# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of virtual reality and the effect of rose scent on onexiety , quality sleep and happiness hemodialysis

### Protocol summary

**Study aim**
Comparison of virtual reality and the effect of rose scent on onexiety , quality sleep and happiness hemodialysis

**Design**
The clinical trial has 4 groups on 80 patients without blinding, and the days of the intervention are randomized.

**Settings and conduct**
This study was conducted in the dialysis department of Mehr Madar Hospital, Four groups of aromatherapy, virtual reality, combined group and control group. In the aromatherapy group, 3 drops of essential oil were dripped on the cloth and placed inside the mask, and in the virtual reality group, relaxing images were played using virtual reality glasses. And in the combined group, two interventions were performed together.

**Participants/Inclusion and exclusion criteria**
- Not having physical problems, mental illness, smell sensitivity, not taking sleeping pills - Allergy to essential oil, death

**Intervention groups**
Four groups of aromatherapy, virtual reality, combined group and control group. In the aromatherapy group, 3 drops of essential oil were dripped on the cloth and placed inside the mask, and in the virtual reality group, relaxing images were played using virtual reality glasses. And in the combined group, two interventions were performed together.

**Main outcome variables**
Comparison of virtual reality and the effect of rose scent on onexiety , quality sleep and happiness hemodialysis

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20221225056922N1**
Registration date: **2023-01-04, 1401/10/14**
Registration timing: **retrospective**

Last update: **2023-01-04, 1401/10/14**
Update count: **0**

**Registration date**
2023-01-04, 1401/10/14

**Registrant information**

**Name**
Fahime Heyrati

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 51 5254 7480

**Email address**
heyratifahime1364@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-02-20, 1400/12/01

**Expected recruitment end date**
2022-03-30, 1401/01/10

**Actual recruitment start date**
2022-02-20, 1400/12/01

**Actual recruitment end date**
2022-03-30, 1401/01/10

**Trial completion date**
2022-03-30, 1401/01/10

**Scientific title**
Comparison of virtual reality and the effect of rose scent on onexiety , quality sleep and happiness hemodialysis

**Public title**
Comparison of virtual reality and the effect of rose scent on onexiety , quality sleep and happiness hemodialysis

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

- Satisfaction and willingness to participate in research- Having at least 3 months of hemodialysis experience- Not having hearing, vision and smell problems- No mental illness or accident in the past 6 years- Not having debilitating diseases (dementia and Parkinson's)- Not sensitive to smell- Not using sleeping and anti-anxiety drugs or other therapeutic measures such as using herbal essences during the intervention period

**Exclusion criteria:**

- Death or absence of a session in intervention sessions- Sensitization to essential oil- Refusal to continue participating in the research

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

Actual sample size reached: **73**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The selected community was divided into four groups: aroma therapy (B), virtual reality (C), combined group (aroma therapy and virtual reality) (D) and control group (A). Dialysis was randomized and an intervention was randomly performed every day.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

The study was done in 4 groups and comparing the groups with each other

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Birjand University of Medical Sciences

**Street address**

third alley on the right , 39 Imam Khomeini Street

**City**

Torbat jam

**Province**

Razavi Khorasan

**Postal code**

9591783753

**Approval date**

2022-01-29, 1400/11/09

**Ethics committee reference number**

IR.BUMS.REC.1400.360

## Health conditions studied

### 1

**Description of health condition studied**

Anxiety, happiness, sleep quality

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Anxiety score in the Spielberger questionnaire

**Timepoint**

Before the start of the intervention and after the end of the intervention

**Method of measurement**

Spielberger Anxiety Questionnaire

### 2

**Description**

Sleep quality score in the Pittsburgh Questionnaire

**Timepoint**

Before the start of the intervention and after the end of the intervention

**Method of measurement**

Pittsburgh Questionnaire

### 3

**Description**

Happiness score in the Oxford Happiness Questionnaire

**Timepoint**

Before the start of the intervention and after the end of the intervention

**Method of measurement**

Oxford Happiness Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Intervention group: Aromatherapy group, 3 drops of rare rose essential oil (rose water) with a concentration of 25%, which is readily available in the market, was dripped on absorbent cloth with a dropper

and placed inside the patient's mask (due to the conditions of Corona). and the patient was asked to breathe normally for 15 minutes due to the possibility of spreading the aroma on the mask and reducing the lasting effects of the aroma, after the duration of aromatherapy the patients' masks were changed. The intervention was done once a week for four weeks

**Category**

Rehabilitation

### 2

**Description**

Intervention group: Intervention group: virtual reality group, in the virtual reality group, using 3D glasses, calming images of the patients' favorite scenes were played for 15 minutes. This was done once a week for four weeks.

**Category**

Rehabilitation

### 3

**Description**

Intervention group: Intervention method: the combined group (aromatherapy and virtual reality) of the scent of rare rose essence (rose water) with a concentration of 25%, which is ready in the market, was dripped 3 drops with a dropper on an absorbable cloth and placed inside the patient's mask (to the reason for the condition of Corona) was placed and the patient was asked to breathe normally for 15 minutes and at the same time, using 3D glasses, soothing images of the patients' favorite scenes were played for 15 minutes. The intervention was once a week for four weeks. Done.

**Category**

Rehabilitation

### 4

**Description**

Control group: Control group: no intervention was performed during the study period, but after collecting the questionnaires at the end of the intervention, for ethical reasons, according to the wishes of the patients in this group, one of the interventions was performed in one session.

**Category**

Rehabilitation

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Dialysis Department of Mehr Madar Hospital in Torbat Jam

**Full name of responsible person**

Fahime Heyrati

**Street address**

the third alley on the right,Imam Khomeini 39

**City**

Torbat Jam

**Province**

Razavi Khorasan

**Postal code**

9591783753

**Phone**

+98 51 5254 7480

**Email**

heyratifahime1364@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Ahmad Nasiri

**Street address**

University of Medical Sciences,Ghaffari Street

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3239 5700

**Email**

nasiriahmad@gmail.com

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Birjand University of Medical Sciences

**Proportion provided by this source**

1

**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**

Birjand University of Medical Sciences

**Full name of responsible person**

Fahime Heyrati

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery
**Street address**
The third alley on the right,Imam Khomeini 39
**City**
Torbat Jam
**Province**
Razavi Khorasan
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9591783753
**Phone**
+98 51 5254 7480
**Email**
heyratifahime1364@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Birjand University of Medical Sciences
**Full name of responsible person**
Fahime Heyrati
**Position**
Student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nursery
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heyratifahime1364@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Birjand University of Medical Sciences
**Full name of responsible person**
Fahime Heyrati
**Position**
Student
**Latest degree**
Bachelor
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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 further information
**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**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available