Pain in endometriosis and the relation to Lifestyle (PEARL). Effectiveness of a dietary intervention and cognitive behavioral therapy in endometriosis-associated pain

Published: 11-07-2024
Last updated: 30-01-2025

To investigate the effectiveness of an anti-inflammatory diet in reducing pain symptoms among patients with endometriosis and to explore whether the addition of CBT enhances this pain-reducing effect apart from the effect of CBT alone. The secondary...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Ovarian and fallopian tube disorders
Study type	Interventional

Summary

ID

NL-OMON56879

Source
ToetsingOnline

Brief title
PEARL study

Condition

- Ovarian and fallopian tube disorders

Synonym
dysmenorrhoe, Endometriosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cognitive behavioral therapy, Dietary intervention, Endometriosis, Pain

Outcome measures

Primary outcome

The main study parameters are the change in HRQoL (as measured by the Endometriosis Health Profile (EHP)-30 and Short Form (SF)-36, as well as a general rating) and pain symptoms (as measured by a Numerical Rating Scale (NRS)).

Secondary outcome

1. Evaluate the impact of the anti-inflammatory diet on improving the quality of life in patients with endometriosis.

2. Evaluate the impact of CBT on improving the quality of life in patients with endometriosis.

3. Investigate the influence of the anti-inflammatory diet on inflammatory markers in peripheral blood, menstrual effluent, and the vaginal and intestinal microbiome among patients with endometriosis.

4. Investigate the influence of CBT on inflammatory markers in peripheral blood, menstrual effluent, and the vaginal an intestinal microbiome among patients with endometriosis.

5. Assess the changes in Natural Killer (NK) cell populations in menstruum as a result of implementing the anti-inflammatory diet in patients with

endometriosis.

6. Assess the changes in Naturel Killer (NL) cell populations in menstruum as a result of implementing CBT in patients with endometriosis.

7. Examine the feasibility of long-term adherence to the anti-inflammatory diet among patients with endometriosis.

8. Determine the effectiveness of CBT in enhancing pain reduction and overall quality of life when combined with the anti-inflammatory diet in patients with endometriosis.

9. To investigate whether pain intensity, pain cognitions, perceived stress, fatigue and objectively measured cortisol levels represent the effects of CBT on QoL in all three groups.

10. To investigate whether CBT serves as a stimulus to promote adherence to the anti-inflammatory diet in patients with endometriosis and whether this reinforces pain-reducing effects.

11. Investigating whether biological data, such as epigenetics and the microbiome, can be used to predict the response to dietary interventions and disease severity.

12. To evaluate the differences in stress (measured by hair cortisol levels), inflammatory markers in peripheral blood, menstrual effluent, and the vaginal and intestinal microbiome between HC and endometriosis patients.

Study description

Background summary

Treatment for endometriosis is often partially or temporarily effective. In addition, medical hormonal treatment is associated with side effects and interferes with fertility. Surgical treatment has a relatively high risk of complications. Therefore, it is crucial to support people with endometriosis through lifestyle interventions. Changing dietary patterns gives patients a means to influence their symptoms. Our hypothesis is that an anti-inflammatory diet could improve immune cell function and reduce inflammation, resulting in improved health-related quality of life (HRQoL) and pain scores. In addition, the integration of cognitive behavioral therapy (CBT) aims to provide insight into pain mechanisms and assist in sustaining dietary modifications.

Study objective

To investigate the effectiveness of an anti-inflammatory diet in reducing pain symptoms among patients with endometriosis and to explore whether the addition of CBT enhances this pain-reducing effect apart from the effect of CBT alone. The secondary objective is to investigate the effect of an anti-inflammatory diet, CBT and the combination of these two interventions on inflammatory characteristics in serum and menstruum samples as well as the effect on the gut and vaginal microbiome. In addition, we want to investigate the differences in stress (measured by hair cortisol levels), inflammatory markers in peripheral blood, menstrual effluent, and the vaginal and intestinal microbiome between healthy controls (HC) and endometriosis patients.

Study design

This study will be a 13-week trial with a pre-post design (T0 to T1) during which endometriosis patients will be randomized between standard care (control group), receive standard care and adhere to an anti-inflammatory diet (DI group), receive standard care and CBT (CBT-group) or receive standard care, adhere to an anti-inflammatory diet and receive CBT (DI + CBT group).

Intervention

Subjects will follow an anti-inflammatory diet based on the Dutch Dietary Guidelines for 13 weeks. They will receive personalized dietary advice from a dietician and recipes will be available. CBT will administered in a total of seven individual sessions led by a psychotherapist. The content of the CBT will be psycho-education regarding pain mechanisms and DI.

Study burden and risks

For this study, subjects need to visit the hospital two times in three months. During these visits, blood samples will be drawn and 3 cm of hair will be taken, subjects will hand over their samples of menstrual effluent, vaginal swab and feces. In addition, subjects will be asked to complete several

questionnaires. Depending on which group subjects are assigned to, subjects will have four consults with a dietician and seven individual sessions of CBT. Since the investigational treatment consists of dietary advice based on the Dutch Dietary Guidelines, there are no risks for the subjects. For the CBT we expect that the intervention has a negligible risk although it could be a potential psychological burden for subjects to undergo CBT sessions. However, we expect that this study will be beneficial to subjects since we expect that DI and CBT will increase HRQoL and pain symptoms might improve.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

- Diagnosed with endometriosi via ultrasound/MRI/surgery*
- Pain NRS score > 4

- Age from 17 years
- Premenopausal status
- Body Mass Index (BMI) 18-30 kg/m2
- Ability to understand the explanation about the diet intervention (DI) and CBT*
- Willing to follow the DI*
- Willing to continue their use of food supplements
- Willing to undergo CBT*
- Willing to collect menstrual effluent
* Not apllicable for healthy controls

Exclusion criteria

- Recurrent miscarriages (> 2)
- Eating disorder
- Diagnosed with Crohn*s disease, Ulcerative Colitis, short bowel syndrome or another chronic inflammatory disease
- Self-reported celiac disease
- Vegan diet
- Smoking
- Use of immunosuppressive or psychotropic medication
- Score on FFQ > 130
- Diagnosed with severe mental disorder currently requiring treatment by psychiatrist
- NRS average score below 4 during the last month
- Participation in another intervention study
- Unable to speak Dutch or to understand the intervention
- Need for surgery during the participation in the study
- Serious pain (NRS > 4) from other origin than endometriosis

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-09-2024
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	11-07-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-01-2025
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT06332560
CCMO	NL86247.091.24