

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Designing and evaluation of Community empowerment and a web based healthy lifestyle intervention in women (Hamyaran)

Protocol summary

Summary

This interventional randomized community trial study aims at designing an educational intervention program based on the Internet in order to increase the empowerment and promote a healthy lifestyle in selected women. The women with inclusion criteria of giving informed consent and willingness to participate in the study; members of the group for more than 6 months; and access to the Internet are randomly put in two intervention and comparison groups. Based on Laverack's Parallel tracking model, the empowerment process will be carried out for the intervention group simultaneous to the health promotion (i.e. the lifestyle promoting) program. To do so, we will plan the program by a bottom up method in four steps of preparation, goal setting, strategic planning for empowering the community and follow up, applying a strategic approach in 9 domains of community empowerment as participation, leadership, organizational structures, problem assessment, resource mobilization, asking why, links with others, role of the outside agents and programme management. This model helps the participants, by applying a bottom up approach and through the consensual workshop, to identify the problems and issues related to their lifestyle by themselves, and to determine the most important ones in order to do Internet based interventions. Then, the educational intervention program will be designed and available online for the participants, based on the determined issue. Measuring the empowerment changes is carried out in 9 fields through the process of empowerment.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015041821445N2**

Registration date: **2016-03-20, 1395/01/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-20, 1395/01/01

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Tehran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

f-bakhshi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2016-04-08, 1395/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and evaluation of Community empowerment and a web based healthy lifestyle intervention in women (Hamyaran)

Public title

Community empowerment and a web based healthy lifestyle intervention in Hamyaran

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Informed consent to participate in the study; Join more than 6 months in Hamyaran group; Internet access
Exclusion criteria: Unwillingness to cooperate

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 250

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Sort random draw will be conducted at the level of population centers with Sealed envelope method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

School of Public Health, Tehran University of Medical Sciences, Poursina Avenue, Qods Street, Enqelab Square, Tehran

City

Tehran

Postal code

Approval date

2015-04-21, 1394/02/01

Ethics committee reference number

IR.TUMS.REC.1394.138416

Health conditions studied

1

Description of health condition studied

Problems related to education and literacy

ICD-10 code

Z55

ICD-10 code description

Problems related to education and literacy

Primary outcomes

1

Description

Lifestyle

Timepoint

Before intervention, 3 months after intervention and 6 months after intervention

Method of measurement

Health Promoting Lifestyle Profile II

2

Description

Empowerment

Timepoint

Health- Promoting Lifestyle Profile

Method of measurement

Psychological empowerment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention in lifestyle includes designing an educational website based on a healthy lifestyle selected by the majority of votes by the participants. For instance, if the choice of most participants is "obesity", a weight loss Intervention including a diet, recipes for healthy food and nutrition information will be useful. The participants will be offered a personal username and password so they can log in to their personalized webpage and receive their especial diet defined by a nutritionist. Reminders will be sent to them via message. Intervention in empowerment includes group discussion meetings in order to find strategies to eliminate the obstacles to the participants' empowerment. Finally, 3 and 6 months after the Intervention begins, the participants will be re evaluated using the tools in from the pretest phase.

Category

Lifestyle

2

Description

Control Group: No Intervention

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Gilan's collaborators health office

Full name of responsible person

Zahra Rashidi

Street address

Number57, Daneshjoo Street, Hamidian Street, Rasht

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Yunesian

Street address

6th floor, Central Organization of University, Ghods Street, Keshavarz Boulevard, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fataneh Bakhshi

Position

PhD Candidate of Health Education & Promotion

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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Name of organization / entity

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Davoud Shojaeizadeh

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Professor

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty