Somatocognitive Therapy in the Management of Women with Provoked Vestibulodynia

A multimodal physiotherapy intervention

Mette Bøymo Kaarbø

OsloMet Avhandling 2023 nr 8

OSLO METROPOLITAN UNIVERSITY
STORBYUNIVERSITETET

Somatocognitive Therapy in the Management of Women with Provoked Vestibulodynia

A multimodal physiotherapy intervention

Mette Bøymo Kaarbø

Dissertation for the degree of Philosophiea Doctor
Department of Rehabilitation Science and Health Technology
Faculty of Health Sciences
OsloMet – Oslo Metropolitan University

Spring 2023

OsloMet Avhandling 2023 nr 8

ISSN 2535-471X (trykt)
ISSN 2535-5414 (online)
ISBN 978-82-8364-468-5 (trykt)
ISBN 978-82-8364-541-5 (online)

OsloMet – storbyuniversitetet
Universitetsbiblioteket
Skriftserien
St. Olavs plass 4,
0130 Oslo,
Telefon (47) 64 84 90 00

Postadresse:
Postboks 4, St. Olavs plass
0130 Oslo

Trykket hos Byråservice

Trykket på Scandia 2000 white, 80 gram på materiesider/200 gram på coveret

Acknowledgements

This PhD project started in February 2019 and was carried out at the Department of Rehabilitation Science and Health Technology, Faculty of Health Sciences, Oslo Metropolitan University. A special thank you to Hege Bentzen and Mari Klokkerud, heads of the Department, for providing facilities, as well as practical and administrative support during my PhD period. I would like to express my sincere gratitude to Oslo Metropolitan University for funding this PhD project and to the Norwegian Fund for Post-Graduate Training in Physiotherapy, for funding the qualitative part of the project.

Conducting research is teamwork, with many individuals contributing along the way and I have been fortunate to be part of such a wonderful team of researchers. First, I sincerely want to thank my main supervisor Associate Professor Slawomir Wojniusz for providing me with such excellent supervision. I am so grateful for all your invaluable support and strong encouragement. I have received insightful, constructive and pragmatic advice, as well as prompt revision of all the manuscripts. I truly appreciate all the time you have invested in me, our many conversations and all your contributions to this project. It has been such a privilege and pleasure working with you, thank you!

I would also like to thank my second supervisor Associate Professor Gro Killi Haugstad for all your support and guidance, your warmth and ongoing encouragement. You are the pioneer of somatocognitive therapy and together with the team we have further developed the intervention for women with provoked vestibulodynia. Thank you for sharing your clinical experience, and I am forever grateful that I have had the privilege to learn from you.

Thank you to my third supervisor Dr Anne Lise Helgesen for your supervision, constructive feedback on the manuscripts, positive words of encouragement and all you support in recruitment of participants to the study.

Thank you to team members and co-authors Kristine Grimen Danielsen and Professor Karen Synne Groven, for providing your expertise in qualitative research and providing constructive feedback and input on the manuscripts. I am especially grateful to Kristine for our close working relationship and our many discussions. You have done an excellent job leading the qualitative part of the project. It has been such a joy working together these years.

Thank you to everyone at the Vulva Clinic who kindly assisted in the recruitment of participants to the ProLoVe-feasibility project.

Thank you to all the women who participated in the study, without you this study would not have been possible.

I want to express my deepest gratitude to everyone at the MUSK Health Research group at Oslo Metropolitan University. A special thank you to both Professor Margreth Grotle and Professor Britt Elin Øiestad for your excellent leadership, providing such an inspiring learning environment as well as opportunities for support. We have been a fantastic group of PhD students during these past years. A special thank you to Kristine Grimen Danielsen, Ane Sigrid Nygaard, Linn Myrtveit Stensrud, Fiona Aanesen, Rikke Munk Killingmo, Daniel H. Major, Tarjei Langseth Rysstad, Ørjan N. Vigdal, Henriette Jahre and Nina Bjerketveit Ødegaard for fun times and valuable support in PhD life.

To all my dear colleagues at the Department of Pain Management and Research, Oslo University Hospital, thank you for your ongoing support.

I am deeply grateful to all my friends, UK physiotherapy friends, Tai Chi friends and friends around the globe. Thank you especially to my girlfriends Elisabeth, Beate, Hanne, Ragnhild, Heidi and Frederikke for your friendship, supportive conversations and laughter, cabin trips and mountain hikes.

I am especially grateful to my family, particularly my parents and parents-in-law, for all your love and support. A big thank you to my mother-in-law, Margaret Kaarbø, for all your invaluable help with proof-reading the manuscripts, including my thesis.

And finally, thank you to my wonderful husband Tom, you are my rock and to my precious boys, Oscar and Eirik. Thank you for all your patience, love and support, for keeping me grounded and providing balance in everyday life. I so appreciate all our fun times together at the cabin and in the great outdoors. I love you very much.

Mette Bøymo Kaarbø
Oslo, October 2022

Summary

Background

Provoked vestibulodynia (PVD) is a prevalent chronic pain condition adversely affecting women's sexual life, the relation to their partners and their psychological health. Pain is localised to the vulvar vestibule and is provoked by physical contact, such as penetrative intercourse. There is an urgent need for well-designed randomised clinical trials (RCTs) to identify the most effective interventions for this neglected women's health condition. Somatocognitive therapy (SCT) is a multimodal physiotherapy treatment which has in recent years been further developed for PVD. The main aims of this PhD thesis were 1) to assess the feasibility and acceptability of SCT for women with PVD in preparation for a full-scale RCT, 2) to evaluate the tampon test as a primary outcome measure in preparation for the main trial, 3) to explore women's experiences with SCT and gain further insight into meaningful processes towards improved sexual health and 4) to develop a conceptual model for PVD with SCT including a detailed description of SCT as a treatment for PVD.

Methods

This thesis is based on data from a feasibility study and uses quantitative and qualitative methods. Paper I-III are based on data from 10 women with PVD, aged 18-33, recruited from the Vulva Clinic, Oslo University Hospital. Paper I is a multimethod study with a single arm before-after trial and qualitative interviews, the latter undertaken at two time points. The women were treated with SCT at Oslo Metropolitan University. Tampon tests and self-report questionnaires were undertaken at baseline, post-treatment and at 8 months follow-up. The main feasibility outcomes were evaluation of recruitment rate, adherence to assessment tools and follow-up rate. Experiences with the outcome measures and the SCT intervention were explored with semi-structured interviews. Paper II is a mixed methods study utilising an explanatory sequential design, integrating quantitative and qualitative methods to evaluate the tampon test as a primary outcome measure. In phase one, pain intensity levels were evaluated with the tampon test on day 1, 7 and 14, and rated on the Numerical Rating Scale (NRS), (0-10), 10 being worst possible pain. In phase two, the participants' experiences with the test were explored with semi-structured interviews. Paper III is a qualitative study, where the women were interviewed towards the end of the treatment period and one year later to develop insight into therapeutic processes unfolding over time. Following the thematic analysis by Braun and Clarke (2006), the data were analysed inductively. In Paper IV a conceptual model for PVD

with SCT was developed based on findings in the feasibility study (Paper I and III), past research and clinical experience.

Results

Ten out of 18 eligible patients were recruited, with none lost to follow-up. Adherence to outcomes ranged from excellent (self-report questionnaires), good (tampon tests and reporting of treatments) to poor (14-day diary). No adverse events were reported. SCT was found to be an acceptable treatment based on Global Perceived Effect scores and the qualitative interviews. In Paper II, the tampon test data and interviews were brought together to see how the interviews could help to explain the quantitative findings. The tampon test data demonstrated large intra- and inter-individual variability. Median tampon pain intensity was 4.5 (min=1.7; max=10; Q1=2.5; Q3=6). Four participants had a mean score of four or lower on the NRS, whilst concurrently reporting high levels of pain during sexual intercourse. Many experienced the test as an inadequate representation of pain during intercourse. In Paper III the findings illustrated how; 1) developing positive feelings of embodiment, 2) developing a greater awareness of internal feelings and bodily states and 3) developing sex-positive beliefs and behaviours, were experienced as important pathways towards improved sexual health. Paper IV is based on findings from Paper I and III, leading to a refinement of the SCT intervention in preparation for the main trial. In Paper IV a conceptual model for PVD with SCT is presented.

Conclusions

The integration of quantitative and qualitative work in this thesis suggests that it is feasible to deliver a full-scale RCT to evaluate the effect of SCT versus standard PVD treatment for women with PVD. Some changes are suggested, such as increasing recruitment sites, change of primary outcome measure and adding a booster session. The findings of Paper II indicate several problems with the application of the tampon test as a primary outcome measure in PVD. The tampon test may be more useful as a secondary outcome, preferably undertaken repeatedly in order to increase precision of the pain estimation. The findings indicate that SCT is a promising intervention for women with PVD. The findings further suggest that SCT can support meaningful processes towards improved sexual health. Findings from Paper I and III lead to a refinement of the SCT intervention and to the development of a conceptual model for PVD with SCT. Providing an in-depth and complete description of SCT allows replication in clinical practice and clinical trials.

Sammendrag (Summary in Norwegian)

Bakgrunn

Provosert vestibulodyni (PVD) er en utbredt langvarig smertetilstand som negativt påvirker kvinners seksualliv, forholdet til deres partnere og deres psykiske helse. Smerter er lokalisert til vulvavestibylen og fremprovoseres av fysisk kontakt, som penetrerende samleie. Det er et umiddelbart behov for randomiserte kliniske studier (RCT) med gode forskningsdesign for å identifisere de mest effektive intervensjonene for denne forsømte kvinnehelsetilstanden. Somatokognitiv terapi (SCT) er en multimodal fysioterapibehandling som i de senere årene har blitt utviklet for PVD. Hovedmålene med denne PhD avhandlingen var 1) å vurdere gjennomførbarhet og aksepterbarhet av SCT for kvinner med PVD som forberedelse til en fullskala RCT, 2) å evaluere tampongtesten som et primært utfallsmål som forberedelse til hovedstudien, 3) å utforske kvinners erfaringer med SCT, samt oppnå ytterligere innsikt i meningsfulle prosesser opp mot forbedret seksuell helse og 4) å utvikle en konseptuell modell for PVD med SCT, inkludert en detaljert beskrivelse av SCT som behandling for PVD.

Metode

Denne avhandlingen er basert på data fra en feasibility studie som benyttet både kvantitative og kvalitative metoder. Artikkel I-III er basert på data fra ti kvinner med PVD, alder 18-33 år, rekruttert fra Vulvaklinikken, Oslo universitetssykehus. Artikkel I er en multimetodestudie, en enkeltarm før-etter studie, med kvalitative intervjuer som ble utført på to tidspunkter. Kvinnene ble behandlet med SCT ved OsloMet-storbyuniversitet. Tampongtester og selvrapporterende spørreskjemaer ble utført ved baseline, etter behandling og ved 8-måneders oppfølging. De viktigste feasibility resultatene var evaluering av rekrutteringsrate, oppfølging av utfallsmål og oppfølgingsrate. Erfaringer med utfallsmålene og intervensjonen ble utforsket med semistrukturerte intervjuer. Artikkel II er en mixed methods studie som bruker et sekvensielt forklarende design, hvor kvantitative og kvalitative metoder integreres for å evaluere tampongtesten som et primært utfallsmål. I fase én, ble smerteintensitetsnivåene evaluert med tampongtesten på dag 1, 7 og 14 med numerisk smertekala (NRS), (0-10), hvor 10 er verst mulig smerte. I fase to ble deltakernes erfaringer med testen utforsket med semistrukturerte intervjuer ved bruk av et beskrivende og induktivt kvalitativt design. Artikkel III er en kvalitativ studie, hvor kvinnene ble intervjuet mot slutten av behandlingsperioden og ett år senere, for å gi innsikt i hvordan terapeutiske prosesser forløp over tid. I fortolkningsarbeidet ble Braun og Clarks (2006) tematisk analyse benyttet, og dataene ble analysert induktivt. I artikkel IV ble en

konseptuell modell for PVD med SCT utviklet, basert på funn fra artikkel I og III, tidligere forskning og klinisk erfaring.

Resultater

Ti av 18 kvalifiserte pasienter ble rekruttert, ingen frafall ble registrert under oppfølging. Overholdelse av utfallsmål varierte fra utmerket (selvrapporterende spørreskjema), god (tampongtester og rapportering av behandlinger) til dårlig (14-dagers dagbok). Det var ingen negative bivirkninger rapportert som følge av SCT. Resultater fra Global Perceived Effect skala og de kvalitative intervjuene indikerer at SCT er en aksepterbar behandling. I artikkel II ble tampongtestdata og intervjudata brakt sammen for å se hvordan intervjuene kunne bidra til å forklare de kvantitative funnene. Tampongtestdataene viste stor intra- og interindividuell variasjon. Median smerteintensitet for tampongtesten var 4,5 (min=1,7; maks=10; Q1=2,5; Q3=6). Fire deltakere hadde en gjennomsnittlig skår på fire eller lavere på NRS, mens de samtidig rapporterte høye smertenivåer under samleie. Mange opplevde testen som et utilstrekkelig mål, og at den ikke var representativ for samleiesmerter. I artikkel III viste funnene hvordan 1) å utvikle positive følelser til egen kropp, 2) å utvikle en større bevissthet om indre følelser og kroppslige behov, og 3) å utvikle positive tanker og atferd knyttet til seksualitet, ble opplevd som viktige prosesser i retning av bedre seksuell helse. Artikkel IV er basert på funn fra artikkel I og III, noe som førte til en fininnstilling av SCT som forberedelse til hovedstudien. I artikkel IV presenteres en konseptuell modell for PVD med SCT.

Konklusjon

Integrering av kvantitativt og kvalitativt arbeid i denne avhandlingen antyder at det er mulig å gjennomføre en fullskala RCT for å evaluere effekt av SCT versus standard PVD behandling for kvinner med PVD. Noen endringer er foreslått, som å øke antall rekrutteringssteder, endring av primært utfallsmål og legge til en oppfølgningstime. Funnene i artikkel II indikerer flere problemer med bruken av tampongtesten som et primært utfallsmål ved PVD. Tampongtesten kan være mer nyttig som et sekundært utfallsmål, fortrinnsvis utført gjentatte ganger for å øke nøyaktigheten av smerteestimeringen. Funnene indikerer at SCT er en lovende behandling for unge kvinner med PVD. Funnene tyder videre på at SCT kan støtte meningsfulle prosesser i retning av bedre seksuell helse. Funn fra artikkel I og III førte til en fininnstilling av SCT og til utvikling av en konseptuell modell for PVD med SCT. Å gi en grundig og fullstendig beskrivelse av SCT gir mulighet til replikasjon i klinisk praksis og kliniske studier.

Table of Contents

List of papers

This thesis is based on the following papers, which are referred to in the text by their Roman numerals.

I. Kaarbø, M.B., Danielsen, K.G., Haugstad, G.K., Helgesen, A.L.O. and Wojniusz, S. 2022. Feasibility and acceptability of somatocognitive therapy in the management of women with provoked localized vestibulodynia – ProLoVe Feasibility Study. *Pilot Feasibility Stud*, 8(1), 1-11. https://doi.org/10.1186/s40814-022-01022-2

II. Kaarbø, M.B., Danielsen, K.G., Haugstad, G.K., Helgesen, A.L.O. and Wojniusz, S. 2021. The tampon test as a primary outcome measure in provoked vestibulodynia: A mixed methods study. *J Sex Med*, 18(6), 1083−1091. https://doi.org/10.1016/j.jsxm.2021.03.010

III. Danielsen, K.G., Kaarbø, M.B., Groven, K.S., Helgesen, A.L.O., Haugstad, G.K. and Wojniusz, S. Toward improved sexual health among women with provoked vestibulodynia: experiences from a somatocognitive therapy approach. *Eur J Physiother.* https://doi.org/10.1080/21679169.2023.2168749

IV. Kaarbø, M.B., Danielsen, K.G., Helgesen, A.L.O., Wojniusz, S. and Haugstad, G.K 2022. A conceptual model for managing sexual pain with somatocognitive therapy in women with provoked vestibulodynia and implications for physiotherapy practice. *Physiother Theory and Pract,* 10th of July 2022, published ahead of print. https://doi.org/10.1080/09593985.2022.2096516

Abbreviations

ACT	Acceptance and Commitment Therapy
BMI	Body Mass Index
BPS	Biopsychosocial
CBT	Cognitive Behavioural Therapy
DSM-5	Diagnostic and Statistical Manual of Mental Disorders – 5th revision
FSFI	Female Sexual Function Index
HSCL-25	Hopkins Symptom Check List – 25
IASP	International Association for the Study of Pain
ICD-11	International Classification of Diseases, eleventh revision
IMMPACT	Initiative on Methods, Measurement and Pain Assessment in Clinical Trials
IPPS	International Pelvic Pain Society
ISSVD	International Society for the Study of Vulvovaginal Disease
ISSWSH	International Society for the Study of Women's Sexual Health
MBCT	Mindfulness-Based Cognitive Therapy
M-gCBT	Mindfulness-based group Cognitive Behavior Therapy
NRS	Numeric Rating Scale
PCS	Pain Catastrophizing Scale
PFMs	Pelvic Floor Muscles
ProLoVe	Provoked Localised Vestibulodynia
PVD	Provoked Vestibulodynia
RCT	Randomised Clinical Trial
SCT	Somatocognitive Therapy
TIDierR	Template for Intervention Description and Replication
TSD	Tjeneste for sensitive data (Services for sensitive data)

List of figures and tables

List of appendices

1.0 Introduction

Vulvodynia is a debilitating chronic pain condition of unknown cause which affects a significant proportion of adult women. The condition has been investigated for many years by various disciplines and consequently is described using numerous and varied terms and definitions. Although chronic vulvar pain constitutes a significant women's health problem, it continues to be poorly understood, is often unrecognised or misdiagnosed, and neglected (Bornstein et al. 2019a; Paavonen and Eschenbach 2021). As a consequence, women consult as many as four to six physicians about their pain before receiving a diagnosis (Gordon et al. 2003; Pukall 2016), with an average time of four years between symptoms-debut and final diagnosis (Lester, Brotto and Sadownik 2015). Vulvodynia not only carries a heavy personal cost to patients but is a significant financial burden to society (Lua et al. 2017; Xie et al. 2012).

The most common subtype of vulvodynia is provoked vestibulodynia (PVD) (Lamvu et al. 2015). Pain in PVD is localised to the vulvar vestibule and is induced by physical contact at the vaginal entrance (Bornstein et al. 2019b). The condition represents the most common cause of painful intercourse (Sadownik 2014), adversely affecting women´s sexual life, their relationships and their psychological health. Moreover, women with vulvodynia frequently report low self-efficacy and poor quality of life (Desrochers et al. 2009; Xie et al. 2012; Benoit-Piau et al. 2018; Dargie, Gilron and Pukall 2017). There are several pharmacological and non-pharmacological treatment approaches available for vulvodynia (Rosen et al. 2019), however empirically supported treatment guidelines are still lacking (Bergeron et al. 2020). Historically, there has been a tendency to conceptualise vulvodynia in a dualistic fashion, pain seen either as psychological or biomedical in nature (Chisari and Chilcot 2017). Research investigating effects of treatment has been scarce, often uncontrolled and based on small samples, with few randomised controlled trials (RCTs) available (Corsini-Munt et al. 2017; Rosen et al. 2019). Physiotherapy is a recommended first-line treatment for PVD (Bergeron et al. 2020; Goldstein et al. 2016). A 2017 systematic review highlighted the need for high quality well-designed RCTs to identify the most effective physiotherapy interventions for PVD (Morin, Carroll and Bergeron 2017b). Few studies have investigated women's experiences with physiotherapy interventions for PVD, and we have limited knowledge about their experiences with addressing sexual health in a physiotherapy context. Insight into such experiences is vital to develop targeted physiotherapy interventions which are in line with the women's preferences and perspectives on what encompasses meaningful processes of change.

Somatocognitive therapy (SCT) is a multimodal physiotherapy approach developed in the early 2000s to manage patients with longstanding pelvic and gynaecological pains of unknown aetiology (Haugstad et al. 2006b; Haugstad et al. 2006c; Haugstad et al. 2008). In recent years, SCT has been adapted to treat women with PVD, based on experiences from a pilot study (Haugstad et al. 2019), from PVD patients (Groven et al. 2016) and from physiotherapy students treating PVD patients (Danielsen et al. 2019; Fougner and Haugstad 2015). SCT is designed to target the multiple dimensions of vulvar pain utilising a biopsychosocial approach, where the overall aim is to reduce vulvar pain and improve sexual function. The lack of high quality RCTs evaluating physiotherapy, combined with the promising results of SCT for PVD, was the basis for developing a study to evaluate this treatment intervention. The **Pro**voked **Lo**calised **Ve**stibulodynia (ProLoVe) study is a collaboration between the Vulva Clinic at Oslo University Hospital and the Department of Rehabilitation Science and Health technology (previously named Department of Physiotherapy) at Oslo Metropolitan University. The ProLoVe study consists of three phases; 1) a feasibility study with qualitative interviews (completed), 2) an ongoing RCT utilising quantitative and qualitative data and 3) implementation studies to be undertaken following the RCT. This thesis contains findings from phase one, the ProLoVe feasibility study.

Before commencing a RCT, it has been recommended to run a feasibility study in order to establish whether a full trial would be feasible to conduct (Leon, Davis and Kraemer 2011; Eldridge et al. 2016b; Thabane et al. 2010). Feasibility studies are designed to answer whether the study protocol can work and allows for adjustment of the protocol before the start of the main trial (Lancaster, Dodd and Williamson 2004; Lancaster 2015; Orsmond and Cohn 2015; Thabane et al. 2010). Evaluating the acceptability of a complex intervention at an early stage can also highlight if the intervention needs to be modified before a definite trial. The overall aim of this thesis was to evaluate the feasibility and acceptability of SCT as a multimodal physiotherapy approach for women with PVD, in preparation for a full-scale RCT. Furthermore, the aim was to evaluate the tampon test as a primary outcome measure and explore these women's experiences with the SCT intervention. The latter involved gaining insight into meaningful processes towards improved sexual health. Finally, the aim was to develop a conceptual model for PVD with SCT including a detailed description of SCT as a treatment for PVD. In the following chapter the theoretical and empirical background for the thesis will be presented.

