

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Evaluation of Effectiveness of Communication Skills Training on Marital Satisfaction in Wives of Men are in Drugs Withdrawal Period

#### Protocol summary

##### Study aim

Determine the effect of Communication Skills Training on Marital Satisfaction in Wives of Men are in Drugs Withdrawal Period

##### Design

Randomized field trial with a control group, and a sample size of 40 wives of men are in drugs withdrawal

##### Settings and conduct

there are 1 governmental drug addiction center with a population of about 600 people and 70 private drug addiction centers with a population of about 150 people in Gorgan. we divide the society into two governmental and private classes and consider each center as a cluster according to the geographical location of the addiction centers (north, center, south). Then, we select 10 women from government centers and 30 women from private centers in a two-stage cluster sampling and randomly based on the score of the questionnaire. they are categorized by Block random allocation method into two groups of control and intervention. The intervention group is invited to 8 communication skills training sessions, while the control group does not receive any counseling. In the case of statistical analyzer, there is blindness and they do not know about the intervention and control of the codes. Complete the demographic information form and Enrich marital satisfaction questionnaire with the supervision of a research collaborator (assessor of the questionnaire).

##### Participants/Inclusion and exclusion criteria

Wives of Men are in Drugs Withdrawal Period: Ages between 18 to 45 years old! At least one year of common life!

##### Intervention groups

The experimental group will trained in 8 weeks group sessions on communication skills. Every session will last 90 minutes. The control group does not receive the sessions. Participants will complete an Enrich Marital Satisfaction Questionnaire before and after the end of the intervention

#### Main outcome variables

Marital satisfaction score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171026037015N5**

Registration date: **2018-09-30, 1397/07/08**

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

Last update: **2018-09-30, 1397/07/08**

Update count: **0**

##### Registration date

2018-09-30, 1397/07/08

##### Registrant information

##### Name

Houri Alijani

##### Name of organization / entity

Golestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3243 0360

##### Email address

alijani@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-23, 1397/06/01

##### Expected recruitment end date

2019-06-22, 1398/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of Effectiveness of Communication Skills Training on Marital Satisfaction in Wives of Men are in Drugs Withdrawal Period

**Public title**  
Evaluation of Effectiveness of Communication Skills Training on Marital Satisfaction

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Ages between 18 to 45 years old At least one year of common life Being a single wife The desire to participate in the study The Enrich Score 120 and Lower  
**Exclusion criteria:**  
The presence of chronic psychological illnesses of couples (using a structured psychiatric interview) Experience of severe stressful events during the past 6 months (a car crash or death of one of first grad relatives, Strong conflict in the family, especially divorce) History of participation in psychotherapy classes and communication skills Drug abuse of woman Pregnancy Lactation

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

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Considering the fact that there are 1 state drug addiction center with a population of about 600 people and 70 private drug addiction centers with a population of 150 people in Gorgan, they first divide the society into two public and private classes and according to the geographical location Addiction treatment centers (north, center, south) consider each center as a cluster. Then, by choosing two-stage cluster sampling, 10 from the government center and 30 from private centers, we will randomly match and according to the graphic variables and type of use and duration of use and ..., and with the use of Using block random allocation method, we allocate ten selected from the state center to the letter A and five others to the letter B. Similarly, we divide 30 selected individuals from the private sector into two groups. Now, using a throwing coin of a group as an intervention group and a control group will enter the study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**  
The statistical analyzer and The outcome evaluator is not informed about intervention and control groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**  
**Name of ethics committee**  
Ethics Committee of Golestan University of Medical Sciences  
**Street address**  
Hirkan Blvd, The Shast kola Ave, Deputy of Research and Technology, Golestan University of Medical Sciences, Gorgan Town  
**City**  
Gorgan  
**Province**  
Golestan  
**Postal code**  
4934174515

**Approval date**  
2018-07-21, 1397/04/30

**Ethics committee reference number**  
IR.GOUMS.REC.1397.068

## Health conditions studied

1

### Description of health condition studied

Wives of Men are in Drugs Withdrawal

### ICD-10 code

### ICD-10 code description

## Primary outcomes

1

### Description

Marital satisfaction score

### Timepoint

Marital Satisfaction Score Measurement before the beginning of the first Communication Skills Training session and immediately and one month after the last session

### Method of measurement

Enrich Marital Satisfaction Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention group will receive Communication Skills Training at 8 sessions of 90 minutes, which will be held in groups of 5 to 10 people. Training include active listening, empathy, respect for the other side, explicit, important relationship in marital relationship, conflict resolution patterns...

#### Category

Behavior

### 2

#### Description

Control group: Control group: No intervention received

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Drug Clinics of Gorgan City

##### Full name of responsible person

Roghaieh Hajigholikhany

##### Street address

Abozar 7, Iranmehr Ave, Pegah Drug Clinic, Gorgan town

##### City

Gorgan

##### Province

Golestan

##### Postal code

4918685346

##### Phone

+98 17 3222 2043

##### Email

roghaieh.gholikhany@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gorgan University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Reza Honarvar

##### Street address

Shast kola Ave., Hirkan Blvd., Deputy of research and technology., Golestan University of Medical Sciences., Gorgan Town

##### City

Gorgan

##### Province

Golestan

##### Postal code

4915767446

##### Phone

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##### Email

roghaieh.gholikhany@yahoo.com

##### Web page address

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

##### Full name of responsible person

Roghaieh Hajigholikhany

##### Position

Master's student in midwifery counseling

##### Latest degree

Bachelor

##### Other areas of specialty/work

Midwifery

##### Street address

Shast kola Ave., Hirkan Blvd., Faculty of Nursing Midwifery., Golestan University of Medical Sciences., Gorgan Town

##### City

Gorgan

##### Province

Golestan

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##### Email

roghaieh.gholikhany@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Gorgan University of Medical Sciences  
**Full name of responsible person**  
Dr Fatemeh Seifi  
**Position**  
Professor Assistant and Faculty Member of Golestan  
University of Medical Sciences  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Health Service Management  
**Street address**  
Shast kola Ave, Hirkan Blvd, Faculty of Nursing  
Midwifery, Golestan University of Medical Sciences,  
Gorgan Town  
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4913815739  
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## Person responsible for updating data

**Contact**  
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Roghaieh Hajigholikhany  
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Master's student in midwifery counseling  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Shast kola Ave., Hirkan Blvd., Faculty of Nursing  
Midwifery., Golestan University of Medical Sciences.,  
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**Province**

Golestan  
**Postal code**  
4914716179  
**Phone**  
+98 17 3443 0763  
**Email**  
roghaieh.gholikhany@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**  
Yes - There is a plan to make this available  
**Statistical Analysis Plan**  
Yes - There is 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**  
Yes - There is a plan to make this available  
**Data Dictionary**  
Yes - There is a plan to make this available  
**Title and more details about the data/document**  
Information on the main outcome or the like can be  
shared.  
**When the data will become available and for how  
long**  
Start the access period 6 months after printing the  
results  
**To whom data/document is available**  
Data will be available to researchers working in  
academic and academic institutions.  
**Under which criteria data/document could be used**  
The data will be available for scientific research with  
reference to the research. In order to access the data,  
they can reply to the person's e-mail address.  
**From where data/document is obtainable**  
En responsible person's email address:  
roghaieh.gholikhany@yahoo.com  
**What processes are involved for a request to access  
data/document**  
Applicants can respond to the email of the respondent  
and receive a response within a week.  
**Comments**