Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of home based Kegel exercise on decreasing severity of symptoms and improving quality of life in Omani females identified to have Stress Urinary Incontinence: A prospective randomized controlled study

Protocol summary

Study aim
Effects of Kegel exercise training versus no training, on frequency and severity of symptoms of Stress Urinary Incontinence (SUI) and on the quality of life.

Design
Randomized, superiority, parallel group trial with blinded outcome assessment. Randomization was centralized and computerized .

Settings and conduct
The study will be conducted at three Primary Health Centers in Muscat, Oman. Patients in the intervention group will receive individualized training about Kegel's exercise wheres those in control group will be invited for a group lecture. The research physiotherapist will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion: non-pregnant women; 20-to-50 years; able to read and write. Exclusion: Women either in postnatal period; requiring wheel-chair; attending for emergency services or having prolapse grade III and IV.

Intervention groups
Intervention group: educated individually using audio-visual aids about Kegel's exercise; prescribed daily schedule and will be contacted weekly. The control group participants will receive a group lecture as above but will not be supervised.

Main outcome variables
Frequency of urinary incontinence, severity and quality of life; Measure PFM strength (Oxford Grading System); PFM strength and endurance assessment using perniometer.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180527039868N1**
Registration date: **2018-07-04, 1397/04/13**
Registration timing: **prospective**

Last update: **2018-07-04, 1397/04/13**
Update count: **0**

Registration date
2018-07-04, 1397/04/13

Registrant information

Name
Maisa Al-Kiyumi

Name of organization / entity
Sultan Qaboos University Hospital

Country
Oman

Phone
+968 24 143407

Email address
drmaysa@squ.edu.om

Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2639-10-03, 2018/07/11

Expected recruitment end date
2639-11-02, 2018/08/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of home based Kegel exercise on decreasing severity of symptoms and improving quality of life in Omani females identified to have Stress Urinary Incontinence: A prospective randomized controlled study

Public title
Kegel exercise and stress urinary incontinence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Non-pregnant females. Able to read and write Attending the primary healthcare centers for any reason
Exclusion criteria:
Females in the postnatal period (who delivered in the past 6 months). Women requiring wheel-chair. Women attending for emergency services. Women with prolapse grade III and IV according to the classification of International Continence Society (ICS)
Age
From **20 years** old to **50 years** old
Gender
Female

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The study involves three primary healthcare centers (PHC) in the same area with nearly similar sociodemographic profile of the attendees who avail PHC services. Hence for the purpose of this study and analysis, the three PHCs will be treated as one unit. From among the participants identified having Stress Urinary Incontinence from our ongoing phase I study titled "Prevalence, risk factors, impact on quality of life of Urinary incontinence in urban Omani women", the PI and Co-PI will contact all identified eligible females on telephone; explain the importance of the phase II RCT and invite her to participate in the phase II RCT after explaining the protocol in brief over phone. The subjects willing to be a part of phase II study will be requested to report on a pre-specified day to the same PHC where they were enrolled, explained the protocol of the trial individually by the PI/Co-PI and informed consent taken. The consenting subjects will be assigned identification numbers. A computer based simple random sequence generator will then be used separately at each PHC to direct the subject either to the intervention or control group. The random allocation process will continue till the required sample size target is achieved. Allocation concealment is not possible due to the nature of our study. Adequate care will be taken to prevent contamination. Two days will be allocated to each of the PHC for conduct of the trial. The whole research team consisting of PI, Co-PI and physiotherapist will be available at each center of study on the specified days.
Blinding (investigator's opinion)
Single blinded
Blinding description
The research physiotherapist , is the investigator and outcome assessor also, will be assessing all the subjects at baseline and also 12 weeks post-intervention will be blinded to the groups to which the subject belongs.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ministry of Health
Street address
P.O.Box:393, Post code:100, Muscat, Oman
City
Muscat
Postal code
100
Approval date
2639-06-19, 2018/03/29
Ethics committee reference number
MoH/CSR/17/6555

Health conditions studied

1

Description of health condition studied
Stress urinary incontinence
ICD-10 code
N39.3
ICD-10 code description
Stress Urinary Incontinence

Primary outcomes

1

Description
The frequency of Stress Urinary Incontinence symptoms
Timepoint
At baseline and 12 weeks after intervention
Method of measurement
International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-SF)

2

Description

The severity of Stress Urinary Incontinence symptoms

Timepoint

At baseline and 12 weeks after intervention

Method of measurement

International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-SF)

3

Description

The quality of life of women with Stress Urinary Incontinence

Timepoint

At baseline and 12 weeks after intervention

Method of measurement

International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-SF)

Secondary outcomes

1

Description

Measure Pelvic Floor Muscle (PFM) strength

Timepoint

At baseline and 12 weeks after intervention

Method of measurement

Vaginal palpation (Oxford Grading System)

