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Evaluation of a treatment for women with superficial sexual intercourse pain

Submission date
13/10/2015

Recruitment status
No longer recruiting

Registration date
15/10/2015

Overall study status
Completed

Last Edited
26/11/2015

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Vulvodynia is a persistent, unexplained pain in the vulva (skin surrounding the vagina) or where the vulva meets the vagina (vestibule). This pain can either be constant with no definable trigger (unprovoked) or triggered when the vulva or vestibule is touched (provoked), such as during sexual intercourse. The exact cause of provoked vvulvodynia (PVD) is not known which makes it very difficult to treat. Many remedies have been suggested, including medications, exercises to help relax and strengthen vaginal muscles so they are not as sensitive to pain (desensitisation) and even taking therapies such as cognitive behavioural therapy (CBT). The aim of this study is to find out whether a treatment involving special exercises and CBT can help women to regain their interest in sex and sexual satisfaction as well as helping to relieve pain during sex.

Who can participate?
Women who have been experiencing PVD for at least six months.

What does the study involve?
Participants are given a ten week programme consisting of weekly CBT sessions, and specially designed exercises which work on relaxing the vaginal muscles and desensitising them to pain. At the start of the study and the end of the ten week period, women complete questionnaires in order to find out whether the programme is able to make a difference to the quality of their sex lives.

What are the possible benefits and risks of participating?
There is currently very little evidence for how to best treat women having sexual difficulties. Women involved in this trial could potentially benefit from the treatments given. There are no risks of participating in the study.

Where is the study run from?
Helsingborg Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2012 to August 2014

Who is funding the study?
1. Stig & Ragna Gorthon Foundation (Sweden)
2. Thelma Zoégas Foundation (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Treatment of provoked vulvodynia in a Swedish cohort using desensitization exercises and cognitive behavioral therapy

Study objectives
Treatment of provoked vulvodynia by desensitization exercises and cognitive behavioral therapy (CBT) will result in a 5% increase in scores on the McCoy Female Sexuality Questionnaire.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee in Lund, Sweden, ref: 2012/116

Study design
Single-centre case series study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vulvodynia

Interventions
During a ten-week period the women recruited to the study attended ten treatment sessions. These sessions focused on discussions about the woman's intimate relationship, on improving the individual's knowledge of her bodily functions, helping her to train her sexual responses and learning to feel sexual pleasure on the same terms as her partner so that both could experience pleasure and no one's needs dominated. Each session took approximately 60 minutes.
Discussions about the individual woman's life situation, about couple relationships and about how sexual pain may reflect relationship problems were an integral part of the CBT. During the ten-week period the woman had contact with the same therapist. The therapist herself received regular supervision sessions with a cognitive psychotherapist / psychiatrist. All treatments were carried out by the same therapist and were individualised which meant that some women made quicker progress than others but all were offered the full ten sessions.
The sessions included information and education about dyspareunia, PVD and vaginismus and how pain impacts desire, sexual response and arousal. A presentation was given of the female genital anatomy, using a detailed plastic model and photographs of the vulva and vagina. A gynaecological examination was carried out sensitively and carefully and the woman's individual pain problems were confirmed. With the aid of a hand mirror the woman showed where her pain was located and explained her sensations of pain. The woman was asked to avoid soap for intimate hygiene and instead to use neutral oil. If the woman lived in a relationship with a partner she was instructed that penile penetration should be avoided until there was improvement in her experience of pain. Goals for treatment were negotiated between the patient and therapist and it was important also to formulate interim goals, such as being able to carry out a vaginal examination or penile penetration without pain or with reduced pain.
The woman was given information about CBT which required some homework in the form of training to re-direct negative thought-pathways. Many women have repressed their thoughts about sexual activity and part of their homework was also to allow these thoughts freedom and to give thought to what they wanted and needed sexually. An important example of this kind of re-direction is in how the woman might express her pain and problems for her partner.
Exercises aimed to desensitize the pain memory response were gradually initiated and included training to feel tension and relaxation in the muscles of the pelvic floor and vagina by insertion into the vagina of one or two of the woman's own fingers and progressively the partner's fingers. Rather than avoidance of touch to the painful area the woman was instructed in regular, daily self-examination using a hand mirror, to touch and massage the area with oil and to use acupressure. Use of tampons during menstruation was encouraged. When the woman felt that she had mastered the exercises and if she was living together with a partner she was asked to gradually introduce the partner to partake in the exercises. Results of the homework were discussed each time the woman and therapist met.
At each new session an agenda was formulated by the woman and therapist together and was always initiated with the question "How have things been since our last meeting"? The woman was also encouraged to give a synopsis and critique of the previous session. At each session a vaginal examination was carried out with the woman partaking actively by means of a hand mirror. A dialogue was upheld about how the woman's sex life and relationship was developing. Sex resources such as vibrators, dildos and lubricating gels were introduced progressively if

these were acceptable. A discussion ensued about how the homework had progressed and new homework was negotiated. Finally the woman was asked to make a summary of the day's session and feed-back was given by the therapist.

Intervention Type
Mixed

Primary outcome(s)
Changes in the total MFSQ scores and in individual items on the MFSQ before and directly after treatment completion, using statistical measures.

Key secondary outcome(s))
Statistical comparison of the answers to the separate questions on the MFSQ before treatment and six months after treatment, using the Wilcoxon signed-rank test.

Completion date
27/02/2015

Eligibility

Key inclusion criteria
1. Women aged 18 years or over
2. A diagnosis of provoked vulvodynia (PVD) based on the patient's self-report of pain at the entrance to the vagina during any attempt at penetration and confirmed by the cotton-swab test
3. Experiencing symptoms for at least six months and had:
3.1. Severe pain upon vestibular touch or attempted vaginal entry
3.2. Tenderness to pressure localized within the vulvar-vestibule
3.3. Vestibular erythema of various degrees.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Current infection or diagnosed dermatological disease of the genital area
2. Diagnosis of acute psychiatric illness or any other major medical problems requiring medical treatment

Date of first enrolment

01/06/2012

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
Sweden

Study participating centre
Helsingborg Hospital
Södra Vallgatan 5
Helsingborg
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Sponsor information

Organisation
Lund University

ROR
https://ror.org/012a77v79

Funder(s)

Funder type
Charity

Funder Name
Stig & Ragna Gorthon Foundation

Funder Name
Thelma Zoégas Foundation

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/11/2015		Yes	No