Functional near-infrared spectroscopy as biofeedback to assist pelvic floor muscle training: a randomized controlled trial.

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The main aim is to study whether fNIRS is a reliable non-invasive alternative to invasive pelvic floor EMG in order to provide biofeedback during pelvic floor physical therapy in patients with SUI.

Ethical review	Not approved
Status	Will not start
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Observational non invasive

Summary

ID

NL-OMON50823

Source
ToetsingOnline

Brief title
fNIRS and pelvic floor muscle training.

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
stress urinary incontinence., Urine leakage

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Electromyography, Functional near-infrared spectroscopy, Pelvic floor, Stress urinary incontinence

Outcome measures

Primary outcome

The main study parameter is change in cortical activation during pelvic floor muscle contraction. Activation is measured as the oxygenated/deoxygenated haemoglobin ratio in the cerebral cortex, measured with fNIRS.

Secondary outcome

The secondary outcomes are: change in pelvic floor muscle force, change in pelvic floor muscle endurance, and change in pelvic floor muscle coordination which are measured with EMG using the MAPLe device. The correlation between fNIRS and pelvic floor EMG, change in pelvic floor related quality of life, and change in symptom severity (frequency of incontinence episodes) are additional secondary outcomes. These secondary outcomes will be assessed with validated questionnaires on symptoms and quality of life in pelvic health. The validated Dutch PRAFAB, UDI-6, IIQ-7, EQ-5D-5L, and HADS will be used to assess pelvic health related symptoms and quality of life. These outcome measures will be assessed at baseline and after six weeks.

Study description

Background summary

The primary treatment of stress urinary incontinence (SUI) is pelvic floor physical therapy which sometimes includes invasive EMG measurement of the pelvic floor musculature. A possible non-invasive alternative to indirectly

measure pelvic floor muscle activity is functional near-infrared spectroscopy (fNIRS). FNIRS is a functional neuroimaging modality that measures changes in oxygenation of the cerebral cortex.

Study objective

The main aim is to study whether fNIRS is a reliable non-invasive alternative to invasive pelvic floor EMG in order to provide biofeedback during pelvic floor physical therapy in patients with SUI.

Study design

A prospective randomized controlled trial.

Study burden and risks

The intervention groups will have seven site visits at the Erasmus MC, a visit at baseline and a follow-up visit six weeks later, in-between these patients have weekly in office physical therapy sessions, this is standard care. The Control group has two site visits, one at baseline and one six weeks later, they perform pelvic floor exercises in-between at home as instructed by a leaflet, after the study period they will be offered standard care. Both groups will have a site visit at baseline and six weeks later of approximately 60 minutes. These visits consist of physical examination, anamnesis, filling in five validated questionnaires, and the measurements of pelvic floor EMG and fNIRS during a block paradigm including pelvic floor muscle contractions and a control task. The physical examination, anamneses, filling out one of five questionnaires, and pelvic floor EMG are part of standard care. Additionally 4 short questionnaires are filled out and fNIRS measurements are performed which are part of this study but not part of standard care. The risks are negligible. The usage of the intravaginal EMG probe (MAPLe device) is part of standard clinical practice in pelvic floor physical therapy. No further burden or risks, other than the usual burden and risks that are associated with pelvic floor physical therapy, associated with participation are expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Referred for physical therapy to treat mixed (predominant SUI) or SUI.
- Right-handed.
- Female, between the age of 18 up to and including 60 years old.
- Signed informed consent.

Exclusion criteria

- Using any medication for urinary complaints.
- Using any medication which may influence the function of the lower urinary tract (i.e. neuroleptics, anti-depressants, morphine-like medication).
- Having had PFMT in the past six months.
- Any known neurological disorder.
- Any known psychiatric disorder.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Not approved

Date:	12-03-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL75816.078.20