Effect of Guided Imagery on pain, anxiety and some other hemodynamic factors in patients undergoing coronary angiography.

Protocol summary

Summary
This randomized control clinical trial will be conducted on 62 cardiac catheterization patients in Vasei hospitals in Sabzevar. This study is planned to evaluate the effect of Guided Imagery on pain, anxiety and some hemodynamic factors in patients undergoing coronary angiography. The trail will be performed in 62 patients between 35 to 68 years of age. Inclusion criteria: Aged between 35 to 68 years; state anxiety scale less than 64 and the Trait Anxiety scale of less than 62; can be reading and writing. Exclusion criteria: Reluctance to continue participating in the study; Death. After approving of the study by sciences vice chancellor of Sabzevar University of medical sciences and completing written consent form by all participants in the study, Patients will be divided randomly into two equal groups: 32 patients in experimental and 32 in control group. The necessary data will collected through a demographic information sheet, a hemodynamic variable sheet, the STAI anxiety questionnaire and a pain scale. Before the treatment, the participants in both groups will ask to fill out the demographic information sheet. In addition, they will require to answer the hemodynamic sheet both before and after the treatment, and the STAI questionnaire just after the treatment. The numerical pain scale will give to the subjects in both groups just after angiography procedure. The experimental group subjects will ask to listen to a Guided Imagery CD for 18 minutes one hour before the angiography procedure. Before the subjects of both groups will go the angiography room, their anxiety and hemodynamic will measure and record.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2014010916148N1
Registration date: 2014-07-04, 1393/04/13

Registration timing: retrospective

Last update:
Update count: 0
Registration date
2014-07-04, 1393/04/13

Registrant information
Name
Samira Foji
Name of organization / entity
Sabzevar University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 57 1265 4874
Email address
foji.s1@medsab.ac.ir

Recruitment status
Recruitment complete

Funding source
Sabzevar University of Medical Sciences

Expected recruitment start date
2013-08-22, 1392/05/31
Expected recruitment end date
2013-11-21, 1392/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Guided Imagery on pain, anxiety and some other hemodynamic factors in patients undergoing coronary angiography.

Public title
Effect of Guided Imagery on pain, anxiety and some other hemodynamic factors

**Purpose**
Supportive

**Inclusion/Exclusion criteria**
Inclusion criteria: Age should be between 35 years to 68 years, the state anxiety scale less than 64 and the Trait Anxiety scale of less than 62, can be reading and writing. Exclusion criteria: Reluctance to continue participating in the study, death.

**Age**
From *35 years* old to *68 years* old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
No information

**Sample size**
Target sample size: 62

**Randomization (investigator’s opinion)**
Randomized

**Randomization description**

**Blinding (investigator’s opinion)**
Double blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

**Secondary Ids**
empty

**Ethics committees**

1
**Ethics committee**
Name of ethics committee
Sabzevar University of Medical Sciences

Street address
School of Nursing and Midwifery, next to the police station to SHahroud road, Sabzevar

City
Sabzevar

Postal code
Approval date
2013-08-19, 1392/05/28

Ethics committee reference number
92.11.medsab.Rec

**Health conditions studied**

1
**Description of health condition studied**
Coronary Artery Disease

**ICD-10 code**
I25.1

**ICD-10 code description**
Atherosclerotic heart disease

**Primary outcomes**

1
**Description**
Anxiety

**Timepoint**
Before intervention, After intervention

**Method of measurement**
STAI Anxiety questionnaire

2
**Description**
Hemodynamic Factors

**Timepoint**
Both before and after the intervention

**Method of measurement**
Manometer

3
**Description**
Pain

**Timepoint**
After Angiography

**Method of measurement**
numerical pain scale

**Secondary outcomes**
empty

**Intervention groups**

1
**Description**
The experimental group subjects will ask to listen to a Guided Imagery CD for 18 minutes one hour before the angiography procedure and they will require to answer the hemodynamic sheet both before (morning of angiography, an hour before angiography) and after the Intervention, and the STAI questionnaire Before (an hour angiography) and after the Intervention. The numerical pain scale will give to the subjects in experimental groups just after angiography procedure.

**Category**
Behavior

2
**Description**
NO intervention in control group and thy will require to answer the hemodynamic sheet both before (morning of angiography, an hour before angiography) and after the Intervention, and the STAI questionnaire Before (morning of angiography) and after the intervention. The numerical pain scale will give to the subjects in control...
groups just after angiography procedure

**Category**  
Behavior

**Recruitment centers**

1

**Recruitment center**  
Name of recruitment center  
Sabzevar Vasei Hospital  
**Full name of responsible person**  
Samira Foji  
**Street address**  
Vasei Hospital; Sabzevar  
City  
Sabzevar

**Sponsors / Funding sources**

1

**Sponsor**  
Name of organization / entity  
Sabzevar University of Medical Sciences  
**Full name of responsible person**  
Moosa Reza Tadayonfar  
**Street address**  
School of Nursing and Midwifery; next to the police station to SHahroud road, Sabzevar  
City  
Sabzevar  
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source  
Sabzevar 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  
Sabzevar University of Medical Sciences  
**Full name of responsible person**  
Samira Foji  
**Position**  
Student of MSc Nursing  
**Other areas of specialty/work**
**Street address**
School of Nursing and Midwifery; next to the police station to SHahroud road, Sabzevar
City  
Sabzevar
Postal code
Phone
+98 57 1226 4404
Fax
Email  
samirafoji@yahoo.com
Web page address

**Person responsible for scientific inquiries**

Contact  
Name of organization / entity  
Sabzevar University of Medical Sciences  
**Full name of responsible person**  
Moosa Reza Tadayonfar  
**Position**  
MSc./Member of Faculty  
**Other areas of specialty/work**
**Street address**  
School of Nursing and Midwifery; next to the police station to SHahroud road, Sabzevar
City  
Sabzevar
Postal code
Phone
+98 57 1226 4404
Fax
Email  
mtadayonfar@yahoo.com
Web page address

**Person responsible for updating data**

Contact  
Name of organization / entity  
Sabzevar University of Medical Sciences  
**Full name of responsible person**  
Samira Foji  
**Position**  
Student of MSc Nursing  
**Other areas of specialty/work**
**Street address**  
School of Nursing and Midwifery; next to the police station to SHahroud road, Sabzevar
City  
Sabzevar
Postal code
Phone
Fax
Email  
samirafoji@yahoo.com
Web page address

**Sharing plan**

Deidentified Individual Participant Data Set (IPD)
empty
<table>
<thead>
<tr>
<th>Study Protocol</th>
<th>Clinical Study Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>empty</td>
<td>empty</td>
</tr>
<tr>
<td>Statistical Analysis Plan</td>
<td>Analytic Code</td>
</tr>
<tr>
<td>empty</td>
<td>empty</td>
</tr>
<tr>
<td>Informed Consent Form</td>
<td>Data Dictionary</td>
</tr>
<tr>
<td>empty</td>
<td>empty</td>
</tr>
</tbody>
</table>