

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

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<b>Registration date</b> 31/05/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 31/05/2023	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 PFM 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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Principal Investigator

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Ph1

## **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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital, Other therapist office

**Study type(s)**

Prevention, Treatment

**Participant information sheet**

See trial outputs table

## **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 measure**

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

## **Secondary outcome measures**

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

**Overall study start date**

01/01/2009

**Completion date**

31/12/2012

## Eligibility

**Key inclusion criteria**

1. Women  $\geq 18$  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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

90 Years

**Sex**

Female

**Target number of participants**

64

**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

Agios Pavlos

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Thessaloniki

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## **Sponsor information**

**Organisation**

Aristotle University of Thessaloniki

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<https://www.auth.gr/en>

**ROR**

<https://ror.org/02j61yw88>

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

01/06/2023

**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?
<a href="#">Participant information sheet</a>			31/05/2023	No	Yes