Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The impact of multi-media education on the knowledge and practice of mothers of infants with colostomy :A randomized clinical trail

Protocol summary

Summary

The aim of this randomized controlled clinical trial is to determine the impact of multimedia education on the knowledge and practice of mothers of infants with colostomy. In this study; 60 mothers of the infants with colostomy will contributed. Inclusion criteria: infants aged between 2-28 days; having colostomy due to a disease of the digestive system; infants with only malformations of the digestive system; 2 days after the infants surgery; mothers' willingness to participate in the study; mothers should be a main caregiver; mothers who are literate) and the mother will be excluded from study in the case of infant death or cooperation refusal. All mothers of the infants with colostomy will be randomly assigned into two groups by using sealed envelopes. There is written allocation code of participants study groups. The intervention group will learn how to take care of colostomy through using one CD and control group will learn the process using one booklet. Booklet and CD contents both are identical. In both groups; knowledge questionnaire and practice checklist will be completed before intervention and 5 days and one month after intervention and mean of mothers' knowledge and practice will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601264613N17**
Registration date: **2016-10-01, 1395/07/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-01, 1395/07/10

Registrant information

Name
Sousan Valizadeh Dehkharghani
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
009804134751706- 34796770
Email address
valizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tabriz University of Medical Sciences

Expected recruitment start date

2016-09-29, 1395/07/08

Expected recruitment end date

2017-01-18, 1395/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of multi-media education on the knowledge and practice of mothers of infants with colostomy :A randomized clinical trail

Public title

Multi-media education's impact on the knowledge and practice of mothers of infants with colostomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria for mothers: age between 18-45 years; mothers' willingness to participate in the study; mothers

should be a main caregiver; mothers who are literate. Inclusion criteria for infants: age 2-28 days; with colostomy due to a disease of the digestive system; only malformations of the digestive system; 2 days after the infants surgery. Exclusion criteria from study in the case noncooperation or refusal of mother. Exclusion criterion for infants: infant death

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
All mothers of the infants with colostomy will be randomly assigned into two groups by using sealed envelopes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Regional committee of ethics in medical research of Tabriz University of Medical Sciences

Street address
Vice Chancellor for Research and Technology, Tabriz University of Medical Sciences, Golgasht street

City
Tabriz

Postal code
Iran

Approval date
2016-05-09, 1395/02/20

Ethics committee reference number
IR.TBZMED.REC.1395.603

Health conditions studied

1

Description of health condition studied
infants colostomy

ICD-10 code
Z93.3

ICD-10 code description
Colostomy status

Primary outcomes

1

Description
Mothers' knowledge

Timepoint
Before intervention, 5 days and 1 month after intervention

Method of measurement
Knowledge questionaire

2

Description
Practice of mothers

Timepoint
Before intervention and 5 days and 1 month after intervention

Method of measurement
Observation checklist for practice

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group will receive the education on how to take care of colostomy through a film that will be displayed by researcher personal laptop in a twenty-minute session.

Category
N/A

2

Description
Control group will learn how to take care of colostomy using routine booklet in one twenty-minute session.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Children Hospital

Full name of responsible person
Akram Mehri Gavgani

Street address

Sheshgelan street, before Qari bridge
City
Tabriz

2

Recruitment center
Name of recruitment center
Mofid Children's Hospital
Full name of responsible person
Dr. Ahmad Khalegh Nejad Tabari
Street address
Mofid Children's Hospital, near Mirdamad Blvd., Dr Ali Shariaty Street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research of Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Rashidi
Street address
Deputy of Research and Technology,Tabriz University of Medical Sciences, Golgasht street,Tabriz, East Azarbaijan,
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Research of Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Akram Mehri Gavgani
Position
Student of master degree in Neonatal Intensive Care Nursing
Other areas of specialty/work
Street address
School of Nursing and Midwifery, South Shariati Street , Tabriz
City
Tabriz
Postal code
44199-51668
Phone
+98 41 3442 4864
Fax
Email
ayleen1386@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Sousan Valizadeh
Position
Associate professor of Child health and Neonatal Intensive Care Department,Phd in Nursing Education
Other areas of specialty/work
Street address
Nursing and Midwifery Faculty, South Shariati Street,Tabriz, Iran
City
Tabriz
Postal code
44199-51668
Phone
+98 41 3479 0364
Fax
+98 41 3479 6969
Email
valizades@tbzmed.ac.irvalizadehsousan13@gmail.com
Web page address
http://researchvice.tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz Universityof Medical Sciences
Full name of responsible person
Akram Mehri Gavgani
Position
Student of Master degree in Neonatal Intensive Care Nursing
Other areas of specialty/work
Street address
School of Nursing and Midwifery, South Shariati street, Tabriz
City
Tabriz
Postal code

44199-51668
Phone
+98 41 3479 0364
Fax
+98 41 3479 0364
Email
ayleen1386@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty