Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Nursing Consultation based on Peplau’s theory on Perceived Stress and Anxiety of Patient's mothers with Gastrointestinal atresia

Protocol summary

Study aim
Evaluation of Nursing Consultation based on Peplau’s theory on Perceived Stress and Anxiety of Patient's mothers with Gastrointestinal atresia

Design
Clinical trial with control group, with parallel groups, one-way blind, randomized, on 60 patients. Permutation blocks were used for randomization.

Settings and conduct
Due to the nature of the study, it is not possible to blind the participants. In both groups, a questionnaire of demographic characteristics and a questionnaire of stress and anxiety will be done. In the intervention group, the therapeutic relationship theory of Peplao will be done individually in 4 stages of acquaintance-identification-exploitation and dissolution. The first stage is a session with a time between 25 to 35 minutes, the second stage 2 to 3 sessions with a time between 30 to 40 minutes, the third stage 2 to 3 sessions with a time of 40 minutes, the fourth stage 2 to 3 sessions with a time between 20 to 30 minutes . Counseling will be individual. After nursing counseling, both groups will be asked to refill out two stress and anxiety questionnaires.

Participants/Inclusion and exclusion criteria
Inclusion criteria: mother with a child with gastrointestinal atresia, willingness to participate in research, new ward admission, informed consent. Failure to enter: Maternal illness and mental disorder

Intervention groups
Intervention group: Counseling based on Hilgard-Peplau theory, oral, individual, face to face.Introduction: Introduction of the researcher. Familiarity of the client with the dimensions of the problem and the degree of need for help. Identification: Identifying the client's fears and anxieties. And termination of therapeutic communication. Control group: Benefit from the usual consultations in the department

Main outcome variables
Stress score and anxiety score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210511051260N1**
Registration date: **2022-02-12, 1400/11/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-12, 1400/11/23**
Update count: **0**

Registration date
2022-02-12, 1400/11/23

Registrant information

Name
Nasrin Safapour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 58 3622 5822

Email address
safapourmn961@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-10, 1400/10/20

Expected recruitment end date
2022-04-20, 1401/01/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Nursing Consultation based on Peplau’s theory on Perceived Stress and Anxiety of Patient's mothers with Gastrointestinal atresia

Public title

Determining the effect of nursing counseling on maternal anxiety

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers whose children have gastrointestinal atresia with a doctor's approval Willingness to participate in research Having informed consent of a healthy mother (has no known psychiatric disorder and is not being treated { has no mood disorders and anxiety and is not being treated in this regard}) The patient is the new admission of the ward and her first surgery in this field.

Exclusion criteria:

Existence of major stressful events in life (death of first-degree relatives, financial bankruptcy, accident, severe family dispute with spouse) during the last 6 months Diagnosis of a known psychiatric disorder in the mother (having a mood and anxiety disorder and being treated) Severe medical disorder known in previous child

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

Stress score and anxiety score (overt and covert)

Randomization (investigator's opinion)

Randomized

Randomization description

In order to assign samples to each of the intervention and control groups, the randomization method with blocks will be used, so that first the size of 4 blocks will be considered. According to the sample size (60 people), 15 blocks will be selected based on a table of random numbers and individuals will be assigned to groups based on their position in the blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

To reduce the bias or bias related to the intervention and evaluate the consequences, the method of blind or covering a blind single blind is followed, with this method, the outcome can be measured objectively. In this method, the trial is planned in such a way that the participant does not know which of the two control or test groups he belongs to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Nursing and Midwifery Mashhad University of Medical Sciences

Street address

Taghiabad Street,PhD Cross,School of Nursing and Midwifery.Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

95671-63941

Approval date

2021-07-06, 1400/04/15

Ethics committee reference number

IR.MUMS.NURSE.REC.1400.041

Health conditions studied

1

Description of health condition studied

Gastrointestinal atresia

ICD-10 code

Q41.8

ICD-10 code description

Congenital absence, atresia and stenosis of other specified parts of small intestine

Primary outcomes

1

Description

Perceived stress score

Timepoint

Perceived stress score with the help of a questionnaire in two stages before the intervention (beginning of the study) and after the intervention (end of the study)

