Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The effect of bright light therapy on depression and sleep quality during pregnancy

Protocol summary

Study aim
Determining the effect of bright light therapy on depression and sleep quality during pregnancy

Design
Clinical trial with control group, community based and pragmatic, with parallel, double blind, and randomized groups

Settings and conduct
The place of the study was the selected health service centers affiliated to Tehran University of Medical Sciences, such as Akbarabad, Ayat, Farmanfarmai'yan and Imam Mohammad Bagher clinics. Samples will be assigned to one of the two groups, intervention or control, by simple randomization or drawing. Before the study starts, participants are informed that they are randomly assigned to one of two groups, intervention or control. Due to the similarity of the lamps used in intervention or control groups, the researcher, participants, evaluator and data analyzer may not detect the types of lamps, and only the designer and manufacturer of the lamps can distinguish them.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 18–35 years of age, 14–28 weeks pregnant, mild depression and moderate depression from Beck Depression Inventory. exclusion criteria:History of any known medical and obstetric complications of pregnancy, History of known chronic diseases and other psychiatric disorders, History of hospital admission due to known psychological problems, History of known ocular diseases and eye surgery in a recent year.

Intervention groups
The intervention group received therapy with the bright light (9000 lux) and the control group with the dark red light (100 lux) during the first 30min after waking up at the morning for 5 weeks. This light is emitted from light boxes, which include a frame, stand and LED lamps. These equipments are purchased from Aj Teb Co. and designed and manufactured by a member of the research team

Main outcome variables
Depression Score, Sleep Quality Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190706044118N1**
Registration date: **2020-01-12, 1398/10/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-12, 1398/10/22**
Update count: **0**

Registration date
2020-01-12, 1398/10/22

Registrant information

Name
Omecolsom Azizi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7728 5091

Email address
fatemehazizi18965@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2020-01-21, 1398/11/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of bright light therapy on depression and sleep quality during pregnancy

Public title

Effect of phototherapy on depression and sleep quality during pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18–35 years of age 14–28 weeks pregnant Single-fetal pregnancy Spontaneous pregnancy Score of 10_17 (mild depression) and score of 18 _29 (moderate depression) frome Beck depression inventory

Exclusion criteria:

History of any known medical and obstetric complications, such as gestational diabetes, placenta previa, placental apruptio or preeclampsia in the present pregnancy History of other known psychiatric disorders such as bipolar disorder History of hospital admission due to known psychological problems History of known chronic diseases such as epilepsy History of known ocular diseases History of eye surgery in a recent year History of using antidepressants in the past 2 months Recent history of suicide attempt Having Shift-work (Morning and Night Shifts) History of Previous bright light therapy Having drug addiction, smoking, alcohol and psychotropic substances The occurrence of any horrible event during the last 6 months

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the samples were under intervention or control through simple randomization in one of two groups. Simple randomization is performed individually by simple drawing and randomization unit, in such a way that 35 numbers from 1 to 70 are randomly selected and assigned to the intervention group and the rest of the numbers will be assigned to the control group. .

Blinding (investigator's opinion)

Double blinded

Blinding description

Before the study starts, participants are informed that they are randomly assigned to one of two groups, A or B, and also that they may be treated with a illuminant light (9000 LUX), which, according to some studies, have been effective in treating depressive symptoms, or weak light (100LUX). Due to the similarity of the lamps used in Groups A and B, the researcher, participants, evaluator and data analyzer may not detect the types of lamps, and only the designer and manufacturer of the lamps, i.e. Mr. Radfar (Ph.D. in Medical physics) can distinguish between the lamps. All of the above have been addressed in the Ethical Committee, and considering all of these aspects, the Code of Ethics has been issued, which is attached to the relevant section

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Schole of Nursing and Midwifery & Rehabilitation - Tehran University of Medical Science

Street address

School of Nursing and Midwifery, Dr Mirkhani Ave (Eastern Nusrat), Tohid Square

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2019-06-25, 1398/04/04

Ethics committee reference number

IR.TUMS.FNM.REC.1398.058

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

f32

ICD-10 code description

Major depressive disorder, single episode, mild

Primary outcomes

1

Description

Depression score in Beck Questionnaire

Timepoint
Before the study, immediately and 4 weeks after the end of intervention
Method of measurement
Beck Depression Inventory

2

Description
sleep quality score in Pittsburgh questionnaire
Timepoint
Before the study, immediately and 4 weeks after the end of intervention
Method of measurement
Pittsburg Standard Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention in this group will be light therapy (9000 lux) for 5 weeks, for 30 minutes daily for the first 30 minutes when they are awake at home. This light is emitted by light boxes, which include a frame, stand and LED lamps. The equipment is purchased from AjTeb Company and designed and manufactured by a member of the research team, Dr. Radfer (Ph.D. in Medical Physics, Optics) and also Laboratory of Research and Technology Center of Tehran University will calculate appropriate distance from the light device to provide light intensity determined in this research with Luxmeter device. The samples will be asked to be placed in front of this device with measured distance.
Category
Treatment - Devices

2

Description
Control group: Interventions in this group will be treated with Dim Red light (100 lux) for 5 weeks, 30 minutes daily for the first 30 minutes when they are awake at home. This light is emitted by light boxes, which include a frame, stand and LED lamps. The equipment is purchased from AjTeb Company and designed and manufactured by a member of the research team, Dr. Radfer (Ph.D. in Medical Physics, Optics) and also Laboratory of Research and Technology Center of Tehran University will calculate appropriate distance from the light device to provide light intensity determined in this research with Luxmeter device. The samples will be asked to be placed in front of this device with measured distance.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbarabad Health Services Center
Full name of responsible person
Ms. Kermanchi
Street address
Next to Former region 10 Education, West Mahbob Mogaz Ave, Navab Ave
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Tehran
Province
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Postal code
1353688973
Phone
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Fax
+98 21 5513 9791
Email
nahidmashhod@gmail.com
Web page address
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2

Recruitment center
Name of recruitment center
Ayate Health Services Center
Full name of responsible person
Mr. Dr. Karimi
Street address
Opposite Shariati Park, Shariati Town, Mahan Street, behind Ghaleh Morghi garrison
City
Tehran
Province
Tehran
Postal code
1894787545
Phone
+98 21 5585 4000
Email
jamal.karimi48@gmail.com
Web page address
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3

Recruitment center
Name of recruitment center
Farmanfarmaeyan Health Service Center
Full name of responsible person
Ms. Dr. Varmarziyary
Street address
In front of meli Bank, It's not reached the crossroads Roshdiyeh, Azerbaijan Street
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Web page address
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4

Recruitment center

Name of recruitment center
Imam Mohammad Bagher Health Service Center

Full name of responsible person
Ms. Dr. Ahadpor

Street address
Behdasht street after school first Alley, Morteza Gard town, Azadegan right, Turn east, Western Azadegan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mohammad Ali Sahraian

Street address
Sixth Floor of assistance Research and Technology, Central University Organization, Corner of Qods Ave., Keshavarz Blvd

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msahrai@sina.tums.ac.ir

Web page address
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Dr. Seyedeh Fatemeh Vasegh Rahimparvar

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Dr. Seyedeh Fatemeh Vasegh Rahimparvar

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Omecolsom Azizi
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Latest degree
Bachelor
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Midwifery
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School of Nursing and Midwifery, Dr Mirkhani Ave (Eastern Nusrat), Tohid Square
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fatemehazizi18965@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available