

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Clinical Trial of the Effectiveness of Social Skills Training on Students' Mental Health

Protocol summary

Study aim

This study will be designed to investigate the effectiveness of social skills training on students' mental health as a single-blind clinical trial.

Design

This study will be designed to investigate the effectiveness of social skills training on students' mental health as a clinical trial. The study population includes 21 third-grade elementary students studying at the non-profit school of Baran Andisheh in Rasht. This is a semi-experimental study using pre-test and post-test. Students will be selected by a psychiatrist and by questionnaires. The participants will be included in the study by easy and convenience sampling method after receiving informed consent from parents and teachers by considering criteria of entering and leaving the study. After sampling, samples will be assigned to the intervention group. Parents' dissatisfaction or the history of participation in other social skills training programs will cause to leave the research process. The intervention process will be taken place in 10 sessions of 90 minutes. The effectiveness of treatment after the end of the school year will be assessed based on the score obtained from the strengths and difficulties questionnaire (SDQ) for assessing mental health and Matson evaluation of social skills.

Settings and conduct

For social skills training to students, the relevant teacher will be used that each week is in relation with them. The content of the social skills training protocol include the Teacher Guidebook and the Child Workbook. This package will be prepared to provide a comprehensive, simple, functional and appropriate with features of Iranian children of 6 to 12 years old. This protocol includes a step-by-step application guide with examples appropriate with age of child for the performer that can be a teacher or training adviser from diploma level to high degrees and includes 10 skills. 1- Self-efficacy 2- Empathy 3. Effective communication 4. Creative thinking

5. Critical thinking 6. Problem-solving 7. Management of emotions 8. Conflict with stress 9. Decision-making. 10. Dare skill and telling No. (Introduction of Social Skills Training Package is presented in the Appendix). For elimination of the possibility of any bias due to the knowledge of patients or physicians evaluation of the results, and possible impact on the outcomes of research a single blind study will be performed, the participants will be blind to the intervention type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Students of elementary school in Rasht city aged 9 to 11 years old Exclusion criteria: Children whose parents do not consent to participate in the research Children with a history of participation in other programs of social skills training

Intervention groups

The training is provided by the program executives through 10 sessions of 90 minutes with the presence of a teacher in the class. The teacher is allowed to use these methods during the week if necessary. At the end of the school year, the questionnaires will be filled by parents again and they will be evaluated. The goal of the sessions is to increase social skills in school and home environments and reduce their problematic behaviors. The methods of cognitive behavioral skills and positive reinforcement will be used. Group practice methods will be used in the classroom and homework will be given to them for training. The content of the social skills training protocol include the Teacher Guidebook and the Child Workbook. This package will be prepared to provide a comprehensive, simple, functional and appropriate with features of Iranian children of 6 to 12 years old. This protocol includes a step-by-step application guide with examples appropriate with age of child for the performer that can be a teacher or training adviser from diploma level to high degrees and includes 10 skills. 1- Self-efficacy 2- Empathy 3. Effective communication 4. Creative thinking 5. Critical thinking 6. Problem-solving 7. Management of emotions 8. Conflict with stress 9. Decision-making. 10. Dare skill and telling No. (Introduction of Social Skills Training Package is

presented in the Appendix.)

Main outcome variables

Mental Health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110806007237N3**

Registration date: **2018-03-13, 1396/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-13, 1396/12/22**

Update count: **0**

Registration date

2018-03-13, 1396/12/22

Registrant information

Name

Maryam Kousha

Name of organization / entity

Guilan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 13 1666 1163

Email address

m-kousha@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-29, 1396/11/09

Expected recruitment end date

2019-01-29, 1397/11/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of the Effectiveness of Social Skills Training on Students' Mental Health

Public title

Clinical Trial of the Effectiveness of Social Skills Training on Students' Mental Health

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Students of elementary school in Rasht city aged 9 to 11 years old

Exclusion criteria:

Children whose parents do not consent to participate in the research Children with a history of participation in other programs of social skills training

Age

From **9 years** old to **11 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **21**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

This pilot will be conducted in a third-grade elementary school in the first semester. Initially, a correspondence will be provided with education for the implementation of the project. After giving enough explanations about the objectives of the project and collected confidential documents from the questionnaires, informed consent will be received from the students' parents. After convenience sampling and giving adequate explanations about the project to the sampled people, self-administered questionnaires will be extracted from parents and then the theory of social skills training will be provided to students by the research team according to the instructions. Training is during 10 sessions, 90 minutes per week, which will be conducted inside the classroom with the presence of the entire students and principal teacher. The purpose of the training sessions is to increase their social skills in school and home environments and reduce their troublesome behaviors. The teacher is allowed to use the instructions during the week based on the training that will be observed (the accompaniment of the teacher is part of the package, not confounding but part of the intervening).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Guilan University of Medical Sciences, Rasht, Namjoo Blvd

City

Rasht

Province

Guilan
Postal code
4193893345
Approval date
2018-01-29, 1396/11/09
Ethics committee reference number
IR.GUMS.REC.1396. 412

Health conditions studied

1

Description of health condition studied

Mental Health

ICD-10 code

Z04.6

ICD-10 code description

Encounter for general psychiatric examination, requested by authority

Primary outcomes

1

Description

Mental Health

Timepoint

The effectiveness of intervention will be assessed the first study and after the end of the school year based on the score obtained.

Method of measurement

from the Strengths and difficulties questionnaire (SDQ) for assessing mental health and Matson's assessment of social skills.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For social skills training to students, the relevant teacher will be used that each week is in relation with them. The content of the social skills training protocol include the Teacher Guidebook and the Child Workbook. This package will be prepared to provide a comprehensive, simple, functional and appropriate with features of Iranian children of 6 to 12 years old. This protocol includes a step-by-step application guide with examples appropriate with age of child for the performer that can be a teacher or training adviser from diploma level to high degrees and includes 10 skills. 1- Self-efficacy 2- Empathy 3. Effective communication 4. Creative thinking 5. Critical thinking 6. Problem-solving 7. Management of emotions 8. Conflict with stress 9. Decision-making. 10. Dare skill and telling No. (Introduction of Social Skills Training Package is presented in the Appendix.)

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Baran Andisheh Elementary School

Full name of responsible person

Dr Maryam Kousha

Street address

Shahid Ansari Blvd, Baran Andisheh Elementary School, Rasht

City

Rasht

Province

Guilan

Postal code

419395599

Phone

+98 13 3366 6268

Email

maryamkousha@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Mirsaeed Atarchi

Street address

Guilan University Of Medical Sciences, Namjo Blvd, Rasht

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Rasht

Province

Guilan

Postal code

419395599

Phone

+98 13 3333 5820

Email

msattarchi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

50

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
Rasht University of Medical Sciences
Full name of responsible person
Dr Maryam Kousha
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
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Position
Associate Professor, Psychiatry
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Dr Reihane Saber Ofoghi
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Latest degree
Medical doctor
Other areas of specialty/work
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Phone
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Email
kavosh1400@gmail.com

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

No - There is not a plan to make this available

Title and more details about the data/document

The data will be specified and saved by assigning the code

When the data will become available and for how long

After the study and publication of its paper

To whom data/document is available

Researchers and academic people

Under which criteria data/document could be used

According to the ethics code of the researchers from the Department of Research and Technology of Guilan University of Medical Sciences, the documentation will be usable.

From where data/document is obtainable

DR Maryam Kousha, Guilan University Of Medical Sciences

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

Examining the qualifications of the requesting person and having a code of ethics from a university center will be carried out

Comments