

At-home yoga for endometriosis-related pain.

Published: 16-12-2019

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What is the effectiveness of at-home yoga-intervention for women suffering from pain due to endometriosis when compared to no yoga intervention.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Interventional

Summary

ID

NL-OMON55960

Source

ToetsingOnline

Brief title

Yoga for endometriosis.

Condition

- Uterine, pelvic and broad ligament disorders

Synonym

Endometriosis

Research involving

Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Endometriosis, Pain, Quality of life, Yoga

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
- Pain Catastrophizing
- Affective Symptoms
- Gastrointestinal symptoms
- Pain reduction after 4 and 12 weeks
- Use of analgesics
- Reduction of dysmenorrhoea (if applicable)
- Reduction of dyspareunia (if applicable)
- The differences in pain reduction assessed by ESM compared to end of day pain scores and end of week pain scores.

Study description

Background summary

Endometriosis related (pain)symptoms have a significant impact on the quality of life of these women. However, the extent of this disease is not directly related to the degree of symptoms. 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. The literature suggests that affective symptoms like anxiety and depression occur more often in these patients. Participants with greater self-esteem and self-efficacy are less distressed and efficient emotion regulation is

associated with the ability to cope with chronic pain. The care of patients with endometriosis has been complicated by the coronavirus disease pandemic as healthcare appointments and surgeries are being temporarily postponed. In combination with medical therapies, or as an alternative, patients are encouraged to consider self-management strategies to combat endometriosis symptoms during the pandemic. At-home yoga led by an online instructor may be useful.

Study objective

What is the effectiveness of at-home yoga-intervention for women suffering from pain due to endometriosis when compared to no yoga intervention.

Study design

Multicenter randomized trial.

Intervention

At-home online livestream yoga sessions scheduled for 75 minutes once a week during 8 weeks vs no intervention (control).

Study burden and risks

Yoga is generally considered a safe form of physical activity when performed properly, under the guidance of a qualified instructor. However, as with other forms of physical activity, injuries can occur. The most common injuries are sprains and strains. Serious injuries are rare. The risk of injury associated with yoga is lower than that for higher impact physical activities.

Participating in this research also means:

- patients fill in different kinds of questionnaires (smartphone app, paper questionnaires and online questionnaires).

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion 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

- 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)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	22-10-2020
Enrollment:	82
Type:	Actual

Ethics review

Approved WMO	
Date:	16-12-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	
Date:	15-01-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	
Date:	05-10-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	
Date:	18-02-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	

Date:	03-08-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	
Date:	30-10-2023
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22833
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL71244.015.19
Other	NL8113
OMON	NL-OMON22833