

The social role of menstrual health interventions

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Ethical review	Not available
Status	Pending
Health condition type	Economic and housing issues
Study type	Observational non invasive

Summary

ID

NL-OMON57493

Source

Onderzoeksportaal

Brief title

The social role of menstrual health interventions

Condition

- Economic and housing issues
- Menopause related conditions
- Menstrual cycle and uterine bleeding disorders

Synonym

Menstruation, heavy menstrual bleeding, dysmenorrhoea

Research involving

Human

Sponsors and support

Primary sponsor: Máxima MC

Source(s) of monetary or material Support: Stichting Van Dam Van Os
10.3

Intervention

- Medicine
- Surgical procedure

Explanation

N.a.

Outcome measures

Primary outcome

<p>Absenteeism and presenteeism</p>

Secondary outcome

<p>- Menstrual-related quality of life
- Overall quality of life
- Pain
- Experience of treatment</p>

Study description

Background summary

Scientific research shows that about 30 percent of women in the Netherlands suffer from painful and/or heavy periods. 1 in 3 women cannot carry out their daily activities during their periods, 1 in 7 women sometimes take time off work or school during their periods and 80 percent of women report being less productive during their periods. We are therefore curious whether providing treatment for menstruation-related complaints affects absenteeism or productivity loss due to complaints around menstruation. With this study, we want to investigate whether treatments have an impact and what the effect of these treatments is for work and for schoolactivities.

Study objective

Máxima MC is organising this study. The aim of the study is to gain insight into the effect of different treatments (medication, IUD, endometrial ablation, uterus removal) for menstruation-related complaints on labour and educational participation. For this study, we created a questionnaire to investigate this subject.

Study design

Patients are contacted by mail after they have been given an appointment at the

Gynaecology outpatient clinic. The patient will receive the patient information by mail. If the patient wants to participate, the patient can give consent at the start of the questionnaire. After giving consent, the questionnaire can be started. This questionnaire is about menstruation-related complaints and the impact on work or school. The questionnaire consists of several multiple-choice questions and some open-ended questions. The questionnaire should be completed prior to the appointment or start of treatment. A second questionnaire is sent 3 months after the start of treatment for menstruation-related complaints. The questionnaire takes about 15-30 minutes to complete.

Intervention

We would like to investigate the effect of the following medical interventions on work and school:

- Contraceptive pill
- Hormonal IUD
- Ryeqo
- Lucrin
- Endometrial ablation
- Uterine removal

Study burden and risks

Patients spend 15-20 minutes twice during the questionnaire. Otherwise, there are no risks for the patient.

Contacts

Scientific

Máxima MC
N. S. W. M. Bosma
De Run 4600
Veldhoven 5504DB
Netherlands
(040) 888 8384

Public

Máxima MC
N. S. W. M. Bosma
De Run 4600
Veldhoven 5504DB
Netherlands
(040) 888 8384

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Adolescents (16-17 years)

Inclusion criteria

Dutch- and/or English-speaking

Working gynaecological patients aged 18-52 years or studying gynaecological patients aged 16-25 years for at least 8 hours a week.

Exclusion criteria

None

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	No intervention
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-04-2025
Enrollment: 300
Duration: 3 months (per patient)
Type: Anticipated

Medical products/devices used

Product type: Medicine
Brand name: Lucrin
Generic name: Leuprorelin
Product type: Medicine
Brand name: Microgynon 30
Generic name: Levonorgestrel 150mcg / Ethinylestradiol 30 mcg
Product type: Medicine
Brand name: Ryeqo
Generic name: Relugolix/Estradiol/Norethisterone
Product type: Medicine
Brand name: Mirena/Kyleena
Generic name: Levonorgestrel-releasing intrauterine system

IPD sharing statement

Plan to share IPD: Yes

Plan description

Na een redelijke aanvraag kunnen de antwoorden van de vragenlijsten gedeeld worden in de vorm van een SPSS databestand. Deze gegevens bestaan uit leeftijd, medische voorgeschiedenis, werk, onderwijsparticipatie, ervaren pijn, menstruatie-gerelateerde kwaliteit van leven en algemene kwaliteit van leven. Deze data worden beschikbaar gesteld via een beveiligde mail.

Ethics review

Not available
Date: 21-03-2025

Application type: First submission
Review commission: CCMO

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
Research portal	NL-009684