

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### Multifaceted Intervention Based on Theory of health Action Process Approach to the Health of Divorced female headed-households: Protocol of a Controlled Randomized Trial

#### Protocol summary

##### Study aim

Determining the Impact of Multidimensional Intervention Based on Theory of Action Process Approach on the Health of Divorced female headed-households

##### Design

Randomized controlled trial with parallel groups, one-way blind, randomized by blocking method, with the participation of 100 divorced female-headed households

##### Settings and conduct

The study will be conducted in Tehran, welfare units. health education in the form of face-to-face and educational video CD based on the theoretical constructs of the health practice process approach for breast self-examination; And in the psycho social field, they will receive CBT family in person and offline application. The results obtained in the two groups of intervention and control are compared immediately after the intervention and three months after the intervention.

##### Participants/Inclusion and exclusion criteria

Divorced female headed-households - with children - covered by Welfare organization Tehran - no mental health problems and addiction

##### Intervention groups

Intervention group: Educational intervention sessions in the form of face-to-face and applied-educational application in two physical dimensions (breast self-examination behavior) and psycho-social dimension (mental health and support of family and others) Control group: without intervention

##### Main outcome variables

Depression - Anxiety - Breast self - examination and family adoption

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200923048813N1**

Registration date: **2020-11-15, 1399/08/25**

Registration timing: **prospective**

Last update: **2020-11-15, 1399/08/25**

Update count: **0**

#### Registration date

2020-11-15, 1399/08/25

#### Registrant information

##### Name

Farzaneh Golboni

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8145 4462

##### Email address

f.golboni@behdasht.gov.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-01-20, 1399/11/01

#### Expected recruitment end date

2021-03-19, 1399/12/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Multifaceted Intervention Based on Theory of health Action Process Approach to the Health of Divorced

female headed-households: Protocol of a Controlled Randomized Trial

## Public title

Evaluation of multifaceted intervention on the health of divorced female-headed households

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Divorced female headed-households covered by welfare  
Having children No history of severe mental illness and  
addiction Having Smart phone Willing to participate

### Exclusion criteria:

Drugs or psychotropic substances abuse Use of  
psychiatric drugs Participate in cognitive sessions or  
similar training sessions

## Age

From **20 years** old to **60 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Data analyser

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random allocation of participants in two groups will be done by random blocking method with 4 blocks. The block randomization method is such that the allocation sequence is written before the start of the research. Given that the two groups will be studied, 4 blocks are used and each letter is assigned to a group (A: intervention group: B control group). All possible modes are written and numbered for a block of 4. Then, in a simple random method (using a table of random numbers), a number of numbers are selected from the block numbers and by writing the contents of the blocks related to those numbers (until the specified sample size is reached), The random assignment sequence is specified.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The analyzer does not know about the groups

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

#### Street address

QAZVIN UNIVERSITY OF MEDICAL SCIENCES -  
BAHONAR BLV

#### City

QAZVIN

#### Province

Qazvin

#### Postal code

15315-34199

#### Approval date

2020-07-29, 1399/05/08

#### Ethics committee reference number

IR.QUMS.REC.1399.121

## Health conditions studied

## 1

### Description of health condition studied

Divorced female headed-households` health

### ICD-10 code

### ICD-10 code description

## Primary outcomes

## 1

### Description

self breast examination

### Timepoint

Immediately after the intervention and 3 month later

### Method of measurement

check list

## 2

### Description

depression and anxiety

### Timepoint

Immediately after the intervention and 3 month later

### Method of measurement

Questionnaire standard of HOST

## 3

### Description

family adaption

### Timepoint

Immediately after the intervention and 3 month later

### Method of measurement

FACE 3 Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Training with HAPA and CBT Family model for 6 weeks through face-to-face , online with and without application training. Intervention sessions: Interventional training sessions will be designed both in person and offline training application. In this application, approved educational materials in The mentioned areas will be included. content of Education will be evaluated in terms of general criteria such as accuracy, non-contradiction and integrity, clarity, appropriateness to the audience, attractiveness, acceptability and creativity, as well as the content presented in terms of content and presentation of the message. Will take. Educational materials designed before the intervention will be provided to 10 divorced women apart from the sample size to be evaluated in terms of comprehensibility and acceptability. Interventions for divorced women with inclusion criteria will be performed and in the control group will receive only individual cognitive-behavioral training program and two training pamphlets Before starting the study, in a 2-hour training class, the intervention group and the control group will be taught separately how to work with the application, and the researcher will provide people with their phones to answer any type of question related to the application or other questions. Educational items designed in a very simple and understandable way for clients. CBT Family / CBT training interventions are prepared in three ways online and in the application in the form of video and writing and event recording that at any time a person can use any of the methods that are possible for him. Interventions after 2 hours of application training for Members of the intervention group begin CBT Family training will done in 6 sessions of 1.5 hours and also providing educational package content interventions (educational pamphlet and CD) for the field of reproductive health (breast cancer screening) and 1 45-minute CBT session and educational pamphlet (breast cancer screening) Will receive the control group. The training content is designed based on the Health Action Process Approach model in six half-hour sessions on CD and application in which three training sessions for risk perception structures, expectation of results in the HAPA (Health Action Process Approach) motivational phase and three sessions for the structure Self-efficacy of self-efficacy is designed and the level of awareness before and after training will be completed by the researcher-made questionnaire and checklist made by the individual. Awareness before and after training will be completed by the individual using a questionnaire and a researcher-made checklist. And CBT Family evaluation will be done by recording the data in the application using the standard HADS questionnaire and the adaptation and continuity assessment scale of 3 or 4 FACES family. Finally, the results obtained in the two groups of intervention and control are compared immediately after the intervention and three months after the intervention. First sessions: Familiarity with the

