

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of audio-visual nature Clip on level of anxiety and physiologic parameters of patients under gastric endoscopy

Protocol summary

2019-10-11, 1398/07/19

Study aim

Determination of the effect of nature audio-visual clip on anxiety level and physiologic parameters of patients referred for gastric endoscopy

Design

The intervention consists of a collection of Nature sounds and landscapes related to the sounds of Nature that are observed and listened to by a patient using a tablet and headphones for 5 minutes. The control group is seated on a chair for 5 minutes and receives routine care.

Settings and conduct

The study will be conducted at Kowsar Hospital affiliated to Semnan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

The participants of this study are patients referred to Kowsar Hospital of Semnan for gastric endoscopy. Inclusion criteria included being over 30 years of age, minimum education at the end of elementary school, lack of hearing and vision problems, no previous endoscopy and no emergency endoscopy.

Intervention groups

Each of the intervention and control groups have 32 participants.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140721018550N7**

Registration date: **2019-10-11, 1398/07/19**

Registration timing: **prospective**

Last update: **2019-10-11, 1398/07/19**

Update count: **0**

Registration date

Registrant information

Name

Nayyereh Raiesdana

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 23 3345 3867

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nr_dana@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of audio-visual nature Clip on level of anxiety and physiologic parameters of patients under gastric endoscopy

Public title

The effect of nature Clip on level of anxiety and physiologic parameters

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Minimum age of 30 years Minimum elementary

education No deafness and no visual impairment Lack of history of previous endoscopy Lack of emergency endoscopy order

Exclusion criteria:

Patients' unwillingness to continue cooperation Severe changes in the patient's physical condition

Age

From **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

We first assign four subgroups (stratum): 1 - Women 30 to 45 years 2 - Men 30 to 45 years 3 - Women over 45 years 4 - Men over 45 years old. Each patient enrolled in the study is placed in one of these four groups. Then, using the randomized random list for each stratum (4 predefined lists), that person is in the intervention group A or control B. To create the desired list of 6 possible blocks, we assign quadrants to each numerical block (from I to VI): According to the random numbers table, numbers 1 through 6 correspond to the above blocks and do not count numbers 7 to 9 and 0. Random numbers are generated with Excel. Then the assignment list (from left to right) is determined for each stratum.

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 Semnan University of Medical Sciences

Street address

Nursing and Midwifery college, Semnan University of Medical Sciences, Kilometer5 Damghan road, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3513138111

Approval date

2019-09-17, 1398/06/26

Ethics committee reference number

IR.SEMUMS.REC.1398.113

Health conditions studied

1

Description of health condition studied

Gastric endoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety

Timepoint

Immediately before the intervention and immediately after end of intervention

Method of measurement

6- item Spielberg inventory

Secondary outcomes

1

Description

Systolic and diastolic Blood pressure

Timepoint

Immediately before intervention and immediately after end of intervention

Method of measurement

Digital Sphygmomanometer

2

Description

Pulse rate

Timepoint

Immediately before intervention and immediately after end of intervention

Method of measurement

Digital Sphygmomanometer

Intervention groups

1

Description

Intervention group: At first, the demographic information questionnaire was completed and then anxiety measured by a six-item Spielberg inventory by the subjects and their physiological parameters (blood pressure and pulse rate) were measured and recorded in a sitting position with the same digital device. Then audio - video clip of nature music including sea, birds and forest sound was

played for 5 minutes via tablet connected to headphones and immediately afterwards, Spielberger anxiety questionnaire and their physiological parameters (blood pressure and pulse rate) will be measured and recorded in sitting position.

Category

Other

2**Description**

Control group:At first,the demographic information questionnaire was completed and then anxiety measured by a six-item Spielberger inventory by the subjects and their physiological parameters (blood pressure and pulse rate) were measured and recorded in a sitting position with the same digital device. Then control group receive routine care in a sitting position equivalent to intervention time in intervention group and immediately afterwards, Spielberger anxiety questionnaire and their physiological parameters (blood pressure and pulse rate) will be measured and recorded in sitting position.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kowsar hospital,Semnan

Full name of responsible person

Dr.Mohammad Memarian

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Parviz kokhaei

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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

Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

Nayyereh Raiesdana

Position

Faculty memeber(Assisstant professor)

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact**

Name of organization / entity

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

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no additional data.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Not applicable

Data Dictionary

Not applicable