

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The Effect of the Self-Care Educations on Knowledge and Protective Behaviors of 5-6 Aged Children of Kindergartens of Tehran Welfare Organization

Protocol summary

Study aim

The determination of effectiveness of self-care educations on knowledge and protective behaviors of children

Design

Randomized clinical trial with two control and intervention group.35 children are chosen as intervention group .35 children are chosen as control group . Systematic randomized sampling method .One blinded study.

Settings and conduct

This study is a randomized clinical trial that will be done in the kindergartens of welfare organization of Tehran.Samples are 70 children between the age of 5-6 that are allocated into two control and intervention group by randomization. Four educational sessions are represented to intervention group.One educational session is represented to control group.Post test is done one month after the intervention.The study is one-blinded and samples aren't informed of allocation into control and intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children between the age of 5-6. Children with no physical or mental disability. Children who haven't participated in child sexual abuse educational programm in the past. Exclusion criteria: Children whose parents didn't consent to their participation in the study Physical or mental disability during the study

Intervention groups

Intervention group :35 children between the age of 5-6 are chosen as intervention group .Four educational sessions about child sexual abuse are represented to them . Children will learn that some places and things are private , also they will learn about privacy, different kinds of touches and requests. Saying firm "no" is taught. they will learn how to react in the situation of abuse .

Control group::35 children between the age of 5-6 are chosen as control group. One educational session about safety of accidents is represented to them .

Main outcome variables

Knowledge of children protective behaviors of children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190713044192N1**

Registration date: **2019-11-03, 1398/08/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-03, 1398/08/12**

Update count: **0**

Registration date

2019-11-03, 1398/08/12

Registrant information

Name

Zohreh Maleki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3348 4604

Email address

iris_decor_group@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of the Self-Care Educations on Knowledge and Protective Behaviors of 5-6 Aged Children of Kindergartens of Tehran Welfare Organization

Public title

The Effect of the Self-Care Educations on Knowledge and Protective Behaviors of Children

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Children between the age of 5-6 . Children with no physical or mental disability. Children who haven't participated in child sexual abuse prevention educational programs in the past

Exclusion criteria:

Children whose parents didn't consent to their participation in the study Physical or mental disability during the study

Age

From **5 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method is cluster sampling.Tehran is divided in to 5 clusters (north, south, east, west and the center).One kindergarten is chosen as intervention group and one kindergarten is considered as control group.In each kinder garten , samples are chosen by systematic randomization .For this randomization, one number is chosen from 1-10.the population of each kindergarten is divided to the considered sample size to determine the samples interval.the determined interval is added to the randomized beginner number till the sampling is done.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this research, one kindergarten is chosen as intervention group and another one is chosen as control group in each cluster, so samples aren't informed of allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Science

Street address

Ghods street, Enghelab square

City

Tehran

Province

Tehran

Postal code

3439123900

Approval date

2019-05-19, 1398/02/29

Ethics committee reference number

IR.TUMS.FNM.REC.1398.021

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

Knowledge and protective behavior of children

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

The earned score of children's knowledge about child sexual abuse based on PSQ(personal safety questionnaire).

Timepoint

Evaluation of children's knowledge before the intervention via pre-test and evaluation of children's knowledge one month after the intervention via post-test

Method of measurement

PSQ(personal safety questionnaire) for evaluation of knowledge level

2**Description**

The earned score of children's protective behavior based on WIST(what if situation test)

Timepoint

Evaluation of children's protective behavior before the intervention via pre-test and evaluation of children's protective behavior one month after the intervention via post-test

Method of measurement

WIST(what if situation test) questionnaire for evaluation of protective behavior of children

Secondary outcomes

empty

Intervention groups

1

Description

4 educational sessions about child sexual abuse prevention are represented to intervention group . Children will learn about privacy and private things, different types of touches and requests.They will acquire the skill of saying firm "no", also will learn how to react in the situation of abuse and how to protect themselves.

Category

Prevention

2

Description

Control group: One educational session about safety of accident is represented to control group.Children learn how to protect themselves in the situation of flood and earthquake.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kindergartens of Tehran

Full name of responsible person

Tehran state welfare organization

Street address

Zafar street-Valiasr street

City

Tehran

Province

Tehran

Postal code

1968713111

Phone

+98 21 8887 9594

Email

child@behzisti.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadali Sahraeian

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1417653761

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Email

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Farnaz Farnam

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Tohid square-Faculty of nursing and midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zohre Maleki

Position

Midwife

Latest degree

Bachelor

Other areas of specialty/work

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

Tehran University of Medical Sciences

Full name of responsible person

Zohre Maleki

Position

Midwife

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participant's informations are secret.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

One copy of thesis is kept in library of Faculty of midwifery and nursing of TUMS

When the data will become available and for how long

No limited timespan

To whom data/document is available

All the collegians of Faculty of midwifery and nursing of TUMS

Under which criteria data/document could be used

-

From where data/document is obtainable

Faculty of midwifery and nursing of TUMS

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

-

Comments