2.0 Background

2.1 Vulvodynia

2.1.1 History, current terminology and classification

Over the years, terminology, definition and classification of vulvodynia has greatly evolved. Although chronic vulvar pain of unknown aetiology appears to have been recognised for centuries, no documented descriptions of this condition appear in the medical literature until about 50 years ago (Moyal-Barracco and Lynch 2004). Early discussions in this field focused on the primary complaint of these women who presented to their physician with pain during sexual intercourse i.e. *dyspareunia,* the termed coined by Barnes in 1874 (Amalraj, Kelly and Bachmann 2008). Since the 1970s, several different terms have been used to describe chronic vulvar pain, such as *burning vulva syndrome*, *vulvar vestibulitis syndrome*, *vestibulitis* and *dysesthetic vulvodynia* (Danby and Margesson 2010). In the late 1990s there was a shift in conceptualisations from focusing on "pain during intercourse" to "vulvar pain", conditions in which dyspareunia could be one of the symptoms. In 2003, at the International Society for the Study of Vulvovaginal Disease (ISSVD) world congress, the first worldwide evidence-based consensus terminology was achieved, and the term *vulvodynia* was adopted for the first time (Moyal-Barracco and Lynch 2004).

The inconsistent use of terms and definitions to describe vulvar pain has been a challenge with research in this field (Loflin, Westmoreland and Williams 2019). In 2015, three leading scientific societies; the ISSVD, the International Society for the Study of Women's Sexual Health (ISSWSH) and the International Pelvic Pain Society (IPPS) came together and adopted and approved a new classification system for vulvar pain conditions (Bornstein et al. 2016). *The 2015 Consensus Terminology and Classification of Persistent Vulvar Pain*, distinguishes between vulvar pain caused by a specific disorder, (e.g., infection, inflammatory, trauma or neurologic), and vulvodynia. Vulvodynia is defined as "vulvar pain of at least 3 months duration, without clear identifiable cause, which may have potential associated factors" (Bornstein et al. 2016). The descriptors of vulvodynia were arranged in four groups: location, provocation, onset and temporal pattern (Bornstein et al. 2019b). In terms of location, pain can be *generalised* (i.e., affecting the entire vulva), *localised* (affecting a portion of the vulva e.g., the vestibule or clitoris) or *mixed*. In terms of provocation, pain can be *provoked* by physical contact (e.g., penetrative intercourse, pelvic examination, sitting) (Lev-Sagie and Witkin 2016),

spontaneous (symptoms occur without provocation) or *mixed*. Onset of vulvodynia can be *primary* or *secondary* and is only used to describe the provoked type (Pukall 2016). Women presenting with primary PVD report pain the first time a provoking contact occurred, such as first intercourse or tampon insertion, whereas women with secondary PVD typically develop the pain after years of pain-free vulvar contact. Temporal pattern includes intermittent, persistent, constant, immediate and delayed (Bornstein et al. 2019b).

The most common subtype of vulvodynia is PVD (Lamvu 2015) which is the subtype that has received the most research attention. PVD is characterised by moderate to severe pain described with both nociceptive and neuropathic words, such as burning, stabbing, sharp, stinging, aching, and tearing pain (Schlaeger et al. 2019), which is localised to the vulvar vestibule in response to physical contact such as touch or pressure to the vaginal opening. Other words may include discomfort, irritation, or itching (Bergeron et al. 2020). Although painful intercourse is often the main problem and the patient's presenting complaint, pain can also occur during non-sexual activities, such as with tight clothing, sitting or with tampon use.

In addition to being conceptualised as a vulvar pain condition, vulvodynia can also be conceptualised as a sexual dysfunction in the fifth revision of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)* (American Psychiatric Association 2013). Here the previous diagnoses of dyspareunia and vaginismus (involuntary muscular contraction of the pelvic floor muscles) was replaced with 'genito-pelvic/penetration pain disorder'. This entails pain during vaginal intercourse, fear of pain, and tension of the pelvic floor muscles with attempts at penetration, which overlaps with PVD. Genito-pelvic/penetration pain disorder is however a broader diagnostic category and includes vulvar pain, deep pain or pelvic pain. This thesis will reference prior work encompassing primarily studies conceptualising vulvar pain as a chronic pain condition, where PVD diagnosis is the main focus of study.

2.1.2 Diagnosis and pain assessment

The ISSVD, ISSWSH and IPPS recommend utilising both the 2015 consensus terminology and the definitions of vulvodynia descriptors for diagnosis and description of vulvar pain and vulvodynia, in the process of setting a diagnosis (Bornstein et al. 2019b). The diagnosis of vulvodynia involves a thorough medical history with specific focus on pain history, sexual history and psychosocial assessment, followed by a comprehensive gynaecological

examination (Sadownik 2014). The latter includes a careful visual inspection of the vulva, and a cotton swab test (Q-tip test), which is the standard test for diagnosis of PVD to identify the pain location. The cotton swab test involves light palpation at each point on the vestibule, i.e., the mucosa that lies between the Hart's line and the hymen, at 12, 2, 4, 6, 8 and 10 o'clock (Stenson 2017). Increased pain sensitivity to light touch is typically reported in PVD with the cotton swab test (Sadownik 2014), where the patients can report pain intensity levels on the Numeric Rating Scale (NRS) (0 to 10). In addition, a sensitive speculum investigation and musculoskeletal examination of the pelvic floor muscles can be performed using one finger. As vulvodynia is a diagnosis of exclusion it is important to rule out other vulvar pain conditions caused by a specific disorder (such as dermatologic, infectious, or neoplastic) which may contribute to pain (Stenson 2017).

In the clinical setting, vulvar pain can be assessed in "real time" with the cotton-swab test. In PVD research, objective pain measurements are particularly challenging since pain is mostly experienced upon provocation in a specific context, such as during sexual intercourse. In addition, some women may not engage in penetrative intercourse due to the lack of a partner, fear of pain, or previous medical recommendation (Wammen Rathenborg, Zdaniuk and Brotto 2019). Consequently, using intercourse pain as a primary outcome measure may be a challenge for recruitment, but also for data analysis and generalisation of results (Foster et al. 2009). In research, vulvar pain can be assessed in "real time" with the vulvalgesiometer or the tampon test. The vulvalgesiometer standardises the amount of pressure applied to the vestibule to quantify levels of sensitivity and is used primarily in research (Goldstein et al. 2016). The tampon test on the other hand, is self-administered and can be carried out at home by the patient. Pain is rated on the 11-point Numerical Rating Scale (NRS) from zero to 10, where 10 is worst possible pain, on the total tampon insertion and removal experience. The tampon test has previously been evaluated to be reliable and to have good construct validity and responsiveness for women with PVD (Foster et al. 2009).

2.1.3 Prevalence

The reported prevalence of vulvodynia varies greatly. This is possibly due to the different definitions and inclusion criteria applied in studies, thereby hindering epidemiological research and comparative studies (Havemann et al. 2017; Goldstein et al. 2016). Across different populations and studies, the lifetime prevalence of vulvodynia ranges from 10-28% among

premenopausal women (Arnold et al. 2007; Harlow and Stewart 2003; Reed et al. 2004; Vieira-Baptista et al. 2014). In the US, population-based estimates have been found to be around 7-8% (Harlow et al. 2014; Reed et al. 2012b). Similarly, the reported prevalence of vulvodynia in Spain is 6.6% (Gomez et al. 2019) and 6.5% in Portugal (Vieira-Baptista et al. 2014). Although vulvodynia occurs in women of all ages, incidence rates are highest among women in their early twenties (Harlow et al. 2014) and is higher amongst Hispanic women than non-Hispanic white women (Reed et al. 2014). According to Italian registry data, PVD accounts for 72.6% of all vulvar pain, all women of all ages are affected by PVD and the frequency peaks between 20-29 years (Bautrant et al. 2019).

2.1.4 Aetiology

Although vulvodynia is highly prevalent, this is a chronic pain condition where the aetiology remains largely unknown. Multiple associated factors have been suggested to play a role in the initiation and/or maintenance of vulvodynia and include inflammatory, hormonal, genetic predisposition, musculoskeletal, neurologic mechanisms (peripheral and central pain mechanisms), structural and psychosocial factors (Bergeron et al. 2020; Bornstein et al. 2016; Bornstein et al. 2020b). In terms of biomedical aetiology, it has been suggested that inflammation is one underlying mechanism which may lead to the development of vulvodynia (Falsetta et al. 2017; Falsetta et al. 2021). Vulvovaginal infections such as recurrent vulvovaginal candidiasis are often identified as the inciting event for the development of vulvodynia (Leusink et al. 2018; Wesselmann, Bonham and Foster 2014). Elevated levels of pro-nociceptive proinflammatory mediators have been found in women with PVD (Falsetta et al. 2021), Bergeron et al. (2020) however argue that their role in vulvodynia pathogenesis needs further investigation. Other suggested associated factors are hormonal (Greenstein et al. 2007; Harlow, Vitonis and Stewart 2008) such as early onset and prolonged use of oral contraceptives (Bouchard et al. 2002), genetics (i.e., polymorphisms in genes regulating inflammatory response) (Gerber et al. 2003; Heddini et al. 2014) and musculoskeletal (Morin et al. 2014). In terms of musculoskeletal factors, PVD has been associated with a degree of pelvic floor muscle dysfunction, including pelvic floor muscle hypertonicity, poor muscle control and altered contractility (Gentilcore-Saulnier et al. 2010; Morin et al. 2017a). Regarding neurologic mechanisms, there is evidence of both peripheral and central pain mechanisms involved in the pathogenesis (Wesselmann, Bonham and Foster 2014; Zhang et al. 2011). Women with PVD display allodynia (pain from a nonpainful stimulus) and hyperalgesia (increased sensitivity to

a painful stimulus) in response to stimuli applied to the vulvar vestibule and non-vulvar sites (Sutton et al. 2020). According to Bornstein and Palzur (2020a), several studies have found hyperinnervation and nerve sprouting in the vestibule of women with PVD, the increased density causing an increase in allodynia. Torres-Cuecoa and Nohales-Alfonso (2021) argue that in vulvodynia, pain is not associated with relevant nociception, but is a dysfunctional response of the central nervous system. Multimodal neuroimaging studies support the possible role of central sensitization and alterations in endogenous pain modulatory systems in the central nervous system in PVD (Bhatt et al. 2019). This is further supported by the fact that vulvodynia often coexists with other chronic pain conditions, such as fibromyalgia, irritable bowel syndrome, painful bladder syndrome and orofacial pain (Lester, Brotto and Sadownik, 2015; Nguyen et al. 2012; Reed et al. 2012a), suggesting similar underlying pathophysiological processes.

There are several psychosocial factors suggested to be important players in the development of and maintenance of vulvodynia, such as depression (Burri, Hilpert and Williams 2020), catastrophizing (Flink et al. 2017), anxiety (Haugstad et al. 2019; Paquet et al. 2018) and early-life chronic stressors (Khandker et al. 2019). These women commonly present with avoidance behaviour, avoiding painful activities due to catastrophic misinterpretation of pain, and pain-related-fear (Benoit-Piau et al. 2018; Thomtén and Karlsson 2014). Several factors are associated with pain severity such as distress, illness perceptions, fatigue and cognitive-behavioural factors (Chisari and Chilcot 2017), as well as fear avoidance and pelvic floor muscle function (Benoit-Piau et al. 2018).

Although vulvodynia is highly prevalent the condition continues to be poorly understood causing significant physical and psychological distress, impacting on the quality of life of the affected women and their partners.

2.1.5 Impact of vulvodynia

Vulvodynia is a complex and prevalent multifactorial pain condition which leads to adverse consequences for those affected and for society. It results in negative impacts on sexual functioning (Chisari et al. 2021), including decreased sexual desire, orgasm, arousal and lower levels of sexual satisfaction, than women without this type of pain (Smith, Pukall and Chamberlain 2013; Sutton, Pukall and Chamberlain 2009). This distressing condition can

therefore have a detrimental impact on the sexual health[1] of young women. Furthermore, vulvodynia adversely impacts quality of life (Tribó et al. 2020), affecting both women and their partners' mental, physical and sexual well-being (Sadownik et al. 2017; Sadownik, Seal and Brotto 2012; Jodoin et al. 2008). Vulvodynia carries a heavy psychosocial burden with affected women reporting higher levels of psychological distress (Chisari and Chilcot 2017). Qualitative studies have shown that women with vulvodynia report feelings of guilt or shame, such as being an inadequate sexual partner, or have fears about disappointing their partners (Ayling and Ussher 2008; Shallcross et al. 2018). There are also women who do not tell about the pain and continue to endure sex despite pain (Elmerstig, Wijma and Bertero 2008), "fulfilling his needs not mine" (Carter et al. 2019).

Aspects related to the relationship such as family planning (Johnson, Harwood and Nguyen 2015) and sexual communication (Rosen and Bergeron 2019) are also negatively affected. The relationship factor which has been most studied are partner responses to women's vulvar pain (Bergeron et al. 2020). These responses can be solicitous (such as being attentive or sympathetic), negative (demonstrations of anger or hostility) and facilitative (encouraging adaptive coping). High pain anxiety and frequent solicitous partner responses to women's pain has been found to predict higher pain-related sexual disability in PVD (Maunder, Dargie and Pukall 2022). Greater facilitative partner responses, on the other hand, have been associated with lower levels of pain, better sexual functioning and relationship satisfaction, responses which might be beneficial to women and their partners (Rosen et al. 2013; Rosen et al. 2014; Rosen et al. 2015).

There is some evidence that negative cognitions, such as catastrophizing, are associated with greater pain intensity and pain interference in women with vulvodynia (Chisari and Chilcot 2017) and in women with intercourse related vulvovaginal pain (Flink et al. 2017). Furthermore, negative cognitions around pain and penetration have been associated with increased pain and decreased sexual function in PVD (Anderson et al. 2016). Negative cognitions related to the body have also been found amongst women with PVD, such as negative or lower body image

[1] Sexual health is defined by the World Health Organization (WHO) as *"a state of physical, emotional, mental, and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility to having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence"* (WHO, 2006).

(Granot and Lavee 2005; Maille, Bergeron and Lambert 2015) and body-exposure anxiety during intercourse (Chisari et al. 2022a). Additionally, women have also reported to have a difficult, distant and negative relationship with their vulva, the vulva feeling disconnected from the body (Danielsen et al. 2019).

Despite the personal impact of vulvodynia, many women suffer in silence and report not seeking treatment (Harlow et al. 2014; Reed et al. 2012b). One study found that only 60% of affected women seek help and 40% of those were never given a diagnosis (Harlow, Wise and Stewart 2001). Unfortunately, vulvodynia continues to be a neglected women's health condition (Bergeron et al. 2020; Bornstein et al. 2019a), where patients are often overlooked or misdiagnosed by health care professionals (Graziottin et al. 2020; Harlow et al. 2014; Reed et al. 2012b) and are left without correct treatment (Lua et al. 2017). In qualitative studies, women report that health care professionals (especially GPs) lack adequate training (Leusink et al. 2019) and knowledge about the condition (Shallcross et al. 2019). This, combined with receiving insensitive (Webber et al. 2020) and uninformed advice (Shallcross et al. 2018), has negative repercussions for these women, leading many to report feeling judged, dismissed or disbelieved by health care professionals in their quest for diagnosis (LePage and Selk 2016; Sadownik, Seal and Brotto 2012; Shallcross et al. 2019). Such experiences further compound women's sense of suffering and pain and elicit feelings of anger towards the health professionals providing their care (Shallcross et al. 2019).

Research suggests that vulvodynia is not just a significant burden to the affected women and their partners, but also to the healthcare system and society. The estimated annual economic burden of vulvodynia in the United States is approximately 31–72 billion dollars (Xie et al. 2012), with an annual estimate of direct health care cost reported to be $8054.06 per patient in 2012, and $9591.80 per patient in 2017 (Lua et al. 2017).

In summary, vulvodynia imposes a profound personal and societal economic burden, influencing biological, psychological, psychosexual and social aspects of life. Furthermore, the exact causal mechanisms are unknown. Sound theoretical frameworks are therefore needed to understand the possible underlying causes, their impact upon these women and how to manage vulvodynia effectively. As the focus of study in this PhD is on women suffering with PVD, this term will be used from now on.

2.2 Theoretical framework

2.2.1 Provoked vestibulodynia and biopsychosocial model of health

Although PVD has a large impact on the psychological, physical and sexual health of women with PVD, research in this field has a long tradition of studying physical and physiological markers of genital pain, focusing primarily on causality from a biomedical perspective. In 1977 George Engel highlighted the inadequacies and limitations of the traditional biomedical model, criticising the model's dualistic nature, with its separation of body and mind. Furthermore, Engel argued that individuals were viewed in mechanistic ways and anything that could not be objectively verified or explained physiologically, was ignored or devalued (Engel 1977). Engel proposed the biopsychosocial model to broaden the biomedical approach by promoting a more humanistic view of healthcare, recognising biological, psychological and social influences (Engel 1977; Engel 1979).

In the field of chronic pain, the biomedical model has also received considerable critique, as this model could not explain the complex array of pain experiences. Historically there has been a tendency to conceptualise PVD in a dualistic fashion; either as a psychogenic sexual condition or as a biomedical condition (Chisari and Chilcot 2017). The lack of clinical findings during physical examination has led some practitioners to believe this was strictly a psychological problem. In the past twenty years however, there has been a growing consensus that PVD needs to be studied in a broader perspective beyond the biomedical model, and that a biopsychosocial approach should be applied in diagnosis and management of PVD (Chisari et al. 2021; Desrochers et al. 2010; Thomtén and Linton 2013) with emphasis on "improvement" in health, rather than cure of disease (Sadownik 2000). In utilising a biopsychosocial approach to diagnosis and management of women with PVD, the biological, psychological, psychosexual and interpersonal factors that contribute to the women's illness can be taken into account (Sadownik 2014). The importance of finding these numerous contributors to an individual's chronic pain is also highlighted in the new ICD-11 classification for chronic pain (Treede et al. 2019). Recent discussions on aetiology hold a biopsychosocial perspective, where multiple factors interact in the development and maintenance of PVD (Bergeron et al. 2020). In the biopsychosocial model emphasis was now placed on the patient's perspective in the social context in which the person lived (Engel 2012). This holistic model is considered one of the most appropriate conceptual frameworks for understanding chronic pain (Gatchel et al. 2007). The theoretical perspective chosen for this thesis is based upon both the biopsychosocial model

of health (Engel 1977) and the Developmental Theory of Embodiment (Piran 2017). In figure 1, a biopsychosocial model of PVD is proposed, based on the literature presented in this thesis.

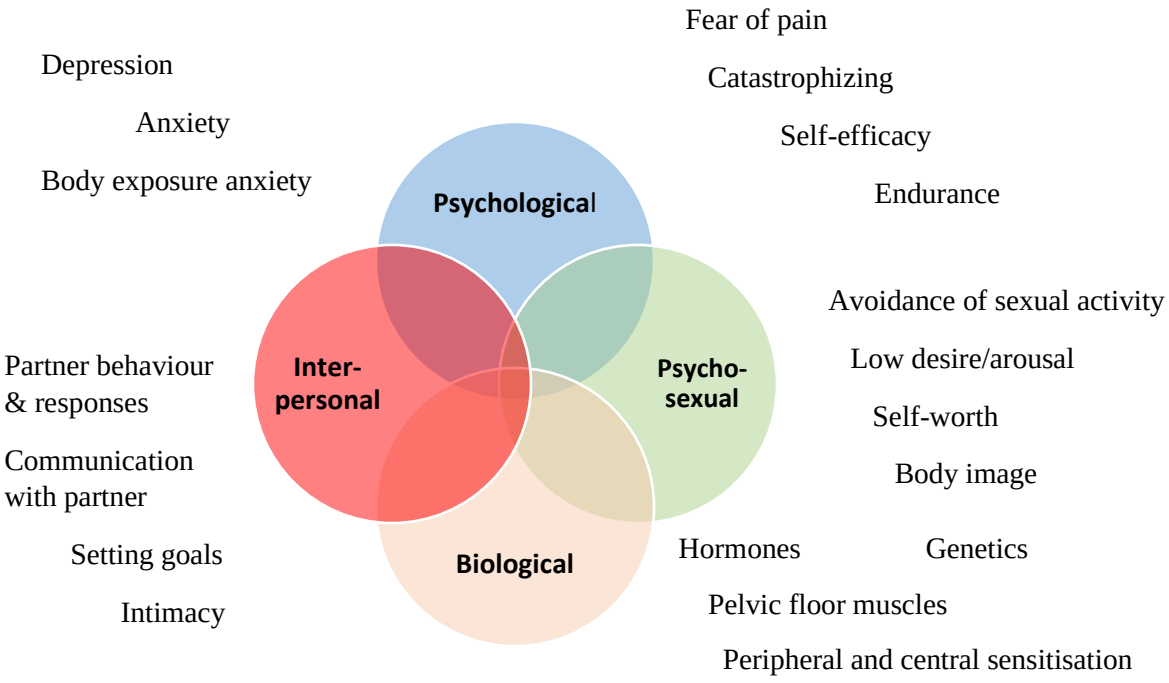

Figure 1. Biopsychosocial model of provoked vestibulodynia

2.2.2 Developmental Theory of Embodiment

The theoretical perspective chosen for this thesis is also based on the Developmental Theory of Embodiment (DTE) (Piran 2017). In the qualitative study, in Paper III, we draw on Piran's theory, further allowing us to understand the women's body-anchored experiences within broader sociocultural contexts. Developed through grounded theory approach, the DTE is a research-based social theory aiming to explain the development and experience of embodiment among girls and women. This theory builds on Merleau-Ponty's understanding of embodiment as lived experience and of the mind and body as an inseparable whole, existing in a reciprocal relationship with culture. The DTE refers to critical and feminist theorists such as Foucault (Foucault 1977), Bartky (Bartky 1998), and Simone de Beauvoir (Beauvoir 1989), and leads our attention to how women´s bodies are a site of social control, where social discourses socialise women to inhabit "compliant" and "docile" feminine bodies.

