

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Investigating the effect of teaching lifestyle measures of Iranian medicine in premarital counseling centers on the marital satisfaction of couples

#### Protocol summary

##### Study aim

Determining the effect of teaching lifestyle measures of Iranian medicine in premarital counseling centers on increasing marital satisfaction of couples in 1401

##### Design

The clinical trial with a control group, with parallel groups, without blinding, was divided into two groups of intervention (61 couples) and control (61 couples) using the randomized block method.

##### Settings and conduct

In this study, which is a clinical trial type, it is conducted on 122 couples who come to Haji Maqsoodi counseling center during three months who are planning to get married and to participate in pre-marriage training courses. After visiting the researcher in person and coordinating with the management of Haji Maghsoudi Comprehensive Health Center, they attended the pre-marriage counseling section and the couples who met the conditions to enter the study were explained by the researcher and the informed consent questionnaire was completed for them. The questionnaires are provided to the participants by trained interviewers and are completed before the study. Two face-to-face training workshops were held one week after the delivery of the training package (two workshops one week apart) and one workshop using the collaborative method (group discussion, question and answer) two weeks apart from the first two workshops.

##### Participants/Inclusion and exclusion criteria

The condition of the couple's first marriage Obtaining consent to participate in the study

##### Intervention groups

Intervention group: Intervention group: The educational content for the workshops is prepared after reviewing the reliable sources of Iranian medicine and the articles available in this field and the consensus of opinion among the Iranian medical experts collaborating in the project. Control group: They do not receive any training in the field of Iranian medicine.

#### Main outcome variables

Marital quality Marital Satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201122049458N1**

Registration date: **2023-06-12, 1402/03/22**

Registration timing: **prospective**

Last update: **2023-06-12, 1402/03/22**

Update count: **0**

##### Registration date

2023-06-12, 1402/03/22

##### Registrant information

##### Name

razieh nabimeybodi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-22, 1402/04/01

##### Expected recruitment end date

2023-09-23, 1402/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of teaching lifestyle measures of Iranian medicine in premarital counseling centers on the marital satisfaction of couples

**Public title**

Investigating the effect of teaching lifestyle measures of Iranian medicine on the marital satisfaction of couples

**Purpose**

Education/Guidance

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

The couple's first marriage Obtaining consent to participate in the study

**Exclusion criteria:**

Failure to participate in training classes

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **122**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

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

empty

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

Shahid Dr. Rahnamon Hospital, Yazd (ethics committee in research)

**Street address**

Farrokhi

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**Province**

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**Postal code**

8913814396

**Approval date**

2023-03-05, 1401/12/14

**Ethics committee reference number**

IR.SSU.SRH.REC.1401.027

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

Marital Satisfaction

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

Marital satisfaction level based on Enrich Marital Satisfaction Questionnaire

**Timepoint**

The questionnaire is completed before the start of the training and 3 months after the start of the training

**Method of measurement**

Enrich Marital Satisfaction Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The intervention is carried out on 122 couples who come to Haji Maqsoodi counseling center during three months, who intend to get married and to participate in pre-marriage training courses. The educational content for the workshops is prepared after reviewing the reliable sources of Iranian medicine and the articles available in this field and the consensus of opinion among the Iranian medical experts collaborating in the project, which includes teaching the six principles of maintaining health and a healthy lifestyle from the perspective of Iranian medicine, in addition, an educational package containing an educational booklet + a video that contains audio-visual training along with the talks of an Iranian medical expert will be delivered to the participants of the project. one week apart) and a workshop using the collaborative method (group discussion, question and answer) will be held two weeks apart from the first two workshops. The maximum capacity of each workshop is 35 couples. The virtual group will remain after the end of the workshop to answer the possible questions of the couples, and the questions about the topics raised will be answered by an Iranian medical expert. Educational content: The six principles of lifestyle, including eating and drinking according to the mood and slowly. Eating and avoiding liquids with meals, sleeping and waking up including the best sleeping hours between 10 pm and 2 am,

controlling mental and emotional states, weather conditions according to the person's mood, eliminating waste from the body and eliminating constipation, exercise and rest. According to the person's temperament, educational content: lifestyle factors in Iranian medicine. In this topic, the six lifestyle factors that all humans are exposed to are described under the title "Six Essential Principles for a Healthy Life". The six essential principles are important because all people deal with them on a daily basis and life is impossible without them. The correct management of these cases has been the concern of Iranian traditional medicine scientists for a long time. These six vital principles are: 1. Air and environment 2. Movement and stillness (exercise and rest) 3. Sleep and wakefulness 4. Eating and drinking 5. Disposal of unnecessary materials and preservation of essential materials 6. Pay attention to mental states: the things recommended in this section are taught and applicable to maintain health in healthy people and prevent them from getting sick.

