

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of Benson's relaxation and mindfulness on the sleep quality of pregnant women

Protocol summary

Study aim

Determining the Comparing the effect of Benson's relaxation and mindfulness on the sleep quality of pregnant women

Design

Field trial with control group, with parallel, randomized groups, 102 pregnant women

Settings and conduct

Approval of the research plan in the university ethics committee. At the beginning of the study, complete the demographic characteristics checklist and the Pittsburgh Sleep Quality Index. Intervention group 1: Benson relaxation: the interventions will be carried out according to the protocol, during 8 weeks and 1 day a week. Intervention group 2: Mindfulness: the intervention includes; 8 sessions, the duration of each session will be 1 hour and 1 session per week, for a total of 8 weeks, according to the protocol. immediately after completing the interventions, complete the Pittsburgh Sleep Quality Index. The location of the training is a room in the women's department of Hazrate Zeinab Hospital, in order to maintain the privacy and peace of the participants.

Participants/Inclusion and exclusion criteria

Admission requirements: Being 18-35 years old; monogamy. Conditions of non-entry: Not wanting to continue participating in the study; Previous participation in studies similar to the current research.

Intervention groups

Intervention group 1: Benson relaxation: the interventions will be carried out according to the protocol, during 8 weeks and 1 day a week. Intervention group 2: Mindfulness: the intervention includes; 8 sessions, the duration of each session will be 1 hour and 1 session per week, for a total of 8 weeks, according to the protocol. Control group: non-intervention: this training group will not be given.

Main outcome variables

Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221108056445N1**

Registration date: **2022-12-07, 1401/09/16**

Registration timing: **prospective**

Last update: **2022-12-07, 1401/09/16**

Update count: **0**

Registration date

2022-12-07, 1401/09/16

Registrant information

Name

Fatemeh Shams

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Benson's relaxation and mindfulness on the sleep quality of pregnant women		Secondary Ids	empty
Public title	Comparing the effect of Benson's relaxation and mindfulness on the sleep quality of pregnant women	Ethics committees	
Purpose	Supportive	1	
Inclusion/Exclusion criteria		Ethics committee	
Inclusion criteria:	Ability to communicate and answer questions from patients or patients Being 18-35 years old Consent to participate in the study and sign the informed consent form Having a gestational age of 28-36 weeks (last 3 months of pregnancy) (according to LMP or ultrasound) Being belly first monogamy	Name of ethics committee	Ethics committee of Yasuj University of Medical Sciences
Exclusion criteria:	Not wanting to continue participating in the study Previous participation in studies similar to the current research Lack of inclusion criteria Suffering from a chronic disease such as: heart disease and diabetes and needing medicine or special care Suffering from mental illnesses such as depression during the last year Use of neuropsychiatric drugs and addiction to drugs and cigarettes	Street address	Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran
Age	From 18 years old to 35 years old	City	Yasuj
Gender	Female	Province	Kohgilouyeh-va-Boyerahmad
Phase	N/A	Postal code	7591741417
Groups that have been masked	No information	Approval date	2022-11-08, 1401/08/17
Sample size	Target sample size: 102	Ethics committee reference number	IR.YUMS.REC.1401.134
Randomization (investigator's opinion)	Randomized	Health conditions studied	
Randomization description	Block random assignment will be done in such a way that according to the number of study groups (three groups) consisting of intervention 1 (mindfulness), intervention 2 (Benson's relaxation) and control and calculated based on the factorial law, i.e. $3! = 3 \times 2 \times 1 = 6$, all the possible arrangement modes of people will be compiled based on the table below, considering A for intervention group 1 (Benson's relaxation), B for intervention group 2 (mindfulness) and C for control group: 1 2 3 4 5 6 CBA CAB BCA BAC ACB ABC Then, since the estimated sample size was 120 people, in each block, three samples, each representative of a study group and their arrangement order was also different, from these blocks, placement sampling will be done.	1	
Blinding (investigator's opinion)	Not blinded	Description of health condition studied	Normal pregnancy
Blinding description		ICD-10 code	z34.8
Placebo	Not used	ICD-10 code description	supervision of other normal pregnancy
Assignment	Parallel	Primary outcomes	
Other design features		1	
		Description	Sleep quality
		Timepoint	The amount of sleep quality of pregnant women at the beginning of the study (before the start of the intervention) and immediately after the intervention
		Method of measurement	Pittsburgh Sleep Quality Index (PSQI)
		Secondary outcomes	empty
		Intervention groups	
		1	
		Description	Intervention group 1: Benson relaxation: At first, the Benson relaxation method will be taught to the

participants in a 60-minute session in groups of 5 to 10 people. Then the interventions will be carried out according to the protocol, during 8 weeks and 1 day a week. Then there will be a telephone follow-up to inform about the exercises at home.

Category

Lifestyle

2

Description

Intervention group 2: Mindfulness: People will be divided into groups of 5 to 10 people. The intervention includes; 8 sessions, the duration of each session is 1 hour and 1 session per week, for a total of 8 weeks, according to the protocol, will be conducted as follows: First session: 1. Introduction of the participants and a brief description of the 8 sessions 2. Eating technique Raisins and then meditate for 30 minutes, scan the body and talk about the feelings caused by doing these meditations. Second session: 1. Body scan and discussion about this experience 2. Doing sitting meditation. The third session: 1. Practicing seeing and focusing on emotions 2. Paying attention to the practice at the moment of doing it, paying attention to breathing and paying attention to the body 3. Three-minute practice of the breathing space. The fourth session: 1. Meditation with attention to breathing 2. Practicing speaking and listening to your feelings. The fifth session: 1. Doing meditation 2. Practicing accepting yourself and your feelings. Sixth session: 1. Practicing breathing space 2. Practicing not judging feelings and events. Seventh session: Meditation and awareness of everything that comes into consciousness at the moment. Eighth session: review of experiences and post-test implementation.

Category

Lifestyle

3

Description

Control group: non-intervention: this training group will not be given.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Zeinab Hospital

Full name of responsible person

Fatemeh Shams

Street address

Hazrate Zeinab Hospital, Defaé Moghadas
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

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Yasuj University of Medical Sciences, Shahid Motahari
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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

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Fatemeh Shams

Position

Msc student in Medical-Surgical nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Msc student in Medical-Surgical nursing

Latest degree

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Other areas of specialty/work

Nursery

Street address

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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