The DTE outlines five dimensions that shape the quality of one´s Experience of Embodiment, each representing a scale from positive to negative:

Dimension 1. Body Connection and Comfort vs Body Disconnection and Discomfort
Dimension 2. Agency and Functionality vs Restricted Agency and Restraint
Dimension 3. Experience and Expression of Desire vs Disrupted Connection to Desire
Dimension 4. Attuned Self-care vs Disrupted Attunement, Self-harm, and Neglect
Dimension 5. Inhabiting the Body as a Subjective Site vs as an Objectified Site

Building on these dimensions, the DTE defines positive embodiment as "*positive body connection and comfort, embodied agency and passion, and attuned self-care"* (Piran 2017). The opposite is disrupted embodiment, defined as *"disrupted body connection and discomfort, restricted agency and passion, and self-neglect or harm"* (Piran 2017). By collating these five dimensions previously understood and studied as distinct phenomena, under the wider concept of embodiment, the DTE provides an integrative framework from which to explore the women´s embodied therapeutic journeys.

Experiences of embodiment among women with PVD and how the quality of embodiment intersects with their sexual health, and how these phenomena can be negotiated in a physiotherapy context, has to the best of our knowledge, not yet been explored. The limited existing literature which explores connections between the quality of one's embodiment and the quality of one's sexual health, suggests that embodiment can be linked to feeling more comfortable with one's sexual desire and feeling entitled to sexual pleasure, as well as a stronger sexual agency (Chmielewski, Bowman and Tolman 2020). Experiencing the body as a subjective site and being aware of bodily sensations can help women to connect with pleasurable bodily feelings and encourage more positive sexual experiences (Hirschman et al 2006). A recent qualitative study found that taking part in regular embodied practice encouraged a shift from experiencing sexuality from an objectified perspective to sexuality as a lived experience, connected to internal bodily states (Ellison and Papps 2020). A feminist embodiment framework can help us understand how social pressures might interfere with the women´s experiences of embodiment and with their embodied experiences of sexual health.

2.3 Management of provoked vestibulodynia

PVD is a complex condition which is not easy to treat. There is a growing consensus that PVD should be diagnosed and managed with a biopsychosocial approach, yet there are no recommended international evidence-based clinical guidelines for the management of PVD. The 2016 European guideline for vulvar conditions provides a guide on vulvodynia management (van der Meijden et al. 2017), however this guideline is brief and lacking in detail. Treatment recommendations for PVD are based on clinical experiences, observational studies, uncontrolled trials, or reports of expert committees (Lev-Sagie and Witkin 2016), with few high quality RCTs available. Although there are many treatment approaches applied in the treatment of PVD, including medical, surgical, physical, and psychological, a consensus has not been reached concerning their efficacy. The most common treatments are topical (85%), physiotherapy (52%) and oral medications (45%) (Lamvu et al. 2018). Even though topical steroids and oral antidepressants are the most commonly used treatments provided by primary care physicians, no medication has been shown to be significantly more effecive than placebo (Brown et al. 2018; Miranda Varella Pereira et al. 2018). Women with severe PVD who do not respond to conservative treatement, may benefit from surgery, with retrospective follow-up studies demonstrating that vestibulectomy can have successful long-term outcomes (David and Bornstein 2020; Tommola, Unkila-Kallio and Paavonen 2011). Control groups were lacking in these studies, hence the effects of spontaneous recovery or placebo cannot be ruled out. Pharmacological and surgical treatments is beyond the scope of this thesis and will not be further described. Both physiotherapy and psychological interventions are first-line treatments and demonstrate promising effects. In the literature, a patient-focused multidisciplinary treatment is often recommended (Smith et al. 2019), yet the evidence for such an approach is lacking.

A newly published systematic review aiming to summarise existing controlled trials of the effects of various treatment interventions for women with PVD, underlines the need for more methodologically stringent trials on PVD interventions (Bohm-Starke et al. 2022). The authors could not draw any conclusions about treatment effects due to the very low certainty of evidence. The inherent limitations of the available studies in the PVD literature have included small patient numbers, large variation in treatments and absence of standard outcome measures. The need for agreed-upon standard outcome measures for vulvodynia clinical trials is essential to enable cross-study comparisons and synthesize the treatment evidence (Pukall et al. 2017;

Sadownik, Yong and Smith 2018; Rosen, Bergeron and Pukall 2020). In addition, earlier clinical trials did not differentiate among the different subtypes of vulvodynia, as described in the 2015 nomenclature.

In the following paragraphs, a short overview of physiotherapeutic and psychological interventions as applied in the treatment of PVD will be presented, as both of these treatment interventions have important components utilised and incorporated in the SCT intervention.

2.3.1 Physiotherapy

Physiotherapy is a recommended first-line treatment for PVD (Bergeron et al. 2020; Goldstein et al. 2016) where the goal of physiotherapy is to provide treatment that reduces pain and improves sexual function. A range of different physiotherapy approaches are used in clinical practice, either in combination or alone, with multimodal interventions most closely portraying current practice (Hartmann, Strauhal and Nelson 2007). The most common interventions include electromyography (EMG) biofeedback, manual therapy, dilators and insertion techniques, electrotherapy, education, multimodal physiotherapy and multidisciplinary approaches (Morin et al. 2017b). Studies have shown that women with PVD present with heightened pelvic floor muscle tone, as well as difficulties with muscle relaxation, reduced strength and control (Morin et al. 2017a). Pelvic floor physiotherapy aims to rehabilitate the pelvic floor muscles with several techniques such as EMG biofeedback to retrain the pelvic floor muscles and hands-on manual therapy to normalise muscle tone, enhance muscle proprioception and facilitate relaxation. A recent systematic review suggests that pelvic floor physiotherapy can be beneficial in patients with pelvic floor hypertonicity (van Reijn-Baggen et al. 2022). The quality of these studies however, was low to moderate, of which only one of the studies in this review included women with PVD (Gentilcore-Saulnier et al. 2010). In this study, 11 women with PVD were compared with 11 healthy controls, the results of the study suggesting that pelvic floor physiotherapy may be beneficial in the management of PVD.

The effectiveness of physiotherapy for PVD has been evaluated in a systematic review by (Morin et al. 2017b). Forty-three studies were found to be eligible which included seven RCTs, 20 prospective studies, five retrospective studies, six case reports and six study protocols. The various treatments demonstrated promising effects in terms of reducing intercourse pain and improving sexual function (when measured). The largest number of studies investigated

multimodal physiotherapy, which overall appeared to exceed isolated modalities in terms of treatment effect, including one small pilot RCT (Goldfinger et al. 2016). The authors of this review described several methodological limitations, including high risk of bias, which made it difficult to interpret the findings. Further shortcomings described included the lack of a control group, insufficient sample sizes, non-validated outcomes and non-standardised treatments. The efficacy of physiotherapy has since been supported by a multicentre parallel-group RCT comparing multimodal physiotherapy with overnight topical lidocaine for 10 weeks, in 212 women with PVD (Morin et al. 2021). The intervention group received a combination of education, pelvic floor muscle exercises using EMG biofeedback and manual therapy. The home exercises included pelvic floor contractions and stretching exercises using a vaginal dilator and vestibule tissue mobilisation. The intervention group demonstrated significantly better results for pain during intercourse and all secondary outcomes post treatment and at 6 months follow-up.

2.3.2 Psychological treatments

Over the past decade there has been an increased shift towards psychological treatments for PVD (Brotto et al. 2019). Several psychological interventions for PVD exist including cognitive behavioural therapy (CBT) and mindfulness. CBT is the most commonly used psychological intervention for PVD (Rosen et al. 2019). These interventions are designed to target the multiple dimensions of pain (Corsini-Munt et al. 2017), aiming to reduce pain and psychologic distress, restore sexual function and improve the sexual relationship. The delivery of these interventions varies, albeit with some overlapping treatment techniques. Patients are taught self-management skills that aim to challenge and alter maladaptive thoughts, feelings and behaviours that are associated with PVD (Bergeron et al. 2016). The CBT programs differ, but can include psychoeducation, desensitisation exercises, diaphragmatic breathing, relaxation and sexual communication skills training (Goldfinger et al. 2016), delivered in individual, couple or group formats (Corsini-Munt et al. 2017).

The psychological interventions are often based on cognitive behavioural models of chronic pain, such as the fear-avoidance model of pain (Vlaeyen and Linton 2000), a highly influential model in chronic pain research and clinical practice. This model suggests that fearful, catastrophic interpretations of pain can generate muscle tension and hypervigilance towards pain sensations. These responses further exacerbate pain and can lead to avoidance of activities

or movements associated with pain. The avoidance prevents new learning from occurring, further creating a viscous cycle. Treatment involves a graded exposure to stimuli that induces pain related fear, such as specific movements or activities intended to challenge unhelpful or catastrophic beliefs about pain (Crombez et al. 2012; Vlaeyen and Linton 2012). The fear-avoidance model has been further adapted to sexual pain (Thomtén and Linton 2013). Women with PVD commonly present with avoidance behaviour i.e., abstaining from penetrative intercourse or other painful activities, due to catastrophic misinterpretation of pain and pain-related-fear (Benoit-Piau et al, 2018; Thomtén and Karlsson, 2014). Here, graded exposure may include exposure for threatening thoughts, and communication about pain and sex, with a partner or healthcare professionals. As previously mentioned, some women do not inform their partners about the pain and continue to endure sex despite pain (Elmerstig, Wijma, and Bertero 2008). In a recent PhD dissertation, Engman (2021) introduces the fear-avoidance-endurance model of vulvodynia, a new model which combines the fear-avoidance model and the avoidance-endurance model (Hasenbring and Verbunt 2010) in the same framework, to demonstrate how psychological factors are involved in the development and maintenance of PVD.

There is a growing body of evidence supporting the efficacy of CBT for PVD with several RCTs evaluating the effects of CBT, either performed as a single intervention, or in combination with other interventions. One early RCT compared group CBT to surface EMG biofeedback and vestibulectomy in 78 women. All three treatments were found to be effective, with the vestibulectomy group demonstrating 70% pain reduction, CBT 28.8% reduction and surface EMG biofeedback 23.7% reduction (Bergeron et al. 2001). Another RCT evaluated group CBT versus a topical steroid (Bergeron et al. 2016). In this trial both groups demonstrated reductions in pain and increased sexual function following treatment, however patients who received group CBT showed significantly more pain reduction six months later. A recent trial investigated the effectiveness of a novel cognitive-behavioural couple therapy and topical lidocaine in 108 women with PVD and their partners. The group treatment demonstrated significantly more improvements than lidocaine, in terms of pain, sexual functioning and pain anxiety and pain catastrophizing (Bergeron et al. 2021).

There is growing evidence for mindfulness-based therapies in the management of PVD, which adds acceptance and mindfulness training to the CBT techniques. One RCT investigated Mindfulness-based group Cognitive Behaviour Therapy (M-gCBT) versus online education

support group therapy (n=31) (Guillet et al. 2019). Both interventions were effective in reducing pain and distress. Another RCT, investigated Mindfulness-Based Cognitive Therapy (MBCT) versus CBT in 130 women with PVD. Both groups improved following treatment, but reduction in self-reported pain during vaginal penetration was largest in the MBCT intervention group (Brotto et al. 2019). Trials investigating Acceptance and Commitment Therapy as a treatment for vulvodynia are starting to emerge, an intervention which has been successfully applied in persistent pain populations (Hughes et al. 2017). A recent single-case experimental design by Chisari et al. 2022, investigated the effect of online ACT in seven participants with mixed vulvodynia, demonstrating improvements in two or more outcomes (Chisari et al. 2022b).

2.4 Summary of background

In summary, PVD is a prevalent and neglected pain condition which places a substantial burden on the individual, their romantic partners and society. Methodological challenges in this field have been the absence of standard outcome measures, the inconsistent use of pain measures as well as a lack of well-designed RCTs. Although a number of studies have examined the effect of various interventions for PVD, including physiotherapy, research is both scarce and of poor quality, furthermore evidence is inconclusive. There is an urgent need for well-designed RCTs to identify the most effective interventions for this neglected women's health condition. It is essential to provide women with evidence-based treatments that lead to clinically meaningful and lasting improvements in their symptoms. In order to improve quality of research and reduce research waste, it has been recommended to run a feasibility study. Running a feasibility study is therefore an important stepping-stone in preparation for a full size RCT, to allow alterations to the research protocol, including adjustments to the intervention prior to the main trial. There is also a need for in-depth and complete descriptions of physiotherapy interventions used in clinical trials (Yamato et al. 2016), allowing for replication in clinical practice and clinical trials. In addition, we know little about women's experiences with outcome measures used in vulvodynia research and little about their experiences with receiving physiotherapy. Multidisciplinary, also termed interdisciplinary, treatments are often recommended (Smith et al. 2019), yet the evidence for such an approach is lacking. Furthermore, they can be more difficult to establish, expensive to run and usually only cover densely populated areas. Developing and testing single discipline treatments which utilise a multimodal approach, may therefore be a good alternative.

3.0 Aims

The main aim of this thesis was to evaluate the feasibility and acceptability of SCT, a multimodal physiotherapy intervention, in a sample of Norwegian women with PVD, referred from the Vulva Clinic at Oslo University Hospital as part of the preparation for an upcoming RCT.

The specific aims were:

1. To assess the feasibility of undertaking a full-scale RCT of the SCT intervention for women with PVD. To evaluate the implementation and acceptability of SCT and its potential treatment effectiveness in PVD (**Paper I**).
2. To evaluate the tampon test as a primary outcome measure for an upcoming RCT for women with PVD (**Paper II**).
3. To gain insight into meaningful processes towards improved sexual health among women receiving SCT for PVD **(Paper III).**
4. To develop a conceptual model for PVD with SCT, provide a theoretical rational for this treatment and describe in detail SCT as a treatment for PVD (**Paper IV**).

4.0 Methods

The four papers presented in this thesis are all part of the ProLoVe feasibility study, conducted by the ProLoVe research group, which is part of the MUSK Health Research Group at OsloMet. The study commenced in 2019.

4.1 Philosophical underpinning

This thesis is built on both a post-positivist and phenomenological worldview. I used both quantitative and qualitative methods in this thesis to answer the research questions, making it possible to draw on the strengths and minimise the weaknesses of both methods. Combining different scientific approaches can offer a more complete and comprehensive account of phenomena under study (Doyle, Brady and Byrne 2009) and both worldviews can be used to seek answers to different problems. The quantitative approach was informed by a post-positivist worldview. Post-positivism serves the thinking after positivism, in that it challenges the traditional belief of the absolute truth of knowledge. In studying the behaviour and actions of humans it is recognised that we cannot gain the absolute truth. Gaining knowledge is based on careful observation and measurement of the objective reality "out there" in the world. For a post-positivist it is vital to develop numeric measures of observation and study the behaviour of humans (Creswell and Creswell 2018). The researcher gathers information on instruments based on measures completed by the participants. Being objective and value free is essential (Proctor 1998) as far as possible and methods and conclusions for bias must be examined, including attentiveness of valid and reliable outcome measures. The qualitative approach was informed by a phenomenological worldview, where the aim was to explore and give voice to the subjects' perspectives and lived experiences, which gives meaning to their world (Kvåle and Brinkman 2009). A phenomenological approach was utilised as a basis for the interviews, where the researcher is subjective using an inductive strategy, with theory developing from the area of study (Proctor 1998). Here the researcher is looking to gain insight into the women's own experience with the phenomena of somatocognitive therapy.

4.2 Study design

To address the multiple aims of this thesis, different study designs were applied. In Paper I, a multimethod feasibility study with a single arm before-after trial and qualitative interviews was utilised. In Paper II, an explanatory sequential mixed methods study design was applied to see how the qualitative data could help to explain and clarify the quantitative findings (Doyle, Brady and Byrne 2016) i.e., how PVD women's experiences with the tampon test could explain the tampon test findings. In Paper III, a qualitative inductive design with semi-structured interviews was applied. In Paper IV, a conceptual model for PVD with SCT was developed. This included a detailed description of the SCT intervention which has been further developed and refined, based on findings from Paper I and III, previous research and clinical experience.

4.3 Study Population

Ten participants were recruited from the Vulva Clinic, Department of Obstetrics and Gynaecology, at Oslo University Hospital. The same sample was used in Paper I-III. Participant's eligibility assessment was based on a comprehensive medical history and gynaecological examination. The assessment was undertaken by a specialist in gynaecology or dermatology, using a standardised protocol for PVD diagnosis (Stockdale and Lawson 2014). Patients were invited to participate in the study if they met the following inclusion criteria: 1) pain experienced during intercourse, pressure applied to the vulvar vestibule or usage of tampon, 2) aged between 18 and 35 and 3) fluent in Norwegian. Both women with primary PVD (pain with first penetrative attempts e.g., tampon insertion, sexual intercourse) and secondary PVD (pain developed after years of pain-free penetrative activities) were included. The exclusion criteria included the presence of an active infection or dermatologic lesion in the vulvar region. Eligible patients were verbally informed about the study and received an information leaflet at the Vulva Clinic. Ten out of 18 eligible women contacted the primary investigator, received a detailed explanation about the study and agreed to participate. Eight eligible women did not contact the project leader and the reason for this is not known. As both quantitative and qualitative methods were utilised, with interviews undertaken at two time-points, it was decided that ten participants would be enough subjects for this study. Additionally, during the final two interviews from the first interview round, no new themes emerged from the women's narratives and the sample was considered adequate to ensure saturation on the topic.

4.4 Ethical considerations, trial registration and funding

This trial was conducted in accordance with the principles of the Declaration of Helsinki. All participants were provided with written and oral information about the study. All participants provided written informed consent prior to participation in this research. The Regional Committees for Medical and Health Research Ethics in South-East Norway (ref. no. 2018/1036, 01.10.18) approved the project (Appendix 1). The trial was registered retrospectively (December 23, 2019) at Clinical.Trials.gov under the identifier NCT04208204. The first paper was reported according to the Consolidated Standards of Reporting Trial (CONSORT) 2010 statement: extension for pilot/feasibility studies (Eldridge et al. 2016a) (Appendix IV).

The studies included in this thesis were funded by The Norwegian Fund for Post-Graduate Training in Physiotherapy and Oslo Metropolitan University. The Norwegian Fund for Post-Graduate Training funded the qualitative interviews. At no stage of the study were the funding sources involved.

Sexuality can be a sensitive theme. Painful sex and topics related to disrupted sexual health is often associated with shame and taboo and can be embarrassing and painful to talk about. The interviewer therefore started each interview with an informal chat about non-sensitive topics to establish an atmosphere of trust and comfort. As the interviews touched on sensitive and private experiences, the interviewer was attentive to any signs that the participants were uncomfortable sharing their stories and did not press for further elaboration if she felt a limit was being reached.

4.5 Study intervention – somatocognitive therapy

SCT is an existing multimodal physiotherapy treatment developed in the early 2000s at Oslo University Hospital to treat women with chronic pelvic pain (Haugstad et al. 2006b; Haugstad et al. 2008) and has in recent years been further developed to treat PVD (Haugstad et al. 2018; Haugstad et al. 2019). SCT is built on theoretical principles from both Norwegian Mensendieck physiotherapy (Klemmetsen and Rugseth 2005) and Cognitive therapy (Beck 2005). The Mensendieck physiotherapy tradition was founded on principles of functional anatomy and motor learning (Fitts 1954; Fitts and Posner 1967) cited in Haugstad et al. (2006a). Movement, both global quality of movement, and isolated movements, and a conscious sensory awareness of own body, which includes the state of muscle tension, are inherent principles of the

Mensendieck tradition (Haugstad et al. 2011). Cognitive therapy was developed by Aaron T. Beck, a psychiatrist, in the early 1960s (Beck 2005) and is based on the theory that thoughts, emotions, body sensations, and behaviours are all connected, and that what we think and do affects the way we feel.

The primary conceptual model for understanding and managing PVD with SCT is based on the biopsychosocial model of health. As PVD is considered a multifactorial persistent pain condition, SCT emphasises integrating physical, psychosexual, interpersonal and psychological dimensions when addressing the individual's pain experience. Central components of this complex multimodal treatment include therapeutic alliance, bodily exploration, education, coping with thoughts and emotions and structured homework to be practiced between sessions. The treatment is tailored to the individual's needs. The term multimodal is utilised due to the concurrent application of several therapeutic modalities. An intervention is complex if one of the following criteria are met; the intervention includes many components or targets a range of behaviours, a high level of skills is required from those delivering the interventions, many groups or settings are involved, or the intervention is delivered flexibly (Skivington et al. 2021).

The main goal of treatment is to facilitate change to improve women's sexual function and reduce vulvar pain. Bodily exploration is at the core of the SCT approach, with the aim of promoting body awareness and facilitating new bodily experiences and insights. A high level of body awareness amongst therapists is important, an awareness aimed to be transferred to the patient (Haugstad et al. 2006a). Important subgoals of SCT are also the development of cognitive coping strategies. Through pain education, the women learn how PVD can be understood as a multifactorial pain condition, furthering the participants' sense of self-efficacy and mastery of own life. In SCT, the women are encouraged to be actively engaged in their own therapeutic process and are empowered to take ownership of their body, sexuality and recovery process. To support these processes, a strong emphasis in SCT is on developing a sound therapeutic alliance with the patients (Haugstad et al. 2011), through shared-decision making (Hutting et al. 2022) and setting patient-centred goals. The quality of the therapeutic relationship is therefore essential. Several elements and principles from Cognitive Therapy are utilised in SCT approach, such as a treatment that is structured, time-limited, goal-oriented, individualised, educative and collaborative. The homework is also an essential component of SCT. Functional movements, relaxation and graded tasks are consciously practiced several times a day to learn new motor patterns which are applied, become automized and internalised,

and integrated to activities of daily living (Haugstad et al. 2011). These new movement patterns lead to new strategies for coping and gaining control of own body. Furthermore, the women are encouraged to begin to relate to their vulva and sexuality in a more compassionate and more positive, embodied manner. For further details and descriptions of the intervention see Paper I and IV.

