

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The Effect of Multidisciplinary Brief Intervention on Reduction of Cardio-Metabolic Risk Factors in Women Admitted to the Emergency Department

#### Protocol summary

##### Study aim

Determining the effect of multidisciplinary brief intervention on reduction of cardio-metabolic risk factors in women.

##### Design

In this randomized controlled clinical trial, with parallel groups, 110 women with cardio metabolic-syndrome who are eligible to enter the study, will be assigned into one of the intervention or control groups by randomized blocking method.

##### Settings and conduct

110 included women with cardio-metabolic syndrome referring Shahid Madani and Shahid Rahimi Hospital in Khorramabad, will be allocated into two groups of intervention and control. At the beginning of the study, all subjects of the two groups will complete the research questionnaires. Then, in the intervention group, the multidisciplinary intervention will be performed in three telephone follow-up and three visits. The control group would not receive any intervention from the researcher. After completing the intervention, research questionnaires will be completed for both groups and the results will be compared with each other.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Women aged 18-75. 2) Risk factor of cardio-metabolic. 3) Level of 3, 4, 5 triage. 5) Having at least 60 minutes per week physical activity for three months. Exclusion criteria: 1) Getting with a severe psychological illness. 2) Chronic diseases. 3) Getting covid 19.

##### Intervention groups

The intervention with focus on three components of motivational interviewing, motivational feeding consulting and motivational physical activity consulting includes three personal visits during admission and hospitalization in the hospital and three telephone calls follow up in the second and fourth and eighth week after discharge , provided by the multidisciplinary team. In control group, the routine care method of the emergency

department is generally performed.

##### Main outcome variables

cardio-metabolic risk factors

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150919024080N21**

Registration date: **2022-02-20, 1400/12/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-02-20, 1400/12/01**

Update count: **0**

##### Registration date

2022-02-20, 1400/12/01

##### Registrant information

##### Name

Mohammad Gholami

##### Name of organization / entity

Lorestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 509 1279

##### Email address

gholami.m@lums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-20, 1400/12/01

##### Expected recruitment end date

2022-05-22, 1401/03/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect of Multidisciplinary Brief Intervention on Reduction of Cardio- Metabolic Risk Factors in Women Admitted to the Emergency Department

**Public title**

The Effect of Multidisciplinary Brief Intervention on Reduction of Cardio- Metabolic Risk Factors

**Purpose**

Education/Guidance

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

Women with metabolic heart disease aged 18 - 75  
Patient with moderate to high risk and with two risk factor of cardiometabolic according to risk assessment scale (prediabetic situation or metabolic syndrome)  
Exposure in the level of 3, 4, 5 ESI triage Ability to understand and perception Persian language Willingness and consent to participate in research and to complete the form of research ethics Admission and accommodation in the emergency department for at least 24 hours and having a medical record Psychological disorder, such as severe mood disorders BMI>27 (in the weight of overweight and obese) On average , more than 60 minutes per week physical activity (moderate and severe) has occurred over the past three months Having a fixed phone or cell phone

**Exclusion criteria:**

getting with a severe psychological illness after the diagnosis of the disease. the present experience of cardiovascular disease like dyspnea or tachycardia Chronic diseases such as renal failure , liver failure getting viral disease and acute infected disease such as covid 19 Patients at the risk of suicide according to the Nurses Global Assessment of Suicide Risk criteria . Heart Rate<60 AND Heart Rate>100 Systolic Blood Pressure>160 AND Diastolic Blood Pressure>100 Engagement in other counseling programs and changing behavior for lifestyle hospitalization for more than a week

**Age**

From **18 years** old to **75 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **110**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to unify the important distribution of age and education, class based on these variables related to pre menopause/post menopause, a diploma/ high diploma, and then a block random method (Block randomization) in two studies groups are balanced. It should be noted that the volume of each block is 4, which makes six different combinations of block (4 blocks) and choose random selection by placing blocks. Using this method the sample volume will be equal to the two study arms and the difference between the two groups in terms of sample volume will be equivalent to half the block.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Blinding groups as a ( intervention group ) and b ( control group ) are performed by a nursing that does not play a role in the study. The code occasionally runs to the independent nurse until the end of the data analysis. Data analyst and evaluation nurse are unaware of the random allocation of groups in the control and intervention groups. Participants prior to randomization become aware of their possible allocation in one of the control and intervention groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Lorestan Medical Sciences Ethics Committee

**Street address**

Lorestan University of Medical Sciences, Campus Kamalvand, Vice Chancellor for Research and Technology, Khorramabad, Lorestan