participant and explanation of the program Second sessions: Educate the participant about the cognitive-behavioral approach with emphasis on communication skills Third sessions: Familiarity with negative thoughts and ideas and mental stereotypes about the occurrence of social behaviors and the degree of belief in these thoughts Fourth sessions: Familiarity with spontaneous thoughts in dealing with family and community Fifth sessions: Examining the evidence confirming and rejecting negative beliefs about behavior in the family Sixth sessions: Functional analysis and establishing a therapeutic relationship HAPA-based breast self-examination structures- Action Self-efficacy: Be optimistic about doing the breast self-examination correctly- Outcome expectations: life span And increase the level of reproductive health in the family- Risk perception: Breast loss due to cancer and family loss as well as the prevalence of overhead breast cancer in women- Behavioral intention: Enough motivation to do monthly breast self-examination- Action Plan: Set the schedule and the order of the examination by the person herself- Coping plan: Schedule a proper monthly breast self-examination by the person in the presence of the researcher to ensure that it is done correctly- Self-efficacy: Perform proper breast self-examination by the individual Content of breast self-examination training sessions in the training package (30 minutes each session):- First session: Importance of breast self-examination Meet women and get their awareness of breast cancer risk and its consequences and their awareness of breast cancer screening Risk of late detection of breast cancer and its impact on quality of life and longevity- Second session: The effect of breast self-examination on quality of life Show death statistics for breast cancer Show slides of breast cancer surgeries and their impact on beauty and quality of life and longevity of women- Third session: Preparation of schedule and schedule of breast self-examination by a woman How to plan a monthly breast self-examination during the menstrual cycle or after menopause- Fourth session: Perform breast self-examination in order and step by step from observation to accurate touching of different parts of the breast- Fifth session: Breast self-examination with the help of the researcher's instructions, first all the steps of observation and then the touch stage in two positions in a supine position and then the right lymph nodes and relying on abnormal points that may be found in the examination - practice and eliminate Find out the objections of the researcher and answer the questions and concerns of women- Sixth session: Perform step by step Breast examination View to touch the tissue To examine the lymph nodes Repeat until the stage is done without any problems and completely correct and record the problems related to the examination in each stage in a sheet. Family for 6 weeks through face-to-face training, practical application

#### Category

Behavior

### 2

#### Description

Control group: Get a brief pamphlet and CBT education

in one session (1.5 hour)

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Welfare organization of Tehran

**Full name of responsible person**

Farzaneh Golboni

**Street address**

Next to the School of Rehabilitation-Shemiran-  
Enghelab Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۱۳۶۵/۴۱۸۷

**Phone**

+98 21 7751 0065

**Email**

f.golboni@behdasht.gov.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Mehdi Emam Jome

**Street address**

Deputy of Research- Mavadat Allay- Shahjid Beheshti  
Blvd-Ghazvin

**City**

Tehran

**Province**

Tehran

**Postal code**

13911/34156

**Phone**

+98 28 3333 7006

**Email**

research.dpt@qums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Qazvin 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**

Qazvin University of Medical Sciences

**Full name of responsible person**

Farzaneh Golboni

**Position**

PhD student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

S Elslamic Republic of Iran Ministry of Health &  
Medical Education A bolck -6 floor Eyvanak Shahrak  
Gharb Tehran -

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۹۹۴۳۴۷۱

**Phone**

+98 21 8145 4462

**Email**

f.golboni@behdasht.gov.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Farzaneh Golboni

**Position**

PhD candidate

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Ministry of health and medical education- 6 floor - -  
East Eyvanak- Shahrak Gharb- Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۹۹۴۳۴۷۱

**Phone**

+98 21 8145 4462

**Email**

f.golboni@behdasht.gov.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Farzaneh Golboni

**Position**

PhD candidate

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Ministry of health and medical education- 6 floor- East  
Eyvanak- Shahrak Gharb- Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۹۹۴۳۴۷۱

**Phone**

+98 21 8145 4462

**Email**

f.golboni@behdasht.gov.ir

## 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 can be shared in the form of an article or  
protocol after unidentifiable

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

one year after article published

**To whom data/document is available**

students and masters

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

only with reference

**From where data/document is obtainable**

Qazvin university of medical sciences

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

request to deputy of research Qazvin university of  
medical sciences

**Comments**