

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

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419395599

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+98 13 3366 6268

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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

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Guilan University Of Medical Sciences, Namjo Blvd, Rasht

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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

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Rasht University of Medical Sciences  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Dr Reihane Saber Ofoghi  
**Position**  
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**Phone**  
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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