Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

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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
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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 pamphletsBefore 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 beginCBT 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 skillsThird sessions: Familiarity with negative thoughts and ideas and mental stereotypes about the occurrence of social behaviors and the degree of belief in these thoughtsFourth sessions: Familiarity with spontaneous thoughts in dealing with family and communityFifth sessions: Examining the evidence confirming and rejecting negative beliefs about behavior in the familySixth sessions: Functional analysis and establishing a therapeutic relationshipHAPA-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 individualContent 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

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Sponsors / Funding sources

1

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Full name of responsible person

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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

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

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Latest degree

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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 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 refernce

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