Cognitive behavioral therapy to improve quality of life after surgical treatment of women with endometriosis

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Ethical review	Approved WMO
Status	Completed
Health condition type	Reproductive tract disorders NEC
Study type	Interventional

Summary

ID

NL-OMON52725

Source
ToetsingOnline

Brief title
COGENS

Condition

- Reproductive tract disorders NEC
- Psychiatric therapeutic procedures

Synonym
The presence of endometrium like tissue outside the wobe

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,Deel universitair

gefinancierd. Deel wordt gefinancierd vanuit Rijnstate

Intervention

Keyword: Cognitive behavioral therapy, Endometriosis, Pain, Quality of Life

Outcome measures

Primary outcome

The primary objective of this study is to investigate whether usual care

combined with CBT improves QoL in patients undergoing surgery for endometriosis

compared to usual care only.

Secondary outcome

Secondary objectives are to investigate whether pain intensity, pain

cognitions, perceived stress and objectively measured cortisol levels mediate

the effects of CBT on QoL in both groups.

Study description

Background summary

Endometriosis affects 10% of reproductive aged women and causes severe pain and impaired quality of life. Surgery for endometriosis results in long term symptom relief in only 40% of women. QoL in endometriosis improves after surgery, but not to the level of healthy women. Mediators in QoL include pain intensity, pain cognitions, and stress. In a preliminary study, patients with negative pain cognitions reported higher pain intensities compared to patients with positive pain cognitions. This indicates that psychological factors explain considerable variance in pain, suggesting that changing these factors by psychological interventions may contribute to improving QoL. Cognitive behavioral therapy is proven effective as a psychological treatment for pain-related symptoms. QoL after surgery for endometriosis should be improved. Pain cognitions could be psychosocial targets in the treatment of endometriosis related symptoms. We hypothesize that CBT focusing on cognitions towards pain for women undergoing surgery for endometriosis improves pain cognitions, leading to improvement of QoL.

Study objective

The primary objective of this study is to investigate whether usual care combined with CBT improves QoL in patients undergoing surgery for endometriosis compared to usual care only. Secondary objectives are to investigate whether pain intensity, pain cognitions, perceived stress and objectively measured cortisol levels mediate the effects of CBT on QoL in both groups.

Study design

In a randomized controlled trial, 100 endometriosis patients undergoing surgery will be randomized between usual care with CBT (CBT group) and usual care only (control group). Women in the CBT group will receive, in addition to usual care, one pre-surgery and six post-surgery sessions of CBT, aimed at positively influencing mediators of QoL. Women in the control group will receive only usual care. Follow up will be 7,5 months. In both groups QoL, pain intensity, pain cognitions, perceived stress (using questionnaires) will be assessed one month before surgery (baseline) and four months (T1) and 7,5 months (T2) after surgery, and hair cortisol levels (using ELISA) will be assessed at baseline, T1 and T2. Recruitment and treatment of patients will take place in Rijnstate hospital, Radboud University Medical Center (UMC) and Catharina hospital.

Intervention

Cognitive behavioral therapy administered in a total of seven sessions.

Study burden and risks

The control group will receive usual care. The intervention group will receive usual treatment plus a total of seven sessions of CBT. In addition, all participants are asked to fill in seven questionnaires at baseline assessment (4 weeks prior to surgery) and at four and 7,5 months after surgery: the EHP-30, SF-36, PSC, PASS, NRS and PSS. At baseline and T2 participants will receive one extra questionnaire containing items about motivation towards therapy and the use of additional psychological treatment during this study. Furthermore, the researcher will carefully collect a scalp hair sample of at least 0,5 cm thickness. This will be done at baseline assessment, T1 and T2. The hair sample will be analyzed for cortisol levels in a laboratory. We expect that the intervention has negligible risk although it could be a potential psychological burden for patients to undergo CBT sessions. However, we expect that this study will be beneficial to subjects since we expect that CBT will increase QoL and reduce pain intensity.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

Age: 18 to 50 years
Proven endometriosis (by ultrasound, MRI or surgery)
An indication for endometriosis debulking surgery due to endometriosis-related pain
Being able to understand, read and write Dutch

Exclusion criteria

An mood, anxiety or personality disorder diagnosis according to the DSM-5 at the moment of inclusion
Undergoing psychological treatment at the moment of inclusion
Use of psychopharmacologic medication aimed at altering mood at the moment of inclusion
Patients that have endometriosis-related unwanted childlessness only

Scalp hair shorter than 4 cm

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-11-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	02-09-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-09-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-10-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-11-2020

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-06-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-07-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-02-2024
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	NCT04448366
CCMO	NL73632.091.20