Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of exercise and acupressure on flushing in women with breast cancer

Protocol summary

Study aim
the effect of exercise and acupressure on flushing among women with breast cancer

Design
Patients will be assigned to three groups of exercise, acupressure and control using RAS software. To hide the allocation, the type of intervention will be written on the paper and will be inserted Inside the opaque envelopes.

Settings and conduct
This study was conducted on 99 women with breast cancer (after the completion of chemotherapy and radiotherapy) referring to the oncology clinic located at Imam Reza and Al-Zahra educational centers in Tabriz.

Participants/Inclusion and exclusion criteria
Entry requirements include women with breast cancer who have completed their chemotherapy and radiotherapy and have hot flashes, and have no cardiovascular disease or motor disorder. Unsupported conditions include hot flashes before breast cancer and over 45 years of age, and continuation of chemotherapy and radiotherapy.

Intervention groups
For the acupressure group, the pressure on the HE7 and HE GU points on the hands and Sp6 point will be applied to the feet. Pressure on these points will be performed three days a week for 15 minutes, with 3 minutes of pressure for each point and 2 minutes for the spot, under the supervision of an acupuncturist (collaborator) at their office for 8 weeks. For a sports activity group, an aerobic exercise program is considered in an exercise room under the supervision of a sports coach, a weekly 3 days for 60 minutes in 8 weeks. During this period, the researcher will supervise the exercise program on a regular basis. The control group will receive routine care from an oncology specialist along with both acupuncture and exercise intervention groups.

Main outcome variables
The amount of flushing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150424021917N8**
Registration date: **2018-06-03, 1397/03/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-03, 1397/03/13**
Update count: **0**

Registration date
2018-06-03, 1397/03/13

Registrant information

Name
Sevil Hakimi

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 41 3479 6770

Email address
hakimis@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-22, 1397/02/02

Expected recruitment end date
2018-10-24, 1397/08/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of exercise and acupressure on flushing in women with breast cancer

Public title
The effect of exercise and acupressure on hot flash

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18-45 years old Women with hot flash at least twice a day for 6 weeks Completion of radiotherapy and chemotherapy at least 8 weeks before, the next referral of chemotherapy at least 10 weeks later Women with 5 or more score in pittsburgh sleep disturbances questionnaire Women with ductal or lobular insitu breast cancer or 1,2,3 stage without metastastasis Without experience hot flash before breast cancer without any sensory motor disorder

Exclusion criteria:
Women with BMI higher than 30 kg/m2 Use of hot flash reducing and sedative drugs Women with hyperthyroidism Doing any kind of exercise regularly and professionally Apply acupuncture within 2 weeks before starting the study Cardiovascular disease Restrictions on physical activity

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **99**

Randomization (investigator's opinion)
Randomized

Randomization description
Using RAS software, through blocks with six and nine blocks will randomly (There are groups, in each group in which 6 or 9 people come in each category)assigned to Three groups of exercise, acupressure and control . To hide the allocation, the type of intervention will be written on paper and placed inside the packets matched and numbered sequentially(Allocation Concealment)

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 Tabriz University of Medical Sciences

Street address
Third Floor, Central Building of Number2, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5138665793

Approval date
2017-12-16, 1396/09/25

Ethics committee reference number
IR.TBZMED.REC.1396.926

Health conditions studied

1

Description of health condition studied
flushing

ICD-10 code
R23.2

ICD-10 code description
Flushing

Primary outcomes

1

Description
hot flash

Timepoint
Before Intervention,Week 4 Intervention and Week 8 Intervention

Method of measurement
Hot flash scale

Secondary outcomes

1

Description
sleep disorders

Timepoint
Before intervention, week 4 intervention and week 8 intervention

Method of measurement
Pittsburgh Sleep Quality Index

2

Description
Satisfaction with the treatment

Timepoint
after intervention

Method of measurement

Survey

Intervention groups

1

Description
Intervention: acupressure.For the acupressure group, the pressure on the HE7 and HE GU points on the hands and Sp6 point will be applied to the feet. Pressure on these points will be performed three days a week for 15 minutes, with 3 minutes of pressure for each point and 2 minutes for the spot, under the supervision of an acupuncturist (collaborator) at their office for 8 weeks.
Category
Treatment - Other

2

Description
Intervention group: Sports activities.For a sports activity group, an aerobic exercise program is considered in an exercise room under the supervision of a sports coach, a weekly 3 days for 60 minutes in 8 weeks. During this period, the researcher will supervise the exercise program on a regular basis.
Category
Lifestyle

3

Description
Control group: Receives routine training,In accordance with,tutorials provided in the program of the ministry of Saba(Iranian women's health)
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Radiotherapy-Oncology Clinic of Imam Reza Hospital
Full name of responsible person
Reza Eghdamzamiri
Street address
university avenue, 29 Bahman Boulevard, Imam reza Hospital
City
Tabriz
Province
East Azarbaijan
Postal code
۳۳۳۵۹۶۸۰
Phone
+98 41 3335 5921
Email
shadikhanipoor@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Abolghasem Jouyban
Street address
29 Bahman Boulevard, Tabriz Town
City
Tabriz
Province
East Azarbaijan
Postal code
۳۳۳۵۵۹۲۱
Phone
+98 41 3335 5921
Email
shadikhanipoor@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Sevil Hakimi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Shariati Boulevard, Tabriz Town
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone

+98 41 3479 6770

Email

hakimis@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Sevil hakimi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Nursing and midwifery Faculty, Shariati Avenue. Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3475 3907

Email

hakimis@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Sevil Hakimi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Shariati BLV,Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6770

Email

hakimis@tbzmed.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Only part of the information, such as information on the main outcome or the like, can be shared

When the data will become available and for how long

Start publishing period 6 months after printing results

To whom data/document is available

Only available to scholars working in academic institutions

Under which criteria data/document could be used

All university students and scholars. By email

From where data/document is obtainable

Sevil Hakimi hakimis@tbzmed.ac.ir

What processes are involved for a request to access data/document

The applicant sends an application via e-mail. After receiving the email, the results will be sent

Comments