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
shadi1aramesh@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

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No. 32, 6 Sajidi Fadak Crossroads, Mashhad

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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

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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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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
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