

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Design, implementation and evaluation of mental health promotion program based on Lazarus and Folkman theory on stress management in working women with work-life conflict

#### Protocol summary

##### Study aim

Promoting the mental health of working women with work-life conflict

##### Design

The study is a quasi-experimental intervention with two groups of intervention and control without blinding with a sample size of 100 people and the randomization method will be simple.

##### Settings and conduct

The study population will be women working in two universities in Birjand. A cross-sectional census of all eligible women will be conducted using Carlson's standard work-life balance questionnaire. The person in need of intervention is considered. The two universities will be randomly divided into control and intervention groups. The intervention will be performed according to the model in the intervention group and then, post-test 3 months after the intervention in the intervention and control groups and the results will be analyzed. The control group is compared. The educational content used will be designed according to the key structures of stress and adaptation theories. Content is a combination of organizational and environmental training activities to support the health behaviors of employees and their families. Blindness is not the case in this study.

##### Participants/Inclusion and exclusion criteria

1- Having at least one year of work experience 2- Being a resident of Birjand 3- Being married and living with a spouse 4- Not being pregnant 5- Ability to express 6- Not passing work-life balance training courses 7- Achieving a score of less than 50% in the work-life conflict questionnaire based on the researchers' decision

##### Intervention groups

Training sessions in the intervention group and providing an educational booklet to the control group

##### Main outcome variables

Promoting mental health, learning stress management

skills, learning work and life conflict management skills

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210918052508N1**

Registration date: **2021-09-21, 1400/06/30**

Registration timing: **prospective**

Last update: **2021-09-21, 1400/06/30**

Update count: **0**

##### Registration date

2021-09-21, 1400/06/30

##### Registrant information

##### Name

Seyyede fateme Rahimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3242 3313

##### Email address

fateme.rahimi64@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-21, 1400/07/29

##### Expected recruitment end date

2021-12-21, 1400/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Design, implementation and evaluation of mental health promotion program based on Lazarus and Folkman theory on stress management in working women with work-life conflict

**Public title**

"Stress management intervention in women with work-life conflict"

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Achieve a score of less than 50% in the Work-Life Conflict Questionnaire  
Have at least one year of work experience  
Married and living with a spouse  
Do not take work-life balance training courses

**Exclusion criteria:**

Dissatisfaction with participating in the study  
Lack of cooperation in training sessions  
Women with a spouse who was suffering from a physical or mental illness

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Given that two organizations have been selected as the field of study, one organization will be randomly selected as the intervention and one as the control.

**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 Hormozgan University of Medical Sciences

**Street address**

Jomhuri Eslami Blvd, Bandar Abbas, Iran

**City**

Bandar abbas

**Province**

Hormozgan

**Postal code**

7919915519

**Approval date**

2021-08-22, 1400/05/31

**Ethics committee reference number**

IR.HUMS.REC.1400.214

**Health conditions studied****1****Description of health condition studied**

Conflict of work and life

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Work-life balance

**Timepoint**

Measurement of work-life balance at the beginning of the study and three months after the end of the educational intervention

**Method of measurement**

Carlson Standard Questionnaire

**2****Description**

Mental health

**Timepoint**

Measurement of mental health at the beginning of the study and three months after the end of the educational intervention

**Method of measurement**

General Health Questionnaire

**3****Description**

Perceived Stress

**Timepoint**

Measurement of perceived stress at the beginning of the study and three months after the end of the educational intervention

**Method of measurement**

Cohen Perceived Stress Questionnaire

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: The health promotion approach used in this study at the individual level includes empowering women to recognize and control stresses and stresses that create work-life conflict and increase coping and resilience with methods such as practical demonstration, role-playing and It is a group discussion. At the interpersonal level, health promotion interventions will be aimed at gaining comprehensive support in the relationship between employee and family members, employee and co-workers, and employee and managers. Interventions at this level will include meetings with counselors and psychologists to simulate various situations that create work conflict and women and their spouses and employee - employee and employee - boss based on predetermined scenarios. At the organizational level The strategy used to lobby and seek support from managers will be effective. It is anticipated that meetings will be held to justify the importance and necessity of this issue in organizational policies for greater productivity with the University President's Advisor on Women and Physical Education to hold relaxation and meditation courses in the gym and the Vice Chancellor for Development on staff day. will be . The purpose of intervention at this level is to increase organizational support for women and create a supportive work environment as a result of organizational policies.

#### Category

Lifestyle

### 2

#### Description

Control group: The control group will complete a general health questionnaire and a perceived stress questionnaire before the intervention. This group does not receive educational intervention. 3 months later, the questionnaires will be completed again by the control group. In order to observe the ethics in the research, after the end of the research, the training booklet on stress management and the booklet on controlling life conflicts will be given to the people in the control group.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Birjand University of Medical Sciences

##### Full name of responsible person

Seyyede Fateme Rahimi

##### Street address

Birjand University of Medical Sciences , Ghafari Street, Birjand, South Khorasan, Iran.

##### City

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##### Province

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##### Web page address

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### 2

#### Recruitment center

##### Name of recruitment center

Birjand University

##### Full name of responsible person

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##### Street address

Administration Building, University of Birjand, University Blvd., Birjand, Southern Khorasan, Iran

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##### Web page address

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Dr Teamur Aghamolae

##### Street address

Jomhuri Eslami Blvd, Bandar Abbas, Iran

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iasc.info@hums.ac.ir

**Web page address**  
https://hums.ac.ir/  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Bandare-abbas 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**  
Bandare-abbas University of Medical Sciences  
**Full name of responsible person**  
Seyyede Fateme Rahimi  
**Position**  
Phd student  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Health Promotion  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Position**  
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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

Not applicable

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

**Data Dictionary**  
Not applicable