

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of nurse's empathy on perceived empathy and anxiety among the elderly patients.

Protocol summary

Study aim

The core of nursing is the communication between the nurses and patients. This is a professional relationship and based on a well-respected approach. One component of this relationship is empathy, which is often described as the ability to feel rather than the other person and from the point of view of others. From the point of view of care, empathy is the ability of accepting a patient and being in the mind of others. The importance of this issue in elderly people can be emphasized due to its population increase as its more vulnerable, in terms of physiological, psychological, social and spiritual (all aspects of health). Anxiety is one of the most important issues and problems of the elderly, which needs special attention. Many studies have been conducted to reduce anxiety by nurses. But little insights have affected the nurse's empathy effect on old patient's anxiety and empathy perception that have been surveyed in this research.

Design

This study is a simple randomized clinical trial with pre-test and post-test design. In this study, 124 old patient admitted to adult surgical wards of Namazi Hospital were randomly assigned to the experimental group (62) and control group ($n = 62$). At the time of admission, they were asked to answer the questions of Jefferson and Spielberger anxiety questionnaire and demographic information. During the hospitalization period, for the test group, in addition to the usual care, the empathy intervention was carried out by the nurses. But control group received a routine care. At the time of discharge, the respondents in both groups answered the questionnaires and asked questions.

Settings and conduct

In this study, 124 old patient admitted to adult surgical wards of Namazi Hospital were randomly assigned to the experimental group (62) and control group ($n = 62$). At the time of admission, they were asked to answer the questions of Jefferson and Spielberger anxiety

questionnaire and demographic information. During the hospitalization period, for the test group, in addition to the usual care, the empathy intervention was carried out by the nurses. But control group received a routine care. At the time of discharge, the respondents in both groups answered the questionnaires and asked questions. The nurse that helped all of patients for completing questionnaires (outcome assessor) and all of patients didn't know which patient is in control or study group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The person's willingness to participate in the study and physical ability to interview and answer the questions of the questionnaires and 60 years old and more patients. Exclusion criteria: Cognitive disorders (Alzheimer and dementia) and use of sedative medications or other methods of such as relaxation and meditation during the study and sedative medications or other methods of reducing anxiety such as relaxation and meditation during the study.

Intervention groups

In both groups, patients were over 60 years of age and they had admitted in surgical wards in Namazi Hospital and were willing to participate in the study with appropriate psychological conditions to participate in the research and answer questions.

Main outcome variables

Analyzing the results of the research presents that the hidden anxiety of the members of both groups didn't have changed (in comparison between the time of the discharge and the time of admission and comparison between two groups). But the apparent anxiety of the research community significantly had decreased in both groups. However, these changes were not significant in comparison with the two groups. Patient's perception of nurse's empathy just had increased in experimental group significantly.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131117015426N6**

Registration date: **2018-01-01, 1396/10/11**

Registration timing: **retrospective**

Last update: **2018-01-01, 1396/10/11**

Update count: **0**

Registration date

2018-01-01, 1396/10/11

Registrant information

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

2017-06-22, 1396/04/01

Actual recruitment end date

2017-10-23, 1396/08/01

Trial completion date

empty

Scientific title

The effect of nurse's empathy on perceived empathy and anxiety among the elderly patients.

Public title

The effect of nurse's empathy on the elderly patients.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The person's willingness to participate in the study.

Physical ability to interview and answer the questions of the questionnaires.

Exclusion criteria:

known case of cognitive disorders (Alzheimer and dementia). use of sedative medications or other methods of such as relaxation and meditation during the study.

Use of sedative medications or other methods of reducing anxiety such as relaxation and meditation during the study.

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **124**

More than 1 sample in each individual

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

In this study,patient's perceived empathy and patient's anxiety assessed.

Actual sample size reached: **124**

More than 1 sample in each individual

Actual sample size in each individual: **2**

In this study,patient's perceived empathy and patient's anxiety assessed.

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a simple randomized clinical trial with pre-test and post-test design. In this study, 124 old patient admitted to adult surgical wards of Namazi Hospital were randomly assigned to the experimental group (62) and control group (n = 62). At the time of admission, they were asked to answer the questions of Jefferson and Spielberger anxiety questionnaire and demographic information. During the hospitalization period, for the test group, in addition to the usual care, the empathy intervention was carried out by the nurses. But contrl group received a routine care. At the time of discharge, the respondents in both groups answered the questionnaires and asked questions.

Blinding (investigator's opinion)

Double blinded

Blinding description

The nurse that helped all of patients for completing questionnaires(outcome assessor)and all of patients didn't know which patient is in control or study group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University Of Medical Sciences

Street address

Zand street

City

Shiraz

Province

Fars

Postal code
71348-14336
Approval date
2016-11-27, 1395/09/07
Ethics committee reference number
IR.SUMS.REC.1395.144

Health conditions studied

1

Description of health condition studied
anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

2

Description of health condition studied
empathy perception
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
empathy perception score with Jefferson questionnaire
Timepoint
patient's admission and discharge times
Method of measurement
Jefferson patient's empathy perception questionnaire(JSPPE)

2

Description
anxiety score with spilberger questionnaire
Timepoint
patient's admission and discharge times
Method of measurement
anxiety spilberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazee hospital
Full name of responsible person
Mehdi Maher
Street address
Namaze hospital, Namazee square, Zand street, Shiraz
City
Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyyed Basir Hashemi
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Grant name
Shiraz University of Medical Sciences, Vice Chancellor for Research Affairs
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Hazrati

Position

Professor assistant

Latest degree

Ph.D.

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