

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of self care education By workshop method for mothers in prevention of self medication to children

Protocol summary

Study aim

General purpose: determination the effect of self care education By workshop method for mothers in prevention of self medication to children

Design

Clinical trials with community based control group, with parallel and randomized blocks, with a block size of 53 samples per group (106)

Settings and conduct

The present study is a randomized clinical trial study. The research population includes all mothers under the age of six years covered by health centers in Shazand. Methods: At first, the pretest will be taken from the control group and then the pretest and educational intervention will be performed for the test group. The control group will receive the usual care at the center. The research includes 5 sessions of 2 hours in a workshop that includes education self care in mild illnesses in children and self-medication in this regard and the expression of the complications and consequences of drug abuse for children based on cognitive theory constructs The Bandura Social will be taught .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers with child under the age of 6 years Mothers who have the ability to read and write Mothers self reported about not having mental problems Mothers with child without chronic disease Exclusion criteria: Mothers who are Health Ambassadors Unwillingness to continue to participate in research Absence of more than two consecutive sessions in classrooms

Intervention groups

Intervention group: Participate in training sessions includes 5 sessions 2 hours with self-care educational content in minor children's illnesses Control group: Get regular care at the health center

Main outcome variables

Self-care education based on the structures of social

cognitive theory Self-care knowledge, Expectations of the consequences , Social support, Self efficacy in self care Mothers' practice in self medication

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180524039819N1**

Registration date: **2018-07-28, 1397/05/06**

Registration timing: **prospective**

Last update: **2018-07-28, 1397/05/06**

Update count: **0**

Registration date

2018-07-28, 1397/05/06

Registrant information

Name

Akram Naeimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

a-naeimi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-30, 1397/05/08

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of self care education By workshop method for mothers in prevention of self medication to children

Public title
The effect education in prevention of self medication

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Mothers with child under 6 years of age Mothers who have the ability to read and write Mothers self-reported about not having mental problems Mothers with child without chronic disease
Exclusion criteria:
 Mothers who are Health Ambassadors

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: block Random unit: Individual
Randomization Tool: Online Software

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Use of Bandura Social Cognitive Theory

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Tehran University of Medical Sciences
Street address
 Ghodss St,Keshavarz Blvd, Central Office of Tehran University of Medical Sciences
City
 Tehran

Province
Tehran
Postal code
1417653761
Approval date
2017-09-05, 1396/06/14
Ethics committee reference number
IR.TUMS.FNM.REC.1396.3391

Health conditions studied

1

Description of health condition studied

Prevention of self medication

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Practice on self medication

Timepoint

Before the beginning of the study and 3 months after the educational intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Knowledge and awareness

Timepoint

Before the beginning of the study and 3 months after the educational intervention

Method of measurement

Questionnaire

2

Description

Expect the outcome

Timepoint

Before the beginning of the study and 3 months after the educational intervention

Method of measurement

Questionnaire

3

Description

Social support

Timepoint

Before the beginning of the study and 3 months after the educational intervention

Method of measurement

Questionnaire

4

Description

Self-efficacy

Timepoint

Before the beginning of the study and 3 months after the educational intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: 5 sessions of 2 hours, in a workshop for 2 months, the content of the education included self-care book on minor illnesses the part childhood approved by the Ministry of Health and Medical Education

Category

Prevention

2

Description

Control group: Get regular health care center care

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Services Centers number1

Full name of responsible person

Majid Shams

Street address

Enghelab Street, Imam Hossein Square, Comprehensive Health Services Center

City

Shazand

Province

Markazi

Postal code

3861818547

Phone

+98 86 3822 2050

Fax

+98 86 3822 6377

Email

shazandshabakeh@arakmu.ac.ir

Web page address

https://shazanddh.arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

Ghods St, Keshavarz Blvd, Central Organization of the University, Sixth Department of Research and Technology

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3698

Email

rmo@tums.ac.ir

Web page address

http://vcr.tums.ac.ir

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

Akram Naeimi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Dr Mirkhani St. (Eastern Nusrat), Tavid Square, School of Nursing and Midwifery

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Fax
+98 21 6690 4252
Email
mnaeimi88@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahzad PashaeiPour
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Dr Mirkhani St. (Eastern Nusrat),Tavid Square. School of Nursing and Midwifery
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Fax
+98 21 6690 4252
Email
pashaeypoor.sh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akram Naeimi
Position
Student Master
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Dr Mirkhani St. (Eastern Nusrat),Tavid Square,Faculty of Nursing and Midwifery

City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Email
mnaeimi88@yahoo.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

Not applicable

Informed Consent Form

Yes - There is 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 main implications are interchangeable, including mothers'practice in self medication use and And the effect of education on the structures of social cognitive theory

When the data will become available and for how long

Start one year after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Access to data and documentation is available in accordance with Tehran University of Medical Sciences

From where data/document is obtainable

To access the data, I am referring to Akram Naeimi E-mail: mnaeimi88@yahoo.com

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

The applicant receives the data after sending the email to the address given and presenting the goals of accessing the data and after clarifying the accuracy of the goals according to the criteria of the Tehran University of Medical Sciences and the magazine that scanned the article can access the data.

Comments