

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Investigating the effect of Family Centered Care education to health care provider based on meaningful learning theory on caregiver burden and self-efficacy in the parents of hospitalized children

Protocol summary

Study aim

Determining the effect of PFCC education to health care provider based on meaningful learning theory on caregiver burden and self-efficacy in the parents of hospitalized children

Design

A before and after semi-experimental study with simultaneous and unequal control group on 30 parents of hospitalized children in each control and intervention group

Settings and conduct

The study will be performed in two hospitals Pediatric Medical Center and Mofid. Research samples will be parents of children with chronic diseases in two gastrointestinal sections of both hospitals. In both sections, the questionnaire "Parent Participation Attitude Scale" will be completed. Also, sampling of parents will be done consecutively until the sample size is reached. Care burden and self-efficacy questionnaires will be completed by parents. Then, health care of the intervention group will be trained in PFCC care training program based on the theory of meaningful learning in 5 sessions. The questionnaire will be completed again two months after the last staff training sessions. Care burden and self-efficacy questionnaires will be completed by re-sampling 30 parents.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a child hospitalized because of chronic illness; Having a child hospitalized more than twice because of chronic illness; No parents or other family members have a chronic illness; The mother is not the head of the family. Exclusion criteria: There is no criteria.

Intervention groups

PFCC training based on the theory of meaningful learning will be provided to the health care of intervention group. In this study, parents will be examined for care burden,

self-efficacy, PFCC perception, and staff for attitudes toward parental participation.

Main outcome variables

Care burden; parental self-efficacy; Parent Participation Attitude; Parental PFCC perception

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211111053035N1**

Registration date: **2022-02-06, 1400/11/17**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-06, 1400/11/17**

Update count: **0**

Registration date

2022-02-06, 1400/11/17

Registrant information

Name

Soheila Moutamedifard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3673 0678

Email address

smoutamedifard@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Family Centered Care education to health care provider based on meaningful learning theory on caregiver burden and self-efficacy in the parents of hospitalized children

Public title

Effect of family centered care on parent's caregiver burden and self-efficacy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a child hospitalized because of chronic illness
Having a child hospitalized more than twice because of chronic illness
No parents or other family members have a chronic illness
The mother is not the head of the family

Exclusion criteria:

There is no criteria.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: 30

Randomization (investigator's opinion)

Not randomized

Randomization description**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 nursing an midwifery school and Rehabilitation school of tehran university of me

Street address

Nosrat St, District 6, Tehran Province, Tehran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2021-09-01, 1400/06/10

Ethics committee reference number

IR.TUMS.FNM.REC.1400.183

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

Care burden

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Parental self-efficacy

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Patient and Family Centered Care

ICD-10 code**ICD-10 code description****4****Description of health condition studied**

Meaningful learning

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

Care burden score in Family Impact Scale

Timepoint

Before intervention and 2 months after the last educational session for health care

Method of measurement

"Impact on family" scale for assessing parental care burden and

2**Description**

parental self-efficacy score in perceived self-efficacy questionnaire

Timepoint

Before intervention and 2 months after the last educational session for health care

Method of measurement

"perceived maternal parenting self-efficacy"
questionnaire far parental self-efficacy

Secondary outcomes

1

Description

Perception score of family-centered care

Timepoint

Before intervention and 2 months after the last session of educating health care

Method of measurement

Perception family centered care of parents (PFCC-P)

2

Description

Health care attitudes scale toward parent participation in hospitalized children's care.

Timepoint

Before intervention and 2 months after the last session of educating health care

Method of measurement

"Health professionals' attitudes toward parent participation in hospitalized children's care" questionnaire.

Intervention groups

1

Description

Intervention group: The intervention will be PFCC education based on David Azobel's theory of meaningful learning. Educational content will be presented in 5 educational sessions for 90 minutes after content validity. Training of 5 main sessions in accordance with the conditions of the Covid-19 pandemic will be done online by recording the content of the classes. So that the content of the meetings can be made available to people who could not attend the meetings. It will also be done in proportion to the time available in the discussion section on the subject at the time of changing shifts and with the presence of the maximum number of healthcare and during the group meetings of physicians.

Performance of healthcare will be completed by a checklist for observing and evaluating the performance of the researcher in three different shifts for each health care, and if any of the options are not observed, the necessary explanations will be given to the health care. Due to the fact that patients and families are in more direct contact with physicians, nurses and assistant nurses, educational content will be provided to these three groups. After the training sessions, the approved plan is expected to be implemented during the training sessions during the work shifts and during the patient care-treatment process. At this time, the main role will be played by the honorable head of the ward and the head nurse of the ward in the implementation of the plan. The steps of teaching patient and family-centered

content based on the theory of meaningful learning are described below. At the beginning of the meeting, the purpose of the meeting and a brief explanation of the topic is presented in the form of a question. Then the participants' knowledge of different aspects of the topic will be measured (pre-organizer). In the next step, participants are asked about what they do not know or would like to know about the topic (motivating and preparing for new knowledge). In the next stage, the new knowledge is taught by expressing the case method, giving similar examples and asking questions of the participants and asking them to express their similar experiences. Health care are then asked to apply what they have learned, ask parents about the issues raised, and finally participate in the next session by drawing a concept map of the content of the session (role of assignments in theory).

Category

Other

2

Description

Control group: The control group will only complete the study questionnaires and will not receive any intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Children health medical center

Full name of responsible person

D.r Reza Shervin Badvi

Street address

No. 62, D.r Mohammad Gharib Ave., the end of Keshavarz Blvd., next to Emam Khomeini hospital

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cmcpr@tums.ac.ir

Web page address

<https://chmc.tums.ac.ir/>

2

Recruitment center

Name of recruitment center

Mofid

Full name of responsible person

D.r Shamsollah Nooripour

Street address

Shari'ati Ave., after Hosseinie Ershad, before Mirdamad Ave.

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1551415468

Phone

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Fax

Email

www.info-mch@sbmu.ac.ir

Web page address

https://mch.sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

D.r Mozhgan Karbakhsh Davari

Street address

Ghods Ave., IT center, 6th floor, room 605, Technology Management and Research Unit

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Phone

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Fax

+98 21 8163 3639

Email

www.research@tums.ac.ir

Web page address

https://rmo.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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

Soheila Moutamedifard

Position

Student

Latest degree

Master

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Soheila Moutamedifard

Position

Soheila Moutamedifard

Latest degree

Master

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

Soheila Moutamedifard

Position

Student

Latest degree

Master

Other areas of specialty/work

Pediatrics

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

Yes - There is 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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be 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

Unidentifiable demographic information is fully shareable. The results of the questionnaires on family impact, self-efficacy, parents 'perception of family-centered care and health care providers' attitudes toward parental involvement in inpatient child care can be shared. Educational content is also shareable.

When the data will become available and for how long

It will be possible to share document from the time the results are published.

To whom data/document is available

Data file can be available for people working in academic institutions and students.

Under which criteria data/document could be used

Nothing

From where data/document is obtainable

1. To receive documents and data, send a request to the email address "smoutamedifard@razi.tums.ac.ir". or 2. Sending request to "soheilamotamedifard@yahoo.com"

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

Documents and information will be shared within one month of submitting the request.

Comments