

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Effect of therapy reminder application on therapy-adherence in adult with Beta thalassemia major patients

Protocol summary

Study aim

Investigating the effect of treatment reminder application on treatment adherence in adults with thalassemia major

Design

A randomized clinical trial with a control group is conducted with parallel groups on 80 patients. Randomization is conducted with the help of permutations and random library.

Settings and conduct

This research is carried out in Sarvar clinic in Mashhad. The random sequence method will be used in the block method. The intervention group will use an offline app for 8 weeks. The control group will not receive this app. Before and after the intervention, a questionnaire is used to check compliance with the treatment

Participants/Inclusion and exclusion criteria

Included thalassemia major with aged 18 years and older Having an active smartphone They have sufficient skills in Farsi or English to work with a smartphone and the ability to use it They do not have mental illness and hearing and vision problems informed consent Exclusion Patients were excluded if they themselves used a medication reminder app for example calendar alerts on their phones. Patients with smartphones that are unable to download apps If a person reports not using the reminder program in two phone calls by the researcher, he will be excluded from the study. Patients who do not want to continue cooperation

Intervention groups

The intervention group will use an offline app for 8 weeks. The control group will not receive this app.

Main outcome variables

Adherence to treatment Medication Adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240222061079N1**

Registration date: **2024-03-04, 1402/12/14**

Registration timing: **prospective**

Last update: **2024-03-04, 1402/12/14**

Update count: **0**

Registration date

2024-03-04, 1402/12/14

Registrant information

Name

Mahdieh Arian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3768 9730

Email address

shadi1arameh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2024-08-26, 1403/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of therapy reminder application on therapy-adherence in adult with Beta thalassemia major patients

Public title

Effect of therapy reminder application on therapy-adherence

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
1- Patients with thalassemia major aged 18 years and older who have an active file in Sarwar Clinic and are being treated with blood transfusion and iron removal drugs 2- Having an active smartphone that works with the Android operating system, 3- They have sufficient skills in Farsi or English to work with a smartphone and the ability to use it 4- They do not have mental illness and hearing and vision problems (due to hearing and seeing application alarms) 5- Provide written informed consent to participate in the research.
Exclusion criteria:
1- Patients were excluded if they themselves used a medication reminder app or other electronic reminder systems to adhere to their medication regimen, for example calendar alerts on their phones. 2- Patients with smartphones that are unable to download apps are excluded. 3- If a person reports not using the reminder program in two phone calls by the researcher, he will be excluded from the study. 4- Patients who do not want to continue cooperation for any reason will be excluded from the study during the study period.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation will be done with Python version 3 with the help of permutations and random library. These two libraries will be used to generate a random sequence using the block method (here, blocks of 4 and 2 are used that will be randomly generated and randomly generate the sequence). In order to hide, before assigning the person, the assigned group will not be known. It is organized using a sealed opaque envelope with a random allocation sequence. Each of the generated random sequences is recorded on a card and the cards are placed in the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes will be numbered in the same order. Finally, the lids of the envelopes are glued and placed in a box respectively. At the time of registration, based on the order in which the eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed .

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo

Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

دانشکده پرستاری و مامایی مشهد

Street address

Khorasan Razavi, Azadi Square, east gate of Ferdowsi University of Mashhad, university campus, educational complex of Shahid Dr. Kharazmi

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2024-02-06, 1402/11/17

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.116

Health conditions studied

1

Description of health condition studied

Major Thalassaemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes

1

Description

Adherence to treatment

Timepoint

Before and after the intervention (8 weeks apart)

Method of measurement

Moriski questionnaire and chronic patient treatment adherence questionnaire

Secondary outcomes

1

Description

Evaluation of the designed application

Timepoint

Once designed
Method of measurement
Application evaluation questionnaire

Intervention groups

1

Description
Intervention group: Using an offline app for 8 weeks
Category
Behavior

2

Description
Control group: They receive routine treatment without an app
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Sarvar Specialized Polyclinic affiliated to Mashhad University of Medical Sciences
Full name of responsible person
Mahdieh Arian
Street address
No. 32, 6 Sajidi Fadak Crossroads, Mashhad
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9196816353
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Khorasan, Razavi, Mashhad, University St., next to Hoize Cinema, Qurashi Building, Research and Technology Vice-Chancellor
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Web page address
<https://v-research.mums.ac.ir/moavenat/2021-04-06-05-57-55>

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
Mahdieh Arian
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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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

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

Complete information such as: work method, implementation, informed consent, analysis and analysis results will be shared in the article after the work is completed.

When the data will become available and for how long

after finishing the work

To whom data/document is available

Researchers and patients can have access by receiving an article or thesis

Under which criteria data/document could be used

For research and educational work

From where data/document is obtainable

E-mailing the researcher or downloading articles from reputable sites

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

E-mailing the researcher or downloading articles from reputable sites

Comments