

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effect of supportive intervention during unplanned transition of the patient from the general ward to the intensive care unit on anxiety and resilience of the family member.

Protocol summary

Study aim

Determining the effect of supportive intervention during unplanned transition of the patient from the general ward to the intensive care unit on anxiety and resilience of the family member.

Design

Randomized clinical trial; whit control group, with parallel groups, without blindness

Settings and conduct

The research community included is the family of adult patients admitted to internal and surgical departments. Patients who are not scheduled are candidates for transfer to a special section. Family members are selected based on defined entry criteria. The research environment will be the internal and surgical sections of the National Bank Hospital.

Participants/Inclusion and exclusion criteria

Entry requirements: 1. The patient is accompanied by relatives of grade 1 (spouse, parents, children, siblings). 2. There is no psychological diagnosis. 3. During the transfer, attend the patient. 4. During the intervention, attend the patient's bedside. 5. The age of the patient is 18 years and older. 6. The family member has not experienced an unplanned transfer to the special department. 7. The family member's anxiety is 40 or older.

Intervention groups

The intervention consists of a patient's family support program by a researcher's nurse who, starting with the patient's change of mind and the team decision, will start emergency delivery to the Icu unit and continue until 72 hours after the transfer of the patient to this department. The control group receives the usual measures to transfer the patient to the special department

Main outcome variables

Investigating anxiety and resilience of a family member of patients who are unplanned as candidates for transfer

to a intensive care unit. The effect of supportive intervention on family anxiety and resilience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100725004443N26**

Registration date: **2019-05-01, 1398/02/11**

Registration timing: **prospective**

Last update: **2019-05-01, 1398/02/11**

Update count: **0**

Registration date

2019-05-01, 1398/02/11

Registrant information

Name

Masoumeh Zakerimoghadam

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supportive intervention during unplanned transition of the patient from the general ward to the intensive care unit on anxiety and resilience of the family member.

Public title

The effect of supportive intervention on anxiety and resilience of family members of patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient is accompanied by relatives of grade 1 (spouse, parents, children, siblings). There is no psychological disorder diagnosed. Be at the patient's side when moving. Being present during the intervention on the patient's bedside. The age of the patient is 18 years and older. The family member has not experienced an unplanned transfer to the special department. The family member's anxiety score is 40 or higher.

Exclusion criteria:

The family member leave the hospital during transfer process. The patient will be transferred from the special department within less than 72 hours. The patient will die during transmission.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **176**

Randomization (investigator's opinion)

Randomized

Randomization description

An easy sampling method is used. To allocate samples, a lottery will be initially selected to select the control group or the test, and then the sampling will be carried out one by one.

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**

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Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.TUMS.FNM.REC.1397.204

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

Unplanned transition of the patient from the general ward to the intensive care unit

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

Anxiety Scale in the The State-Trait Anxiety Inventory (STAI) Questionnaire

Timepoint

Upon notification of the patient's transfer, 2 hours after the transfer of the patient and 72 hours after the transfer of the patient

Method of measurement

State-Trait Anxiety Inventory (STAI) Questionnaire

2**Description**

Resilience scale in the Connor-Davidson Resilience Scale (CD-RISC)

Timepoint

Immediately upon notification of the patient's transfer and 72 hours after the patient's transfer

Method of measurement

Connor-Davidson Resilience Scale (CD-RISC)

Secondary outcomes

empty

Intervention groups

1

Description

Control group:receive the usual care to transfer the patient to the intensive care unit

Category

Treatment - Other

2

Description

Intervention group: In addition to the usual care, they receive supportive care from the moment the patient changes their situation and the treatment team's decision to transfer to the Icu unit for up to 72 hours after the patient's transfer to this department.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

BMI hospital

Full name of responsible person

Masoumeh Zakerimoghadam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Research deputy of Tehran University of Medical Sciences, No. 21, Qods St., Keshavarz Blvd., Tehran Town

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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

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

Zakerimoghadam Masoumeh

Position

Nursing education PHD, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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

Nursing midwifery faculty of Tehran university of medical sciences

Full name of responsible person

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Associate professor

Latest degree

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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