

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of Happiness on the Psychological capital of Middle aged women

Protocol summary

Study aim

Determining the The effect of Happiness on the Psychological capital of Middle aged women of kashan, 2020

Design

clinical trial with control group and blinded statistical analyzer

Settings and conduct

Clinical trial study will be conducted in two experimental group- 30 middle aged women (happiness planning) and control group- 30 middle aged women(without intervention) in Selected Health Centers of Kashan City (Muslim Ibn Aqil and Sadeghzadeh)

Participants/Inclusion and exclusion criteria

Having informed consent to participate in research, Age 40-65 years, Living in Kashan, Iranian nationality, The ability of talking and listening, Ability to communicate in Persian, Earning a score of less than 112 (on a scale of 156-26) From the psychological capital tools of McGee et al., Having the physical ability to attend meetings, No known mental illness (self-reporting), No known mental retardation, Failure to deal with acute and serious stress in the last 6 months (death of relatives, serious illness or relatives, etc).

Intervention groups

The intervention group will be received a Happiness intervention based on the Fordyce protocol for 4 weeks, 8 sessions of 90 minutes. The first session will begin with welcoming, presenting the researcher to members, reviewing goals, reviewing the structure of the sessions, and the main rules. After that the questionnaires will be completed by the participants. At the beginning of each session, the researcher invites the participants to active participation in discussions, and at the end of each session, the participants will be given homework according to the protocol regarding the subject of the meeting. At the end of each session, the hour and the title of the next session will be indicated. Control group will not receive any intervention.

Main outcome variables

Psychological capital

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100211003329N4**

Registration date: **2020-02-27, 1398/12/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-27, 1398/12/08**

Update count: **0**

Registration date

2020-02-27, 1398/12/08

Registrant information

Name

Zahra Sooki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

sooki_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-05, 1398/10/15

Expected recruitment end date

2020-04-24, 1399/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Happiness on the Psychological capital of Middle aged women

Public title

The effect of Happiness on the Psychological capital

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having informed consent to participate in research Age 40-65 years Living in Kashan Iranian nationality The ability of talking and listening Ability to communicate in Persian Earning a score of less than 112 (on a scale of 156-26) From the psychological capital tools of McGee et al. Having the physical ability to attend meetings

Exclusion criteria:

Known mental illness (self-reporting) Known mental retardation Deal with acute and serious stress in the last 6 months (death of relatives, serious illness or relatives, etc.)

Age

From **40 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be assigned two groups Using the block randomization technique by the software sealed Envelope Ltd.2017 Available from through www.sealedenvelope.com,12 blocks (6 blocks with 6 people and 6 block with 4 people) were defined. The blocks are divided into 2 categories based on the list taken from the site and randomly each category of blocks will be selected from one center. After identifying the members of the groups by random allocation, for people in intervention group, group intervention will be conducted in two separate groups in each center.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analyzer is unaware of experimental and control group characteristics

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Kashan University of Medical Sciences

Street address

Ghotb Ravandi Blvd, Pezeshk Blvd, Kashan University of Medical Sciences

City

kashan

Province

Isfahan

Postal code

8715985191

Approval date

2019-09-21, 1398/06/30

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1398.041

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

Psychological capital

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

Psychological capital

Timepoint

Start, Immediately after the intervention and one month later

Method of measurement

(Psychological capital Questionnaire (McGee et al)

Secondary outcomes

empty

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

The intervention group will receive a group happiness program based on the Fordisee protocol during 8 sessions of 90 minutes (2 sessions per week at least two days apart). The first session begins with welcoming the members, introducing the group leader to the members and members to each others, discussing the goals, reviewing the structure of the meetings, the rules governing the group, and the duties and responsibilities of the members and the group leader.The goals of the sessions in the intervention group from the first to the

eighth meeting respectively including; the need for happiness in life, Importance of leisure and entertainment, Increasing intimacy and social relationships, Stop worrying and living in the present time, lowering the level of optimism and positive thinking and optimism, planning and organization affairs, healthy personality and self-importance and the importance of happiness that can be achieved through group discussion, practicing group, home and community exercises. At the beginning of each session the members report and discuss the exercises and tasks, then work on the purpose of the meeting. At the end of each session, members of the group will be welcomed and the time and title of the next meeting will be indicated.

Category

Treatment - Other

2

Description

Control group: The control group will have no intervention about happiness and will only receive routine care at the health center including assessment of chronic diseases and cancers, etc.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers in Kashan

Full name of responsible person

Fahime sadeghi

Street address

Ghotb Ravandi Blvd, Pezeshk Blvd, Kashan University of Medical Sciences

City

kashan

Province

Isfahan

Postal code

8715985191

Phone

+98 31 5554 0021

Email

Fahime.sadeghi.6368@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Hamid Reza Banafsheh

Street address

Ghotb Ravandi Blvd, Pezeshk Blvd, Kashan University of Medical Sciences

City

kashan

Province

Isfahan

Postal code

8715985191

Phone

+98 31 5554 0021

Email

banafsheh_h@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Fahime sadeghi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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City

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Province

Isfahan

Postal code

8715985191

Phone

+98 31 5554 0021

Email

sadeghi-f@kaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Khadijeh Sharifi- Zahra Tagharrobi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Ghotb Ravandi Blvd, Pezeshk Blvd, Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

8715985191

Phone

+98 31 5554 0021

Email

sharifi_kh@kaums.ac.ir

Postal code

8715985191

Phone

+98 31 5554 0021

Email

sooki_z@kaums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no need to publish data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data will be received in the form of a questionnaire from the participants and will eventually be shown in the table.

When the data will become available and for how long

6 month after publication

To whom data/document is available

for everyone who interested in the subject

Under which criteria data/document could be used

no specific condition is required

From where data/document is obtainable

sharifi81k@yahoo.com Dr. Khadijeh Sharifi

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

Once the email is received, it will be answered

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Zahra Sooki

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Ghotb Ravandi Blvd, Pezeshk Blvd, Kashan University of Medical Sciences

City

Kashan

Province

Isfahan