

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison the Effect of Peer Support with Health Care Support Through Cyberspace on Family Care Burden and Self-Efficacy in Adolescents with Type 1 Diabetes

Protocol summary

Study aim

Comparison the Effect of Peer Support with Health Care Support through Cyberspace on Family Care burden and Self-Efficacy in Adolescents with type 1 Diabetes

Design

A clinical trial with two intervention groups and one control group, single blind and 90 sample size

Settings and conduct

The study is single blind. Statistical analyst will be unaware of intervention groups (intervention 1 and 2) and control. Intervention group one: adolescents receiving peer support through cyberspace for three months. Intervention group: adolescents receiving health care support through cyberspace for three months. Adolescent control group finds routine activities in Akbar hospital of Mashhad.

Participants/Inclusion and exclusion criteria

Entry requirements: 1-Willingness to participate in the study. 2-Written parental consent to participate in the study. 3-Type 1 diabetes, at least 6 months. 4-Ability to use smartphones and cyberspace (social networks). 5-Minimum elementary education. 6-No other chronic comorbidities. 7-Not passing similar peer support courses 8-years 12 to 18 years. Exclusion criteria: Not having high conditions; leave the group or being inactive for a long time.

Intervention groups

For adolescents in intervention group one, Peer-to-peer support will run for three months (at least three times a week) Intervention group two, cybersecurity support will run for three months (at least three times a week). For the control group, routine measures will be taken during Akbar Hospital in Mashhad. The self-care-support content is designed for diabetes care. This content is being shared with peers to use their subgroups in addition to their experiences in self-care.

Main outcome variables

Self-efficacy of adolescents (Areas of diet, medication use, physical activity and blood glucose measurement); family care burden (objective and subjective dimension).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200224046602N1**

Registration date: **2020-04-10, 1399/01/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-10, 1399/01/22**

Update count: **0**

Registration date

2020-04-10, 1399/01/22

Registrant information

Name

Zohreh Faramarzizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3509 8501

Email address

faramarzizadehz1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-05, 1398/12/15

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of Peer Support with Health Care Support Through Cyberspace on Family Care Burden and Self-Efficacy in Adolescents with Type 1 Diabetes

Public title

Comparison the Effect of Peer Support with Health Care Support Through Cyberspace on Family Care Burden and Self-Efficacy in Adolescents with Type 1 Diabetes

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Minimum elementary education Written parental consent to participate in the study Ages 12-18 Ability to use smartphones and cyberspace Type 1 diabetes at least 6 months Parental consent to participate in the study

Exclusion criteria:

Confirmed disease or chronic comorbidities Attend peer support similar courses

AgeFrom **12 years** old to **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget sample size: **90****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Statistical analyst will be unaware of intervention groups (intervention 1 and 2) and control.

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

Mashhad School of Midwifery Nursing, Doctora Crossroads, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2020-02-23, 1398/12/04

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.102

Health conditions studied**1****Description of health condition studied**

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes**1****Description**

Efficacy

Timepoint

At baseline and 3 months later

Method of measurement

Diabetes Management Self-efficacy Questionnaire (DMSES)

2**Description**

Family care burden

Timepoint

At baseline and 3 months later

Method of measurement

Family Caring Bar Questionnaire (CBI)

Secondary outcomes**1****Description**

The economic situation

Timepoint

At baseline and 3 months later

Method of measurement

Monthly income status and patient spending less than adequate, adequate, more than adequate (based on officially declared poverty line)

2**Description**

Economic situation

Timepoint

At baseline and 3 months later

Method of measurement

Monthly income status and patient spending less than adequate, adequate, more than adequate (based on officially declared poverty line)

3

Description

Underlying diseases

Timepoint

At baseline and 3 months later

Method of measurement

Patient with other chronic diseases other than type 1 diabetes

4

Description

Blood sugar

Timepoint

At baseline and 3 months later

Method of measurement

blood test

5

Description

Insulin consumption

Timepoint

At baseline and 3 months later

Method of measurement

Investigation of patient records

Intervention groups

1

Description

Intervention group1: Adolescents receiving peer support through cyberspace for three months (at least three times a week)

Category

Lifestyle

2

Description

Intervention group2: Adolescents receiving health care support through cyberspace for three months (at least three times a week)

Category

Lifestyle

3

Description

Control group: No extra work

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Shahr Hospital of Mashhad

Full name of responsible person

Rezaian Aramesh

Street address

Shahid Fakouri Boulevard- Akbar Hospital

City

mashhad

Province

Razavi Khorasan

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9186818831

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+98 51 3763 1506

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faramarzizadehz1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Rabab Latifnejad Rudsari

Street address

Doctoral Ave- Mashhad University of Medical Sciences

City

Mashhad

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Razavi Khorasan

Postal code

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Phone

+98 51 3859 1511

Fax

+98 51 3859 7313

Email

NMS.IT@mums.ac.ir

Web page address

<https://nurse.mums.ac.ir/assistances/res-vice/r-v-intro>

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
Aramesh Rezaian
Position
Professor
Latest degree
Master
Other areas of specialty/work
Nursery
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School of Midwifery Nursing, Daneshgah Street
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Person responsible for scientific inquiries

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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

All data can be shared after unidentifiable individuals

When the data will become available and for how long

Start of access period 3 months after publication of results

To whom data/document is available

Researchers and nurses working in medical institutes of Iran

Under which criteria data/document could be used

Use of research results is permitted

From where data/document is obtainable

faramarzizadehz1@mums.ac.ir

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

As soon as possible after emailing

Comments