Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Country

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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
کمیته اخلاق دانشگاه علوم پزشکی تهران
Street address
Office building of Tehran University of medical Sciences, Keshavarz St, Tehran.
City
Tehran
Province
Tehran
Postal code
1419733171
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
Dr. Mohammadali Sahraian
Street address
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.
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Person responsible for scientific inquiries

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Person responsible for updating data

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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