Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

+98 21 8898 9128

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 massage. 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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

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Davoud Shojaeizadeh

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Professor

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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