

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of pre-procedural psycho-education on pain perception and anxiety in women undergoing colposcopy

Protocol summary

Study aim

To determine the effect of pre-procedural psycho-education on pain perception and anxiety in women undergoing colposcopy

Design

a randomized, not blinded, parallel group, controlled trial

Settings and conduct

This study is a clinical trial conducted on women undergoing colposcopy in Imam Reza clinic.

Participants/Inclusion and exclusion criteria

The inclusion main criteria: women aged 20 to 50 years anxiety score more than 30 with no history of psychological disorder and no history of previous colposcopy and no consumption of anti-anxiety drugs. The lack of inclusion main criteria: not completing the questionnaires in any phase of study

Intervention groups

The intervention group receives a 60 to 75 session of psychoeducation. The control group receives an informational pamphlet about colposcopy to study in waiting time.

Main outcome variables

pain & anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130721014086N12**

Registration date: **2019-09-03, 1398/06/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-03, 1398/06/12**

Update count: **0**

Registration date

2019-09-03, 1398/06/12

Registrant information

Name

Mohammad Aghajani

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 2001

Email address

aghajani_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-21, 1398/04/30

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pre-procedural psycho-education on pain perception and anxiety in women undergoing colposcopy

Public title

The effect of pre-procedural psycho-education on pain perception and anxiety in women undergoing colposcopy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

women aged 20 to 50 years anxiety score more than 30

Exclusion criteria:

history of psychological disorder history of previous colposcopy consumption of anti-anxiety drugs

Age

From **20 years** old to **50 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

patients are divided into two groups consisting the case and the control group by permuted block randomization using 10 blocks of 6. randomization is done by using computer and random digit table

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Kashan University of Medical Sciences

Street address

vise chancellor of research and technology, kashan university of medical sciences, 5th km of Ravand Ghotb Blvd, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2019-07-17, 1398/04/26

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.047

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

anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

2**Description of health condition studied**

pain

ICD-10 code

R10.2

ICD-10 code description

Pelvic and perineal pain

Primary outcomes**1****Description**

anxiety

Timepoint

before intervention and immediately after intervention

Method of measurement

The Stat- Trait Anxiety Inventoty

2**Description**

pain

Timepoint

after colposcopy

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

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

Intervention group: The intervention group received a psychoeducational session before undergoing the colposcopy. Psychoeducation consisted of a 60 to 70 face to face session consist of 2 to 5 patients where patients are introduced to each other and a trained researcher provides information about the aims of the group as well as, active listening to patients feelings and problems, educating patients about Papsmear and necessity of doing colposcopy and preventing cervical cancer, introducing medical staff and the procedure of colposcopy, emotional support, through empathy, congruence, and unconditional positive acceptance. Also the researcher provides psychological anxiety reducing techniques such as trying to improve patients tendency to accept the importance of the procedure, Training deep breath, imagination, muscle relaxation and pain reducing techniques.

Category

Behavior

2

Description

Control group: The control group received an informational pamphlet containing information about colposcopy

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza clininc, Beheshti St, Kashan

Full name of responsible person

Mahshid Jamalzade

Street address

Kashan University of medicine, Km 3 Ravand Road, Kashan

City

Kashan

Province

Isfahan

Postal code

87155988141

Phone

+98 31 5554 0021

Email

m74jamalzade@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafshe

Street address

Ravand

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 0021

Email

aghajani1362@yahoo.com

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

Muhammad Aghajani

Position

lectuerer

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Km 3 Ghotbe Ravandi, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 0021

Fax

+98 31 5554 3366

Email

aghajani1362@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Aghajani

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Km 3 Pole Ravand, kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 36 5551 0021

Email

aghajani1362@yahoo.com

+98 36 5551 0021

Fax**Email**

aghajani_m@kaums.ac.ir

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

Kashan University of Medical Sciences

Full name of responsible person

Mohammad aghajani

Position

lecturer

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Km 3 Pole Ravand,
kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available