A COGNITIVE BEHAVIOURAL GROUP PROGRAMME - PLUS FOR WOMEN WITH DYSPAREUNIA: A RANDOMIZED WAITING LIST CONTROLLED MULTI-CENTER TRAIL OF EFFICACY

Published: 18-12-2017
Last updated: 17-01-2025

Primary objective: to evaluate whether the group programme-plus improves pain during intercourse in women with superficial dyspareunia compared to women in a waiting-list control condition.

Ethical review	Approved WMO
Status	Completed
Health condition type	Sexual dysfunctions, disturbances and gender identity disorders
Study type	Interventional

Summary

ID

NL-OMON53106

Source
ToetsingOnline

Brief title
CBT for women with dyspareunia: an RCT

Condition

- Sexual dysfunctions, disturbances and gender identity disorders

Synonym
dyspareunia, pain during intercourse, PVD

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,een deel van de kosten wordt gefinancieerd uit eerder verkregen onderzoeksgeld (ESSM)

Intervention

Keyword: CBT, dyspareunia, PVD, treatment

Outcome measures

Primary outcome

Main study parameters/endpoints: The mean level of pain during penile/vaginal intercourse in the CBT condition and the WLC condition at 6 months.

Secondary outcome

Secondary Objective(s): are to evaluate a) women (and partners) sexuality (sexual function, distress & satisfaction), b) women*s psychological adjustment (negative and positive penetration beliefs, pain/penetration coping behaviour); c) relationship factors (partner responses and relationship satisfaction) (Q2), cost-effectiveness of the intervention (Q3), and whether an improvement in pain during intercourse is moderated by pre-treatment patient characteristics, such as age, sexual functioning, relationship satisfaction, abuse history, and mediated by a) reduction of negative penetration beliefs avoidance behaviour and/or improvement in positive penetration beliefs and sexual function (i.e. sexual arousal) (Q4).

Study description

Background summary

Rationale: Superficial dyspareunia, a frequent form of chronic genital pain, is associated with decreased sexual function for afflicted women, as well as impoverished sexual satisfaction for women and their partners. While recent research has showed that cognitive-behavioral therapy (CBT) interventions have effects in regards to reducing pain, enhancing sexual function and improving relational, randomized controlled trials are still sparse. Despite recommendations in the literature to include the partner in the CBT treatment targeted at improving pain and sexuality outcomes, no randomized CBT controlled trial has incorporated the partner in the treatment until now. The current study will employ a CBT treatment programme of 10 group sessions and 3 couple sessions targeting the thoughts, emotions, behaviors and couple interactions associated with the experience of dyspareunia. It is hypothesed that the group programme-plus is more effective in improving pain during intercourse in women with superficial dyspareunia compared to women on a waiting-list control period.

Study objective

Primary objective: to evaluate whether the group programme-plus improves pain during intercourse in women with superficial dyspareunia compared to women in a waiting-list control condition.

Study design

Study design: Eligible women and their partners in one of the participating centres (n=4, in two conuntries) will be randomized to either the CBT group programme-plus (CBT group -plus) or waiting list control-period group (WLC), using a block randomization design stratified for each centre. The waiting-list period of 6 months is comparable to the period from the start of the active treatment until the post treatment measurement. After the WLC, the patients from the WLC will receive the active treatment.

Intervention

Intervention: The CBT group programme-plus consists of three 1- hr CBT couple sessions and ten 2-hr CBT group sessions over a period of 6 months. The manualized treatment comprize, pain- and sexual education, relaxation and gradual exposure exercises, sensate focus and sexual communication exercises for the couple. Six to eight women can participate in each group. Two psychologists will conduct the couple and group sessions.

Study burden and risks

Participating in this study will not cause any (physical) harm for the participants and the partners. Participants will be asked to fill in questionnaires 10 times and partners will be asked to fill in questionnaires

four times. This may cause some discomfort because of the time investment they have to make (for the participants 20 - 60 min; partners: 20 min per assessment). The participants will undergo a sexual and psychological interview (screening) and two times a gynecological examination. Apart from the expected benefits from the intervention compared to waiting list period, there will be no benefits for the study participants and partners.

Contacts

Public
Academisch Medisch Centrum

Albinusdreef 2 x
2300 RC Leiden 23333 ZA Leiden
NL
Scientific
Academisch Medisch Centrum

Albinusdreef 2 x
2300 RC Leiden 23333 ZA Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

heterosexual female, aged 18-45 years, having a heterosexual relationship for at least 3 months, with a diagnosis of superficial dyspareunia with no apparent ongoing physical cause to the condition (i.e. ongoing infections). The diagnosis of superficial dyspareunia will be assessed after full sexual history taking. The criteria for the diagnosis conform to DSM-5; the pain should be

experienced as superficial pain/pain around the vulvar opening, and have lasted for more than 6 months during at least 80% of the intercourse attempts. Furthermore, the participants should have the experience of a successful intercourse, and have attempted intercourse during the last year.

Exclusion criteria

: if reporting to never have had full intercourse at any time in life or the partner is not willing to participate in the study. Further exclusion criteria are: major affective disorder, psychotic disorder, substance-related disorder or post traumatic-stress disorder related to the genitals (e.g., as a sequel to sexual abuse) according to DSM-5 criteria; being pregnant or having gone through child delivery during the last year; not speaking Dutch or Swedish well enough to participate in assessment and treatment; or receiving concurrent ; or receiving concurrent psychological therapy or physiotherapy for superficial dyspareunia or other sexual complaints during CBT or WLC period.

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):	05-09-2018
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	18-12-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	12-03-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	07-11-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	24-10-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	18-09-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	28-06-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	15-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL62089.058.17