Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 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

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Iran (Islamic Republic of)

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+98 17 3243 0360

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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
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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
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4915767446
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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
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Shast kola Ave., Hirkan Blvd., Faculty of Nursing Midwifery., Golestan University of Medical Sciences., Gorgan Town
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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

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Person responsible for updating data

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Position

Master's student in midwifery counseling

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Other areas of specialty/work

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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

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