Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of self-selected calming music on pain intensity due to needle insertion in to a fistula in hemodialysis patients.

Protocol summary

Summary

The purpose of this study is to determine the effect of self-selected calming music on pain intensity due to needle insertion into a fistula in hemodialysis patients. The research community in this study is patient treated with hemodialys by arteriovenous fistula in Fatemeh Zahra and Imam Khomeini hospital in sari, Iran. This study is a randomized clinical trial in which 114 patients of hemodialysis randomly allocated to 3 groups of music, headphone and control group. Inclusion criteria: willing to listen to music; being 18 years or older; lack of neuropathic disorders; havingno known history of depression; being treated with hemodialysis for at least 3 months; not being administered analgesics and sedatives within 3 hours before needle insertion into a fistula; having no history of taking antipsychotic drugs; not being mentally impaired; having no visual and hearing dysfunction and not being habited to listen to music during hemodialysis. Exclusion criteria: existence the acute pain in other area of body; need to try for needle insertion in to a fistula more than once; change in physical condition; refusing to continue study and death. First the pain intensity due to venopuncture is measured in 3 group without any intervention after needle insertion in arteriovenous into a fistula. Then during the next session of hemodialysis in the music group; favorite song will be played 6 minutes before needle insertion into a fistula by headphone and mp4 player and In the headphone group, it will be used headphone without play music 6 minutes before needle insertion into a fistula and also in the control group, it will be done based on the ward's routine. Then, in 3 group, pain degree due to needle insertion in to a fistula will be measured with visual analogue scale, one minute after the completion fixing needle.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607297494N20**
Registration date: **2016-08-08, 1395/05/18**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-08-08, 1395/05/18

Registrant information

Name
Masoumeh Bagheri Nesami
Name of organization / entity
Mazandaran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 11 3336 7551
Email address
mbagheri@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-11-19, 1395/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-selected calming music on pain intensity due to needle insertion in to a fistula in

hemodialysis patients.

Public title
The effect of self-selected calming music on pain intensity due to needle insertion in to a fistula in hemodialysis patients.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: willing to listen to music; being 18 years or older; lack of neuropathic disorders; havingno known history of depression; being treated with hemodialysis for at least 3 months; not being administered analgesics and sedatives within 3 hours before needle insertion into a fistula; having no history of taking antipsychotic drugs; not being mentally impaired; having no visual and hearing dysfunction and not being habited to listen to music during hemodialysis. Exclusion criteria: existence the acute pain in other area of body; need to try for needle insertion in to a fistula more than once; change in physical condition; refusing to continue study and death.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **114**
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
Ethics Committee of Mazandaran University of Medical Science
Street address
Sart of valiye asr highway, Imam Square, Sari, Mazandaran
City
Sari
Postal code
4736131167
Approval date
2016-07-10, 1395/04/20
Ethics committee reference number
IR.MAZUMS.REC.95.2435

Health conditions studied

1

Description of health condition studied
pain
ICD-10 code
R52.9
ICD-10 code description
pain, unspecified

Primary outcomes

1

Description
pain
Timepoint
before and after intervention
Method of measurement
visual analoug scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention of group 1: First in intervention group with music, pain degree due to needle insertion into an arteriovenous fistula will be recorded with visual measure immediately after needle insertion without any intervention. In the next session of hemodialysis, favorite song of every patient will be played by using headphone and mp4 player 6 minutes before needle insertion in to a fistula until the end of venopuncture and participants will be asked to entirely focus on music. Then one minute after the completion of venopuncture and fixing a needle, pain intensity due to neddle insertion in to a fistula will be recorded by visual analogue scale.
Category
Other

2

Description
Other interventions Intervention of group 2(headphone group): First in the intervention group with headphone during a session of hemodialysis, without any intervention, the pain degree due to needle insertion into a arteriovenous fistula will be recorded with visual measure immediately after needle insertion. In the next session of hemodialysis in this group, it will be used

headphone without playing music 6 minutes before needle insertion into a fistula. Then, one minute after the completion venopuncture and fixing needle insertion, pain intensity due to needle insertion into a fistula will be measured with visual analogue scale.

Category

Other

3

Description

Control group: For control group based on ward's routine, needle insertion in to a fistula will be done without any intervention. Then a minute after end of venopuncture and fixing needle, the pain degree due to needle insertion in to a fistula during 2 sessions of hemodialysis will be measured with visual analogue scale.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari, Emam Khomeini hospital and FatemehZahra hospital.

Full name of responsible person

DR Masoumeh Bagheri- Nesami

Street address

Sari, Emam Khomeini hospital and FatemehZahra hospital.

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Mazandaran University of Medical Sciences.

Full name of responsible person

Dr.Ahmadali Enayati

Street address

Vice Chancellor for research Mazandaran University of Medical Sciences, Moalem Street ,Moalem Square,Sari, Iran.

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research Mazandaran University of Medical Sciences.

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

Mazandaran University of Medical Science

Full name of responsible person

Dr Masoumeh Bagheri- Nesami

Position

Phd- faculty

Other areas of specialty/work

Street address

of Nursing & Midwifery Mazandaran University of Medical Sciences, Sari, Iran.

City

Sari

Postal code

4816715793

Phone

+98 11 3336 7551

Fax

Email

anna3043@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Science

Full name of responsible person

Dr Masumeh Bagheri Nesami

Position

Ph.D- Faculty member

Other areas of specialty/work

Street address

School of Nursing & Midwifery Mazandaran University of Medical, Sciences, Sari, Iran

City

Sari

Postal code

4816715793

Phone

+98 11 3336 7551

Fax

Email

anna3043@gmail.com

Web page address

www.mazums.ac.ir

Person responsible for updating data

Contact

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