

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Effect of Training Intervention Based on Gagne's Model on Knowledge, Performance, and Decision Making Power of Mothers of young children Regarding Management of Domestic Injuries

Protocol summary

Study aim

The aim of the present research is to investigate the effect of training intervention based on Gagne's model on awareness, performance and decision making power of mothers of young children regarding the management of domestic injuries.

Design

In this research, 110 eligible mothers of young children referring to kindergartens were chosen. then participant were randomly divided into two control and intervention groups.

Settings and conduct

For implementation of this study, in coordination with the management of the selected kindergarten, an invitation will be sent to mothers. At first, the mothers will receive a full description of the implementation of the present study. In this study, for the participant in the intervention group, training sessions will be held based on Gagne's model. There is no blinding for this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria include mothers of young children (3 to 6 year old); a minimum level of education for mothers, high school diploma; consent to participate in the study; mother's health in terms of psychological disorders, communication problems and physical disability; child's health in terms of psychological disorders, developmental, physical, and cognitive delays; parents' employment and education in non medical sciences; and the exclusion criterion is the subject's dissatisfaction with either participating or continuing to participate in the research.

Intervention groups

The intervention group is the mothers who will have training sessions using the steps in the model of Gagne about domestic injuries in young children for them. The control group is a participant who does not receive any intervention in this study.

Main outcome variables

Anticipated consequences are enhanced awareness and decision making power of mothers along with improved performance of them in preventing and managing domestic injuries and effectively memorizing the training content after 21 days of the training intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151019024594N2**

Registration date: **2017-12-31, 1396/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-31, 1396/10/10**

Update count: **0**

Registration date

2017-12-31, 1396/10/10

Registrant information

Name

Seyedeh Zahra Shafipour

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3344 0202

Email address

shafipur@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expenditures approved in the Proposals paid through the government system (Guilan University of Medical Sciences).

Expected recruitment start date

2017-12-26, 1396/10/05

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Training Intervention Based on Gagne's Model on Knowledge, Performance, and Decision Making Power of Mothers of young children Regarding Management of Domestic Injuries

Public title

Effect of Training Mothers of young children Based on Gagne's Model Regarding Management of Domestic Injuries

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Mothers of young children (3 to 5 year old) A minimum level of education for mothers, high school diploma Consent to participate in the study Mother's health in terms of psychological disorders, communication problems and physical disability Child's health in terms of psychological disorders, developmental, physical, and cognitive delays Parents' employment and education in non medical sciences

Exclusion criteria:

Dissatisfaction with participating in any stage of the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **110****Randomization (investigator's opinion)**

Randomized

Randomization description

After getting the necessary permissions from the authorities in question and getting consent from the mothers for participating in the study, the kindergartens of Rasht and the samples will be selected randomly using a two stage cluster sampling. In the first stage, cluster sampling will be conducted using the list obtained from Guilan Welfare Organization, according to which 132 active kindergartens work in Rasht, and according to random numbers table and from each geographical point of Rasht (north, south, center, east and west), one kindergarten will be selected as the intervention and one kindergarten as a the control. Overall, 10 kindergartens will be sampled for intervention and control groups.

Then, in the second stage of cluster sampling, in the selected kindergartens, given the register and with the help of random numbers table, the children from 3 to 5 will be selected and by holding a meeting to introduce the present study, we will talk with the mothers of these children on the participation in the study. Finally, in each of the two intervention and control groups, 55 subject with the inclusion criteria will be selected.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

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

Ethics committee of Guilan University of Medical Sciences

Street address

Deputy of research and technology, Shahid Siadati St., Namjoo Ave, Guilan, Rasht, Islamic Republic of Iran

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2017-11-25, 1396/09/04

Ethics committee reference number

IR.GUMS.REC.1396.337

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

burning

ICD-10 code

T29

ICD-10 code description

Injury, poisoning and certain other consequences of external causes

2**Description of health condition studied**

poisoning

ICD-10 code

X40

ICD-10 code description

External causes of morbidity and mortality

3

Description of health condition studied

fall

ICD-10 code

W13

ICD-10 code description

External causes of morbidity and mortality

4

Description of health condition studied

choking

ICD-10 code

W79

ICD-10 code description

External causes of morbidity and mortality

Primary outcomes

1

Description

Knowledge score of mothers of young children in researcher made questionnaire

Timepoint

Before the intervention, immediately after the intervention and 21 days after the intervention

Method of measurement

questionnaire

2

Description

Performance score of mothers of young children in researcher made questionnaire

Timepoint

Before the intervention, immediately after the intervention and 21 days after the intervention

Method of measurement

questionnaire

3

Description

Decision making power score of mothers of young children in researcher made questionnaire

Timepoint

Before the intervention, immediately after the intervention and 21 days after the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this research, intervention is an educational type. Training sessions will be held for mothers of the intervention group for two sessions in two consecutive days in groups of 5 or 6, and for 90 minutes, using Gagne's model step by step protocols for home injuries in young children. According to the pediatric medical and nursing resources and researches, injuries of falling and falling, poisoning, burning, foreign body swallowing, and choking are the most common domestic injuries in young children, so in this study, these same injuries are also taught to teach how Prevention of injury and training after they occur. It should be noted that on the first day of training the goals associated with burn injuries and falling from the high and on the day two goals associated with the damage to the poisoning and ingestion of foreign body and choking will be implemented.

Category

Prevention

2

Description

Control group: The mothers in control group will not be provided with any training course. However, following the end of the training sessions for the mothers in intervention group, for ethical reasons, the training booklet will be further provided to the mothers in control group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kindergartens

Full name of responsible person

General manager of State Welfare Organization of Guilan Province

Street address

State Welfare Organization of Guilan Province, Parastar Street, Rasht, Guilan, Islamic Republic of Iran

City

Rasht

Province

Guilan

Postal code

413451833

Phone

+98 13 3332 4505

Email

modiriat@behzisty-guilan.ir

Web page address

<http://behzisty-guilan.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati

Street address

Research and Development Deputy of Gilan
University of Medical Sciences, Shahid Siadati St.,
Namjoo Street, Rasht, Guilan, Islamic Republic of Iran

City

Rasht

Province

Guilan

Postal code

4144666949

Phone

+98 13 3333 5820

Fax

+98 13 3333 6395

Email

nemati@gums.ac.ir

Web page address

<http://www.gums.ac.ir/>

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

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**

Rasht University of Medical Sciences

Full name of responsible person

Seyedeh Zahra Shafipour

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahid Beheshti Faculty of Nursing and Midwifery,
Student Street, Shahid Beheshti Highway, Rasht,

Guilan, Islamic Republic of Iran

City

Rasht

Province

Guilan

Postal code

4146939841

Phone

+98 13 3355 5058

Fax

+98 13 3355 0097

Email

shafipur@gums.ac.ir

Web page address

<http://www.gums.ac.ir/>

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Seyedeh Zahra Shafipour

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahid Beheshti Faculty of Nursing and Midwifery,
Student Street, Shahid Beheshti Highway, Rasht,
Guilan, Islamic Republic of Iran

City

Rasht

Province

Guilan

Postal code

4146939841

Phone

+98 13 3355 5058

Fax

+98 13 3355 0097

Email

shafipur@gums.ac.ir

Web page address

<http://www.gums.ac.ir/>

Person responsible for updating data

Contact**Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Neda Asadollahzadeh

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahid Beheshti Faculty of Nursing and Midwifery,
Student Street, Shahid Beheshti Highway, Rasht,
Guilan, Islamic Republic of Iran

City

Rasht

Province

Guilan

Postal code

4146939841

Phone

+98 13 3360 2442

Fax**Email**

hamsangar.kdm@gmail.com

Web page address

<http://www.gums.ac.ir/>

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

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

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