

# 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](http://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

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**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**

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**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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**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

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**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

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**Province**

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