1. Air and environment: One of the most important components of the environment is the air around us. Harmonizing the body with the air in the environment and following its recommendations helps to maintain health. Movement and stillness (exercise and rest): In traditional medicine, movement and stillness are important parts of maintaining health. The best time to exercise is when the weather is mild, so it is around noon in spring, at the beginning of the day in summer, and at the end of the day in winter. But the duration and intensity of exercise should be less in spring and summer, and more in autumn and winter. The time of exercise should be adjusted with the time of eating. Do not exercise when you are hungry because the body needs food in this state. Exercise consumes the same few substances that the body feeds on when it is hungry. You should not exercise immediately after eating, because the digestion of food is not yet complete and the entry of undigested food into the organs will harm the body. It is better that before exercise, the body is cleansed of inappropriate substances and the intestines and bladder are empty of urine and feces. Athletes should not eat heavy or slow-digesting foods two hours before the start of training or competition.

3. Sleep and wakefulness: In traditional medicine, a good sleep in a healthy person has certain conditions, some of which are different in different ages, seasons and temperaments according to the amount of humidity. Therefore, children sleep more than adults, women sleep more than men, and the elderly sleep less. And in winter, due to increasing coldness and humidity, sleep becomes longer. The best sleep duration is 6-10 hours. Of course, the period mentioned is for adults and children and babies need to sleep more than 10 hours a day. Young people need more sleep than old people. From a scientific point of view, the best time to sleep is from early night to early morning (between morning call to prayer and sunrise). This dream gives you vitality and energy.

4. Eating and drinking: Each of the different foods has its own quality and mood. This problem causes the type of food consumed by people to affect their physical and mental characteristics. Food recommendations are expressed with different

approaches in traditional medicine. Fast-digesting foods are mostly recommended for people who do not have strong digestion due to illness or who have recently recovered from illness. Examples of these foods include: grilled chicken, chicken soup with well-cooked wheat bread. Slow-digesting foods are suitable for those who do heavy physical activities, such as athletes, farmers, construction workers, and blacksmiths. Because if these people use fast-digesting food, it will quickly decay and they have to use their body's internal energy. Examples of these foods are: hard-boiled or half-boiled eggs, halim, meat, halwa prepared with oil, flour, starch, honey, or sugar, etc. It is better for sedentary people such as students, employees, etc. Managers should not use the above foods. General food recommendations: correct eating habits from the perspective of traditional medicine: 1. To help the proper digestion of food in the digestive system, do not eat before feeling real hunger (honest appetite) and stop eating before feeling full. 2. Observe moderation in eating. That is, don't eat so much that it causes stomach heaviness, discomfort, nausea, etc., and don't eat so little that it causes weakness and loss of body strength. 3. Observing the order of eating food and avoiding mixing food is one of the instructions to maintain health. Fast-digesting foods should not be consumed after slow-digesting foods. For example, the habit of eating salad or soup after a meal is very wrong and should be stopped gradually. Preferably eat the salad before the main meal or as a snack. 4. Preferably do not use drinks with food. 5. Take small bites. 6. Chew food well (chew each small bite at least 15 times) 7. Create a calm and cheerful environment while eating and don't eat when angry. 8. Eat calmly and slowly and don't talk while eating. 9. While eating, do not occupy your mind with miscellaneous issues (watching TV, listening to music, reading, etc.). 10. Do not eat food too hot or too cold. 11. Do not eat while standing or moving. 12. Do not exercise or heavy activity immediately after eating. 13. Avoid eating fruit or drinks immediately after meals. 14. Avoid sleeping immediately after eating. 5. Disposing of unnecessary substances from the body and maintaining essential substances in the body: Cleansing the body of toxins and waste substances that are created in the body during the digestion process plays an important role in maintaining human health. Also, maintaining vital and essential substances in the body is important for health. If a person eats enough food but does not have enough stool, urine or sweating, sooner or later he will have a problem. Also, if a person eats enough food but has too much feces, urine or sweat, he will soon have problems.

6. Mental states: The mental state affects all aspects of people's lives. Their effect on the body is faster than the previous 5. To maintain peace and remove mental tensions and emotions, it is useful to follow the following recommendations: Hearts are calmed by the remembrance of God. Strengthen your spiritual relationship with God through worship and prayers and trust him in problems and difficulties. Do not suppress your emotions and emotions and share them with relatives and friends. Laugh at the right time and cry at the right time. Do not be ashamed of crying and do not suppress it.

**Category**

Lifestyle

**2****Description**

Control group: They do not receive any training in the field of Iranian medicine.

**Category**

Lifestyle

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Haji Maqsoodi Counseling Center

**Full name of responsible person**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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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**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Razie Nabi Meybodi

**Position**

Academic staff

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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**

All data is potentially shareable after de-identifying individuals

**When the data will become available and for how long**

The access period starts 6 months after the results are published

**To whom data/document is available**

The data will be publicly available

**Under which criteria data/document could be used**

The data will be publicly available

**From where data/document is obtainable**

Dr.Monire Seyed Hashemi m.seiedhashemi@yahoo.com

**What processes are involved for a request to access data/document**

After submitting the application, the documents will be sent in less than a month

**Comments**