# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Nov 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

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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
**Street address**
Vakil Abad 66; Vakil Abad boulevard
**City**
Mashhad
**Province**
Razavi Khorasan
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۹۱۷۹۷۹۳۹۴۵
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hc۱.pr@mums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Dr. Mohsen Tafaghodi
**Street address**
Daneshgah 18 street
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Razavi Khorasan
**Postal code**
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+98 51 3841 3007
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vahedianm@mums.ac.ir
**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
**Street address**
University 18 Ave., School of Public Health
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## Person responsible for scientific inquiries

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Dr Mohammad Vahedian Shahroodi

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Associate Professor, Department of Health Education and Health Promotion
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**Other areas of specialty/work**
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## Person responsible for updating data

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Dr Mohammad Vahedian Shahroodi
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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**
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**