

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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 questionnaire

### **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 Gavvani

##### **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

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**Person responsible for scientific inquiries**

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**Name of organization / entity**

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**Position**

Associate professor of Child health and Neonatal Intensive Care Department, Phd in Nursing Education

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**Full name of responsible person**

Akram Mehri Gavgani

**Position**

Student of Master degree in Neonatal Intensive Care Nursing

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**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*