

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Scheduled Appointments on Family Intensive Care Unit Syndrome

Protocol summary

Study aim

The Effect of Scheduled Appointments on Family Intensive Care Unit Syndrome in the Intensive Care Units (ICU) of Selected Hospitals of Shahid Beheshti University of Medical Sciences.

Design

Semi-experimental study with control group, with parallel groups, without blinding, randomized, on 80 patients. Even and odd case numbers were used for randomization.

Settings and conduct

In the intervention group, family members are present at the patient's bedside and participate in doing daily tasks, and in the control group. The control group will use the routine rules of the intensive care unit of the hospital for visits.

Participants/Inclusion and exclusion criteria

Inclusion criteria: First-degree relatives of patients; Voluntary participation. Exclusion criteria: Lack of doctor's permission for the participation of family members in care; Unwillingness to participate in the study; Self-reported presence of mental disorders; Lack of alertness and full awareness of place, time, person, as well as the ability to speak; The presence of sensory disorders such as vision or hearing problems affecting learning.

Intervention groups

At the beginning and end of the study, the family syndrome check list and the demographic information form will be filled by both intervention and control groups. Intervention Included presence of the patient's family members outside the meeting time (four 20-minute sessions during a week depending on the situation) to participate in daily life activities such as conversation and participating in moving, feeding and massaging the patient, with the presence of researcher. Control group will use the routine rules of the intensive care unit of the hospital for visits.

Main outcome variables

Family Intensive Care Unit Syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210315050712N1**

Registration date: **2022-08-19, 1401/05/28**

Registration timing: **prospective**

Last update: **2022-08-19, 1401/05/28**

Update count: **0**

Registration date

2022-08-19, 1401/05/28

Registrant information

Name

Maedeh Abedi dorcheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2624 4174

Email address

merciful110@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The Effect of Scheduled Appointments on Family Intensive Care Unit Syndrome
Public title	The Effect of Scheduled Appointments on Family Intensive Care Unit Syndrome
Purpose	Health service research
Inclusion/Exclusion criteria	
Inclusion criteria:	Family members of patients hospitalized in the intensive care unit for more than 24 hours First degree relatives of patients Absence of self-reported mental disorders Voluntary participation in the study Absence of sensory disorders such as vision or hearing problems affecting learning
Exclusion criteria:	Lack of doctor's permission for the participation of family members in care Unwillingness to participate in the study Self-reported presence of mental disorders Lack of alertness and full awareness of place, time, person, as well as the ability to speak The presence of sensory disorders such as vision or hearing problems affecting learning
Age	From 18 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization of the study is done by simple random method. At first, two hospitals or two general ICU departments that have more beds and the same conditions in terms of equipment and the same rules and restrictions are selected. Among the family members of patients hospitalized in the relevant departments and those who meet the criteria for entering the study, two intervention and control groups will be selected according to the odd and even file number. In this way, patients are identified with an even file number in the control group and an odd number in the intervention group.
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

Research Ethics Committees of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University

Street address

No. 35, Shahid Mousavi Ave., Kerman Street., Resalat Blvd

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1634678694

Approval date

2022-08-15, 1401/05/24

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.097

Health conditions studied

1

Description of health condition studied

Family Intensive Care Unit Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Family Intensive Care Unit Syndrome

Timepoint

At entering the study (before the intervention), at the end of the first week and at the end of the planned visits.

Method of measurement

The incidence of this syndrome is measured by the score that people get from filling out the syndrome list of the special care patient's family. This list has 31 terms in two dimensions of psychological threat with 17 terms and non-psychological dimension with 14 terms. Scoring on a five-point Likert scale is always (five), usually (four), sometimes (three), rarely (two), never (one). Total scores range from 31 to 155. Based on this, the more points a person gets from the family of the special care patient's syndrome list, the more it will indicate an increase in the special care patient's family syndrome.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before entering the ward, hands are washed according to the instructions and gloves and gowns are worn. In the first meeting with the patient, which will be in the presence of the researcher, according to the doctor's opinion, based on the needs and conditions of the patient and the desire of the family members, participation in daily life activities such as position change and massage will be done. In the next session, depending on the patient's needs, participation in mouthwash or patient nutrition is done in addition to the previous two cares. In the remaining sessions, all contributions will be made depending on the patient's needs. Completing the syndrome list of the patient's family in the intensive care unit is designed in person or by press line and is completed by the research sample (one of the family members). After that, according to the opinion of the visiting person, care training sessions will be arranged and face-to-face in one to two sessions based on the needs of the person, and then a phone number will be provided to them to answer questions.

Category

Prevention

2

Description

Control group: This group will use the routine rules of the intensive care unit of the hospital for visits. Four meetings will be held in accordance with the regulations and restrictions of the department and at the time of the meeting in one week. The control group also receives training related to special care department regulations and meeting hours and compliance with health protocols for special care patients in the form of pamphlets and educational clips. Completing the syndrome list of the patient's family in the intensive care unit is designed in person or by press line and is completed by the research sample (one of the family members). After that, according to the opinion of the visiting person, training sessions will be arranged and face-to-face in one to two sessions based on the needs of the person, and then a phone number will be provided to them to answer questions.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modares and Imam Hossein Hospital

Full name of responsible person

Maedeh Abedi Dorcheh

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No. 35, Unit 3, Kerman St., Mousavi St., Majidieh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Tehran, Shahid Chamran Highway, Yemen St., Shahid Arabi St., Building No. 2, 5th Floor

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Mpajouhesh@sbmu.ac.ir

Web page address

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maedeh Abedi Dorcheh

Position

Nursing master's degree student, Nursing in the intensive care unit

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Leila Khanali Mojn

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Nursing master's degree student, specialized in special care nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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