The SCT intervention took place at the Department of Rehabilitation Science and Health Technology, Oslo Metropolitan University. I was the therapist conducting the treatment, a female physiotherapist trained in SCT and experienced in chronic pain management. The number of treatment sessions delivered were individualised, up to 15 sessions, from 2-4 sessions per month, with each session lasting 60 minutes. In Paper I, an overview of the intervention is presented in a table as it was provided in the feasibility study, utilising the Template for Intervention Description and Replication (TIDierR) (Hoffmann et al. 2014).

A logic model (Figure 2) is presented below, a diagrammatic representation of the SCT intervention which depicts the anticipated casual chain for the future ProLoVe RCT. This logic model aims to illustrate the intended core components of the intervention, the intervention assumptions, how the components interact to produce change and the anticipated short- and long-term outcomes (Moore et al. 2014).

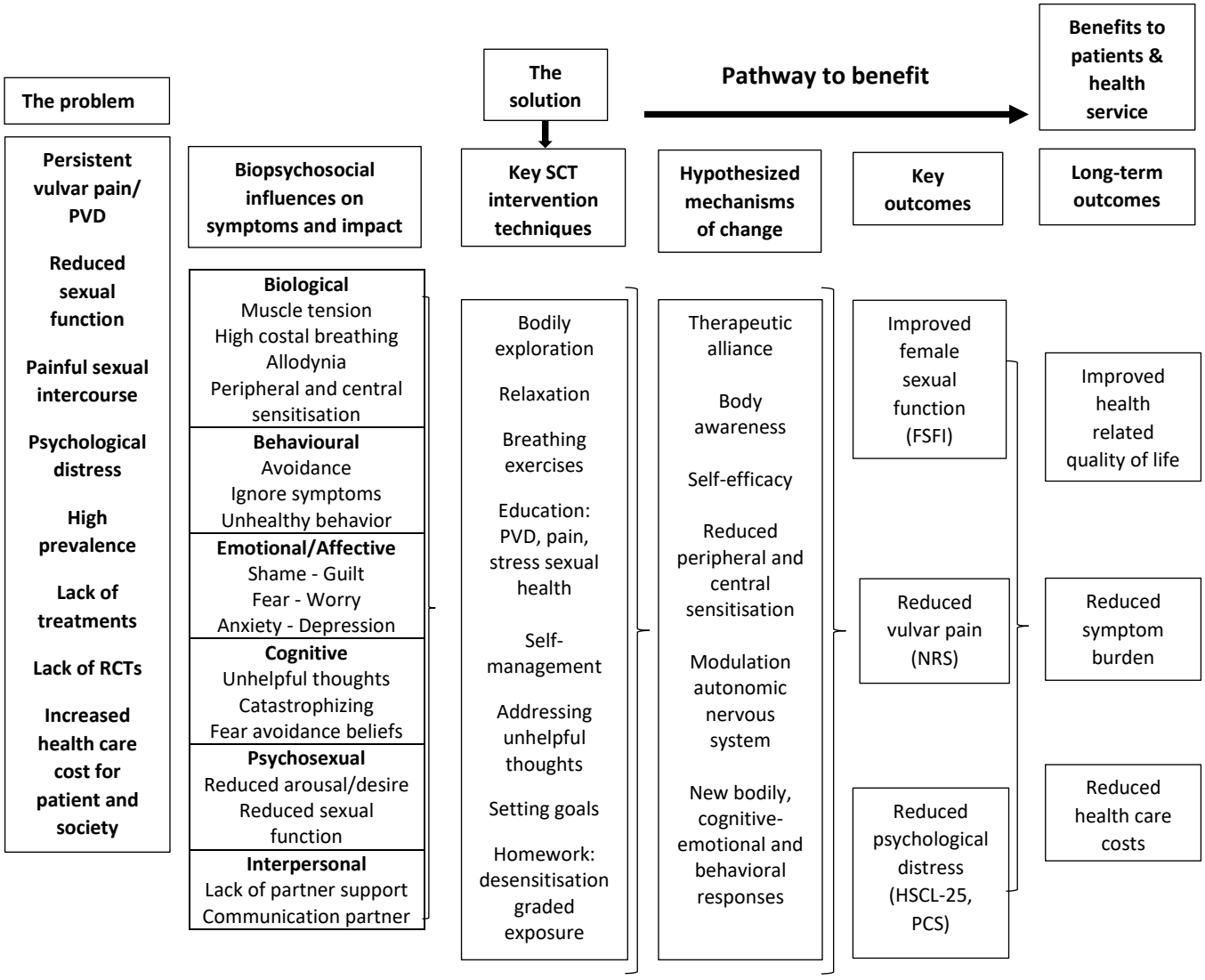

Figure 2 Logic Model in the ProLoVe study illustrating the potential benefits of using a somatocognitive therapy approach for provoked vestibulodynia.

PVD: Provoked vestibulodynia; RCTs: Randomised Clinical Trials, SCT: Somatocognitive Therapy; FSFI: Female Sexual Function Index; NRS: Numeric Rating Scale; HSCL-25: Hopkins Symptom Check List -25; PCS: Pain Catastrophizing Scale

4.6 Data collection

The trial was conducted at Oslo Metropolitan University, Norway. All quantitative data were collected via electronic forms and directly transferred in a secured manner to the Services for Sensitive Data (Tjenester for sensitive data = TSD) research server. The quantitative data was collected at baseline, post-treatment and at 8 months follow-up. Qualitative data were recorded on two occasions with a Dictaphone app, which ensured immediate and direct transfer of the files to the TSD research server. The qualitative data collected through interviews was

transcribed verbatim and uploaded into NVivo 12, towards the end of the treatment period and one year later. Data collection took place between February 2019 and August 2020.

The patients received four electronic assessment packages throughout the study. There were three main assessment time points: baseline, post-treatment and 8 months follow-up.

Assessment package 1

The participants received an electronic link to the main questionnaire package, which included sociodemographic and clinical characteristics and a battery of self-reported questionnaires. At baseline, sociodemographic and clinical characteristics were collected including information about age, number of children, relationship status, education, work status, use of analgesics, body mass index, exercise and intercourse frequency in last four weeks. The battery of self-reported questionnaires was distributed at all three assessment time points and will be described under secondary outcome measures.

Assessment package 2

Vulvar pain intensity was assessed with the tampon test (Foster et al. 2009) undertaken in the evening on days 1, 7 and 14, rated with the Numeric Rating Scale (NRS) (0–10). A score of zero represented no pain and 10 representing the worst possible pain. Information about baseline pain intensity measured with the tampon test was collected and presented in Paper I and Paper II. The tampon test was undertaken at each of the three measurement time points.

Assessment package 3

A 14-day diary (Rost et al. 2016), an *index of emotional instability*, to assess day to day variance in emotional states was delivered daily for 14 days at each of the three measurement time points.

Assessment package 4

Participants received bi-weekly electronic forms up until the 8 months follow-up, recording medication, number of treatments and sick leave days due to PVD in the past 14 days.

4.6.1 Outcome measures

Primary feasibility outcomes

The primary aim of this study was to evaluate the feasibility of undertaking a full-scale RCT of SCT for women with PVD. The primary feasibility outcomes measured in preparation for the main trial included the following:

- **Recruitment rate** is defined as the number of eligible patients and number of recruited participants per week, within a period of five months.
- **The follow-up response rate** was measured by the percentage of participants who were followed up successfully until the 8 months follow-up.
- **Adherence to completion of outcomes**. Adherence was defined as the number of participants who fully completed the battery of self-reported questionnaires, the number of performed tampon tests, the 14-day diary, and biweekly forms about the received treatment, within a time frame of 8 months.
- **Evaluation of the utility value of the tampon test** as a primary outcome measure based on tampon test data and the participants' experiences with the tampon test.
- **Reporting of adverse events**. Events were recorded as adverse if participants were withdrawn from the study because SCT was deemed as an inappropriate treatment.

Secondary outcomes in the feasibility

The secondary aim was to assess implementation and acceptability of SCT, utilising both quantitative and qualitative data (Paper I).

Global Perceived Effect

The 6-point Global Perceived Effect (GPE) scale was used to provide quantitative estimation of participants' perceived effect with the treatment directly after treatment and at the 8 months follow-up (Kamper et al. 2010). The participants were asked "Overall, how much did the treatment you received help your problems?". The scale ranges from one to six; very much better, much better, a little better, no change, much worse, and very much worse. This scale was adapted from an electronic questionnaire packet used at OsloMet called FysioPol (Tveter, Major and Grotle 2015).

To assess potential treatment effectiveness, the following self-reported outcomes were used:

Tampon test

Vulvar pain intensity was measured with the tampon test. This test was chosen as a primary outcome measure based on recommendations for self-report outcome measures in vulvodynia clinical trials (Pukall et al. 2017). The test is an alternative measure for pain associated with vulvovaginal penetration and allows the inclusion of women with PVD who are unable to have intercourse. This test has been used as a primary outcome measure in various clinical trials for vulvodynia, evaluating the effect of various treatments (Brown et al. 2016; Brown et al. 2018; De Andres et al. 2013; Foster et al. 2010; Guillet et al. 2019; Lev-Sagie et al. 2017). The test has demonstrated good construct validity and reliability (Foster et al. 2009). In this study, all participants were provided with the same type of tampon as the validity study, the original Regular Tampax^{TM} Tampons and were provided with detailed instructions about how to undertake and record test, as described by Foster et al. (2009). The participants recorded the degree of pain on the entire tampon insertion and removal experience on the NRS.

Female Sexual Function Index-19

Sexual function was measured with the Female Sexual Function Index-19 (FSFI) (Rosen et al. 2000). This 19-item patient-reported outcome measure has been extensively used in PVD trials to measure female sexual function (Morin et al. 2021; Smith, Pukall and Chamberlain 2013; Smith et al. 2019), and is recommended in the *Recommendations for the study of the vulvar pain in women, part I: review of assessment tools* (Rosen, Bergeron and Pukall 2020). It consists of 6 separate domains of female sexual function, namely desire (items 1-2), arousal (3-6), lubrication (7-8), orgasm (11-13), satisfaction (14-16) and pain (17-19). FSFI total score can also be used as a categorical variable discriminating between women with poor (FSFI<26) and normal sexual functioning (Wiegel, Meston and Rosen 2005). In a 2019 systematic review it was found that the FSFI-19 meets psychometric criteria with respect to internal consistency, reliability and criterion validity, but not for structural validity, measurement error, construct validity and responsiveness (Neijenhuijs et al. 2019). The questionnaire has not been validated in the Norwegian population. A forward-backward translation was used to make consensus, following recommendations for translation (apart from the final report) (Wild et al. 2005).

Hopkins Symptom Checklist-25

Psychological distress was measured with the Hopkins Symptom Checklist-25 (HSCL-25), proved to have satisfactory validity and reliability (Derogatis et al. 1974). The HSCL-25 has an acceptable validity for measuring symptoms of anxiety and depression in the Norwegian population (Strand et al. 2003). The HSCL-25 consists of 25 items and measures symptoms of anxiety (10 items) and depression (15 items) Each item was scored on a four-point Likert scale ranging from "*not at all*" to "*extremely*", where the individuals consider how much each symptom has bothered them or been an inconvenience to them in the past 14 days. The total score is the average of all 25 items. The HSCL-25 can be categorised into a high level of psychological distress and a low level of psychological distress. A higher average score is indicative of higher levels of psychological distress. For the total score, an average cut-off point of 1.75 is a valid predictor of mental disorder (Strand et al. 2003).

Pain Catastrophizing Scale

Pain catastrophizing was measured with The Pain Catastrophizing Scale (PCS (Sullivan, Bishop and Pivik 1995). This self-report measure consists of 13 items about thoughts and feelings related to pain and has been widely used in the research of chronic pain. Answers are given on a five-point Likert scale from 0 (*not at all*) to 4 (*to all the time*), resulting in a total possible score of 52. Higher scores indicate greater levels of catastrophizing. The PCS is broken into three subscales: rumination, magnification and helplessness. The Norwegian PCS demonstrated acceptable psychometric properties when applied to patients with low back pain (Fernandes et al. 2012).

4.6.2 Qualitative data collection

The qualitative approach was informed by a phenomenological worldview, where the aim was to explore and give voice to the subjects' perspectives and lived experiences (Kvåle and Brinkman 2009). At the outset of the ProLoVe project, it was pre-planned that the interviews should be undertaken by another member of the ProLoVe research team. The qualitative data was collected with semi-structured interviews (Moen and Middelthon 2015). The interviews were conducted one to one towards the end of the treatment period and one year later, each interview lasting 60-90 minutes. The interviews were conducted by a female physiotherapist Kristine Grimen Danielsen (co-author in all the papers), experienced with qualitative interview

research and skilled with discussing sensitive topics with patients. She was familiar with the SCT intervention but was not involved in the delivery of the treatment.

During the first interview round, all the participants were interviewed face-to-face at the outpatient Physiotherapy Department at Oslo Metropolitan University. Seven women took part in the second round of interviews which were conducted using Zoom, a digital communication platform, enabling secure sound and video transfer (Archibald et al. 2019) due to the Covid-19 restrictions. In Paper I-III, a descriptive and inductive qualitative design was chosen, seeking to gain a deeper understanding of the physiotherapy intervention and the tampon test (Braun and Clarke 2006). A semi-structured interview guide was utilised to ensure that all areas of interest were addressed during the interview (Appendix III), whilst encouraging the women to talk freely about their experiences (Kvåle and Brinkman 2009). Topics connected to experiences with the outcome measures, the SCT intervention and the therapeutic journeys were introduced with open-ended questions. Experiences and attitudes related to sexual health, and experiences with how PVD impacted on different aspects of their sexual health was homed in on. They were further encouraged to elaborate on bodily and emotional experiences related to sexual health. Salient cues and themes in the participants' answers were pursued by inviting them to elaborate, provide examples or to clarify, in order to elicit rich descriptions. To promote a nuanced data material, the interviewer was in search of variations, different perspectives and conflicting viewpoints (Kvåle and Brinkman 2009). During the final two interviews from the first interview round, no new themes emerged from the women's narratives and the sample was considered adequate to ensure saturation on the topic.

4.7 Positioning of the researchers

In the following paragraphs I will bring in the experiences of the interviewer and my own experiences, how we both position ourselves, our different roles, including our preconceptions and preunderstandings.

Ever since the interviewer was a bachelor student, she has had a particular interest in women's health and in pain management, including the SCT approach. She has comprehensive professional and theoretical knowledge in the field, as well as experience with interviewing women with PVD, as part of her master's thesis. In terms of preconceptions, the interviewer

had an expectation that a broad and holistic approach is effective in the management of PVD, especially long-term. Whilst her background made her well-equipped to undertake the interviews and delve into the material, her prior experiences, beliefs, preconceptions and preunderstandings could subconsciously have led her to seek confirmation of her prior beliefs. To avoid this, the interviewer made a conscious decision to be curious, have an open intention, to be an active listener and following through on any cues provided by the participants during the interview process.

Although relatively new to the field of vulvodynia at the onset of my PhD, my interest in pain and pain research also started as a physiotherapy student. For several years I worked in both in- and outpatient settings, and whether the patients were undergoing investigative procedures, operations or experiencing musculoskeletal problems, the suffering of pain was often the common complaint. My interest in pain management continued to grow and brought me from a teaching hospital in London to a multidisciplinary outpatient pain clinic in Oslo in 2005. Following my MSc *in the Management of Pain*, I started to work closely with a gynaecologist and went on to learn the SCT approach for women with longstanding gynaecological and pelvic pains. In 2019, I started as a PhD student in the pre-planned ProLoVe research project. In this project I have had several roles, both as a PhD researcher and as the therapist conducting the intervention. I did not have access to any of the data until all the participants had finished the study. Having an awareness of my different roles in this project has been important, such as in the preparation for reading and analysing the transcripts. My prior knowledge about these women from the treatments and remembering their experiences with the treatment, could subconsciously have led me to seek confirmation of my prior beliefs, or possibly influence my interpretation of the qualitative data. In terms of my preconceptions, I have confidence in the SCT approach, based on past clinical experience with how women with PVD benefit from this treatment, furthermore I have a comprehensive theoretical knowledge of the pain field. To the best of my ability, I made a conscious decision to attempt separating my roles. I read the transcripts with an open mind and attempted not to let my personal beliefs influence the analysis.

4.8 Blinding

The patients and clinician were not blinded to the treatment. I was the therapist delivering SCT and also the researcher conducting the analyses. I was not involved in recruitment of participants and did not have access to the quantitative or qualitative data until after the 8 months follow-up. The project leader administered the data collection electronically at baseline, post-treatment and at the 8 months follow-up.

4.9 Data Analysis

In Paper I and II the quantitative and qualitative data were analysed separately.

4.9.1 Quantitative data analysis

For the feasibility analysis, the results were expressed as numbers referring to recruitment rate, follow-up, adherence and adverse events respectively. Descriptive statistics were used to assess the feasibility objectives and the self-reported outcomes using SPSS (version 27, IBM, Armonk, NY, United States of America) and Microsoft Excel (2016). Due to the nature of a feasibility study and the low number of participants, no hypothesis testing was performed, hence the continuous variables were presented with median and quartile values. Estimation of sexual function measured with FSFI, pain catastrophizing measured with PCS and psychological distress measured with HSCL-25 are presented with median (Q1; Q3) and quartile values.
An individual mean pain intensity score was calculated from the tampon test measurements. Intra-individual variability in pain intensity scores was calculated as a median spread difference between the highest and the lowest pain intensity score. Estimation of pain intensity with the tampon test is presented as median (min; max; Q1; Q3) scores in Paper II.

4.9.2 Qualitative data analysis

Following the thematic analysis approach by Braun and Clarke (2006), the data was analysed semantically and inductively in Paper I-III. This involved coding the women's experiences related to the SCT intervention (Paper I) and experiences with the tampon test (Paper II). In paper III this involved coding the women´s embodied experiences related to processes towards improved sexual health with the SCT approach. The Developmental Theory of Embodiment: discovering paths in the body journey of girls and women, functioned as a sensitising lens during the final stages of analysis. The data processing software NVivo12 was used to organise

transcripts, codes, and themes through the analytical process. Attentive reading and re-reading of the transcripts helped the interviewer to discern central aspects in the women's experiences and preliminary themes both within and across the participants started to form, related to the research question and aim. Corresponding pieces of text were coded and collated, and various ways of organising the codes into themes and subthemes were explored until a tentative thematic map was in place. During this process I read through the original transcripts and noted down my own immediate thoughts and impressions, before comparing my interpretations with the preliminary thematic map. I then reviewed the map for validity against the original transcripts, considering alternative or contrasting excerpts, angles, and interpretations, and missing or overrepresented statements. Alternative interpretations and themes were discussed among the authors until agreement was reached on a final map over themes and subthemes. In Paper III, we made some important adjustments which included adding the dimension of negative feelings towards the body and incorporating insights into how early adolescent experiences might have impacted the quality of the participants´ embodiment and sexual health. The analytical development from initial codes to themes and subthemes is outlined in the supplementary material of the papers. The findings are presented as analytical summaries and illustrative quotes, which are fitted under relevant subheadings in the results section in Paper II, and III. In Paper I, the qualitative results are nested within the results section. All co-authors of the papers took part in the discussion of the final findings.

4.9.3 Mixed methods data analysis

In the last stage, quantitative and qualitative data analysis were integrated in a joint display to illustrate both the tampon test data and qualitative interviews. This mixed methods analysis which was undertaken in Paper II showed how the qualitative data helped to explain the quantitative data.

5.0 Results

In this chapter a summary of the main results will be presented. The detailed results can be found in the enclosed papers.

5.1 Participant flow, dropouts and adherence

A total of 18 women were considered for study participation. Ten Norwegian women contacted the project leader, gave consent and were included in the study. Eight women did not contact the project leader and the reason for this is not known. Ten women took part in individual qualitative interviews towards the end of the treatment period and seven participants accepted to take part in follow-up interviews one year later. Participants flow through the papers is shown in Figure 3.

Ten women were allocated to the SCT intervention and all ten received and completed the SCT intervention course. None of the participants dropped out before the 8 months follow-up and none were lost to follow-up.

The sociodemographic and clinical characteristics of the participants are presented in Table 1.

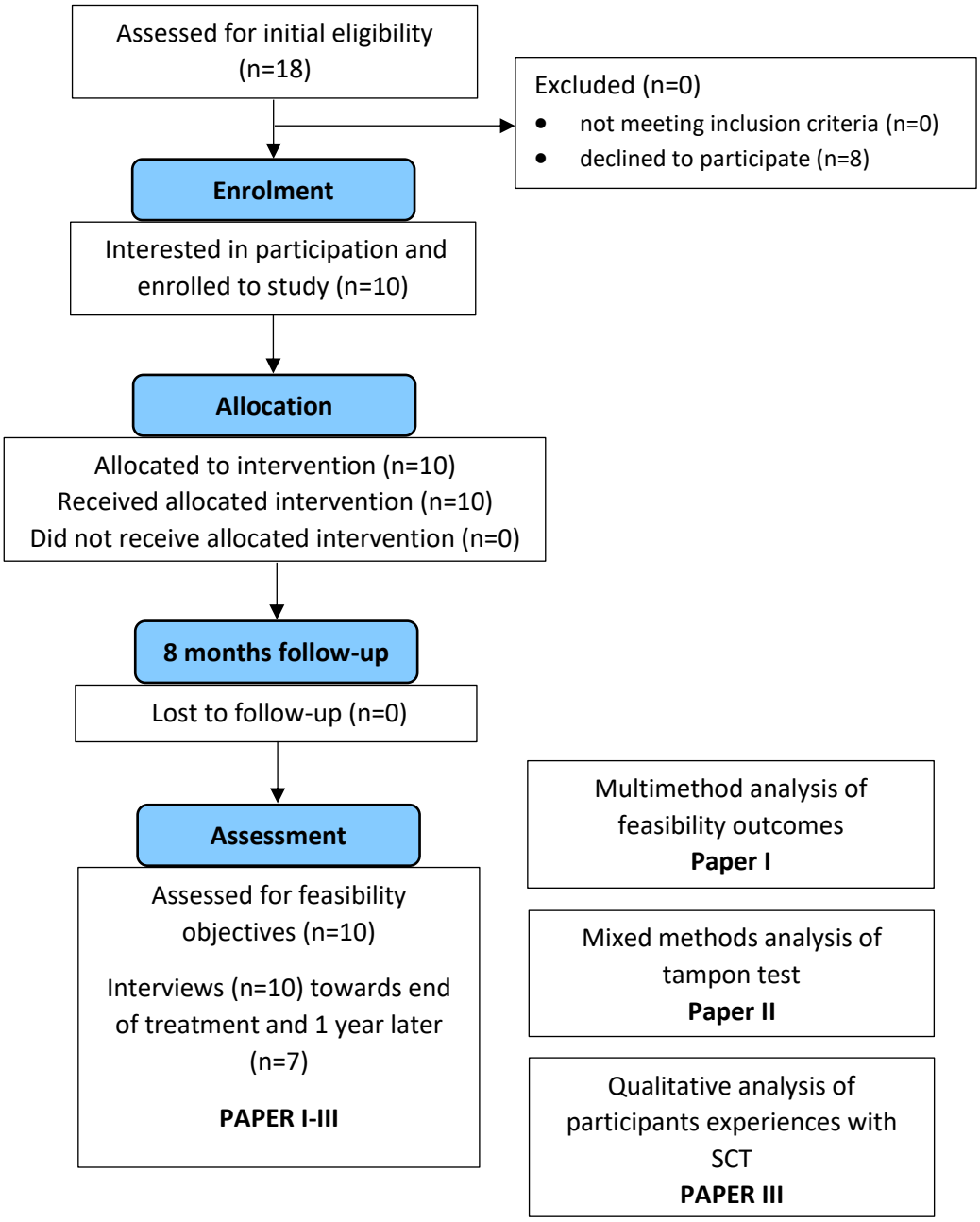

Figure 3. CONSORT 2010 Flow diagram. Design and flow of participants through study.

