Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Age
From **12 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target 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

Email

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

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Mashhad

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Phone

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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

Street address

School of Midwifery Nursing, Daneshgah Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Aramesh Rezaeian

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Person responsible for updating data

Contact

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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