

Yoga for endometriosis related pain

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22833

Source

Nationaal Trial Register

Brief title

Yoga for endometriosis

Health condition

Endometriosis

Sponsors and support

Primary sponsor: Maxima Medical Center.

Source(s) of monetary or material Support: None.

Intervention

Outcome measures

Primary outcome

Pain reduction on the numeric rating scale [NRS] after 8 weeks.

A significant reduction in pain score is defined as a mean difference between groups of at least 1.4 points measured on the NRS.

Secondary outcome

- Quality of life, measured by the Endometriosis Health Profile [EHP-30] (after 8 weeks)

- Pain Catastrophizing, measured by the Pain Catastrophizing Scale [PCS] (after 8 weeks)
- Affective Symptoms, measured by the Generalized anxiety disorder [GAD-7] and patient health questionnaire [PHQ-9] (after 8 weeks)

Outcomes will be assessed by ESM at baseline and after intervention (8 weeks) and results will be compared to the results of the above mentioned validated retrospective questionnaires, measured at 8 weeks.

- Pain reduction on the numeric rating scale [NRS] after 4 and 12 weeks. Pain reduction on NRS is assessed by end of week pain score.
- Use of analgesics, measured by the BPI questionnaire.
- Reduction of dysmenorrhoea on NRS (if applicable)
- Reduction of dyspareunia on NRS (if applicable)
- The differences in pain reduction on NRS assessed by ESM compared to end of day pain scores [BPI] and end of week pain scores on the NRS.

Study description

Background summary

Endometriosis related (pain)symptoms have a significant impact on the quality of life of these women [1]. However, the extent of this disease is not directly related to the degree of symptoms [2]. The difference in pain presentation and therapy refractoriness, has led to the suggestion that the perception of these symptoms may be influenced by psychological and emotional distress [3-5]. The literature suggests that affective symptoms like anxiety and depression occur more often in these patients [6]. Participants with greater self-esteem and self-efficacy are less distressed [7] and efficient emotion regulation is associated with the ability to cope with chronic pain [8]. Yoga could have a successful impact on emotion regulation and could reduce pain and affective symptoms and improve quality of life [9,10]. The objective of this multicentre randomized controlled trial is to investigate the effectiveness of yoga-intervention for women suffering from pain due to endometriosis when compared to no yoga intervention. In total, 64 endometriosis patients ≥ 18 years old, with endometriosis related pain symptoms will be included. Pregnant patients and patients with any other organic explanation for chronic pelvic pain will be excluded. After randomization, the intervention group will participate in 75 minute (hatha-based) yoga sessions once a week during 8 weeks. The control group will receive no yoga-intervention. Both groups will continue with their usual medical care for endometriosis.

[1] Bellelis, P., Dias, J.A., Jr., Podgaec, S., Gonzales, M., Baracat, E.C., Abrão, M.S., Epidemiological and clinical aspects of pelvic endometriosis - a case series, Rev Assoc Med Bras 2010; 56:467-471.

[2] Vercellini, P., Fedele, L., Aimi, G., Pietropaolo, G., Consonni, D., Crosignani, P.G., Association between endometriosis stage, lesion type, patient characteristics and severity of pelvic pain symptoms: a multivariate analysis of over 1000 patient, Hum Reprod 2007;

22(1):266-271.

- [3] Vitale, S.G., La Rosa, V.L., Rapisarda, A.M.C., Laganà, A.S., Impact of endometriosis on quality of life and psychological well-being, *J Psychosom Obstet Gynecol* 2017; 38(4):317-319.
- [4] Laganà, A.S., La Rosa, V.L., Rapisarda, A.M.C., Valenti, G., Sapia, F., Chiofalo, B., Rossetti, D., Frangež, H.B., Vrtačnik Bokal, E., Vitale, S.G., Anxiety and depression in patients with endometriosis: impact and management challenges, *Int J Womens Health* 2017; 9:323-330.
- [5] Vitale, S.G., Petrosino, B., La Rosa, V.L., Rapisarda, A.M.C., Laganà, A.S., A Systematic Review of the Association Between Psychiatric Disturbances and Endometriosis, *J Obstet Gynaecol Can* 2016; 38(12):1079-1080.
- [6] Gambadauro, P., Carli, V., Hadlaczky, G. Depressive symptoms among women with endometriosis: a systematic review and meta-analysis, *Am J Obstet Gynecol* 2019 Mar;220(3):230-241.
- [7] Facchin, F., Barbara, G., Dridi, D., Alberico, D., Buggio, L., Somigliana, E., Saita, E., Vercellini, P., Mental health in women with endometriosis: searching for predictors of psychological distress, *Hum Reprod* 2017; 32(9):1855-1861.
- [8] Agar-Wilson, M., Jackson, T. Are emotion regulation skills related to adjustment among people with chronic pain, independent of pain coping? *Eur J Pain* 2012;16:105-114.
- [9] Kabat-Zinn, J., Lipworth, L., Burney, R. The clinical use of mindfulness meditation for the self-regulation of chronic pain. *J Behav Med* 1985;8:163-190.
- [10] Hansen, K.E., Kesmodel, U.S., Kold, M., Forman, A. Long-term effects of mindfulness-based psychological intervention for coping with pain in endometriosis: a six-year follow-up on a pilot study. *Nord Psychol* 2017;69:100-109.

Study objective

Yoga has a successful impact on emotion regulation and could reduce pain and affective symptoms and improve quality of life.

Study design

Outcomes will be assessed at 4 weeks, 8 weeks and 12 weeks of study.

Intervention

Yoga sessions scheduled for 75 minutes once a week during 8 weeks vs no intervention (control).

Contacts

Public

Maxima Medical Center
Esther van Barneveld

043-3874038

Scientific

Maxima Medical Center
Esther van Barneveld

043-3874038

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Premenopausal women ≥ 18 years old.
- Diagnosed with endometriosis (by physical examination, imaging techniques or laparoscopy).
- Patients who report one of the endometriosis related pain symptoms dysmenorrhoea, abdominal/pelvic pain or dyspareunia; on average, at least 1 day per week in the last 3 months, with a minimum average pain score on the numeric rating scale of 4.
- Ability to understand and speak the Dutch language.
- Owning a smartphone.
- Ability to understand how to utilize the Experience Sampling Method [ESM] tool.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Change of hormonal medication during the past one month.
(for example for endometriosis treatment or fertility treatment).
- Surgery planned during the study period.
- Already performing yoga or mindfulness during the past 3 months.
- Any organic explanation for chronic pelvic pain besides endometriosis.
- Pregnancy.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2019
Enrollment:	64
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 55960
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8113
CCMO	NL71244.015.19

Register

OMON

ID

NL-OMON55960

Study results