Method of measurement

Cohen Perceived Stress Questionnaire (PSS-14)

2

Description
Anxiety score
Timepoint
Anxiety scores with the help of Anxiety Questionnaire in two stages before the intervention (beginning of the study) and after the intervention (end of the study)
Method of measurement
Spielberger Anxiety Inventory (STAI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, Peplae's therapeutic communication theory is performed individually in 4 stages: introduction, identification, exploitation and dissolution, and re-testing is performed after the sessions. Introduction: Introducing the researcher to the child care client with gastrointestinal atresia - Gaining the client's trust - Explaining the present research - Clarifying the client's expectations from the treatment team (nurse, doctor and members of the treatment team) Patient - Defining the problem and deciding on the type of services required - A brief and understandable explanation to the client about the treatment and care that will be provided by the treatment team for the sick child - Determining the help needed by the client with a sick child from the treatment team : Choosing the right professional help - Encouraging the client to express feelings and ambiguities - Asking and answering the client's questions - Talking about the client's fears and stresses and anxiety - Talking about the client's issues and problems in relation to the sick child - Creating a sense of belonging And the ability to deal with the problem in the client. Exploitation stage: Using professional assistance to the client based on the patient's child's problems-Expressing the benefits of services used based on needs-Creating a sense of the client's important role as an integral part of the child care environment Patient-Leading the client to gain independence in caring Sick child-care planning based on each patient's problems-two to three sessions before reaching the closing stage Reminding the client to the sick child-problem solving and closing stage: termination of professional relationships-examining the positive and negative aspects of the program from the client's point of view-evaluation Results or not? - If not, why? - Investigate the reasons for the failure of the program and what should be done to achieve success - Provide pamphlets - CDs - Booklets required to inform the client to continue caring for the sick child In-house meetings are done individually and all face-to-face and oral consultations are done with educational aids such as pamphlets, booklets and educational CDs. The entire course lasts 8 months.
Category
Treatment - Other

2

Description
Control group: They did not receive any training program and in only two sessions, at the beginning and end of the study, they were given the Demographic Information Questionnaire and the Disease Profile Questionnaire, the Cohen Perceived Stress Questionnaire (PSS-14) and the Spielberger Anxiety Inventory (STAI)
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Children's Specialized Hospital, Mashhad
Full name of responsible person
Dr. Seyed Ali Jafari
Street address
14th In front of Shahid Kaveh,Shahid Kaveh Blvd,Mashhad, Khorasan Razavi.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177897157
Phone
+98 51 3871 3801
Email
ak.pr @ mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Vice Chancellor of Mashhad University of Medical Science
Full name of responsible person
Dr Majed Ghayour
Street address
Third floor, Vice Chancellor for Research and Technology, University of Medical Sciences, next to Hoveyzeh Cinema, Daneshgah St., Mashhad, Khorasan Razavi, Iran
City
Mashhsd
Province
Razavi Khorasan
Postal code
9567163940
Phone
+98 51 3859 1511
Fax
+98 51 3859 1511

Email
GhayourM@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Vice Chancellor of Mashhad University of Medical Science
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
Mashhad University of Medical Sciences
Full name of responsible person
Hamid Reza Behnam Vashani
Position
Instructor of the Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Taghiabad Street,PhD Cross,School of Nursing and Midwifery.Mashhad University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
9567163940
Phone
+98 51 3859 1511
Fax
Email
BEHNAMHR@MUMS.AC.IR

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hamid Reza Behnam Vashani
Position
Instructor of the Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences
Latest degree
Master
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Nursery
Street address
Taghiabad Street,PhD Cross,school of Nursing and Midwifery.Mashhad University of Medical Science
City
Mashhad
Province
Razavi Khorasan
Postal code
9567163940
Phone
+98 51 3859 1511
Email
behnamhr@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hamid Reza Behnam Vashani
Position
Instructor of the Faculty of Nursing and Midwifery Mashhad University of Medical Sciences
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Taghiaba Street .PhD Crossroada.School of Nursing and Midwifery .Mashhad University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
9567163940
Phone
+98 51 3859 1511
Email
behnamhr@mums.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