Table 1 Baseline characteristics of the participants in Papers I-III

Characteristics	Participants n=10
Age *(yrs.)*, median (Q1; Q3)	21 (20; 26)
Pain duration *(yrs.)*, median (Q1; Q3)	7 (3; 8)
Primary PVD	7
Relationship category	
Married/common law	2
In a relationship	2
Single	6
Childbirth	0
Intercourse past 4 weeks	2
Education category	
High school student	1
Undergraduate student	7
Completed bachelor's degree	2
Work category	
Student	9
Part time work	5
Full time work	1
Unemployed	0
Participants with comorbidities	7
BMI, median (Q1; Q3)	23 (20; 23)

5.2 Results of individual papers

5.2.1 Paper I

Feasibility and acceptability of somatocognitive therapy in the management of women with provoked localized vestibulodynia – ProLoVe feasibility study

The results of the feasibility outcomes showed that ten out of 18 eligible patients were recruited over 11 weeks. No participants were lost to follow-up. Adherence to self-report questionnaires was excellent, with all participants completing all the questionnaires at baseline, post-treatment and at 8 months follow-up. Adherence to tampon tests and to the reporting of treatments was good. Ninety percent of the tampon tests were completed across the three measurement time points. The 14-day diary however, was poorly adhered to with only two full data sets completed

at the 8 months follow-up. No adverse events were reported. The intervention was found to be an acceptable treatment based on GPE scores and the participants' experiences with the treatment. From the GPE scores at 8 months follow-up, one participant reported to be *very much better*, six participants reported *much better*, two reported *a little better* and one reported *no change*. The participants all expressed positive experiences with the SCT intervention, finding it meaningful to combine physical and psychological aspects. They found it useful to learn techniques for bodily exploration, deep breathing, relaxation and methods to self-manage thoughts, pain and sexuality. A follow-up session was recommended. In evaluating the secondary outcome, i.e., the potential of the SCT intervention to improve sexual function, and reduce pain, pain catastrophizing and psychological distress, all the outcome measures showed tendency towards improvements from baseline to post-treatment, see Table 2.

Table 2. Measurements at baseline, post-treatment and 8 months follow-up (n=10), (none lost to follow-up)

	Pre-treatment	Post-treatment	8 months follow-up
Tampon test NRS (0-10), median (Q1; Q3)	4.5 (2.5; 6)	2 (1.5; 4.2)	3.5 (1.8; 4.5)
Intercourse past 4 weeks, n	2	6	7
FSFI, median (Q1; Q3)			
Total sum (0-36)	14.8 (9.8; 19.8)	22.8 (15.8; 25.4)	20.9 (18; 27.1)
Desire	2.1 (1.6; 3.2)	3.6 (2.3; 3.8)	3.6 (2.7; 4.3)
Arousal	3.2 (1.6; 4.9)	4.4 (2.7; 5.7)	4.4 (3.0; 5.6)
Lubrication	4.2 (2.9; 5.2)	4.8 (3.5; 5.8)	4.7 (3.6; 6.0)
Orgasm	3.2 (0.9; 5.3)	4.8 (2.6; 5.3)	4.8 (1.2; 5.2)
Satisfaction	0.8 (0.4; 2.0)	4.2 (1.1; 5.2)	3.8 (1.2; 5.3)
Pain	0.0 (0.0; 0.3)	1.8 (0.0; 3.6)	2.0 (0.0; 3.6)
PCS (0-52), median (Q1; Q3)	20 (15.3; 29.3)	9.5 (5.3; 20)	12.5 (6.3; 22)
HSCL-25, median (Q1; Q3)	2.0 (1.7; 2.5)	1.6 (1.3; 2.4)	1.8 (1.6; 2.2)

NRS: Numerical Rating Scale; (higher scores indicate more pain) FSFI: Female Sexual Function Index (higher scores indicate better sexual function); PCS: Pain Catastrophizing Scale (higher scores indicate higher levels of catastrophizing; HSCL-25: Hopkins Symptom Check List - 25 (higher scores indicate higher levels of psychological distress).

5.2.2 Paper II

The tampon test as a primary outcome measure in provoked vestibulodynia: A mixed methods study

As part of the feasibility study, the utility value of the tampon test as a primary outcome measure in PVD was evaluated. Overall, the tampon test data demonstrated large intra- and inter-individual variability. At baseline, the median pain intensity was 4.5 (min=1.7; max=10; Q1=2.5; Q3=6). Post-treatment, median pain intensity was 2 (min=0; max=7, Q1=1.5; Q3=4.2) and at the 8 months follow-up it was 3.5 (min=0.7; max=8; Q1=1.8; Q3=4.5).

Through the qualitative analytical process four main themes were conceptualised, representing central aspects of the participants experiences with the tampon test: 1) pain sensation and pain intensity, 2) fluctuating pain intensity, 3) unfamiliar tampons and 4) the significance of context. Many participants experienced the tampon test as an inadequate representation of pain during intercourse as the tampon test was less painful, different in nature, unfamiliar and conducted in an entirely different context. Four participants used tampons with no difficulty. Four of the women had an NRS score that was equal to, or below four whilst concurrently reporting high levels of pain during sexual intercourse. Many women experienced large fluctuations in their pain levels which could explain the large tampon test intra-variability. The significance of context was highlighted as inserting a tampon and having sexual intercourse represents two very different situations. Overall, the findings were achieved by utilising a mixed methods approach, where the qualitative results can help to provide an explanation of the quantitative findings. These interpretations are further discussed in the Chapter 6.

5.2.3 Paper III

Toward improved sexual health among women with provoked vestibulodynia: experiences from a somatocognitive therapy approach

Paper III used qualitative data from individual semi-structured interviews of ten young Norwegian women with PVD who took part in SCT treatment. The study explored their experiences from taking part in the SCT treatment for their vulvar pain. The women were interviewed twice, towards the end of the treatment, exploring their experiences with the intervention, and one year later to allow insight into how therapeutic processes unfolded over time.

The thematic analysis resulted in three themes. The findings illustrate how 1) developing positive feelings of embodiment, 2) developing a greater awareness of internal feelings and bodily states and 3) developing sex-positive beliefs and behaviours, were experienced as meaningful pathways towards improved sexual health. The findings were interpreted through the lens of a feminist embodiment framework, elucidating the importance of experiences of embodiment in sexual health and well-being of women living with PVD. The findings suggest that physiotherapy interventions that aim to promote subjective experiences of bodily comfort, pleasure and agency, and attunement to internal needs and desires, can support meaningful processes towards improved sexual health for these women.

5.2.4 Paper IV

A conceptual model for managing sexual pain with somatocognitive therapy in women with provoked vestibulodynia and implications for physiotherapy practice

Findings from the feasibility study (Paper I and Paper III), which included patient experiences and acceptability to patients, suggested that the SCT intervention needed to be modified before a main trial. In addition, the findings from Paper III, shed light on the importance of experiences of embodiment in sexual health and well-being of women with PVD. In the process of refining this complex multimodal SCT intervention, we also considered clinical experience, clinical guidelines, research evidence and findings from previous research. Altogether, this led to the development of Paper IV. In this paper we provided a conceptual model for managing PVD with SCT, including a theoretical rational for this treatment. We base our conceptual model on the biopsychosocial model, i.e., considering the complex interplay of biomedical, emotional/cognitive, psychosexual and interpersonal factors in PVD management. In addition, implications for practice and a detailed description of SCT for PVD was provided, seeking to provide full transparency to allow replication in clinical practice and in clinical trials. Undertaking the feasibility study and the qualitative study, exploring women's experiences with SCT, has allowed us to move forward, to make adjustments to the protocol before the start of the main trial.

6.0 Discussion

The discussion chapter will cover two main areas. First, the findings of the papers will be discussed in light of the theory and the evidence presented in the background chapter and will be related to aims of the thesis. Secondly the methodological aspects of the studies will be critically discussed addressing both quality in quantitative and qualitative research.

6.1 Discussion of main findings

The main aim of this thesis was to evaluate the feasibility and acceptability of SCT in women with PVD as part of the preparation for an upcoming RCT. The findings demonstrated that the study was feasible with respect to follow-up rate and adherence to outcomes, furthermore no adverse events were reported. We argued that SCT was an acceptable and a promising intervention based on Global Perceived Effect scores, the women's experiences with the treatment and changes seen on the outcome measures (Paper I-III). Based on these findings, a few changes are suggested to optimise the protocol. Moreover, the SCT intervention was further refined in preparation for the main trial, which lead to the development of a conceptual model for PVD with SCT, and a detailed description of the SCT intervention. In the following section these findings will be discussed more thoroughly.

6.1.1 Discussion of feasibility findings: Paper I-II

To establish whether a full trial would be feasible to conduct, it has been recommended to run a feasibility study before the commencement of a RCT (Leon, Davis and Kraemer 2011; Eldridge et al. 2016b; Thabane et al. 2010). The main feasibility objectives evaluated the recruitment rate, follow-up rate, adherence to outcomes, number of adverse events and the primary outcome. In terms of recruitment, 10 out 18 eligible patients were recruited from one site in 11 weeks, achieving a recruitment rate of one participant per week. In order to run a fully powered RCT of approximately 130 participants with PVD, utilising various strategies to increase the recruitment rate will be necessary. Recruiting participants into clinical trials is known to be the most challenging, as well as a critical aspect of a study (Khatamian Far 2018). Challenges with recruiting participants can result in study delay or discontinuation of RCTs (Amstutz et al. 2017). This has substantial scientific, ethical and financial impacts on patients, researchers and society (Malmqvist et al. 2011). In the field of vulvodynia, failure to find and interest eligible participants can be an obstacle to recruitment. Studies have found that it takes

an average time of four years between symptoms-debut and final diagnosis (Lester, Brotto and Sadownik 2015), and once diagnosis is set, the availability of health care providers with PVD experience are often few and far between. To improve clinical trials recruitment, researchers can employ various strategies such as increasing recruitment sites, ensuring regular collaboration with recruiters and advertising through patient organisations or on social media. Preliminary data from a scoping review suggests that social media can increase enrolment rates and reduce per-participants cost (Darmawan et al. 2020).

Another important aspect of recruitment is retention of participants, i.e., encouraging them to continue their participation in the study until the end, which is especially important for longitudinal studies (Khatamian Far 2018). Adherence to completion of outcomes can be a challenge in clinical trials. In research, participants failing to complete the study protocol can affect statistical analyses, study outcomes and how the results are interpreted (Vancampfort et al. 2021). In our feasibility study the follow-up response rate was excellent, with all participants followed-up successfully until 8 months. In larger RCTs however, it is inevitable that patients will drop-out, where previous PVD studies accounted for an expected drop-out rate of 20% after six months (Bergeron et al. 2001; Foster et al. 2010; Morin et al. 2016). In terms of adherence to study outcomes, we found this to be satisfactory. Ninety percent of the tampon tests were completed, and the self-report questionnaire packet was fully completed at all three time points. The 14-day diary had poor compliance and has been removed as an outcome measure in the future RCT. In the study by Morin et al. 2021, which compared multimodal physiotherapy with lidocaine in 212 women with PVD, 95% completed the post-treatment assessment and 92% completed the six-month follow-up.

All the above-mentioned feasibility findings that have been discussed are related to the participants receiving the SCT intervention, as in our study we did not have an active control group. In the main trial, it is planned to compare SCT with standard PVD treatment. This lack of a control group is a weakness of our study as it leaves us with no information about the feasibility of the randomisation process, the follow-up rate, adherence to outcomes and number of adverse events in what would be the control group.

In terms of planning which outcome measures to be utilised in the future trial, a variety of outcomes were chosen to address the various dimensions of PVD. Methodological challenges in the field of vulvodynia have been the absence of standard outcome measures as well as the

inconsistent use of pain measures. The need for agreed-upon standard outcome measures for vulvodynia clinical trials is essential to enable cross-study comparisons and synthesise the treatment evidence (Pukall et al. 2017; Sadownik, Yong and Smith 2018; Rosen, Bergeron and Pukall 2020). In 2017, Pukall et al. recommended outcome measures adapted to PVD, guided by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT). According to IMMPACT, selection of outcome measures should be based on "the domains of interest for the participants, the characteristics of the treatment and its putative effects". Since the commencement of the feasibility study, further recommendations for the utilisation of assessment tools in vulvar pain have been published (Rosen, Bergeron and Pukall 2020).

In evaluating the feasibility of using the tampon test as a primary outcome measure (Paper I and II), we found that the tampon test data demonstrated large intra- and inter-individual variability. Moreover, four of the participants had an NRS score that was equal to four or below, which has been used as exclusion criteria in previous studies. These findings informed the set-up of phase two, the qualitative phase, exploring the women's experiences with the tampon test to further our understanding of what outcomes are the most important and relevant to them. Research studies have repeatedly failed to enclose and report clinical outcomes that are the most important and relevant to patients, caregivers and health professionals (Fleurence et al. 2013).

In our study, four women reported that they normally use sanitary tampons and three of these women had an average score equal to four or below. Sexual intercourse however was reported to be a major challenge for all women. Several women in the study also reported fluctuating and rapid changes in their pain intensity levels which could possibly explain the large variability in the tampon test scores. Additionally, the pain sensation and experience during the tampon test was not comparable to the pain experience during intercourse. The test was less intense, different in nature and conducted in an entirely different context. These findings are in line with Rosen, Bergeron and Pukall's (2020) argument that the tampon test and the context in which it is applied does not equate to real life experience of pain during penetrative intercourse.

In choosing a primary outcome measure, it is also essential to utilise one that is sensitive enough to pick up change following treatment. Based on the tampon test data and the participants' experiences with the test and input from a user representative, we suggested in Paper II that the tampon test is suboptimal as a primary outcome measure in PVD research. Due to the

multifactorial nature of PVD, the findings from Paper I support choosing a multidimensional primary outcome measure, such as the FSFI.

6.1.2 Discussion of acceptability findings: Paper I-III

Another aim of this thesis was to evaluate the implementation and acceptability of SCT. Evaluating the acceptability of a complex intervention at an early stage can highlight if the intervention needs to be modified before a definite trial. The findings from the self-report questionnaires, tampon test data and the qualitative interviews in Paper I-III, support the application of a multimodal physiotherapy intervention which considers the multifactorial biopsychosocial nature of PVD. Overall, these preliminary findings indicate that SCT can potentially be an acceptable and promising treatment for this patient population. These findings are aligned with a previous study where encounters with SCT are described in a similar fashion (Danielsen et al. 2019) and a recent observational study (Danielsen, Fougner and Haugstad 2021). A secondary aim of the feasibility study was to investigate if SCT has potential treatment effectiveness. Although this study was not powered to detect changes over time, all outcome measures pointed in the same direction, with participants improving on the primary outcome and all the secondary outcomes following SCT. The findings suggest that the SCT has potential treatment effectiveness, these findings should however be interpreted with caution. These preliminary findings are also in line with a RCT evaluating the effect of SCT for women with chronic pelvic pain (Haugstad et al. 2006b), demonstrating continued improvement at one year follow-up (Haugstad et al. 2008) and a pilot study evaluating SCT for PVD (Haugstad et al. 2019).

SCT is designed as a short-term therapy where one of the goals is to promote self-management and further avoid over-treatment and therapist-dependency. In the initial treatment protocol, it was planned to deliver the treatment twice weekly for ten weeks. In the feasibility study however, treatment had to be tailored to the individual as participants had different needs, both in terms of treatment amount and frequency. Based on participant experiences, it was also decided to add a booster session at six months post treatment. An important goal of SCT is to empower the women to take ownership of their own recovery process, through gaining bodily awareness and developing self-management strategies. To support these processes, SCT places a strong emphasis on developing a sound therapeutic alliance through empathy and a patient-centred approach. To develop the therapeutic relationship, the physiotherapist needs to establish

meaningful connections with their patients, which can be done through 1) acknowledging the individual, i.e., by meeting them as equals, validating their experiences and individualising treatment, 2) giving-of self and 3) using the body as a pivot point i.e., respecting the patients' bodily experiences and helping patients develop body awareness (Miciak et al. 2019). A key feature in the delivery of high-value care for patients with persistent pain conditions involves a patient-centred approach which includes establishing meaningful connections, self-management and shared decision-making (Hutting et al. 2022). A 2018 systematic review suggests a strong therapeutic alliance may improve pain outcomes for chronic musculoskeletal pain patients receiving physiotherapy (Kinney et al. 2018).

At 8 months follow-up, nine women reported feeling better, following SCT (one was very much better, six much better, two a little better) and one reported no change on the Global Perceived Effect score. These findings were further supported by the qualitative interviews. Meaningful changes included improved body awareness furthermore an improved ability to relax, feel more connected and comfortable in their own bodies. The bodily explorative component of SCT aims to give new positive bodily experiences which can be integrated into activities of daily living. Previous studies have found maladaptive movement and breathing patterns amongst women with PVD (Haugstad et al. 2018), CPP (Haugstad et al. 2006c; Nygaard et al. 2020) and chronic musculoskeletal pain (Kvåle, Ljunggren and Johnson 2003). During SCT, the patients are encouraged to direct their attention inwards, to notice how they move and breathe, to be attentive to subtle bodily changes, and thereby increasing awareness of internal feelings and states (Price and Mehling 2016). Being guided to experience the body from the inside was a valuable shift for the participants in our study.

The SCT approach does not involve intravaginal assessment or direct pelvic floor muscle treatment. Most women in the study valued the gentle desensitising and self-explorative approach towards the vulva and the pelvic floor muscles, which again aimed to help the women integrate the genitals with the rest of their body image. Standard physiotherapy interventions for PVD have traditionally incorporated pelvic floor muscle retraining and treatment, to manage pelvic floor muscle dysfunctions found in some women with PVD (Gentilcore-Saulnier et al. 2010; Morin et al. 2017a). In the qualitative interviews, two women reported that they would have liked intra-vaginal pelvic floor muscle assessment and treatment as part of the SCT approach. Whether the inclusion of this in the SCT approach would improve its effectiveness in PVD management is not known. A recent systematic review argues how the more complex

interventions, such as multimodal physiotherapy, show promising results for patients with PVD, as several modalities are combined to manage pain and its ramifications (Bohm-Starke et al. 2022). It is possible that SCT shares some of the same treatment components as this multimodal physiotherapy approach by Morin et al. (2021), such as pain management and education, topics on sexuality and homework. How the body is approached however, differs. For many participants, the SCT approach supported a shift from relating to the body as an object and bodily shame, towards experiencing the body as a subject. This involved inhabiting the body with comfort and confidence and thereby developing positive feelings of embodiment. As previously described, women with PVD have been found to score high on measures of body-exposure anxiety (Chisari et al. 2022a), hence it possible that some women feel shameful or anxious about their body in intimate settings. SCT aims to foster a healthy curiosity toward own body and sexuality, applying these new bodily experiences to intimate and sexual situations. With this shift towards experiencing the body as a subjective site, women are allowed more freedom to immerse themselves in joyful activities, to engage in the world with agency, comfort and wellbeing (Piran 2017). Furthermore, this shift empowered several of the women to start resisting the objectifying gaze of their culture and enabled a greater attunement to pleasurable bodily feelings, which are aligned with previous findings (Hirschman, Impett and Schooler 2006; Ellison and Papps 2020).

Several women developed a more neutral and less fearful way of thinking about and relating to their pain. Important aspects of treatment incorporate pain neuroscience to increase their knowledge of pain and its effect on body and mind. A recent systematic review found that combining pain neuroscience with traditional physiotherapy, significantly reduced pain and disability in chronic pain patients (Marris et al. 2021). Being well-informed is empowering and can increase the patients' confidence in self-management, furthering their sense of self-efficacy (Bandura 1977). As part of the SCT homework, the patients are taught desensitisation exercises to reduce vulvar oversensitivity and normalise the body's response to sensations. Furthermore, gradually expose patients to feared and/or avoided activities to reduce fear-avoidance behaviour (Haugstad et al. 2019). Negative cognitions, pain related fears, and/or unhelpful behaviours (e.g., engaging in intercourse despite pain) are also addressed in the SCT intervention. The use of desensitisation in combination with CBT has successfully improved sexual function and reduced pain in women with PVD (Lindström and Kvist 2015).

In the interviews, several women also reported that they had developed a more constructive, compassionate and helpful inner dialogue. Greater self-compassion, such as kindness and understanding towards oneself, has been found to be associated with lower anxiety and depression amongst women with vulvodynia and their partners (Santerre-Baillargeon et al. 2018).

