ISRCTN14126416 https://doi.org/10.1186/ISRCTN14126416

The role of abdominal muscle training in combination with pelvic floor muscle training to treat female urinary incontinence. A pilot study

Submission date
24/05/2023

Recruitment status
No longer recruiting

Registration date
31/05/2023

Overall study status
Completed

Last Edited
31/05/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Training of the deep abdominal muscles and, in particular, the transversus abdominis (TrA), restores tonic pelvic floor muscle (PFM) activity. However, current literature is inconclusive on whether TrA training can provide an additional benefit to the training of the PFMs in treating female urinary incontinence. Thus, a study was designed to investigate the synergistic effect of PFM and TrA training compared to PFM-only training on incontinence parameters in women with stress or mixed urinary incontinence with a predominant stress component

Who can participate?
Adult women with (stress or mixed) incontinence

What does the study involve?
Participants were divided into two groups on a 1:1 allocation ratio to either PFM training alone or PFM plus TrA training. They all attended weekly training sessions by a single physical therapist for 12 weeks. They also completed questionnaires to assess changes in the number of incontinence episodes, overall health status, their impressions of any improvement, sexual function and the strength of pelvic floor muscles at both baseline and study completion.

What are the possible benefits and risks of participating?
The benefit of this trial is to assess the potential add-on benefit of transversus abdominus muscle plus pelvic floor muscle training as compared to pelvic floor muscle training alone. Previous results have shown that only women with pure stress urinary incontinence benefit from this combined training and not every woman with urinary incontinence. There was no risk associated with participating in this trial. None of the recruited patients reported any treatment-related complication at 12 weeks of follow-up.

Where is the study run from?
Papageorgiou Hospital, Urology Department (Greece)

When is the study starting and how long is it expected to run for?
January 2011 to December 2013

Who is funding the study?
Investigator initiated and funded (Greece)

Who is the main contact?
Dr Vasileios Sakalis, vsakalis@auth.gr

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number

Study information

Scientific Title
Does training of the transversus abdominis muscle provide an additional clinical benefit to the training of pelvic floor muscles in female urinary incontinence?

Acronym
TrA plus PFMT for female incontinence

Study objectives
It has been proposed that pelvic floor muscle (PFM) rehabilitation is incomplete until the abdominal muscles are also rehabilitated. Thus, training of the deep abdominal muscles and in particular transversus abdominis (TrA), restores tonic PFM activity especially when the automatic and coordinated function has been lost. The aim of this study is to compare the clinical effect of PFM and TrA muscle training on incontinence parameters in women with stress or mixed urinary incontinence with a predominant stress component.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/05/2009, Scientific Council of Papageorgiou University Hospital of Thessaloniki, and the Ethics Committee of Aristotele University of Thessaloniki (Aristotele University of Thessaloniki, Thessaloniki 541 24, Greece; +30 2310 999 900; info@med.auth.gr), ref: 1/ 01/05 /2009

Study design
Single-blind randomized controlled study design

Primary study design
Interventional

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Treatment of female stress and female stress predominant urinary incontinence

Interventions
Pelvic floor muscle and transversus abdominis muscle training under physiotherapist control

Interventions:
All subjects underwent routine assessment with a detailed urological, medical and gynecological history, clinical examination with Cough Stress test (CST) in lithotomy and/or upright position, vaginal assessment of the Pelvic floor Muscles (PFMs) with the PERFECT assessment scheme, uroflowmetry and ultrasonographic assessment of post-void residual. Eligible patients completed a 3-day bladder diary at baseline and at study completion. In addition, they completed the Kings Health Questionnaire (KHQ), the Patient Global Impression of

Improvement, PGI-I), the Quality of Life score and the Female Sexual Function Index (FSFI) both at baseline and at study completion at 12 weeks.

Informed consent and randomization:
Eligible patients signed a written informed consent and were randomized to receive either PFM training plus transversus abdominis muscle (TrA) training (Group A) or PFM training alone (Group B) in a 1:1 allocation ratio. The randomization process was performed on a single sequence of random assignments, using SPSS 19.0 software (IBM Corp, Armonk, NY, USA). The study protocol included weekly training sessions by a single physical therapist for 12 weeks.

Intervention provider:
The training session in both groups was provided by the certified physical therapist (Dr Konstantinidou Eleni) for 12 weeks.

Modes of delivery:
As per protocol, both arms required face-to-face pelvic floor muscle training. Each patient had individual training by the physical therapist.

Location:
The interventions took place in the Female Urology Outpatient Clinics of the 2nd Urology Department of Aristotele University of Thessaloniki, at Papageorgiou Hospital of Thessaloniki.

Intervention Type
Behavioural

Primary outcome(s)
Incontinence episodes measured using a 3-day bladder dairy at baseline and week 12 (end of the study)

Key secondary outcome(s))
The following secondary outcome measures are assessed at baseline and week 12 (end of the study):
1. Overall health status measured using the King's Health Questionnaire (KHQ)
2. Patient's impression of improvement measured using the Patient Global Impression of Improvement (PGI-I) scoring
3. Quality of life measured using the Quality of life (QoL) scoring
4. Sexual function measured using the Female Sexual Function Index (FSFI) scoring
5. The change in the strength of pelvic floor muscles measured using the PERFECT assessment scheme

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Women ≥18 years old and over
2. At least a 3-month history of stress urinary incontinence (SUI) or mixed urinary incontinence (MUI) with a predominant stress component

3. At least 7 incontinence episodes per week, as recorded in a 3-day bladder diary
4. The enrolled women should have a positive cough stress test (CST) and a grade 3 or 4 PFM contraction based on the PERFECT Assessment Scheme

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
90 years

Sex
Female

Total final enrolment
85

Key exclusion criteria
1. Daytime frequency (>8 micturitions per day) or nocturia (>1 voidings per night)
2. Neurogenic incontinence or systemic diseases such as diabetes mellitus, or chronic kidney disease
3. Previously received medications for incontinence or had undergone any type of continence surgery
4. Pregnancy

Date of first enrolment
30/05/2009

Date of final enrolment
15/08/2012

Locations

Countries of recruitment
Greece

Study participating centre
Papageorgiou Hospital
Urology Department
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Sponsor information

Organisation
Aristotle University of Thessaloniki

ROR
https://ror.org/02j61yw88

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during this study are available upon request from the corresponding author, Dr Vasileios Sakalis, vsakalis@auth.gr.

Raw data including baseline and follow-up details will be shared 4-6 weeks from the request. These data are anonymized, however, the participants did not consent to their clinical details being disseminated, therefore, an updated consent is needed. Each participant is given a unique identification number, which is only known to the Principal Investigation.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			31/05/2023	No	Yes