2

Description

Measure Pelvic Floor Muscle (PFM) strength and endurance

Timepoint

At baseline and 12 weeks after intervention

Method of measurement

Perineometer

Intervention groups

1

Description

Intervention group: Patients in the intervention group will report to the Co-PI who is family physician having undergone special training in Kegel Exercise. She will educate the participants individually using audio-visual aids about the anatomy of pelvic floor muscles, continence mechanism and the importance of Kegel's exercise in management of UI problems and advice the subjects about daily schedule of performing the Kegel's exercises. The instructions for Kegel exercise involves endurance and speed training. Endurance training (tonic contractions) of pelvic floor muscles consists of slow velocity close to maximum contractions for 3-10 seconds (according to the initial pelvic floor assessment) followed by relaxation for similar duration. For example, if the initial pelvic floor assessment shows a time of sustained contraction of 5 seconds, the woman will be instructed to have slow contractions for 5 seconds for the first week, then increase it to 6 seconds in the next week and so on with the aim of reaching 10 seconds. Thus, the time of sustained contraction will be increased by 1 second per week up to 10 seconds. Speed training (phasic contractions) involves fast moderately strong contractions for 2 seconds followed by relaxation for 2 seconds. The aim is to have 5 sessions of both slow and fast contractions per day. Each session consists of 10 slow and 10 fast contractions. They will be explained to focus on tightening only pelvic floor muscles and not to flex the muscles in abdomen or thighs. The intervention group subjects will be contacted every week on phone to remind and motivate them about the prescribed intervention.

Category

Treatment - Other

2

Description

Control group: The participants in control group will be invited for a group lecture (number could vary) on the earliest possible day at the same center of their enrollment. They will be given a 15 minutes lecture using audio-visual aids on the anatomy of pelvic floor muscles, continence mechanism and importance of doing Kegel exercise to alleviate problems related to UI. The control group participants will not be supervised or reminded by weekly telephone communication.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Mawaleh Health Centre

Full name of responsible person

Maisa Al-Kiyumi

Street address

Al-Shifa street, Al-Mawaleh South, Muscat

City

Muscat

Postal code

316

Phone

+968 24 548411

Email

maysa8172@gmail.com

2

Recruitment center

Name of recruitment center

Al-Maabelah Health Centre

Full name of responsible person

Zalikha Al-Belushi

Street address

Al-Nebras street, Al-Maabelah, Muscat

City

Muscat

Postal code
316
Phone
+968 24 450567
Email
albelushi11@hotmail.com

3

Recruitment center
Name of recruitment center
Al-Khoudh Health Center
Full name of responsible person
Zalikha Issa Al-Belushi
Street address
Al-Khoudh, Al-Seeb, Muscat
City
Muscat
Postal code
316
Phone
+968 24 537443
Email
albelushi11@hotmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sultan Qaboos University
Full name of responsible person
Dr Yahya Al Wahaibi, Dean of research
Street address
PO Box 83, Al Khoud
City
Muscat
Postal code
123
Phone
+968 24 145923
Fax
+968 24 413449
Email
safiyama@squ.edu.om
Web page address
https://www.squ.edu.om/
Grant name
Deanship of Research Fund Program
Grant code / Reference number
RF/MED/FMCO/18/01
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sultan Qaboos University
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
Sultan Qaboos University Hospital
Full name of responsible person
Maisa Al-Kiyumi
Position
Specialist A Family Medicine
Latest degree
Specialist
Other areas of specialty/work
Family Physician
Street address
1909, Al-Mawaleh South, Muscat, Oman.
City
Muscat
Province
Muscat
Postal code
316
Phone
+968 24 143407
Fax
Email
maysa8172@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Sultan Qaboos University Hospital
Full name of responsible person
Maisa Hamed Sulaiman Al-Kiyumi
Position
Specialist A Family Medicine
Latest degree
Specialist
Other areas of specialty/work
Family Physician
Street address
1909, Al-Mawaleh South, Muscat, Oman
City
Muscat
Province
Muscat
Postal code
316
Phone
+968 24 143407
Email
drmaysa@squ.edu.om

Person responsible for updating data

Contact

Name of organization / entity
Sultan Qaboos University Hospital

Full name of responsible person
Maisa Hamed Sulaiman Al-Kiyumi

Position
Specialist A Family Medicine

Latest degree
Specialist

Other areas of specialty/work
Family Physician

Street address
1909, Al-Mawaleh South, Muscat, Oman

City
Muscat

Province
Muscat

Postal code
316

Phone
+968 24 143407

Email
drmaysa@squ.edu.om

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
Undecided - It is not yet known if there will be 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 collected deidentified IPD from the study titled "Phase II study: The effect of home based Kegel exercise on decreasing severity of symptoms and improving quality of life in Omani females identified to have Stress Urinary Incontinence: A prospective randomized controlled study"

When the data will become available and for how long
Starting 6 months after publication

To whom data/document is available
Academic institutions only

Under which criteria data/document could be used
For Systematic Reviews and Metaanalysis

From where data/document is obtainable
Dr. Maisa Al Kiyumi <drmaysa@squ.edu.om>

What processes are involved for a request to access data/document
Authorized researchers from academic institutions only can get in touch with Dr Maisa Al Kiyumi at her above email address.

Comments