Exploring pelvic floor signs and symptoms in community dwelling women and men: a mixed-method study

Published: 25-01-2019
Last updated: 24-08-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON45972

Source
ToetsingOnline

Brief title
Pelvic floor signs and symptoms in women and men

Condition

- Other condition

Synonym
pelvic floor symptoms; pelvic floor dysfunction

Health condition

pelvic floor disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Cohort Studies, Pelvic Floor Disorders, Surveys and Questionnaires

Outcome measures

Primary outcome

To evaluate the sex- and gender difference in prevalence and incidence of (clinically relevant clusters of) PFS, the following primary parameters are assessed: lower urinary tract symptoms, bowel symptoms, prolapse (in women only), sexual functioning, and pain.

Secondary outcome

Secondary study parameters are factors associated with the development of PFS (*risk factors*), factors that predict the course of PFS (*prognostic factors*), factors that reveal the impact of PFS on daily life, help seeking behavior, and health care use (consultations for PFS and consultation frequency, diagnostic tests, diagnoses, treatment, and referrals).

Study description

Background summary

Pelvic floor symptoms (PFS) are prevalent and often impair quality of life. They include micturition problems, defecation problems, pelvic organ prolapse, sexual problems and genito-pelvic pain. The pelvic floor is an anatomical and functional unit, and therefore different PFS may co-occur. However, literature on prevalence of clusters of PFS is scarce. Furthermore, PFS is understudied in the male population and when studies are performed in male subjects, studies do not assess the complete scope of possible PFS. Currently, different secondary

care specialists treat PFS. This may lead to successive diagnostic tests, sub-optimal treatments, high patient burden, and substantial medical costs. Primary care would be an ideal setting for an integrated approach early in the course of symptom development in order to prevent complexity and chronicity of PFS.

Study objective

The primary aim of the study is to generate a cohort, which provides information on sex- and gender differences in: prevalence and incidence of (clinically relevant clusters of) PFS, risk factors and prognostic factors for PFS, factors that reveal the impact of PFS on daily life, help seeking behavior and use of health care.

Study design

A prospective observational population-based cohort study will be conducted with follow-up moments after 1 year and 2 years. Data of the questionnaire will be connected to medical record data from the participating general practitioners (GPs). A representative sample of female and male subjects with and without PFS will be invited for a physical examination to assess pelvic floor disorders and muscle function. Furthermore, a subsample of patients will be invited for a qualitative study consisting of semi-structured interviews on help seeking behavior, including barriers and facilitators, preferences and satisfaction.

Study burden and risks

Participants have to fill in a questionnaire consisting of eleven parts for female subjects and ten parts for male subjects. The total time to complete the questionnaire will be around 45-60 minutes. As some questions will be on personal, intimate and sexual items, participants might feel uncomfortable filling in those questions. Otherwise, burden of filling in the questionnaire is negligible. Subjects, who provided specific informed consent for sub-study, will undergo additional research consisting of approximately 20 minutes in case of physical examination and 60 minutes in case of an interview.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

16 years or older

Exclusion criteria

• terminal disease
• dementia precluding informed consent
• cognitive impairment precluding informed consent
• current psychological condition precluding informed consent
• not suitable or too ill to participate based on the judgement of the general practitioner.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-05-2019
Enrollment:	5000
Type:	Actual

Ethics review

Approved WMO Date:	25-01-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-01-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT03558802
CCMO	NL67503.042.18