

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### effectiveness of an intervention on aggressive behaviors in elementary students

#### Protocol summary

##### Study aim

Design, implementation and evaluation of an interventional program on aggressive behaviors among primary school students in Kermanshah

##### Design

In this study, among schools with the highest aggression, 280 aggressive students are eligible to enter the study. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

##### Settings and conduct

Interventions will be taken to prevent and reduce aggression in Kermanshah and in the school environment. Participants are randomly divided into two groups of intervention and control. Interventions will be provided in the intervention group

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Students without psychological problems students in schools in Kermanshah; exclusion criteria: Having acute mental illness Rural students

##### Intervention groups

Intervention group: Male and female students in elementary schools with high aggression levels that receive interventions to reduce aggression Control group: Male and female students in elementary schools that do not receive any intervention.

##### Main outcome variables

Social competence; physical aggression; verbal aggression; relational aggression; knowledge; outcome expectations; outcome expectancies ; self-efficacy; observational learning; social impacts; social support

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151112025014N3**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-21, 1396/11/01**

Update count: **1**

##### Registration date

2018-01-21, 1396/11/01

##### Registrant information

###### Name

Nooshin Salimi

###### Name of organization / entity

Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 4833 1629

###### Email address

n.salimi@edu.umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-01-10, 1396/10/20

##### Expected recruitment end date

2019-04-09, 1398/01/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

effectiveness of an intervention on aggressive behaviors in elementary students

##### Public title

effectiveness of an intervention on aggressive behaviors in elementary students

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Students who studying in elementary schools in the Second course Students who studying at the Kermanshah City Schools. Students who have no acute psychological problem. Students whose parents are satisfied with their child's participation in the study.

**Exclusion criteria:**

Mental illness confirmed by a doctor

**Age**

From **9 years** old to **13 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **280**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, stratified random sampling method will be used and the sample classes studied will be based on the gender of students (boy / girl), school status in terms of implementation of the program of health promoting schools(health promotion / non-promotion schools) and the region Urban (semi-possessed / disadvantaged) will be selected. Then the list of schools and the number of elementary students in the second course of the city of Kermanshah will be collected from the Department of Education. The required sample, in terms of student size and the number of schools in each class, will be selected by table of random numbers and by considering the different economic status.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants are unaware of the allocation of study groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

In this study, an ecological model (individual, interpersonal, organizational, and policy levels) will be used to explore the various components of the whole school approach in prevention of aggression.

**Secondary Ids**

empty

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

Ethics committee of Hamadan University of Medical

Sciences

**Street address**

Hamadan University of Medical Sciences; Front of the people park

**City**

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**Province**

Hamadan

**Postal code**

6517838736

**Approval date**

2017-12-16, 1396/09/25

**Ethics committee reference number**

IR.UMSHA.REC.1396.638

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

aggression

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Physical aggression

**Timepoint**

Before intervention, 7 days after intervention and 6 months after intervention

**Method of measurement**

Adolescent Peer Relations Instrument

**2****Description**

Verbal aggression

**Timepoint**

Before intervention, 7 days after intervention and 6 months after intervention

**Method of measurement**

Adolescent Peer Relations Instrument

**3****Description**

Relational aggression

**Timepoint**

Before intervention, 7 days after intervention and 6 months after intervention

**Method of measurement**

Adolescent Peer Relations Instrument

**4****Description**

knowledge

**Timepoint**

Before intervention, 7 days after intervention and 6

months after intervention

**Method of measurement**

Researcher made questionnaire

**5**

**Description**

outcome expectations

**Timepoint**

Before intervention, 7 days after intervention and 6 months after intervention

**Method of measurement**

Researcher made questionnaire

**6**

**Description**

outcome expectancies

**Timepoint**

Before intervention, 7 days after intervention and 6 months after intervention

**Method of measurement**

Researcher made questionnaire

**7**

**Description**

self-efficacy

**Timepoint**

Before intervention, 7 days after intervention and 6 months after intervention

**Method of measurement**

Researcher made questionnaire

**8**

**Description**

social support

**Timepoint**

Before intervention, 7 days after intervention and 6 months after intervention

**Method of measurement**

Researcher made questionnaire

**9**

**Description**

Social impacts

**Timepoint**

Before intervention, 7 days after intervention and 6 months after intervention

**Method of measurement**

Researcher made questionnaire

**Secondary outcomes**

**1**

**Description**

Social competence

**Timepoint**

Before intervention, 7 days after intervention and 6 months after intervention

**Method of measurement**

Social competence questionnaire

**Intervention groups**

**1**

**Description**

Intervention group: 5 Educational sessions; 10 sessions of psychological counseling; educational booklet; poster and educational banner; Role playing

**Category**

Behavior

**2**

**Description**

Control group: This group does not receive any intervention.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Elementary schools in Kermanshah

**Full name of responsible person**

Nooshin Salimi

**Street address**

Hamedan, Shahid Fahmida Blvd, near Bu'ali University, Hamedan University of Medical Sciences, School of Public Health

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N.SALIMI@EDU.UMSHA.AC.IR

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

saeid bashirian

**Street address**

Shahid Fahmidah Boulevard, Daneshgah-e-Bu Ali Sina, Hamadan Province

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**Email**

s\_bashirian@yahoo.com

**Web page address**

http://research.umsha.ac.ir/index.aspx?fkeyid=&siteid=36&pageid=2049

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Nooshin Salimi

**Position**

Phd Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

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**Latest degree**

Master

**Other areas of specialty/work**

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Nooshin salimi

**Position**

Phd candidate

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

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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**

Not applicable

**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**

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