Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 midvifery 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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Phone
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+98 21 6693 0024
Email
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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Tehran

Province
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1551415468

Phone
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Web page address
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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

City
Tehran

Province
Tehran

Postal code
1417653761

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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Position
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Person responsible for updating data

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Full name of responsible person
Soheila Moutamedifard

Position
Student

Latest degree
Master
Other areas of specialty/work
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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