Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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

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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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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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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
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Person responsible for scientific inquiries

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Associate Professor, Department of Health Education and Health Promotion
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Person responsible for updating data

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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