PVD is an individual experience, however the social context is especially relevant considering PVD primarily occurs in the context of sexual intercourse. Promoting sexual health is an important part of SCT and includes conversations about their life situations and how PVD can impact the relationship, sexual desire, arousal and motivation. The women in the study gained more healthy attitudes and strategies regarding their sexuality, developing sex-positive beliefs and behaviours. Past research has also demonstrated how physiotherapy can promote sexual health (Areskoug-Josefsson and Gard, 2015; Rosenbaum 2005; Rosenbaum 2006). Furthermore, addressing topics on sexuality has also been incorporated in other PVD interventions (Brotto et al. 2015; Rosenbaum 2013). Although physiotherapy has an important role in promoting sexual health, studies have found that sexual health is not sufficiently covered in physiotherapy education (Areskoug-Josefsson and Gard 2015). Furthermore, health professional students, including physiotherapists, lack competences and preparedness in this field (Gerbild et al. 2021). Similarly, in long-term female survivors of gynaecological cancer, women had great need for information about their changed bodies and how this impacted their sexuality. Their health professionals however, rarely initiated dialogue with the women about intimacy or sexuality, which again reinforced shyness among the women (Sekse, Råheim and Gjengedal 2015).

6.1.3 Discussion of the conceptual model for managing PVD with SCT: Paper IV

Based on findings in Paper I and III, we were able to refine the SCT intervention in preparation for the main trial. The goal with Paper IV was to develop a conceptual model for managing PVD with SCT. In this paper the conceptual model for understanding PVD with SCT was based on the biopsychosocial model of health by Engel (Engel 1977). This model was chosen as it considers the multifactorial nature of PVD, by providing a broad perspective which is recommended in PVD management (Bergeron et al. 2020). Furthermore, this conceptual model has provided a framework for the assessment and management of people with chronic pain and

has long been cited as providing the theoretical basis for treatments for chronic pain (Bevers et al. 2016; Kamper et al. 2015; Nicholas et al. 2019).

Although the biopsychosocial model has been almost universally advocated as the approach of choice for chronic pain management, the model is not without its limitations. Several authors have argued that in its interpretation and application the model has substantial shortcomings. Consensus on the meaning of the biopsychosocial model in physiotherapy and how to apply it in musculoskeletal pain and LBP continues to be unclear (Daluiso-King and Hebron 2022; Mescouto et al. 2020). Physiotherapy literature attends almost exclusively to the biological, cognitive and behavioural aspects, rarely attending to broader social aspects of care (i.e., cultural, religious/spiritual and political) (Mescouto et al. 2020). In the context of musculoskeletal pain (not specific to physiotherapy), Stilwell and Harman (2019), argue that the biopsychosocial model is poorly conceptualised and has a limited theoretical foundation. This results in a reductionist and simplistic application of the biopsychosocial model which over-compartmentalises the patients' pain into biological, psychological and social fragments.

Although the application of the biopsychosocial model in PVD is recommended, details of how to apply the model both in PVD research and clinical practice, is limited. In Paper IV, we have developed a conceptual model for PVD with SCT based on the biopsychosocial model. In this paper we have provided a theoretical rational and a description of the intervention to allow replication in practice. There is also a need for in-depth and complete descriptions of physiotherapy interventions used in clinical trials (Yamato et al. 2016). In this thesis, I have also provided a Logic model in the methods chapter, to illustrate the intended core components of the intervention, the intervention assumptions, how the components interact to produce change and the anticipated short- and long-term outcomes (Moore et al. 2014). As part of this process, utilising the Developmental Theory of Embodiment perspective enriched our understanding of meaningful processes towards improved sexual health among women with PVD. In the interviews, the participants in our study largely expressed beliefs that PVD is complex and multidimensional in nature, finding it meaningful to combine a bodily approach with cognitive self-management strategies. It is possible that new experiences developed through the bodily approach, combined with pain education and topics and conversations related to sexuality (e.g., partner communication and setting sexual boundaries), can possibly enhance feelings of control of the pain. Moreover, it can potentially enhance positive body connection and thus reduce fear of pain-related movements or activities.

6.2 Discussion of methodological considerations

In this chapter critique related to study theory and design will be presented. Strengths and limitations of the various methodological aspects of the thesis will be discussed. Paper I-III were based on the same sample of participants and same study setting, and a common discussion of the methodological aspects in the thesis follows. The quality in both the quantitative and qualitative research will be discussed.

When assessing the credibility of a quantitative research project, concepts such as reliability, validity and generalisability are typically associated with quantitative research (Wisdom et al. 2012). In clinical research internal and external validity are central terms. Internal validity concerns the degree to which the correct conclusions are drawn about what actually happened in the study. External validity, or generalisability, concerns the degree to which the results or conclusions can be applied to individuals and events outside the study.

6.2.1 Study theory

The strengths and limitations of the biopsychosocial model was discussed under point 6.1.3: *Discussion of the conceptual model for managing PVD with SCT*. In Paper III, we utilised the Developmental Theory of Embodiment (Piran 2017). By combining an explorative, semi-structured interview design with a feminist embodiment perspective, this study has enabled novel insights into possible interactions between the sexual health and quality of embodiment among women with PVD. The chosen theoretical framework contributes to illuminate how disrupted embodiment plays an important role in the sexual narratives of these 10 women and why experiencing embodiment and engaging with the world in an embodied way, can be challenging for them. To our best knowledge, the DTE has not been used as a theoretical framework in previous studies of women with sexual pain. By embedding experiences and expressions of sexual agency and sexual desire firmly within the embodiment domain, the DTE provides a useful framework for understanding the women´s body-anchored processes towards improved sexual health. Follow-up interviews after one year allowed insight into processes of change that developed over time and helped us to see how embodiment was a state the women moved in and out of, a continuous back-and-forth process rather than a set endpoint to arrive at.

6.2.2 Study design

In Paper I, a multimethod feasibility study with a single arm before-after trial and qualitative interviews was applied. A limitation with this design was the lack of an active control group. In retrospect, a better design would have been a feasibility two-armed RCT, as the design of the current study does not match the future main trial. Consequently, we lack information about the participants' willingness to be randomised to either the intervention or the control group, as well as information about recruitment rate, follow-up rate and adherence to outcome measures in the questionnaire packets. In the future trial, it is planned that SCT will be compared to standard PVD treatment, of which the latter can include women's health physiotherapy, topical or oral medication, sex therapy, and/or psychological counselling. Incorporating a control group could have provided us with useful information about the treatments delivered in this group, as well as the feasibility of the randomisation process, including the follow-up rate. A strength with our study design was the incorporation of the qualitative interviews, providing us with in-depth information about the participants' experiences with outcome measures and the intervention.

In Paper II, an explanatory sequential design was chosen. In choosing this design, the qualitative data and its analysis could refine and help to explain the quantitative findings. Here one method can be used to inform the other (Wisdom et al. 2012). Normally in an explanatory sequential mixed methods study the quantitative sample is larger than the qualitative. However, a strength in our study was how the women's experiences could be directly linked to the quantitative data, as all participants were interviewed. To our best knowledge, this is the first study investigating PVD women's experiences with the tampon test, thus providing novel insights to the literature. Utilising both quantitative and qualitative methods in mixed methods bring different perspectives to the study. As mixed methods is still a relatively new research area there is debate and inconsistency among researchers about what mixed methods constitutes. In the mixed methods field a plethora of designs exist which can be confusing for researchers (Doyle, Brady and Byrne 2009). Critics of mixed methods studies argue that quantitative and qualitative research methods cannot be mixed in a single study due to the vastly different ontological, epistemological and methodological origins and assumptions.

There are several broad stances being used in mixed methods research studies. In in our study, the worldviews chosen were based on the study context and the type of mixed methods design,

which involves having the flexibility to use the worldview that best fits the context of the study. In using an explanatory sequential design, Creswell and Plano Clark (2018) recommend using different philosophical assumptions within each phase, hence in the first phase we used a post-positivist worldview and in the second phase a phenomenological worldview. These are two vastly different ontological (singular versus multiple realities), epistemological (distance and impartiality vs closeness and subjectivity) and methodological origins (deductive vs inductive). During the interviews, the attempt was to elicit multiple meanings from the participants to build a deeper understanding than the tampon test numerical data alone and thereby aiming to generate a pattern of responses that can explain the tampon test results. There are several benefits for undertaking a mixed methods study. By seeking corroboration between quantitative and qualitative data, this will allow for greater validity in a study (triangulation) and this method can also offer a more complete and comprehensive account of phenomena under study (Doyle, Brady and Byrne 2009). Mixed methods can also offer a larger selection of methods to meet the aims and objectives of the study. It is possible to expand the breadth and depth of a study, i.e. both generalize the findings to a population and develop a detailed view of the meaning of a phenomenon, thereby answering different research questions (Creswell and Creswell 2018).

There are some methodological and practical limitations of mixed methods. To be able to plan and carry out a mixed methods study it is important for the researcher to have sufficient knowledge and experience of each method independently. On a practical level it might be challenging for one researcher to carry out mixed methods as the approach can be time consuming, especially if the qualitative and quantitative phases are to be undertaken simultaneously (Doyle, Brady and Byrne 2009). Mixed methods may therefore require more resources and depend on a team of researchers, such as was the case in this project. The explanatory sequential design often requires a longer timeframe to undertake the study. As a consequence, recruitment for the second part of the study may become difficult as the sample may no longer be available. On the other hand, the results may help to clarify or illuminate the quantitative findings (Doyle, Brady and Byrne 2016).

In Paper III, a qualitative design was utilised, with women interviewed on two occasions, towards the end of the treatment and one year later. The advantages of this longitudinal design with follow-up interviews allowed insight into processes of change over time, gaining more knowledge about women's own perspectives, about what matters to them.

6.2.3 Study sample

The study sample was a selected group of women referred to SCT after assessment by a specialist in gynaecology or dermatology in a tertiary hospital, following clear inclusion and exclusion criteria. Ten nulliparous women with PVD, aged 18-33, agreed to take part in this feasibility study. Eighteen women were eligible, unfortunately we have no information as to why eight women chose not to contact the project leader. The small sample size is a limitation of this thesis, as it is challenging to compute precision around estimates for recruitment, follow-up and adherence with such small numbers. A small sample is however appropriate for a feasibility study as the goal of the study was not to evaluate effectiveness of the intervention or to detect clinical meaningful differences in change of pain intensity. In terms of sample size for the qualitative interviews, the 10 women in the first interview round and the seven women in the second round provided us with rich qualitative data material. Although the sample size was small, and not representative, the baseline characteristics are similar to other studies investigating women with PVD, scoring similarly on domains of pain, sexual function and psychological distress. The women in our sample were well educated, active and young, presenting with a long duration of pain. Patients were referred from tertiary care which could explain the long duration of symptoms, and multiple comorbidities, combined with the fact that a high proportion had primary PVD. Seven women presented with comorbidities, which is in line with findings from other studies (Lester, Brotto and Sadownik 2015; Nguyen et al. 2012; Reed et al. 2012a). In our sample, living with PVD did not appear to have an impact on their ability to work, study or be physically active. On the contrary to other chronic pain conditions, the women in our study were able to function well, with many participants able to work part-time on top of full-time studies.

In this thesis, none of the participants were lost to follow-up. In the future larger trial, it is likely that we will have missing data, as dropouts are inevitable and difficult to prevent. High levels of dropouts can be a threat to the internal validity. Due to the small sample size, our findings cannot be generalised to a larger population. Addressing the external validity, i.e., the degree to which the results can be applied to individuals outside the study, was however not the aim of this study.

6.2.4 Blinding

In this thesis, I was the therapist delivering the SCT intervention. I was not involved in recruitment of participants, furthermore I was not involved in collecting the data. The project leader administered the data collection electronically at baseline, post-treatment and at 8 months follow-up. I was blinded to the quantitative data until after the 8 months follow-up. Participants were informed of the study objectives and were not blinded to the treatment.

6.2.5 Outcome measures and data collection

The feasibility outcomes in this study were clearly defined, however we did not provide clear progression criteria for each outcome. Other feasibility outcomes could also have been investigated, such as fidelity of the delivery of the intervention, measured by whether the physiotherapist delivered the intended components of the intervention, or added other components. Other feasibility outcomes could have been adherence to the SCT homework.

In terms of selecting the primary and secondary outcome measures to be utilised in the future trial, a variety of outcomes were chosen to address the various dimensions of PVD, such as pain intensity, psychological distress, catastrophizing and female sexual function. Based on the tampon test findings in Paper II, it became more evident that a complex multimodal intervention aiming to improve several dimensions of PVD, would benefit from a multidimensional outcome measure such at the FSFI. Several secondary outcomes were applied in our study. These were all validated self-reported outcome measures, apart from the FSFI which is not validated in the Norwegian population. A limitation with self-reported questionnaires is that respondents may over- or underestimate their symptoms. Since the ProLoVe project started in 2019, further recommendations for the study of vulvar pain have been published (Rosen, Bergeron and Pukall 2020), incorporating recommended assessment tools, recommendations which will be taken into account in the planning a future trial.

The lack of patient participation in the ProLoVe feasibility project was a limitation of this thesis. Since the first decade of this century, active patient engagement in research has steadily evolved, expanded internationally (Brett et al. 2014) and is seen as an essential component of good research practice for all forms of health research (Wright et al. 2010). Patient engagement can bring unique perspectives to research projects and lead to research of better quality (Staniszewska et al. 2011). The findings from the qualitative interviews are not patient

engagement in research per se, but the interview findings provide vital information to the project which can be utilised in the planning for the next stage of the trial.

6.2.6 Study intervention

There are some potential challenges with the SCT intervention. The treatment requires that the patient is motivated, is willing to challenge herself, and is willing to prioritize the tasks at hand and set aside time to practice. For some the treatment can be experienced as demanding or possibly overwhelming, hence may not be suitable for all. Patients wanting a passive treatment approach, to be mended, or who are unable to self-manage for various reasons, or experience frequent setbacks, may lose the motivation to go on. The study intervention is described and discussed in detail in Paper IV.

6.2.7 Statistical considerations

In this thesis, only descriptive statistics were used to assess the feasibility objectives and the self-reported outcomes. No hypothesis testing was performed due to the nature of a feasibility study and the low number of participants.

6.2.8 Quality in qualitative research

When assessing the credibility of a research project, different research traditions use different concepts. The concept of validity in qualitative research has been controversial (Maxwell 2013). Qualitative researchers aim to design methodological strategies to ensure the trustworthiness, authenticity and credibility of the findings, terms which address validity in qualitative research (Creswell and Miller 2000).

In this research thesis, several methods and certain procedures have been implemented to rule out validity threats and check for the accuracy and credibility of our findings, i.e., addressing the qualitative validity. One such method utilised by the interviewer was *member checking,* used to determine the accuracy and trustworthiness of interpretations of the qualitative findings. *Member checking* gives the informant the opportunity to validate the researcher's interpretations (Polit and Beck 2014). Throughout the interviews, the interviewer in the study would follow up with further questions to clarify, summarise and check with the subject to rule out potential misunderstandings. The follow-up interview with the participants a year later also provided an opportunity to use *member checking*.

Peer debriefing is another technique to ensure credibility (Creswell and Creswell 2018). Both the interviewer and I read the transcripts and alternative interpretations and themes were discussed among us until agreement was reached on a final map over themes and subthemes.

Another strategy to determine accuracy of the findings involves clarifying the preconceptions the researcher brings to the study. Personal experiences and social circumstances of both the interviewer and the informant can influence the interview situation. Furthermore, the researcher's pre-understanding and own attitudes to the topic could also have had an impact on the interview and the interpretation of it. The interviewer needs to take steps to avoid the assumption that her own view is the predominant reality (Bowling 2014), as there can be several interpretations of the situation. In this thesis, both the interviewer and I made a conscious attempt to be aware of our own preconceptions, as was described in the methods chapter. To convey the findings, rich and thick descriptions were utilised in the papers, which can make the results more authentic and realistic and further add to the validity of the findings. I believe the voices of the participants can be heard through the quotes and in the way the findings are discussed in the papers. Both information that built a case for the theme, but also information that contradicts the general perspective, was presented, possibly making the account more realistic and valid (Creswell and Creswell 2018). Furthermore, to ensure a transparent research process, I have provided a clear description of the steps taken from the beginning to the end of the investigation in this thesis. Documentation of procedures and steps are important to determine if the approaches are reliable (i.e., consistent or stable) (Creswell and Creswell 2018). The interviewer in our study, documented the procedures, the choices, and the steps she undertook throughout the interview study, including meticulous record keeping, checking the transcripts for potential mistakes and continually comparing the data with the codes, as well as writing memos about the codes.

In situations where there is little pre-existing knowledge, or where the issues are sensitive or complex, such as in this study, the qualitative approach can be advantageous over the quantitative approach (Creswell and Creswell 2018). A strength is its flexible approach, and as the data collection progresses the qualitative researcher is free to shift their focus (Bowling 2014). This flexibility allowed us to home in on interesting topics that emerged during the interview- and analysis process and led to new insights that we had not anticipated beforehand.

There are some limitations with the qualitative data. It is possible that the study sample represents women who are particularly resourceful; women who have sought out and received relevant care for their pain, who were willing to participate in a research study and be interviewed about their experiences related to sensitive issues. Another limitation is that three of the women from the first round of interviews did not, for various reasons, take part in a follow-up interview.

In this research project, I have had several roles, both as a researcher but also as a therapist treating the patients receiving SCT. In this thesis, the first round of interviews was undertaken towards the end of the treatment. As I was the therapist treating the participants, it could have been inappropriate for me to undertake the interviews, as this could possibly add treatment effect, furthermore the findings may not have accurately reflected their true opinions. Conveying their true opinions about their experiences with the intervention to the therapist could have been difficult for some participants. Although I did not gain the skills of interviewing or collecting the qualitative data, I did gain new knowledge and experience of qualitative research through planning the interview guide, reading through all the transcripts and analysing the qualitative data, together with the interviewer. There are possibly some disadvantages with having several roles, being the PhD researcher and the only therapist treating the patients in the feasibility study. As this is an area of research I am particularly interested in, my theoretical knowledge of the field combined with long clinical experience with treating patients with chronic pain, placed me in a position where the patients could potentially be particularly trusting. It is possible that subconsciously my investment in these patients, my strong belief in the intervention will shine through, possibly influencing the women's experiences and treatment responses.

7.0 Conclusions

This thesis evaluated the feasibility and acceptability of SCT, a multimodal physiotherapy intervention for women with PVD, in preparation for a full-scale RCT. The integration of quantitative and qualitative work in this thesis suggests that it is feasible to run a full-scale RCT to evaluate the effectiveness of SCT versus standard PVD treatment in women with PVD. The aims of the feasibility study have been met, but to optimise the study protocol we suggest a few changes before conducting a fully powered RCT. The suggested changes include increasing recruitment sites, the change of primary outcome measure to FSFI, which evaluates female sexual function, and adding a booster session. The mixed methods tampon test study showed several problems with the application of the tampon test as a primary outcome measure in PVD. The tampon test may be more useful as a secondary outcome, preferably undertaken repeatedly to increase precision of the pain estimation. The findings from Paper I and III suggest that SCT is an acceptable intervention in the management of young women with PVD. Our findings further suggest that physiotherapy interventions, such as SCT, that aim to promote subjective experiences of body connection and comfort, agency, and attunement to internal needs and desires, can support several meaningful processes towards improved sexual health. Findings from Paper I and III lead to a refinement of the SCT intervention and to the development of a conceptual model for PVD with SCT. Providing an in-depth and complete description of SCT allows replication in clinical practice and clinical trials. Overall, the conduction of this thesis provided valuable experiences in the preparation for the full-scale RCT utilising a complex multimodal physiotherapy intervention in a group of women with PVD. This thesis provided additional insights about a novel multimodal physiotherapy treatment for women with PVD. Furthermore, it provided additional insights about women's experiences with outcome measures used in vulvodynia research, as well women's experiences with SCT.

8.0 Clinical implications and future perspectives

International evidence-based treatment guidelines for this idiopathic heterogenous vulvar pain condition are still lacking, moreover these women often receive ineffective treatment (Lamvu et al. 2018). To provide treatments that are evidence-based and clinically meaningful to these women, more methodologically stringent trials on PVD interventions are needed (Bohm-Starke et al. 2022). Additionally, in order to advance the knowledge about treatment effectiveness in women with PVD, several reviewers in this field have highlighted the importance of having common defined core outcome sets for intervention trials (Davenport, Voutier, and Veysey 2018; Sadownik, Yong, and Smith 2018). Taking a broad biopsychosocial approach in PVD management is recommended (Chisari et al. 2021; Desrochers et al. 2010; Thomtén and Linton 2013) and preferably undertaken by a multidisciplinary team (Smith et al. 2019). Yet integrating this approach at all stages of the health care system is not always easy or feasible. Single discipline treatment which utilises a multimodal approach may therefore be a good alternative, with evidence emerging to support multimodal physiotherapy for PVD (Morin et al. 2021).

SCT is designed to be easy to learn and easily implemented in primary health care. This intervention is a promising treatment for women with PVD, which warrants further investigation (Fougner and Haugstad 2015; Danielsen et al. 2019; Haugstad et al. 2019). Furthermore, SCT is inexpensive, requires few resources and no specialised equipment. Clinically, SCT is an intervention which can be adapted and applied to other multifactorial longstanding pain conditions. In the treatment of PVD, the physiotherapist is in an ideal position to promote sexual health. Studies however, have shown that sexual health is not sufficiently covered in physiotherapy education (Areskoug-Josefsson and Gard 2015). Furthermore, health professional students, including physiotherapists, lack competence and preparedness in this field (Gerbild et al. 2021). Educating physiotherapists to promote sexual health is therefore an area which warrants further investigation.

The findings of this thesis lead to the decision to go ahead and implement the full-scale RCT. In the RCT planning stage, a former PVD patient from the feasibility study was invited to contribute to the research process, to ensure user participation in research. Evidence suggests that patients can contribute at all stages of the research process in a meaningful way (Forsythe et al. 2016), thus leading to better quality. The planning and running of the RCT, together with the ProLoVe research team, has therefore been an important aspect of my PhD journey.

