Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of education based on family participation on the health-related quality of life of patients with pulmonary tuberculosis

Protocol summary

Study aim
Controlling quality of life variables of pulmonary tuberculosis patients under the influence of education based on family participation

Design
A clinical trial with a control group, with parallel groups, single-blind, randomized block type, on 42 patients (21 patients + 21 families),

Settings and conduct
The intervention will be carried out on the research units at Health Center No. 2 located in Vahdat Blvd., Mashhad, in the form of face-to-face training with the participation of the resident general practitioner and nutritionist in the health center, and virtual as separate groups for the patient and family and SMS.

Participants/Inclusion and exclusion criteria
Family selection with the patient's agreement. Having a smartphone. Iranian. Age over 18; suffering from a different chronic disease.

Intervention groups
The control group will receive routine care in centers. The intervention group will receive training intervention in three ways: face-to-face, virtual, and SMS.

Main outcome variables
Improving the method of handling and caring for patients with pulmonary tuberculosis in the early stages of the disease; improving the education path in the health center

General information

Reason for update

Acronym
ندارد

IRCT registration information
IRCT registration number: **IRCT20220223054111N1**
Registration date: **2024-02-25, 1402/12/06**
Registration timing: **prospective**
Last update: **2024-02-25, 1402/12/06**
Update count: **0**

Registration date
2024-02-25, 1402/12/06

Registrant information

Name
Sadaf Naseri

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-02, 1402/12/12

Expected recruitment end date
2024-03-23, 1403/01/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of education based on family participation on the health-related quality of life of patients with pulmonary tuberculosis

Public title
Investigating the role of education with family cooperation and its impact on the quality of life of pulmonary tuberculosis patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

1-No hospitalization (patient) 2- Two weeks have passed since the start of treatment (patient) 3- The patient has informed consent and completed the form (patient) 4- Must be over 18 years old (patient) 5- Does not have learning problems (auditory-visual-mental) (patient) 6- The patient or family (one person or both) should have a phone and know how to work with it (patient). 7- Be of Iranian origin and have the ability to read and write in Persian (patient) 1- The family has given informed consent and completed the form (family). 2- Must be over 18 years old (family) 3- Does not have learning problems (auditory-visual-mental) (family) 4- The patient or family (one person or both) should have a phone and know how to use it (family). 5- The patient should be satisfied with her presence in the study and be selected as a family member with the patient's agreement 6- Shouldn't be majoring in one of the professions in the field of medical sciences (family) 7- Be of Iranian origin and have the ability to read and write in Persian (family)

Exclusion criteria:

Tuberculosis resistant to treatment and extrapulmonary tuberculosis (patient) Suffering from a chronic disease (heart-kidney-pulmonary-AIDS) at the same time (patient) Does not want to participate in the research (patient) Not able to participate in training sessions for any reason (patient) Attending another study at the same time (patient) A family member is suffering from a chronic heart-pulmonary-kidney disease or tuberculosis (family) Does not want to participate in the research (family) Does not have the ability to participate in training sessions for any reason (family) Attending another study at the same time (family)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **62**

More than 1 sample in each individual

Number of samples in each individual: **2**

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Randomization (investigator's opinion)

Randomized

Randomization description

Randomized Blocked Clustering Design Equation Design: Cluster No layers Type of Trial: Parallel Individuals who have entry criteria should provide information to randomizer.org website. Initially, the size of each block must be determined. Then, the list of blocks should be written, numbers assigned to them, random numbers selected, and the assignment list to the numbers pre-determined. Concealment: The batch packet method will be used in a way that the randomly generated sequence will be kept in the batch packet until each research unit enters the study. To prevent information leakage between intervention and control groups, based on the coordination with the health center, the patient referral program for the control group will be arranged in such a way that they will not be present at the health center during educational classes. Patients in the control and intervention groups are divided in a way that the control group will visit the health center on even days of the week and the intervention group will visit on odd days (Sunday and Tuesday).

Blinding (investigator's opinion)

Single blinded

Blinding description

The analysts of this study perform data analysis without knowledge and bias towards the people allocated in different groups.

Placebo

Not used

Assignment

Parallel

Other design features

Allocation concealment method: the method of closed envelopes will be used in such a way that the random sequence generated in the closed envelope will be kept until the entry of each research unit into the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad Nursing and Midwifery Faculty

Street address

Mashhad University of Medical Sciences, Shahid Kharazmi Educational Complex, School of Nursing

City

Mashhad

Province

Razavi Khorasan

Postal code

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Approval date

2023-07-10, 1402/04/19

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.068

Health conditions studied

1

Description of health condition studied

pulmonary tuberculosis

ICD-10 code

A15

ICD-10 code description

Respiratory tuberculosis

Primary outcomes

1

Description
Quality of life related to the health of patients with pulmonary tuberculosis
Timepoint
before the intervention and one month after the intervention
Method of measurement
Questionnaire of the quality of life of patients with pulmonary tuberculosis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: receiving training with the participation of the patient's caregiver in virtual and face-to-face training sessions (activity, nutrition, familiarity with the disease and complications caused by the disease and its impact on the life of the patient and the family) and receiving 4 motivational text messages with the importance of the role of the family in health and acceleration A short paragraph is sent to the patient's caregiver for 4 weeks during the patient's recovery and taking responsibility. 4 face-to-face sessions for 45-60 minutes and virtual sessions as a separate group of patients and families on the ITA platform in the form of messages, clips and digital educational pamphlets.
Category
Lifestyle

2

Description
Control group: routine care patients of the health center include receiving educational pamphlets and training in the form of an in-person meeting at the beginning of filing and answering the patient's questions when visiting the center to receive oral medications.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad health center number 2
Full name of responsible person
Sadaf Naseri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad 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
Mashhad University of Medical Sciences
Proportion provided by this source
80
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

Sadaf Naseri

Position
Senior students

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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