**City**

Khorramabad

**Province**

Lorestan

**Postal code**

987654321

**Approval date**

2021-03-10, 1399/12/20

**Ethics committee reference number**

IR.LUMS.REC.1399.364

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

Cardio-metabolic syndrome

**ICD-10 code**

E88.81

## ICD-10 code description

Metabolic syndrome

## Primary outcomes

### 1

#### Description

Cardiometabolic risk

#### Timepoint

Before starting treatment and after completing the 60 day treatment period

#### Method of measurement

FINDRISK tool

### 2

#### Description

Physical activity

#### Timepoint

Before starting treatment and after completing the 60 day treatment period

#### Method of measurement

Short International Physical Activity questionnaire

### 3

#### Description

Mediterranean diet score

#### Timepoint

Before starting treatment and after completing the 60 day treatment period

#### Method of measurement

Modified Mediterranean diet score questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: After accepting the patient in the emergency department and choosing the sample based on the criterion of entry into intervention, a brief intervention takes place in this form. The intervention is focused on three components of the motivational interview, the motivational counseling and motivational counseling of the physical activity, including three individual visits and three phone calls, which is being offered by a multi-professional team within eight weeks. This includes medical professionals, trained nurses about motivational interviewing (senior undergraduate, main researcher) as well as a nutritionist. The intervention program contains the intervention program for three individual visits and three phone follow-up, as described below. First visit to the evocative interview: taking a history of the client and determining risk factors are done by findrisk

questionnaire. Then the evocative interview is performed according to the frames model considering six steps including feedback, responsibility, recommendation, list of options, empathy, and work. Second visit to the feeding motivational counseling: the face visit to the second one (according to the patient's desire) after the first visit was done by the nutritionist and by the presence of the main researcher and preferably the patient's family for a period of thirty-eight minutes. The question about the eating habits of the patient and family, the initial assessment of the patient's nutritional status, weight and eating disorder and providing explanations concerning the intake of a healthy diet and the importance of food intake, explanation and interpretation of the food label are the contents of this visit. A third visit to the motivational orientation of the physical activity: A third face visit lasts from 6 to 24 hours (according to the patient's inclination) after the second visit, by the principal investigator, and with the presence of the team physician and preferably the patient's family, for 20-30 minutes. The question about the physical activity of the patient and the family is to explore the condition of physical activity, weight and physical barriers, explain the importance and benefits of physical activity, disadvantages of non-mobility, types of exercises and exercises, as well as planning to consider the barriers to physical activity and provide a "safe and healthy life" to the patient. Early motivational follow-up two weeks after patient release from the hospital, phone calls to the patient can be increased by the researcher for an average of 10 minutes (as per the patient's need). This call involves reviewing the feedback, reviewing the progress of the new incentive for change, reviewing behavioral changes (to increase physical activity and adherence to a healthy diet) and any positive change, an assessment of commitment to change behavior, monitoring the condition of eating and physical activity, motivating to return to the behaviors or lifestyle of prior unhealthy lifestyle and review of the training booklet. The second motivational follow-up of four weeks after the patient's release from the hospital, the patient's phone call can be eligible for an average of 10 minutes (as per the patient's need). The content and purpose of this contact is similar to the first telephone follow-up. A third-week motivational follow-up week after patient release from the hospital, the patient's phone call can be eligible for an average of 10 minutes (as per the patient's need). The content and purpose of this call is similar to the first or second phone calls. "Changing a Woman for Healthy and Healthy Life" booklet aims to remind evocative interviews, foster healthy behaviors, as well as provide supplementary training. The contents of the booklet include: a simple explanation for the definition of cardiovascular risk factors, symptoms and effects of risk factors, risk factors of cardiovascular risk, metabolic inequalities, and their relevance to cardiovascular health, risk reduction in women and eating disorders, introducing well-known Iranian women with healthy lifestyles, healthy eating and physical activity.

#### Category

Behavior

## 2

### Description

Control group: The control group in the emergency department receive regular emergency care and receive a routine training exercise on the patient's illness on the day of their routine training and on patient requests. In order to observe the ethical principles, it will be sent to the post - mail address to control the manual after the intervention is over.

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Rahimi hospital

##### Full name of responsible person

Zahra Bazgir

##### Street address

Kheirabad

##### City

Khorramabad

##### Province

Lorestan

##### Postal code

6814717361

##### Phone

+98 66 3340 7189

##### Email

zahrabazgir70@yahoo.com

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Madani hospital

##### Full name of responsible person

Zahra Bazgir

##### Street address

Kheirabad

##### City

Khorramabad

##### Province

Lorestan

##### Postal code

6814717361

##### Phone

+98 66 3340 7189

##### Email

zahrabazgir70@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Khoram-Abad University of Medical Sciences

#### Full name of responsible person

Morovat Taheri Kalani

#### Street address

Kheirabad

#### City

Khorramabad

#### Province

Lorestan

#### Postal code

6814717361

#### Phone

+98 66 3340 7189

#### Email

zahrabazgir70@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Khoram-Abad University of Medical Sciences

#### Proportion provided by this source

1

#### 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

Khoram-Abad University of Medical Sciences

##### Full name of responsible person

Zahra Bazgir

##### Position

Nurse

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

Kheirabad

##### City

Khorramabad

##### Province

Lorestan

##### Postal code

6814717361

##### Phone

+98 66 3340 7189

##### Email

zahrabazgir70@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Khoram-Abad University of Medical Sciences

**Full name of responsible person**

Mohammad Gholami

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Integrated Lorestan Medical, Opposite to the Kahrizak Village, km 5 Road of Khorram Abad ,Boroujerd

**City**

khorrarnabad

**Province**

Lorestan

**Postal code**

6814993165

**Phone**

+98 912 509 1279

**Email**

gholami.m@lums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Khoram-Abad University of Medical Sciences

**Full name of responsible person**

Zahra Bazgir

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Kheirabad

**City**

Khorramabad

**Province**

Lorestan

**Postal code**

6814717361

**Phone**

33407189

**Email**

zahrabazgir70@yahoo.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