Recruitment to the ProLoVe parallel group RCT started in January 2021, investigating clinical and cost-effectiveness of SCT versus standard treatment for treating women with PVD. In this ongoing trial, both quantitative and qualitative methods are combined, which is particularly relevant in both multifaceted pain conditions and for complex multimodal interventions. Qualitative interviews will provide valuable information about the women's experiences with the treatments provided in both groups. The results of this ongoing RCT can be an important contribution to the research field, as well as to the research participants and the community. The long-term aim of this project is to provide evidence-based recommendations for PVD treatment. Furthermore, the project will provide a broader understanding of PVD as a multifactorial pain condition based on knowledge from the studies. The strength of the study also lies in fact that it has a primary care focus, an arena where those patients are treated.

Although RCTs are the gold standard to evaluate intervention effects, contributing to the dissemination of treatments, they may not provide the information that is needed to increase our understanding of treatment processes. Replicated single-case experimental designs have recently gained recognition as being able to provide a strong basis for establishing intervention effects and may be a promising alternative to RCTs (Kazdin 2019). A single-case experimental design is a prospective study of the individual, where each person is used as their own control (Kazdin 2019). It is possible that this type of study design can increase our understanding of the processes occurring at an individual level, as well as of the mechanisms of change in PVD treatment (Chisari et al. 2022b). As women with PVD is such a heterogenous group, in future trials it may also be useful to investigate if subgroups (e.g., primary or secondary PVD, or different age groups) would benefit from different intervention types.

9.0 References

Amalraj, P., Kelly, S. and Bachmann, G.A. 2008. Historical perspective of vulvodynia. *In:* Goldstein, A. T., Pukall, C. and Goldstein, I. eds. *Female sexual pain disorders.* 1st ed. Oxford, UK: Blackwell Publishing Limited, 1-3.

American Psychiatric Association, DSM-5 Task Force. (2013).*(5th ed.).American Psychiatric Publishing, Inc.* https://doi.org/10.1176/appi.books.9780890425596

Amstutz, A., Schandelmaier, S., Frei, R., Surina, J., Agarwal, A., Olu, K.K., Alturki, R., von Niederhäusern, B., von Elm, E. and Briel, M. 2017. Discontinuation and non-publication of randomised clinical trials supported by the main public funding body in Switzerland: a retrospective cohort study. *BMJ Open*, 7(7), e016216. http://dx.doi.org/10.1136/bmjopen-2017-016216

Anderson, A.B., Rosen, N.O., Price, L. and Bergeron, S. 2016. Associations between penetration cognitions, genital pain, and sexual well-being in women with provoked vestibulodynia. *J Sex Med*, 13(3), 444-452. https://doi.org/10.1016/j.jsxm.2015.12.024

Archibald, M., Ambagtsheer, R., Casey, M. and Lawless, M. 2019. Using zoom videoconferencing for qualitative data collection: Perceptions and experiences of researchers and participants. *Int J Qual Methods*, 18, *18*, 1-8. https://doi.org/10.1177/1609406919874596

Areskoug-Josefsson, K. and Gard, G. 2015. Sexual health as a part of physiotherapy: The voices of physiotherapy students. *Sex Disabil*, 33(4), 513-532. https://doi.org/10.1007/s11195-015-9403-y

Arnold, L.D., Bachmann, G.A., Rosen, R. and Rhoads, G.G. 2007. Assessment of vulvodynia symptoms in a sample of US women: a prevalence survey with a nested case control study. *Am J Obstet Gynecol*, 196(2), 128 e121-126. https://doi.org/10.1016/j.ajog.2006.07.047

Ayling, K. and Ussher, J.M. 2008. "If sex hurts, am I still a woman?" the subjective experience of vulvodynia in hetero-sexual women. *Arch Sex Behav*, 37(2), 294-304. https://doi.org/10.1007/s10508-007-9204-1

Bandura, A. 1977. Self-efficacy: Toward a unifying theory of behavioral change. *Psychol Rev*, 84 191–215. https://doi.org/10.1037/0033-295X.84.2.191

Bartky, S.L. 1998. Foucault, femininity, and the modernization of patriarchal power. *In:* Quinby, I. D. L. ed. *Feminism & Foucault: Reflections on resistance.* Boston: Northeastern University Press.

Bautrant, E., Porta, O., Murina, F., Mühlrad, H., Levêque, C., Riant, T., Ploteau, S., Valancogne, G. and Levesque, A.. 2019. Provoked vulvar vestibulodynia: epidemiology in Europe, physio-pathology, consensus for first-line treatment and evaluation of second-line treatments. *J Gynecol Obstet Hum Reprod*. *48*(8), 685-688. https://doi.org/10.1016/j.jogoh.2019.04.011

Beauvoir, S. D., 1989. *The second sex.* New York: Vintage Books.

Beck, A. 2005. The current state of cognitive therapy: A 40-year retrospective. *Archives of General Psychiatry,* 62, 953–999. https://doi.org/10.1001/archpsyc.62.9.953

Benoit-Piau, J., Bergeron, S., Brassard, A., Dumoulin, C., Khalifé, S., Waddell, G. and Morin, M. 2018. Fear-avoidance and pelvic floor muscle function are associated with pain intensity in women with vulvodynia. *Clin J Pain*, 34(9), 804-810. https://doi.org/10.1097/ajp.0000000000000604

Bergeron, S., Binik, Y.M., Khalifé, S., Pagidas, K., Glazer, H.I., Meana, M., and Amsel, R. 2001. A randomized comparison of group cognitive-behavioral therapy, surface electromyographic biofeedback, and vestibulectomy in the treatment of dyspareunia resulting from vulvar vestibulitis *Pain*, 91(3), 297-306.

https://doi.org/10.1016/S0304-3959(00)00449-8
Bergeron, S., Khalifé, S., Dupuis, M.J., and McDuff, P. 2016. A randomized clinical trial comparing group cognitive-behavioral therapy and a topical steroid for women with dyspareunia. *J Consult Clin Psychol*, 84(3), 259-268. https://doi.org/10.1037/ccp0000072
Bergeron, S., Reed, B.D., Wesselmann, U. and Bohm-Starke, N. 2020. Vulvodynia. *Nat Rev Dis Primers*, 6(1):36. https://doi.org/10.1038/s41572-020-0164-2
Bergeron, S., Vaillancourt-Morel, M.P., Corsini-Munt, S., Steben, M., Delisle, I., Mayrand, M.H. and Rosen, N.O. 2021. Cognitive-behavioral couple therapy versus lidocaine for provoked vestibulodynia: A randomized clinical trial. *J Consult Clin Psychol*, 89(4), 316-326. https://doi.org/10.1037/ccp0000631
Bevers, K., Watts, L., Kishino, N.D., and Gatchel, R.J. 2016. The biopsychosocial model of the assessment, prevention, and treatment of chronic pain. *US Neurology, 12*(2), 98-104. https://doi.org/10.17925/USN.2016.12.02.98
Bhatt, R.R., Gupta, A., Rapkin, A., Kilpatrick, L.A., Hamadani, K., Pazmany, E., Van Oudenhove, L., Stains, J., Aerts, L., Enzlin P, et al. 2019. Altered gray matter volume in sensorimotor and thalamic regions associated with pain in localized provoked vulvodynia. *Pain*, 160(7), 1529-1540. https://doi.org/:10.1097/j.pain.0000000000001532
Bohm-Starke, N., Ramsay, K.W., Lytsy, P., Nordgren, B., Sjöberg, I., Moberg, K. and Flink, I. 2022. treatment of provoked vulvodynia: A systematic review. *J Sex Med*. 19:789–808. https://doi.org/10.1016/j.jsxm.2022.02.008
Bornstein, J., Goldstein, A.T., Stockdale, C.K., Bergeron, S., Pukall, C., Zolnoun, D. and Coady, D. 2016. 2015 ISSVD, ISSWSH and IPPS consensus terminology and classification of persistent vulvar pain and vulvodynia. *Obstet Gynecol*, 127(4), 745-751. https://doi.org/10.1097/AOG.0000000000001359
Bornstein, J. and Palzur, E. 2020a. Provoked vulvodynia: A peripheral neurological pain syndrome. *Pelviperineology*, 39(3), 68-76. https://doi.org/10.34057/PPj.2020.39.03.001
Bornstein, J., Petros, P. and Bornstein, S. 2020b. Provoked vulvodynia: diagnosis of perplexing pain condition. *Pelviperineology*, 39(4), 115-122. https://doi.org/10.34057/PPj.2020.39.04.003
Bornstein, J., Preti, M., Radici, G., Stockdale, C.K. and Vieira-Baptista, P. 2019a. Vulvodynia. *Pain*, 160(7), 1680-1681. https://doi.org/10.1097/j.pain.0000000000001559
Bornstein, J., Preti, M., Simon, J.A., As-Sanie, S., Stockdale, C.K., Stein, A., Parish, S.J., Radici, G., Vieira-Baptista, P., Pukall, C. and Moyal-Barracco, M. 2019b. Descriptors of vulvodynia: A multisocietal definition consensus (International Society for the Study of Vulvovaginal Disease, the International Society for the Study of Women Sexual Health, and the International Pelvic Pain Society). *J Low Genit Tract Dis*, 23(2), 161-163. https://doi.org/10.1097/LGT.0000000000000461
Bouchard, C., Brisson, J., Fortier, M., Morin, C. and Blanchette, C. 2002. Use of oral contraceptive pills and vulvar vestibulitis: a case-control study. *Am J Epidemiol*, 156(3), 254-261. https://doi.org/10.1093/aje/kwf037
Bowling, A. 2014. *Research methods in health.* 4th ed. Maidenhead, England: Open University Press McGraw Hill Education.
Braun, V. and Clarke, V. 2006. Using thematic analysis in psychology *Qual Res Psychol*, 3(2), 77-101. https://doi.org/10.1191/1478088706qp063oa
Brett, J.O., Staniszewska, S., Mockford, C., Herron-Marx, S., Hughes, J., Tysall, C. and

Suleman, R. 2014. A systematic review of the impact of patient and public involvement on service users, researchers and communities. *Patient,* 7(4), 387-395. https://doi.org/10.1007/s40271-014-0065-0

Brotto, L.A., Bergeron, S., Zdaniuk, B., Driscoll, M., Grabovac, A., Sadownik, L.A., Smith, K.B. and Basson, R. 2019. A comparison of mindfulness-based cognitive therapy vs cognitive behavioral therapy for the treatment of provoked vestibulodynia in a hospital clinic setting. *J Sex Med,* 16(6), 909-923. https://doi.org/10.1016/j.jsxm.2019.04.002

Brotto, L.A., Yong, P., Smith, K.B., Sadownik, L.A. 2015. Impact of a multidisciplinary vulvodynia program on sexual functioning and dyspareunia. *J Sex Med,* 12(1), 238-247. https://doi.org/10.1111/jsm.12718

Brown, C., Bachmann, G. A., Wan, J. and Foster, D. 2016. Pain rating in women with provoked vestibulodynia: evaluating influence of race. *J Womens Health,* 25(1), 57-62. https://doi.org/10.1089/jwh.2015.5223

Brown, C.S., Bachmann, G.A., Wan, J., and Foster, D.C. 2018 Gabapentin for the treatment of vulvodynia: A randomized controlled trial. *Obstet Gynecol,* 131(6), 1000-1007. https://doi.org/10.1097/AOG.0000000000002617

Burri, A., Hilpert, P. and Williams, F. 2020. Pain catastrophizing, fear of pain, and depression and their association with female sexual pain. *J Sex Med,* 17(2), 279-288. https://doi.org/10.1016/j.jsxm.2019.10.017

Carter, A., Ford, J.V., Luetke, M., Fu, T.J., Townes, A., Hensel, D.J., Dodge, B., Herbenick, D. 2019. "Fulfilling his needs, not mine": Reasons for not talking about painful sex and associations with lack of pleasure in a nationally representative sample of women in the United States. *J Sex Med,* 16(12), 1953-1965. https://doi.org/10.1016/j.jsxm.2019.08.016

Chisari, C., Budhraja, M., Monajemi, M.B., Lewis, F., Moss-Morris, R., Scott, W. and McCracken, L.M. 2022a. The role of psychological flexibility, perceived injustice and body image in Vulvodynia: A longitudinal study. *Eur J Pain,* 26, 103-113. https://doi.org/10.1002/ejp.1841

Chisari, C. and Chilcot, J. 2017. The experience of pain severity and pain interference in vulvodynia patients: The role of cognitive-behavioural factors, psychological distress and fatigue. *J Psychosom Res,* 93, 83-89. https://doi.org/10.1016/j.jpsychores.2016.12.010

Chisari, C., McCracken, L. M., Cruciani, F., Moss-Morris, R. and Scott, W. 2022b. Acceptance and commitment therapy for women living with vulvodynia: A single-case experimental design study of a treatment delivered online. *J Contextual Behav Sci*, 23, 15-30. https://doi.org/10.1016/j.jcbs.2021.11.003

Chisari, C., Monajemi, M.B., Scott, W., Moss-Morris, R. and McCracken, L.M. 2021. Psychosocial factors associated with pain and sexual function in women with Vulvodynia: A systematic review. *Eur J Pain,* 25(1), 39-50. https://doi.org/10.1002/ejp.1668

Chmielewski, J., Bowman, C. and Tolman, D. 2020. Pathways to pleasure and protection: Exploring embodiment, desire, and entitlement to pleasure as predictors of black and white young women's sexual agency. *Psychol Women Q*. 44(3), 307-322. https://doi.org/10.1177/0361684320917395

Corsini-Munt, S., Rancourt, K.M., Dubé, J.P., Rossi, M.A. and Rosen, N.O. 2017. Vulvodynia: a consideration of clinical and methodological research challenges and recommended solutions. *J Pain Res,* 10, 2425-2436. https://doi.org/10.2147/JPR.S126259

Creswell, J.W. and Creswell, J.D. 2018. *Reseach design: qualitative and quantitative & mixed methods approaches.* 5th ed. Los Angeles, California: Sage.

Creswell, J.W. and Miller, D.L. 2000. Determining validity in qualitative inquiry. *Theory Pract,* 39(3), 124-130. https://doi.org/10.1207/s15430421tip3903_2
Creswell, J.W. and Plano Clark, V.L. 2018. Designing and conducting mixed methods research. 3rd ed Los Angeles: SAGE Publications, Inc.
Crombez, G., Eccleston, C., Van Damme, S., Vlaeyen, J.W. and Karoly, P. 2012. Fear-avoidance model of chronic pain the next generation. *Clin J Pain,* 28, 475-483. https://doi.org/10.1097/AJP.0b013e3182385392
Daluiso-King, G. and Hebron, C. 2022. Is the biopsychosocial model in musculoskeletal physiotherapy adequate? An evolutionary concept analysis. *Physiother Theory Pract,* 38(3), 373-389. https://doi.org/10.1080/09593985.2020.1765440
Danby, C. and Margesson, L. 2010. Approach to the diagnosis and treatment of vulvar pain. *Dermatol Thery,* 23, 485-504. https://doi.org/10.1111/j.1529-8019.2010.01352.x
Danielsen, K.G., Dahl-Michelsen, T., Håkonsen, E., and Haugstad, G.K. 2019. Recovering from provoked vestibulodynia: Experiences from encounters with somatocognitive therapy. *Physiother Theory Pract,* 1-10. https://doi.org/10.1080/09593985.2018.1442540
Danielsen, K.G., Fougner, M. and Haugstad, G.K. 2021. Treating gynecological pain: key factors in promoting body awareness and movement in somatocognitive therapy (SCT). A case study of a physiotherapy student s treatment approaches. *Physiother Theory Pract,* 1-13. https://do.org/10.1080/09593985.2021.1872125 Online ahead of print
Dargie, E., Gilron, I. and Pukall, C. 2017. Provoked Vestibulodynia: A comparative examination of mental health, sleep, sexual functioning, and relationship adjustment. *Clin J Pain,* 33(10), 870-876. https://doi.org/10.1097/AJP.0000000000000480
Darmawan, I., Bakker, C., Brockman, T.A., Patten, C.A. and Eder, M. 2020. The role of social media in enhancing clinical trial recruitment: scoping review. *J Med Internet Res,* 22(10), e22810. https://doi.org/10.2196/22810
Davenport, R.B., Voutier, C.R. and Veysey, E.C. 2018. Outcome measurement instruments for provoked vulvodynia: A systematic review. *J Low Genit Tract Dis,* 22(4), 396-404. https://doi.org/10.1097/LGT.0000000000000418
David, A. and Bornstein, J. 2020. Evaluation of long-term surgical success and satisfaction of patients after vestibulectomy. *J Low Genit Tract Dis,* 24(4), 399-404. https://doi.org/10.1097/LGT.0000000000000552
De Andres, J., Sanchis-Lopez, N., Asensio-Samper, J.M., Fabregat-Cid, G. and Dolz, V. M. 2013. Peripheral subcutaneous vulvar stimulation in the management of severe and refractory vulvodynia. *Obstet Gynecol,* 121(2 Pt 2 Suppl 1), 495-498. http://10.1097/AOG.0b013e31827c60f8
Derogatis, L.R., Lipman, R.S., Rickels, K., Uhlenhuth, E.H., and Covi, L. 1974. The Hopkins Symptom Checklist (HSCL): a self-report symptom inventory. *Behav Sci,* 19(1), 1-15. https://doi.org/10.1002/bs.3830190102
Desrochers, G., Bergeron, S., Khalifé, S., Dupuis, M.J. and Jodoin, M. 2009. Fear avoidance and self-efficacy in relation to pain and sexual impairment in women with provoked vestibulodynia. *Clin J Pain,* 25(6), 520-527. https://doi.org/10.1097/AJP.0b013e31819976e3
Desrochers, G., Bergeron, S., Khalifé, S., Dupuis, M.J., and Jodoin, M. 2010. Provoked vestibulodynia: psychological predictors of topical and cognitive-behavioral treatment outcome. *Behav Res Ther,* 48(2), 106-115. https://doi.org/10.1016/j.brat.2009.09.014
Doyle, L., Brady, A.M. and Byrne, G. 2009. An overview of mixed methods research. *J Res Nurs,* 14(2), 175-185. https://doi.org/10.1177/1744987108093962

Doyle, L., Brady, A.-M. and Byrne, G. 2016. An overview of mixed methods research – revisited. *J Res Nurs,* 21(8), 623-635. https://doi.org/10.1177/1744987116674257
Eldridge, S.M., Chan, C.L., Campbell, M.J., Bond, C.M., Hopewell, S., Thabane, L. and Lancaster, G. A. 2016a. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *Pilot Feasibility Stud,* 2, 64. https://doi.org/10.1136/bmj.i5239
Eldridge, S.M., Lancaster, G.A., Campbell, M.J., Thabane, L., Hopewell, S., Coleman, C.L., and Bond, C.M. 2016b. Defining feasibility and pilot studies in preparation for randomised controlled trials: Development of a conceptual framework. *PLoS One,* 11(3), e0150205. https://doi.org/10.1371/journal.pone.0150205
Ellison, T. and Papps, F.A. 2020. 'Sexuality, without that mirror': The role of embodied practice in the development of sexual potential. *Complement Ther Clin Pract,* 40, 101205. https://doi.org/10.1016/j.ctcp.2020.101205
Elmerstig, E., Wijma, B. and Bertero, C. 2008. Why do young women continue to have sexual intercourse despite pain? *J Adolesc Health,* 43(4), 357-363. https://doi.org/10.1016/j.jadohealth.2008.02.011
Engel, G.L. 1977. The need for a new medical model: A challenge for biomedicine. *Science,* 196(4286), 129-136. https://doi.org/10.1126/science.847460
Engel, G.L. 1979. The biopsychosocial model and the education of health professionals. *Gen Hosp Psychiatry,* 1(2), 156-165. https://doi.org/10.1016/0163-8343(79)90062-8
Engel, G.L. 2012. The Need for a New Medical Model: A Challenge for Biomedicine. *Psychodynamic Psychiatry,* 40(3), 377-396.
Falsetta, M.L., Foster, D.C., Bonham, A.D., and Phipps, R.P. 2017. A review of the available clinical therapies for vulvodynia management and new data implicating proinflammatory mediators in pain elicitation. *Bjog,* 124(2), 210-218. http://dx.doi.org/10.1111/1471-0528.14415
Falsetta, M.L., Wood, R., Linder, M.A., Bonham, A., Honn, K.V., Maddipati, K.R., Phipps, R.P., Haidaris, C.G. and Foster, D.C. 2021. Specialized pro-resolving mediators reduce pro-nociceptive inflammatory mediator production in models of localized provoked vulvodynia. *J Pain,* 22(10), 1195-1209. https://doi.org/10.1016/j.jpain.2021.03.144
Fernandes, L., Storheim, K., Lochting, I., and Grotle, M. 2012. Cross-cultural adaptation and validation of the Norwegian pain catastrophizing scale in patients with low back pain. *BMC Musculoskeletal Disorders,* 13, 111.
Fleurence, R., Selby, J.V., Odom-Walker, K., Hunt, G., Meltzer, D., Slutsky, J.R., and Yancy, C. 2013. How the patient-centered outcomes research institute is engaging patients and others in shaping its research agenda. *Health Affairs,* 32(2), 393-400. https://doi.org/10.1377/hlthaff.2012.1176
Flink, I.K., Engman, L., Ter Kuile, M.M., Thomtén, J. and Linton, S.J. 2017. Coping with pain in intimate situations: Applying the avoidance-endurance model to women with vulvovaginal pain. *Scand J Pain,* 17, 302-308. https://doi.org/10.1016/j.sjpain.2017.08.007
Forsythe, L.P., Ellis, L.E., Edmundson, L., Sabharwal, R., Rein, A., Konopka, K. and Frank, L. 2016. Patient and stakeholder engagement in the PCORI pilot projects: Description and lessons Learned. *J Gen Intern Med,* 31(1), 13-21. https://doi.org/10.1007/s11606-015-3450-z
Foster, D.C., Kotok, M.B., Huang, L.S., Watts, A., Oakes, D., Howard, F.M., Poleshuck, E.L., Stodgell, C.J. and Dworkin, R.H. 2010. Oral desipramine and topical lidocaine for vulvodynia: a randomized controlled trial. *Obstet Gynecol,* 116(3), 583-593. https://doi.org/ 10.1097/AOG.0b013e3181e9e0ab
Foster, D.C., Kotok, M.B., Huang, L.S., Watts, A., Oakes, D., Howard, F.M., Stodgell, C.J.

and Dworkin, R.H. 2009. The tampon test for vulvodynia treatment outcomes research: reliability, construct validity, and responsiveness. *Obstet Gynecol,* 113(4), 825-832. https://doi.org/10.1097/AOG.0b013e31819bda7c

Foucault, M. 1977. *Discipline and punish:the birth of the prison.* New York: Pantheon Books.

