

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Survey the effect of continuous care model on psychiatry health and quality of life in mothers of children with cerebral palsy

Protocol summary

Study aim

The aim of this study was to evaluate the effect of continuous care model on mental health and quality of life in mothers of children with cerebral palsy.

Design

The present study is a clinical trial study with parallel groups that will be performed on 100 mothers of children with cerebral palsy. Randomization will be done with random blocks allocation.

Settings and conduct

After obtaining informed consent, mothers will be randomly assigned to one of the two intervention and control groups. In both groups, quality of life and mental health will be measured before the intervention. In the control group, only mothers will be provided with routine education about their child's illness and other care. The intervention group will be under continuous care for two months. The quality of life and mental health of both groups will be measured again at the end of the first and second months using the mentioned questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers with children 4 to 12 year-old with cerebral palsy hospitalized and no specific problems affecting the mental health of mothers such as financial crisis. Exclusion criteria: mothers suffering from mental illness and severe anxiety.

Intervention groups

In the control group, routine education about child's illness and other care will be provided for mothers. In the intervention group, first the quality of life and mental health questionnaire will be completed by the mothers and then this group will be under continuous care follow up for two months

Main outcome variables

Mental health; quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200112046102N1**

Registration date: **2020-11-09, 1399/08/19**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-09, 1399/08/19**

Update count: **0**

Registration date

2020-11-09, 1399/08/19

Registrant information

Name

Somaye Pouy

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3355 5056

Email address

somayepouy@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of continuous care model on psychiatry health and quality of life in mothers of children with cerebral palsy

Public title

Survey the effect of continuous care model on psychiatry health and quality of life in mothers of children with cerebral palsy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

1-mothers who have 4 to 12 year-old hospitalized children with cerebral palsy 2- parents not working in health systems 3- no special problem affecting mothers' mental health such as financial crisis.

Exclusion criteria:

Exclusion criteria are: mothers suffer from mental illness and severe anxiety.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocks and "Random allocation software" will be used for randomization. Given that we have two groups, four blocks will be used. The sequence of groups in each block will be determined by the software. To start, the first block is selected by lottery and then this process will be done until the sampling is completed

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 Guilan University of Medical Sciences

Street address

Daneshjoo Ave., Yakhsazi BLV., Rasht

City

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Province

Guilan

Postal code

1267348934

Approval date

2019-03-16, 1397/12/25

Ethics committee reference number

IR.GUMS.REC.1397.526

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

Quality of life

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

Mental health

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

Quality of life

Timepoint

The quality of life of both groups will be measured in three time periods, including after discharge, at the end of the first month and the second month.

Method of measurement

Quality of life will be measured using a short form of quality of life.

2**Description**

Mental health

Timepoint

Mental health of both groups will be measured in three time periods, including after discharge, at the end of the first month and the second month.

Method of measurement

Mental health will be assessed by the General Psychological Health Questionnaire.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intervention will be performed face to face and includes four training stages of the continuous care model in the internal ward of 17-Shahrivar Hospital in Rasht. In this way, after introducing themselves to the mothers and justifying the goals and

methods of work and obtaining informed written consent, the researcher will be provided with mental health and quality of life questionnaires to mothers, and therefore mothers' mental health and quality of life before the intervention will be assessed. The continues care model will then be implemented for two months. The continues care model, which is the native care model of Iran, consists of four stages, which include the stage of identification, sensitization, control and evaluation. In the introductory phase, an hour-long session will be held with the presence of mothers with children with cerebral palsy. In person and by phone. In the sensitization phase, childcare counseling will be conducted both in person in six sessions and by telephone. At this stage, understanding the nature of the disease, early and late complications, how to use their child's medications, how to control anxiety and worry, strategies to improve mental health and quality of life such as following a healthy lifestyle, exercising, avoiding stress and anxiety. They will be given and any questions and concerns will be answered. In the control phase, follow-up care counseling and re-sensitization will be provided on a weekly basis by telephone to review the achievement of follow-up care goals. In the evaluation phase, the researcher will examine the mothers. Then the quality of life and mental health will be measured again at the end of the first and second month using the mentioned questionnaires.

Category

N/A

2

Description

Control group: In the control group, quality of life and mental health questionnaires will be provided to them and only mothers will be provided with routine education about their child's illness and other care provided by the ward nurses. Quality of life and mental health will be measured again at the end of the first and second months using the mentioned questionnaires.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Rasht hospital

Full name of responsible person

Somaye Pouy

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Pediatric hospital, Azodi Ave., Rasht.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Somaye Pouy

Position

PhD student in nursing

Latest degree

Master

Other areas of specialty/work

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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