Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of aroma Inhalation and essence massage on fatigue and quality of life in hemodialysis patients

Protocol summary

Summary

This study was carried out to determine the effects of aroma inhaling and essence massage on fatigue and quality of life in patients undergoing hemodialysis. This research is a parallel type clinical trial and was performed after obtaining permission and written presentation of the ethics committee of the University. The study population consisted of hemodialysis patients in dialysis centers in Tehran hospitals from whom 96 men and women were selected according to inclusion and exclusion criteria. They were willingness to participate in the research, having a healthy sense of smell, lack of allergic rhinitis or respiratory problems, lack of skin sensitivity to aromatic herbs, no drug abuse, no chronic physical disorders such as debilitating cardiovascular, respiratory, hepatic or mental diseases, death of the patient during the study, and kidney transplant. Sampling was performed based on odd and even days of the week at two work shifts of morning and evening. The samples were then randomly assigned in three groups of aroma inhalation, essence massage, and control. Aroma inhalation (lavender and orange) and essence massage was done 3 times weekly for 8 weeks. The patients were also taken the routine care of the ward. The control group only received the routine care. The data were collected using the Rhoten Fatigue Scale and the Kidney Disease Quality of Life instrument; they were completed by the researcher before the intervention and one and two months after it. The data were analyzed with SPSS and statistical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101819564N1**
Registration date: **2014-12-07, 1393/09/16**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-12-07, 1393/09/16

Registrant information

Name
Zahra Jalalian
Name of organization / entity
School of Nursing and Midwifery , Tehran of Medical Sciences University
Country
Iran (Islamic Republic of)
Phone
+98 21 6693 7120
Email address
shvaraei@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

A research project has presented in thesis form at the Tehran of Medical Science University

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of aroma Inhalation and essence massage on fatigue and quality of life in hemodialysis patients

Public title

Effect aromatherapy on fatigue and quality of life in

hemodialysis patients

Purpose

Health service research

Inclusion/Exclusion criteria

The main conditions for inclusion were age over 18 years;. at least 1 year of hemodialysis;. dialysis three times a week;. a willingness to participate in the research;. having a healthy sense of smell and no history of aromatherapy and massage therapy during the last 9 months;. having a healthy sense of smell;. lack of allergic rhinitis or respiratory problems;. lack of skin sensitivity to aromatic herbs;. no drug abuse;. no chronic physical disorders such as debilitating cardiovascular, respiratory, hepatic or mental diseases;. The main conditions for exclusion were death of the patient during the study;. and kidney transplant.

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **96**

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 Tehran of Medical Science University

Street address

Sixth Floor, Central Organization of University, Qods St, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2014-09-28, 1393/07/06

Ethics committee reference number

1638/130/93/د

Health conditions studied

1

Description of health condition studied

End Stage Renal Disease

ICD-10 code

N18.5 Chro

ICD-10 code description

Chronic uraemia End stage kidney disease

Primary outcomes

1

Description

Fatigue

Timepoint

Before and one month and two months after intervention.

Method of measurement

Rhoten Fatigue Scale

Secondary outcomes

1

Description

Quality of Life

Timepoint

Before and one month and two months after intervention

Method of measurement

KDQOL - SF™1/3 questionnaire

Intervention groups

1

Description

In group I, two drops of lavender essence with sweet orange at a ratio of 1:1 were dropped on a gas. The gas was pinned to the patient’s collar and the patient was asked to breathe normally for 15-20 minutes. This was done three times a week for 8 weeks.

Category

Other

2

Description

All subjects in the second group were undergone skin testing before massage with aromatic oil to ensure the absence of sensitivity; in case of redness, itching, swelling, and a positive test, the patient was excluded. The subjects in this group were massaged with 5 mL combination of lavender essence with sweet orange at a ratio of 1:1 which was diluted with sweet almond oil to 3%. The massage was performed on toes, feet and ankles as fondling, without hitting and pressure for 10 minutes during dialysis. This was done three times a week for 8 weeks. The patients were also received

routine care of the ward

Category

Other

3

Description

The third group (control) received only the standard care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis Unit of Imam Khomeini Hospital

Full name of responsible person

Jalalian zahra

Street address

Keshavarz Blvd.

City

Tehran

2

Recruitment center

Name of recruitment center

Dialysis Unit of Amir Alam Hospital

Full name of responsible person

Jalalian Zahra

Street address

North Saadi street

City

Tehran

3

Recruitment center

Name of recruitment center

Dialysis Unit of Haft Tir shohadye Hospital

Full name of responsible person

Jalalian Zahra

Street address

Rajai Shahid street, Rey Shahr

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

research of Deputy, Tehran of Medical Sciences University

Full name of responsible person

Younesian Masood ,University of Research and Technology of Deputy

Street address

Sixth Floor, Central Building, Tehran of Medical Sciences University, Qods St, Keshavarz St, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

research of Deputy, Tehran of Medical Sciences University

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

Tehran of Medical Sciences University

Full name of responsible person

Jalalian zahra

Position

Nursing Graduate Student

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Tehran of Medical Sciences University, Eastern Nosrat St, Tohid Sq , Tehran

City

Tehran

Postal code

Phone

+98 21 6693 7120

Fax

Email

zjalali58@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran of Medical Sciences University

Full name of responsible person

Varaei Shokouh

Position

PhD in Nursing

Other areas of specialty/work

Street address

School of Nursing and Midwifery,Tehran of Medical Sciences University , Eastern Nosrat St, Tohid Sq,

Tehran

City

Tehran

Postal code

Phone

+98 21 6693 7120

Fax

Email

Shvaraei@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran of Medical Sciences University

Full name of responsible person

Jalalian zahra

Position

Nursing Graduate Student

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Tehran of Medical Sciences University, Eastern Nosrat St, Tohid Sq, Tehran

City

Tehran

Postal code

Phone

+98 21 6693 7120

Fax

Email

zjalali58@yahoo.com

Web page address

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