

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The Effectiveness of Group Hope Therapy on Self-efficacy of Adolescents with Type 1 Diabetes

Protocol summary

Study aim

Overall Objective: Determining the Effectiveness of Group Hope Therapy on Self-efficacy (SE) of Adolescents with Type 1 Diabetes (T1D) Referred to Isfahan Endocrine and Metabolism Research Center (IEMRC) in 2019

Design

Randomized, not blinded, parallel clinical trial with control group

Settings and conduct

The study is done in IEMRC. Intervention Group will have 8, 90-minute training sessions based on SHTP which is presented in Lecture, question and answer, role-playing and homework in groups and face-to-face training using PowerPoint, film and image and the Control Group will receive no training sessions based on SHTP. They receive only routine diabetes self-care training provided by the center itself. Consent and SE questionnaire are completed by participants at the beginning, immediately after the intervention and two months after, then data of sessions are given to all participants.

Participants/Inclusion and exclusion criteria

T1D, Age of 13 to 19 years, At least 6 months passed since diagnosis, Consent of subjects and their parents, Not participating in other psychotherapy programs during this study, Lack of other physical and mental illness, Lack of crisis and severe mental stress in the past 6 months

Intervention groups

experimental group will have training sessions based on the Snyder's Hope Therapy Program (SHTP), and no intervention for Control group.

Main outcome variables

amount of Self Efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190813044520N1**

Registration date: **2020-04-12, 1399/01/24**

Registration timing: **retrospective**

Last update: **2020-04-12, 1399/01/24**

Update count: **0**

Registration date

2020-04-12, 1399/01/24

Registrant information

Name

Nasim Nikbakhtan Esfahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Group Hope Therapy on Self-efficacy of Adolescents with Type 1 Diabetes

Public title

The Effectiveness of Hope Therapy on Self-efficacy of Adolescents with Diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Type 1 diabetes The age of 13 to 19 years At least 6 months passed since diagnosis of type 1 diabetes The satisfaction of sample subjects and their parents with research participation

Exclusion criteria:

having other physical illness having mental illness and crisis and severe mental stress in the past 6 months

Age

From **13 years** old to **19 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocation of the samples, their names are written on paper cards and then put in a box. The names are then randomly selected by the researcher. The first one is in the experimental group and the second one is in the control group and so on until all of the cards are selected. In this way, participants do not know whether they are in the Experimental or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Science

Street address

Building No. 4, Isfahan University of Medical Science, Hezarjirib Ave., Isfahan

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Province

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Postal code

81745319

Approval date

2019-09-17, 1398/06/26

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.365

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

Type 1 Diabetes

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

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

Self Efficacy Scale measured by Diabetes Management Self-Efficacy Scale (DMSES) and Self-Efficacy Questionnaire –Children (SEQ-C)

Timepoint

before and immediately after the intervention and two months after the intervention

Method of measurement

Diabetes Management Self-Efficacy Scale (DMSES) and Self-Efficacy Questionnaire –Children (SEQ-C)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intervention group will participant in 8, 90-minute training sessions which is held in educational classes of IERC and based on SHTP 2002. Content is provided by the researcher who has passed a Teaching Hope Therapy program and has a valid degree. Content is performed through lectures, question-and-answer, role-playing and practical home works in group and educating face-to-face using PowerPoint, film, image and then sharing them in a Whats app Group. 1st session: Initial familiarity, articulation of study goals and definition of hope based on Snyder's theory. 2nd session: Explaining how hope develops and its necessity, its effect on hopelessness and feeling of emptiness, the importance of hope in life. 3rd session: Telling the life story of each group members, make them notice their strengths and capability. 4th session: reformatting people's stories based on Snyder's Hope Theory, identifying members' past hopes and successes. 5th session: telling and writing a list of current life events and their important aspects for each member and making them determine their importance and satisfaction. 6th session: Goal setting features in hopeful people based on Snyder's Hope Theory and encouraging

participants to write their own goals. 7th session: The characteristics of appropriate pathways and pathways to goal and ways to increase hope are described. 8th session: there will be an overview chat about interventions and strategies for how to be and stay motivated. At the end of the course, each member will report the home works and share their comments with other members.

Category

Behavior

2

Description

Control group: The Control group will have no intervention about hope therapy and they receive only routine diabetes self-care training provided by the center itself.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Endocrine and Metabolism Research Center

Full name of responsible person

Mansour Siavash

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Khorram St, Jomhuri-e-Eslami Square, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Isfahan university of medical science

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Building No 4, Isfahan University of Medical Science, Hezarjirib Ave, Isfahan

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

nasim nikbakhtan

Position

post graduate student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Nasim Nikbakhtan Esfahani

Position

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