

# Yoga for endometriosis related pain

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

|                             |                          |
|-----------------------------|--------------------------|
| <b>Ethische beoordeling</b> | Niet van toepassing      |
| <b>Status</b>               | Werving nog niet gestart |
| <b>Type aandoening</b>      | -                        |
| <b>Onderzoekstype</b>       | Interventie onderzoek    |

## Samenvatting

### ID

NL-OMON22833

### Bron

NTR

### Verkorte titel

Yoga for endometriosis

### Aandoening

Endometriosis

## Ondersteuning

**Primaire sponsor:** Maxima Medical Center.

**Overige ondersteuning:** None.

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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.

# Toelichting onderzoek

## Achtergrond van het onderzoek

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  $\geq 18$  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.

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- [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.

## **Doel van het onderzoek**

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

## **Onderzoeksopzet**

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

## **Onderzoeksproduct en/of interventie**

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

# **Contactpersonen**

## **Publiek**

Maxima Medical Center  
Esther van Barneveld

043-3874038

## **Wetenschappelijk**

Maxima Medical Center  
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# **Deelname eisen**

## **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

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

- Premenopausal women  $\geq 18$  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.

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

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.

## **Onderzoeksopzet**

### **Opzet**

|                  |                         |
|------------------|-------------------------|
| Type:            | Interventie onderzoek   |
| Onderzoeksmodel: | Parallel                |
| Toewijzing:      | Gerandomiseerd          |
| Blinding:        | Open / niet geblindeerd |
| Controle:        | Geneesmiddel            |

### **Deelname**

|                         |                          |
|-------------------------|--------------------------|
| Nederland               |                          |
| Status:                 | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-12-2019               |

Aantal proefpersonen: 64  
Type: Verwachte startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55960

Bron: ToetsingOnline

Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID             |
|----------|----------------|
| NTR-new  | NL8113         |
| CCMO     | NL71244.015.19 |
| OMON     | NL-OMON55960   |

## Resultaten