

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Designing and evaluating a serious educational game to improve controlling emotional skills of members at Center of Children and Adolescents Intellectual Development of Mashhad

Protocol summary

Study aim

Designing and evaluating a serious educational game to improve controlling emotional skills of members at Center of Children and Adolescents Intellectual Development of Mashhad

Design

Participants: Age group 7 to 9 years Assessment tool: Questionnaire in the book entitled "Rabbit Feelings" Randomization: the children will be divided into intervention and control groups using the envelope method. Random numbers will be prepared and printed from www.randomize.com and then placed in an envelope in a way that contents won't be identifiable. Phase 1: All participants will be pre-tested through a questionnaire. Phase 2: Children in the intervention group, in addition to receiving routine training, will interact with a serious educational game (with the aim of training emotional skills including anger, sadness, fear, and happiness). Phase 3: All participants will be evaluated through the post-test. Sample size: 27

Settings and conduct

Setting: Center of Children and Adolescents Intellectual Development of Mashhad

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Membership in Center of Children and Adolescents Intellectual Development of Mashhad 2- Parental consent Exclusion criteria: Dealing with mental disorders

Intervention groups

Intervention group: In this group, in addition to routine training (face-to-face training), they would also be trained through the developed game. Control group: Children in this group will receive routine training which is face-to-face training.

Main outcome variables

anger control skill; sadness control skill; fear control skill; happiness control skill

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170924036366N2**

Registration date: **2021-02-04, 1399/11/16**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-04, 1399/11/16**

Update count: **0**

Registration date

2021-02-04, 1399/11/16

Registrant information

Name

Nahid Sharifzadeh

Name of organization / entity

Faculty of Medicine of Mashhad

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 8299

Email address

sharifzadehn941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Designing and evaluating a serious educational game to improve controlling emotional skills of members at Center of Children and Adolescents Intellectual Development of Mashhad

Public title
Design and evaluation of an educational Serious Game to control emotional skills

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Membership in Center of Children and Adolescents Intellectual Development of Mashhad Parental consent
Exclusion criteria:
Dealing with mental disorders

Age
From **7 years** old to **9 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **27**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization will be used. A numeric code will be assigned to each case. Then these numbers will be attached to randomization.com and after conducting randomization process and assigning numbers into two groups, cases will be randomly assigned to groups including intervention group and 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

Deputy of Research of Mashhad University of Medical Sciences

Street address

Deputy of Research of Mashhad University of Medical Sciences, Faculty of Medicine, Azadi Square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

8771685873

Approval date

2020-10-06, 1399/07/15

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.417

Health conditions studied

1

Description of health condition studied

Emotional skills

ICD-10 code

z73

ICD-10 code description

Problems related to life management difficulty

Primary outcomes

1

Description

Emotional skills (including fear, anger, happiness, sadness)

Timepoint

Before the intervention and two months after the end of the intervention

Method of measurement

emotional skills questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Electronic learning intervention will be done through a serious game. In addition to the routine training, a serious game will be used for training. The game will be developed in a single user environment for android OS to be installed on a tablet in order to help the trainer to do the intervention easily. The game will be design based on the book entitled "Rabbit Feelings" by Trace Moroney. This book is used to train controlling emotional skills including fear, anger, happiness, sadness for children with the age group of 7-9. The child would consider himself/herself as a third person in the game and the training would be done entirely interactive so that a suitable feedback would be given to him/her for every action. The most important advantages of using this approach to train children are being interactive, repetitive and giving feedback. Intervention period will be one month.

Category

Other

2

Description

Control group: The children in the control group will just receive routine training based on the book entitled "Rabbit Feelings" by Trace Moroney which is used to train controlling emotional skills including fear, anger, happiness, sadness for children with the age group of 7-9.. In this approach, the trainer once read the book for the children and try to explain them all mentioned emotions and how to control those emotions orally.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Center of Children and Adolescents Intellectual Development of Mashhad

Full name of responsible person

Seyyed Mohammad Tabatabaei

Street address

Palestine Street No. 26

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9178113456

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sharifzadehn9@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Mashhad University of Medical Sciences

Full name of responsible person

Dr.Maliheh Dadgarmoghaddam

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Deputy of Research of 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

Faculty of Medicine of Mashhad

Full name of responsible person

Nahid Sharifzadeh

Position

Master in Medical Informatics

Latest degree

Master

Other areas of specialty/work

Medical Informatics

Street address

Department of Medical Informatics - Faculty of Medicine of Mashhad

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Province

Razavi Khorasan

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1394491388

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Email

nd.sharifzadeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Medicine of Mashhad

Full name of responsible person

Seyyed Mohammad Tabatabaei

Position

Assistant Professor of Medical Informatics

Latest degree

Ph.D.

Other areas of specialty/work

Medical Informatics

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Person responsible for updating data

Contact

Name of organization / entity

Faculty of Medicine of Mashhad

Full name of responsible person

Nahid Sharifzadeh

Position

Master in Medical Informatics

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data will all be anonymous and encrypted. So, all the
data will be shared.

**When the data will become available and for how
long**

Once the results are published indefinitely, unlimited
access will be possible.

To whom data/document is available

There is no limitation.

Under which criteria data/document could be used

There is no limitation.

From where data/document is obtainable

We pledge to respond by tabatabaeimh@mums.ac.ir

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

We pledge to respond within one business day by
tabatabaeimh@mums.ac.ir

Comments