jamshidian Ghalesefidi:
09132897467

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

Usually three days after data call, data can be
transferred.

Comments