Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of teaching program based on Roy' s adaptation model on quality of life of clients with heart failure

Protocol summary

Summary

From clients with heart failure who refers to Shahid Madani' s heart center 44 patients will be chosen with inclusion criteria by consecutive sampling and conveniently will divided in two intervention and control groups(n=22). The Quality of life and body activity and interpersonal support in two groups will be measured by three tools: Minosuta Quality of life , 6 minute walking Test and Interpersonal Support List, at first and 3 months after intervention. During 3 months the control group will receive the usual care and education, and will not be limited from the routine care, but the intervention group besides the usual care and education, in first two visits will be assessed based on Roy's Assessment form, and their maladaptive behaviors will be determined, then they will receive a teaching booklet based on Roy' s adaptation model and American heart failure association Modules (included: information about their disease, diet, activity, medications, interpersonal relationship) and they will receive discussion and consult with emphasize on their adaptive behaviors. They will receive phone calls about the program objectivities and content of education every week, and every 3 week we will visit them and consult about their problems with emphasize on Roy adaptation model and about how much they follow the booklet guidelines. After 3 months the Quality of life and body activity and interpersonal support in two groups will be measured by the same tools and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101225665N1**
Registration date: **2011-06-06, 1390/03/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-06-06, 1390/03/16

Registrant information

Name
Sima Lakdizaji
Name of organization / entity
Tabriz University of Medical Sciences, Nursing and Midwifery Faculty
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Recruitment status

Recruitment complete

Funding source

Tabriz medical sciense university-Tabriz nursing and midwifery faculty- research deputy

Expected recruitment start date

2011-02-20, 1389/12/01

Expected recruitment end date

2011-12-06, 1390/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of teaching program based on Roy' s adaptation model on quality of life of clients with heart failure

Public title

Effect of teaching program on quality of life in heart failure clients

Purpose

Prevention

Inclusion/Exclusion criteria

1- clients with heart failure who admitted to special heart clinic 2- clients who recognised foe at least one month 3- clients with heart failure in class II or III 4- clients above 18 and below 75 years old. 5- consiuse and could communicate 6- could walking exclution criteria: 1- if clients do not have willing for participation 2- have any other medical problems 3- psychological problems or addiction

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Tabriz Medical Science University- Research Deputy- Etics commitee

Street address

Research Deputy- Amoozesh bulding- Tabriz Medical Sciense University- Daneshgah Ave.- Tabriz

City

Tabriz

Postal code

East Azerbaijan

Approval date

2011-02-19, 1389/11/30

Ethics committee reference number

9562/4/5

Health conditions studied

1

Description of health condition studied

heart failure

ICD-10 code

I50.9

ICD-10 code description

Heart failure, unspecified

Primary outcomes

1

Description

quality of life

Timepoint

3 months

Method of measurement

Minosuta living With Heart Failure Questioneir

Secondary outcomes

1

Description

inter personal support

Timepoint

3 months

Method of measurement

interpersonal support list

2

Description

body activities

Timepoint

3 months

Method of measurement

6 minute walking test

Intervention groups

1

Description

At first in two groups , the Quality of life and body activity level and interpersonal support will be measured by three tools: Minosuta Quality of life , 6 minute walking Test and Interpersonal Support List, at first and 3 months after intervention. The control group During 3 months will receive the usual care and education which is common , and they will not be limited from the routine care. /The intervention group besides the usual care and education, at first two visits will be assessed based on Roy's Assessment form, and their maladaptive behaviors will be determined, then they will receive a teaching booklet based on Roy' s adaptation model and American heart failure association Modules (includes: information about their disease, diet, activity, medications, interpersonal relationship) and they will receive discussion and consult with emphasize on their maladaptive behaviors. They will receive phone calls about the program objectivities and content of study every week, and every 3 week we will visit them and consult about their problems with emphasize on Roy

adaptation model and about how much they follow the booklet guidelines. After 3 months the Quality of life and body activity and interpersonal support in two groups will be measured by the same tools (Minosuta Quality of life , 6 minute walking Test and Interpersonal Support List) and at last two groups will compare.

Category

Lifestyle

2

Description

In Control group the Quality of life and Body activity and Inter personal support in will be measured by Minosuta Quality of life and 6 minute walking Test and Interpersonal Support List at first and 3 months after intervention. During 3 months the control group will receive the usual care and teaching and will not limited the routine care. After 3 months the Quality of life and Body activity and Interpersonal support will be measured and then will compare with intervention group .

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Educational and medical heart center

Full name of responsible person

Sima Lakdizaji

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz Medical Sciense University - Tabriz Nursing and Midwifery Faculty-Reaserch Deputy

Full name of responsible person

Soheila Bani

Street address

5138947-977, Nursing and Midwifery Faculty, Shriati Jnoobi Ave.Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz Medical Sciense University - Tabriz Nursing and Midwifery Faculty-Reaserch Deputy

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz Medical Science University- Research Deputy

Full name of responsible person

Mohammad Khajegodari

Position

Lecturer

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty