THE VULVA STUDY: Online psychotherapy and TENS@HOME for patients with provoked vulvodynia.

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Overall we aim for a more effective treatment of provoked vulvodynia with less relapse, taking into account the patients autonomy as an important key to long term cure. Primary outcome: Decrease of pain during (attempt to) penetration, measured by a...

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

Summary

ID

NL-OMON50940

Source
ToetsingOnline

Brief title
THE VULVA STUDY

Condition

- Sexual dysfunctions, disturbances and gender identity disorders
- Vulvovaginal disorders (excl infections and inflammations)

Synonym
dyspareunia, painful intercourse, Vestibulodynia, vulvodynia

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Schwa Medico,Wetenschapsfonds Amphia

Intervention

Keyword: Pain, Psychotherapy, TENS, Vulva

Outcome measures

Primary outcome

Primary outcome:

Decrease of pain during (attempt to) penetration, measured by a decrease in visual analog scale (VAS) score (VAS score 0-10) with 3 points after 24 months (T24), compared to VAS score at randomization (T0)

Secondary outcome

Secondary outcomes:

- VAS score during (attempt to) penetration after 3 months (T3), 6 months (T6), and 12 months (T12) compared to VAS score at randomization (T0) and at the end of follow-up (T24)
- The use and therapy compliance: TENS and/or online psycho-education
- Quality of life measured with validated questionnaires: pelvic floor distress inventory (PFDI-20), hospital anxiety and depression scale (HADS), sexual function and distress (FSFI and FSDS) and the global impression of improvement (PGI-I)
- Patient would recommend the treatment to fellow patient: scale 1-5
- Patient feels autonomous in her treatment and recovery: scale 1-5
- Penetration is possible: Yes/No

Study description

Background summary

Dyspareunia is a common problem in women worldwide, although its prevalence is underestimated. Prevalences vary from 14-34% in young women to 4,5-45% in the postmenopausal population.

The most common cause of dyspareunia in premenopausal women is provoked vulvodynia (PVD). PVD is characterized by vulvar pain provoked by touch and/or penetration.
Risk factors for PVD include recurrent vulvo-vaginal infection, sexual abuse, mental health issues), although the exact aetiology and pathophysiology is unknown.
Often PVD leads to sexual, relational and mental problems.

Recently PVD is considered to be a chronic pain syndrome with potential socio-economic consequences. In analogy to other chronic pain syndromes an individualized multidimensional approach seems to be most effective.

Such an individualized multidimensional approach was evaluated by Spoelstra et al (2017) in a retrospective cohort study. In 81 % a significant reduction was seen in the average VAS scores (7,4 vs 3,8, $p < 0,001$) and in 80% penetration was possible (follow-up 3-5 years). Unfortunately, in the long-term, in 92% of the women sexual intercourse remained painful. In 11% of the women no difference in VAS scores could be measured and in 8% VAS scores even increased. These results suggest that the current multidimensional approach might not be sufficient.

There is increasing evidence that psycho-education and treatment show significant improvement on painscores, coping and Quality of Life scores. The online approach was shown to be even more effective (less fall back) than the standard approach in different groups of patients with chronic pain. Comparable results were found for patients with vulvodynia and chronic pelvic pain.

The online program that we plan to introduce in this study is Therapieland. Therapieland is a private company that develops e-health platforms based on the needs of patients and therapists. The platform, used by e.g. POH-GGZ and psychologists, provides blended care with user-friendly interfaces, inspiring videos, animations, creative assignments and video therapists.
In the development of online interventions Therapieland uses evidence-based treatment methods, such as ACT, CBT, Mindfulness, EMDR, etc. In addition, the program enables the *therapist* to guide and follow the patients activities and to keep contact on the progress.

We believe that online psychotherapy and education is more approachable and more practical than group or face-to-face therapy and that it enables the

patient to take control in her treatment plan.
Another promising treatment option for vulvodynia patients is transcutaneous nerve stimulation (TENS). In 2008, Murina e.a. performed a prospective cohort study comparing TENS to *sham* TENS in 40 vulvodynia patients. A vaginal probe was used, 2 times a week, 20 sessions in total. The women did not undergo earlier treatments. Questionaire scores (SF-MPQ en FSFI) and VAS scores showed a significant improvement of all scores in de TENS group. Unfortunately duration of follow up was only 3 months.
In the same year, Dionisi et al showed a significant pain score reduction of 75,8% when TENS was combined with pelvic floor physiotherapy (biofeedback en relaxation) during 10 sessions in 145 vulvodynia patients.
In 2015 a Dutch study by Vallinga e.a. was performed to investigate the use of TENS in a therapy resistant group of vulvodynia patients (n = 39) and, after a 10 month follow-up period, showed a significant reduction in VAS, FSFI en FSDS scores. 4% of the women underwent vestibulodectomy, compared to 23% in their historical cohort.

Based on the available evidence, TENS seems to be beneficial in primary and therapy-resistant vulvodynia patients. But little is known on the long term effect of TENS in primary PVD patients. Therefor we aim a longer follow-up duration of all participating patients.

Like online psychotherapy and education, TENS is an approachable treatment option fitted for use at home and -again- increasing the patients participation and autonomy in her treatment plan. We hypothesize that the latter might be an important key to long term cure.

Study objective

Overall we aim for a more effective treatment of provoked vulvodynia with less relapse, taking into account the patients autonomy as an important key to long term cure.

Primary outcome:
Decrease of pain during (attempt to) penetration, measured by a decrease in visual analog scale (VAS) score (VAS score 0-10) with 3 points after 24 months (T24), compared to VAS score at randomization (T0)

Secondary outcomes:
- VAS score during (attempt to) penetration after 3 months (T3), 6 months (T6), and 12 months (T12) compared to VAS score at randomization (T0) and at the end of follow-up (T24)
- The use and therapy compliance: TENS and/or online psycho-education
- Quality of life measured with validated questionnaires: pelvic floor distress inventory (PFDI-20), hospital anxiety and depression scale (HADS), sexual function and distress (FSFI and FSDS) and the global impression of improvement (PGI-I)

- Patient would recommend the treatment to fellow patient: scale 1-5
- Patient feels autonomous in her treatment and recovery: scale 1-5
- Penetration is possible: Yes/No

In the future, we aim to use the results of the current study to develop a practical care pathway for the treatment of vulvodynia patients in primary care organizations.

Study design

We plan to include a total of 84 women (>18) with provoked vestibulodynia, based on dyspareunia >/= 3 months and provoked pain at the vestibulum vaginae. In order to account for a 10 % loss of patients after randomization, we will randomize 93 patients.

We will conduct a prospective intervention study. Three groups (28 patients each) are formed:
- Standard care
- Stardard care + TENS
- Standard care + TENS + online psycho-education

Considering the type of treatment, blinding is not feasible.

Randomisation will be performed in Castor by an independent research nurse.

Patients will be asked to fill in four questionaires and four additional questions (total 15 min) at five different time points: T0 (randomisation), T3, T6, T12 and T24 months.

Outcomes for all groups will be compared with a view to the effect of online psycho-education and/or TENS.

Intervention

Transcutaneous electric nerve stimulation (TENS)

Transcutaneous electrical nerve stimulation (TENS) is a therapy that uses low voltage electrical current to provide pain relief. A TENS unit consists of a battery-powered device that delivers electrical impulses through different types of electrodes for external (surface / skin electrodes) of internal (vaginal / anal probes) use.
The electrodes are placed at or near nerves where the pain is located or at trigger points.
In the VULVA study we will use UROstim equipment from Schwa Medico (Germany) (Art.-No. 101453). UROstim is broadly used in treatment of urinary incontinence as it significantly improves the strength of the pelvic floor

muscles and sphincter muscles. But the device has different other settings, including a pain program, a sensitive program and an acupuncture setting. Therefor UROstim can be used as a TENS device with different probe options. It can be used with needle (PTNS, acupuncture), vaginal or anal probes, but is also effective with self-adhesive electrodes.
In this study protocol we will use the UROstim pain program in combination with a probe that is suitable for vaginal use to make sure that the focus of the TENS is on the vestibulum vaginae.
Another advantage is that the UROstim enables the patient or the therapist to read out the treatment results to check the patients therapy compliance.
After initial administration of the TENS by a pelvic floor physiotherapist the women receive
one or two extra instruction sessions depending on how swiftly each individual can learn the procedure.
Then the women apply the TENS treatment themselves three times a week at home at their own convenience, for a total duration of 30 minutes for at least 12 weeks .
After 1, 6 and 12 weeks respectively, the women return to the physiotherapist to evaluate the
TENS treatment and to read out the results from the UROSTIM to check their therapy compliance. If a patient no longer requires TENS after 12 weeks (i.e., the complaints had diminished to her satisfaction), the treatment was stopped. After 12 weeks (T3), the patient can keep the TENS equipment and is then free to use it according to her needs and wishes

Online psycho-education @ Therapieland.nl

When randomised to online psycho-education, the patient receives an online account in Therapieland. She will get access to 3 different online modules (*geen zin in seks*, *pijn bij vrijen*, *de relatieboost*). Every module provides written and oral (video) information, practical advice and *homework*. We advise the patient to use the program at least once a week without obligation. The *inviting* gynaecologist is able to guide and follow the patients* activities and progress in the program.

About Therapieland
Therapieland is a private company that develops e-health platforms based on the needs of patients and therapists. The platform, used by e.g. POH-GGZ and psychologists, provides blended care with user-friendly interfaces, inspiring videos, animations, creative assignments and video therapists. Therapieland's online interventions are used in various treatment settings, in small practices and mental health care institutions, in general practices and hospitals. The platform also offers a questionnaire portal and video calling. Currently, Therapieland is working on expanding the use of their smaller self-guided platform, Gezondeboel. Gezondeboel focuses on the wider population and opts for a preventive approach. The programs in Gezondeboel contain information in the

form of movies, animations, background information and practical tips.

Study burden and risks

Benefits to be investigated are diminished or decreased amount of pain during touch or intercourse, the ability to have painless intercourse, positive changes in selfesteem and feeling of control/autonomy, and eventually a better quality of life.
Risks which can be experienced are direct problems from local nerve stimulation eg. discomfort or pain that can be adressed by changing the pulse intensity.

Based on results of earlier studies, we expect beneficial effects of the TENS treatment on VAS scores during (attempt to) intercourse.

Furthermore, we expect women to benefit from all the tips and tricks the "therapieland" program provides.

We think that most women will enjoy the fact that both interventions can be applied at home whenever suitable for the patient. Plus, being in the lead of her own therapy, can boost the patients' confidence and feeling of autonomy

The patients starting with TENS, using a vaginal probe, will be guided by experienced pekvic physiotherapists. If necessary the TENS settings can be adjusted to the level of comfort of the patiënt.

Finally all patients will be asked:
- 3 extra check-ups by phone
- Questionaires at follow-up points T0, T3, T6, T12, T24 months
- 2 extra translabial utrasounds

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

women (age > 18) diagnosed with provoked vestibulodynia, based on dyspareunia > / = 3 months and provoked pain at vestibulum vaginae.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Current active psychiatric disease, psychiatric history is no exclusion criterium
- Gynecological malignancy (in history)
- Current active vulvovaginal disease (eg. lichen sclerosis, infection)
- Prior pelvic radiotherapy / brachytherapy
- Neuromuscular disease
- Presence of other electrical devices (pacemaker (ICD), neurostimulator)
- Current pregnancy
- History of cardiac arrhythmia
- History of epilepsy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2024
Enrollment:	93
Type:	Anticipated

Medical products/devices used

Generic name:	TENS (transcutaneous electrical nerve stimulation)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-05-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-01-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL75298.100.21