

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of education based on family-centered empowerment model on the health literacy of caregivers and the behavior of patients with tuberculosis

Protocol summary

Study aim

Determining the effect of family-centered empowerment model on the health literacy of care givers and behavior of patients with Tuberculosis in Mashhad

Design

A clinical trial study with an intervention and control group on 72 caregivers of people with tuberculosis who were randomly divided, parallel, blind, into intervention and control groups and assigned a code to each participant. The educational intervention is performed in 4 sessions of 90 minutes for the intervention group.

Settings and conduct

Place of intervention is the Mashhad Comprehensive Health Service centers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having at least basic literacy of TB caregivers; Having a TB record in comprehensive health service centers. Non-inclusion criteria: not completing the pre-test or post-test questionnaire; Illiteracy of caregivers of TB patients

Intervention groups

Intervention group 1: includes 36 caregivers. Patients with tuberculosis will receive education based on a family-centered empowerment model. Control group: includes 36 caregivers and TB patients who do not receive any training.

Main outcome variables

Health Literacy among care givers, Behavior among patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160917029843N14**
Registration date: **2021-02-02, 1399/11/14**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-02, 1399/11/14**

Update count: **0**

Registration date

2021-02-02, 1399/11/14

Registrant information

Name

Mohammad Vahedian-Shahroodi

Name of organization / entity

Social Determinants of Health Research Center,
Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

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+98 51 3189 2202

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vahedianm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on family-centered empowerment model on the health literacy of caregivers and the behavior of patients with tuberculosis

Public title

Empowering people with TB with a family-centered approach

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Have at least basic literacy care for TB patients Having a TB record in comprehensive health service centers

Exclusion criteria:

Failure to complete the pre-test or post-test questionnaire Illiteracy of caregivers of TB patients

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description

Using a table of random numbers / Using cluster randomization and simple randomization / 2 health centers will be selected from 5 health centers in Mashhad and 90 people from each health center will be randomly selected.

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 Mashhad University of Medical Sciences

Street address

School of Public Health; Daneshgah 18 street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-01-06, 1398/10/16

Ethics committee reference number

IR.MUMS.REC.1398.264

Health conditions studied**1****Description of health condition studied**

Tuberculosis patient behavior

ICD-10 code

A15.0

ICD-10 code description

Tuberculosis of lung

Primary outcomes**1****Description**

Health literacy of caregivers of patients with tuberculosis

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Health Literacy Questionnaire TOFHLA

2**Description**

Tuberculosis patient behavior

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Self made questionnaire on the behavior of a patient with tuberculosis

Secondary outcomes**1****Description**

Self Efficacy

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

2**Description**

Self Esteem

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

3**Description**

Knowledge about Tuberculosis

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

Intervention groups**1****Description**

Intervention group: the intervention group, which includes 36 caregivers of tuberculosis patients, receives educational intervention. Training intervention consists of 4 90-minute sessions and training is based on the dimensions of the family-centered empowerment model (knowledge, self-esteem and self-esteem).

Category

Behavior

2**Description**

Control group: included 36 caregivers of tuberculosis patients and there is no intervention on the control group

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mashhad Health Center No. 1

Full name of responsible person

Nasser Amini

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Vakil Abad 66; Vakil Abad boulevard

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohammad Vahedian Shahroodi

Position

دانشیار گروه آموزش بهداشت و ارتقای سلامت

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohammad Vahedian Shahroodi

Position

Associate Professor, Department of Health Education and Health Promotion

Latest degree

Ph.D.

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

Undecided - It is not yet known if there will be 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

Title and more details about the data/document

The data file is potentially shareable after people are not identified.

When the data will become available and for how long

Get started one month after the results are published

To whom data/document is available

Researchers working in academia and academic

Under which criteria data/document could be used

The data are sent by official request through academic or organizational emails of the researchers after confirmation and identification of the sender.

From where data/document is obtainable

Dr. Mohammad Vahedian-Shahroodi
vahedianm@mums.ac.ir

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

The data are sent by official request through academic or organizational emails of the researchers after confirmation and identification of the sender.

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohammad Vahedian Shahroodi

Position

Associate Professor, Department of Health Education and Health Promotion

Latest degree

Ph.D.

Other areas of specialty/work

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