Fougner, M. and Haugstad, G.K. 2015. Treating gynaecological pain: the experiences of bachelor students in physiotherapy performing somatocognitive therapy. *Physiother Theory Pract,* 1-9. https://doi.org/10.3109/09593985.2014.1003343

Gatchel, R.J., Peng, Y.B., Peters, M.L., Fuchs, P.N. and Turk, D.C. 2007. The biopsychosocial approach to chronic pain: scientific advances and future directions. *Psychol Bull,* 133(4), 581-624. https://doi.org/10.1037/0033-2909.133.4.581

Gentilcore-Saulnier, E., McLean, L., Goldfinger, C., Pukall, C.F. and Chamberlain, S. 2010. Pelvic floor muscle assessment outcomes in women with and without provoked vestibulodynia and the impact of a physical therapy program. *J Sex Med,* 7(2 Pt 2), 1003-1022. https://doi.org/10.1111/j.1743- 6109.2009.01642.x

Gerber, S., Bongiovanni, A.M., Ledger, W.J. and Witkin, S.S. 2003. Interleukin-1β gene polymorphism in women with vulvar vestibulitis syndrome. *Eur. J. Obstet. Gynecol.,* 107(1), 74-77. https://doi.org/10.1016/S0301-2115(02)00276-2

Gerbild, H., Larsen, C.M., Junge, T., Laursen, B.S. and Areskoug-Josefsson, K. 2021. Danish health professional students' attitudes toward addressing sexual health: A cross-sectional survey. *Sex Med,* 9(2), 100323. https://doi.org/10.1016/j.esxm.2021.100323

Goldfinger, C., Pukall, C.F., Thibault-Gagnon, S., McLean, L. and Chamberlain, S. 2016. Effectiveness of cognitive-behavioral therapy and physical therapy for provoked vestibulodynia: A randomized pilot study. *J Sex Med,* 13(1), 88-94. https://doi.org/10.1016/j.jsxm.2015.12.003

Goldstein, A.T., Pukall, C.F., Brown, C., Bergeron, S., Stein, A. and Kellogg-Spadt, S. 2016. Vulvodynia: Assessment and treatment. *J Sex Med,* 13(4), 572-590. https://doi.org/10.1016/j.jsxm.2016.01.020

Gomez, I., Coronado, P.J., Martin, C.M., Alonso, R. and Guisasola-Campa, F.J. 2019. Study on the prevalence and factors associated to vulvodynia in Spain. *Eur J Obstet Gynecol Reprod Biol,* 240, 121-124. https://doi.org/10.1016/j.ejogrb.2019.06.005

Gordon, A.S., Panahian-Jand, M., McComb, F., Melegari, C. and Sharp, S. 2003. Characteristics of women with vulvar pain disorders: responses to a Web-based survey. *J Sex Marital Ther,* 29 Suppl 1, 45-58. https://doi.org/10.1080/713847126

Granot, M. and Lavee, Y. 2005. Psychological factors associated with perception of experimental pain in vulvar vestibulitis syndrome. *J Sex Marital Ther,* 31(4), 285-302. https://doi.org/10.1080/00926230590950208

Graziottin, A., Murina, F., Gambini, D., Taraborrelli, S., Gardella, B., Campo, M. and VuNet Study Group. 2020. Vulvar pain: The revealing scenario of leading comorbidities in 1183 cases. *Eur J Obstet Gynecol Reprod Biol,* 252, 50-55. https://doi.org/10.1016/j.ejogrb.2020.05.052

Greenstein, A., Ben-Aroya, Z., Fass, O., Militscher, I., Roslik, Y., Chen, J. and Abramov, L.. 2007. Vulvar vestibulitis syndrome and estrogen dose of oral contraceptive pills. *J Sex Med,* 4(6), 1679-1683. https://doi.org/10.1111/j.1743-6109.2007.00621.x

Groven, K.S., Råheim, M., Håkonsen, E. and Haugstad, G.K. 2016. "Will I ever be a true woman?" An exploration of the experiences of women with vestibulodynia. *Health Care Women Int,* 37(8), 818-835. https://doi.org/10.1080/07399332.2015.1103739

Guillet, A.D., Cirino, N.H., Hart, K.D. and Leclair, C.M. 2019. Mindfulness-based group cognitive behavior therapy for provoked localized vulvodynia: A randomized

controlled trial. *J Low Genit Tract Dis,* 23(2), 170-175. https://doi.org/10.1097/LGT.0000000000000456
Harlow, B. and Stewart, E. 2003. A population-based assessment of chronic unexplained vulvar pain: have we underestimated the prevalence of vulvodynia? *J Am Med Womens Assoc (1972),* 58(2), 82-88.
Harlow, B.L., Kunitz, C.G., Nguyen, R.H., Rydell, S.A., Turner, R.M. and MacLehose, R.F. 2014. Prevalence of symptoms consistent with a diagnosis of vulvodynia: population-based estimates from 2 geographic regions. *Am J Obstet Gynecol,* 210(1), 40 e41-48. https://doi.org/10.1016/j. ajog.2013.09.033
Harlow, B.L., Vitonis, A.F. and Stewart, E.G. 2008. Influence of oral contraceptive use on the risk of adult-onset vulvodynia. *J Reprod Med,* 53(2), 102-110.
Harlow, B.L., Wise, L.A. and Stewart, E.G. 2001. Prevalence and predictors of chronic lower genital tract discomfort. *Am J Obstet Gynecol,* 185(3), 545-550. https://doi.org/10.1067/mob.2001.116748
Hartmann, D., Strauhal, M.J. and Nelson, C.A. 2007. Treatment of women in the United States with localized, provoked vulvodynia: practice survey of women's health physical therapists. *J Reprod Med,* 52, 48-52.
Haugstad, G.K., Haugstad, T.S., Kirste, U., Leganger, S., Hammel, B., Klemmetsen, I. and Malt, U.F. 2006a. Reliability and validity of a standardized Mensendieck physiotherapy test (SMT). *Physiother Theory Pract,* 22(4), 189-205. https://doi.org/10.1080/09593980600822834
Haugstad, G.K., Haugstad, T.S., Kirste, U.M., Leganger, S., Klemmetsen, I. and Malt, U.F. 2006b. Mensendieck somatocognitive therapy as treatment approach to chronic pelvic pain: results of a randomized controlled intervention study. *Am J Obstet Gynecol,* 194(5), 1303-1310. https://doi.org/10.1016/j.ajog.2005.10.793
Haugstad, G. K., Haugstad, T.S., Kirste, U.M., Leganger, S., Wojniusz, S., Klemmetsen, I. and Malt, U.F., 2006c. Posture, movement patterns, and body awareness in women with chronic pelvic pain. *J Psychosom Res,* 61(5), 637-644. https://doi.org/10.1016/j.jpsychores.2006.05.003
Haugstad, G.K., Haugstad T.S, Kirste U.M, Leganger S, Wojniusz, S., Klemmetsen, I. and Malt, U.F. 2008. Continuing improvement of chronic pelvic pain in women after short-term Mensendieck somatocognitive therapy: results of a 1-year follow-up study. *Am J Obstet Gynecol,* 199(6), 615 e611-618. https://doi.org/10.1016/j.ajog.2008.06.019
Haugstad, G.K., et al. 2015 Vulvodynia treated with somatocognitive therapy in a student out-patient clinic – a preliminary report. ed. *2nd World Congress On Abdominal & Pelvic Pain,* 2015 Nice, France.
Haugstad, G.K., Kirste, U., Leganger, S., Haakonsen, E. and Haugstad, T.S. 2011. Somatocognitive therapy in the management of chronic gynaecological pain. A review of the historical background and results of a current approach. *Scand J Pain,* 2(3), 124-129. https://doi.org/10.1016/j.sjpain.2011.02.005
Haugstad, G.K., Wojniusz, S., Kirschner, R., Kirste, U., Lilleheie, I. and Haugstad, T.S. 2019. Somatocognitive therapy of women with provoked vulvodynia: a pilot study. *Scand J Pain,* 19:725–732. https://doi.org/10.1515/sjpain-2019-0011
Haugstad, G.K., Wojniusz, S., Kirste, U.M., Kirschner R.S, Lilleheie, I., Haugstad, T.S. 2018. Pain, psychological distress and motor pattern in women with provoked vestibulodynia (PVD) - symptom characteristics and therapy suggestions. *Scand J Pain,* 18(2), 221-227. https://doi.org/10.1515/sjpain-2017-0173
Havemann, L.M., Cool, D.R., Gagneux, P., Markey, M.P., Yaklic, J.L., Maxwell, R.A., Iyer, A. and Lindheim, S.R. 2017. Vulvodynia: What we know and where we should be

going. *J Low Genit Tract Dis,* 21(2), 150-156. https://doi.org/10.1097/LGT.0000000000000289
Heddini, U., Johannesson, U., Grönbladh, A., Nyberg, F., Nilsson, K. W. and Bohm-Starke, N. 2014. A118G polymorphism in the mu-opioid receptor gene and levels of beta-endorphin are associated with provoked vestibulodynia and pressure pain sensitivity. *Scand J Pain,* 5(1), 10-16. https://doi.org/10.1016/j.sjpain.2013.10.004
Hirschman, C., Impett, E. and Schooler, D. 2006. Dis/Embodied Voices: What late-adolescent girls can teach us about objectification and sexuality. *Sex Res Social Policy,* 3, 8-20.
Hoffmann, T.C., Glasziou, P.P., Boutron, I., Milne, R., Perera, R., Moher, D., Altman, D.G., Barbour, V., Macdonald, H., Johnston, M., et al. 2014. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ,* 348, g1687. https://doi.org/10.1136/bmj.g1687
Hughes, L.S., Clark, J., Colclough, J.A., Dale, E. and McMillan, D. 2017. Acceptance and commitment therapy (ACT) for chronic pain: A systematic review and meta-analyses. *Clin J Pain,* 33(6), 552-568. https://doi.org/10.1097/AJP.0000000000000425
Hutting, N., Caneiro, J., Ong'wen, O.M., Miciak, M. and Roberts, L. 2022. Patient-centered care in musculoskeletal practice: Key elements to support clinicians to focus on the person. *Musculoskelet Sci Pract,* 57, 102434. https://doi.org/10.1016/j.msksp.2021.102434
Jodoin, M., Bergeron, S., Khalifé, S., Dupuis, M.J., Desrochers, G. and Leclerc, B. 2008. Male partners of women with provoked vestibulodynia: attributions for pain and their implications for dyadic adjustment, sexual satisfaction, and psychological distress. *J Sex Med,* 5(12), 2862-2870. https://doi.org/10.1111/j.1743-6109.2008.00950.x
Johnson, N.S., Harwood, E.M. and Nguyen, R.H. 2015. "You have to go through it and have your children": reproductive experiences among women with vulvodynia. *BMC Pregnancy Childbirth,* 15, 114. https://doi.org/10.1186/s12884-015-0544-x
Kamper, S.J., Apeldoorn, A.T., Chiarotto, A., Smeets, R.J., Ostelo, R.W., Guzman, J. and van Tulder, M.. 2015. Multidisciplinary biopsychosocial rehabilitation for chronic low back pain: Cochrane systematic review and meta-analysis. *BMJ,* 350, h444. https://doi.org/10.1136/bmj.h444
Kamper, S.J., Ostelo, R.W., Knol, D.L., Maher, C.G., de Vet, H.C. and Hancock, M.J. 2010. Global Perceived Effect scales provided reliable assessments of health transition in people with musculoskeletal disorders, but ratings are strongly influenced by current status. *J Clin Epidemiol,* 63(7), 760-766.e761. https://doi.org/10.1016/j.jclinepi.2009.09.009
Kazdin, A.E. 2019. Single-case experimental designs. Evaluating interventions in research and clinical practice. *Behav Res Ther,* 117, 3-17. https://doi.org/10.1016/j.brat.2018.11.015
Khandker, M., Brady, S.S., Rydell S.A., Turner R.M., Schreiner P.J. and Harlow B.L. 2019. Early-life chronic stressors, rumination, and the onset of vulvodynia. *J Sex Med,* 16(6), 880-890. https://doi.org/10.1016/j.jsxm.2019.03.010
Khatamian Far, P. 2018. Challenges of recruitment and retention of university students as research participants: Lessons Learned from a Pilot Study. *J. Aust. Libr. Inf.* Assoc, 67(3), 278-292. https://doi.org/10.1080/24750158.2018.1500436
Kinney, M., Seider, J., Beaty, A.F., Coughlin, K., Dyal, M., and Clewley, D. 2018. The impact of therapeutic alliance in physical therapy for chronic musculoskeletal pain: A systematic review of the literature. *Physiother Theory Pract,* 36(8), 886-898. https://doi.org/10.1080/09593985.2018.1516015
Kvåle, S. and Brinkman, S. 2009. *Det kvalitative forskningsintervju (Interviews: Learning the craft of research interviewing).* 2nd ed ed. Oslo: Gyldendal Akademisk.

Kvåle, A., Ljunggren, A.E. and Johnson, T.B. 2003. Examination of movement in patients with long-lasting musculoskeletal pain: reliability and validity. *Physiother Res Int,* 8(1), 36-52. https://doi.org/10.1002/pri.270

Lamvu, G., Alappattu, M., Witzeman, K., Bishop, M., Robinson, M. and Rapkin, A. 2018. Patterns in vulvodynia treatments and 6-month outcomes for women enrolled in the national vulvodynia registry-an exploratory prospective study. *J Sex Med,* 15(5), 705-715. https://doi.org/10.1016/j.jsxm.2018.03.003

Lamvu, G., Nguyen, R.H.N., Burrows, L.J., Rapkin, A., Witzeman, K., Marvel, R.P., Hutchins, D., Witkin, S. S., Veasley, C., Fillingim, R. and Zolnoun, D. 2015. The evidence-based vulvodynia assessment project: A national registry for the study of vulvodynia. *J Reprod Med,* 60(3), 223-235.

Lancaster, G.A. 2015. Pilot and feasibility studies come of age! *Pilot and Feasibility Studies,* 1(1), 1-4. https://doi.org/10.1186/2055-5784-1-1

Lancaster, G.A., Dodd, S. and Williamson, P.R. 2004. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract,* 10(2), 307-312. https://doi.org/10.1111/j..2002.384.doc.x

Leon, A.C., Davis, L.L. and Kraemer, H.C. 2011. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res,* 45(5), 626-629. https://doi.org/10.1016/j.jpsychires.2010.10.008

LePage, K. and Selk, A. 2016. What Do Patients Want? A needs assessment of vulvodynia patients attending a vulvar diseases clinic. *Sex Med,* 4(4), e242-e248. https://doi.org/10.1016/j.esxm.2016.06.003

Lester, R.A., Brotto, L.A. and Sadownik, L.A. 2015. Provoked vestibulodynia and the health care implications of comorbid pain conditions. *Journal of Obstetrics and Gynaecology Canada,* 37(11), 995-1005. https://doi.org/10.1016/S1701-2163(16)30049-4

Leusink, P., Steinmann, R., Makker, M., Lucassen, P.L., Teunissen, D., Lagro-Janssen, A.L. and Laan, E.T. 2019. Women's appraisal of the management of vulvodynia by their general practitioner: a qualitative study. *Fam Pract,* 36(6), 791-796. https://doi.org/10.1093/fampra/cmz021

Leusink, P., Steinmann, R., Makker, M., Lucassen, P.L., Teunissen, D., Lagro-Janssen, A.L. and Laan, E.T. 2018. Facilitators and barriers in the diagnostic process of vulvovaginal complaints (vulvodynia) in general practice: a qualitative study. *Eur J Gen Pract*, 24(1), 92-98. https://doi.org/10.1093/fampra/cmz021

Lev-Sagie, A., Kopitman, A. and Brzezinski, A. 2017. Low-level laser therapy for the treatment of provoked vestibulodynia-a randomized, placebo-controlled pilot trial. *J Sex Med,* 14(11), 1403-1411. https://doi.org/10.1016/j.jsxm.2017.09.004

Lev-Sagie, A. and Witkin, S.S. 2016. Recent advances in understanding provoked vestibulodynia. *F1000Res,* 5, 2581. https://doi.org/10.12688/f1000research.9603.1

Lindström, S. and Kvist, L.J. 2015. Treatment of provoked vulvodynia in a Swedish cohort using desensitization exercises and cognitive behavioral therapy. *BMC Womens Health,* 15, 108. https://doi.org/10.1186/s12905-015-0265-3

Loflin, B.J., Westmoreland, K. and Williams, N.T. 2019. Vulvodynia: A review of the literature. *Journal of Pharmacy Technology,* 35(1), 11-24. https://doi.org/10.1177/8755122518793256

Lua, L.L., Hollette, Y., Parm, P., Allenback, G., and Dandolu, V. 2017. Current practice patterns for management of vulvodynia in the United States. *Arch Gynecol Obstet,* 295(3), 669-674. https://doi.org/10.1007/s00404-016-4272-x

Maille, D.L., Bergeron, S. and Lambert, B. 2015. Body image in women with primary and secondary provoked vestibulodynia: a controlled study. *J Sex Med,* 12(2), 505-515. https://doi.org/10.1111/jsm.12765

Malmqvist, E., Niklas, J., Lynöe, N. and Helgesson, G. 2011. Early stopping of clinical trials: charting the ethical terrain. *Kennedy Inst Ethics J,* 21(1), 51-78. https://doi.org/10.1353/ken.2011.0002

Marris, D., Theophanous, K., Cabezon, P., Dunlap, Z. and Donaldson, M. 2021. The impact of combining pain education strategies with physical therapy interventions for patients with chronic pain: A systematic review and meta-analysis of randomized controlled trials. *Physiother Theory Pract*, 1-12. https://doi.org10.1080/09593985.2019.1633714

Maunder, L., Dargie, E. and Pukall, C.F. 2022. Moderators of the relationship between pain and pain-related sexual disability in women with provoked vestibulodynia symptoms. *J Sex Med*. 19:809–822. https://doi.org/10.1016/j.jsxm.2022.02.016

Maxwell, J.A., 2013. *Qualitative research design: an interactive approach.* 3rd edition ed. Los Angeles: Sage.

Mescouto, K., Olson, R.E., Hodges, P.W. and Setchell, J. 2020. A critical review of the biopsychosocial model of low back pain care: time for a new approach? *Disabil Rehabil*, 1-15. https://doi.org/10.1080/09638288.2020.1851783

Miciak, M., Mayan, M., Brown, C. Joyce A.S. and Gross, D. 2019. A framework for establishing connections in physiotherapy practice. *Physiother Theory Pract*, 35(1), 40-56. https://doi.org/10.1080/09593985.2018.1434707

Miranda Varella Pereira, G., Soriano Marcolino, M., Silveira Nogueira Reis, Z. and Vale de Castro Monteiro, M. 2018. A systematic review of drug treatment of vulvodynia: evidence of a strong placebo effect. *Bjog*, 125(10), 1216-1224. https://doi.org/10.1111/1471-0528.15223

Moen, K. and Middelthon, A. 2015. Qualitative Research Methods. *Research in Medical and Biological Sciences.* Elsevier Ltd.

Moore, G., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., Moore, L., O'Cathain, A., Tinati, T., Wight, D. and Baird, J. 2014. *Process evaluation of complex interventions. UK Medical Research Council (MRC) guidance*, 1-130.

Morin, M., Bergeron, S., Khalifé, S., Mayrand, M.H. and Binik, Y.M. 2014. Morphometry of the pelvic floor muscles in women with and without provoked vestibulodynia using 4D ultrasound. *J Sex Med*, 11(3), 776-785. https://doi.org/10.1111/jsm.12367

Morin, M., Binik, Y.M., Bourbonnais, D., Khalifé, S., Ouellet, S. and Bergeron, S. 2017a. Heightened pelvic floor muscle tone and altered contractility in women with provoked vestibulodynia. *J Sex Med*, 14(4), 592-600. https://doi.org/10.1016/j.jsxm.2017.02.012

Morin, M., Carroll, M. S. and Bergeron, S. 2017b. Systematic review of the effectiveness of physical therapy modalities in women with provoked vestibulodynia. *Sex Med Rev*, 5(3), 295-322. https://doi.org/0.1016/j.sxmr.2017.02.003

Morin, M., Dumoulin, C., Bergeron, S., Mayrand, M. H., Khalifé, S., Waddell, G. and Dubois, M.F. (2016). Randomized clinical trial of multimodal physiotherapy treatment compared to overnight lidocaine ointment in women with provoked vestibulodynia: design and methods. *Contemp Clin Trials*, *46*, 52-59. https://doi.org/10.1016/j.cct.2015.11.013

Morin, M., Dumoulin, C., Bergeron, S., Mayrand, M.H., Khalifé, S., Waddell, G. and Dubois, M.F. 2021. Multimodal physical therapy versus topical lidocaine for provoked vestibulodynia: a prospective, multicentre, randomized trial. *Am J Obstet Gynecol*, 224., e1-12. https://doi.org/10.1016/j.ajog.2020.08.038

Moyal-Barracco, M. and Lynch, P.J. 2004. 2003 ISSVD terminology and classification of vulvodynia: a historical perspective. *J Reprod Med*, 49, 772–777.

Neijenhuijs, K.I., Hooghiemstra, N., Holtmaat, K., Aaronson, N.K., Groenvold, M., Holzner, B., Terwee, C.B., Cuijpers, P. and Verdonck-de Leeuw, I.M. 2019. The Female

Sexual Function Index (FSFI)-A systematic review of measurement properties. *J Sex Med*, 16(5), 640-660. https://doi.org/10.1016/j.jsxm.2019.03.001
Nguyen, R.H., Ecklund, A.M., MacLehose, R.F., Veasley, C. and Harlow, B. L. 2012. Co-morbid pain conditions and feelings of invalidation and isolation among women with vulvodynia. *Psychol Health Med*, 17(5), 589-598. https://doi.org/10.1080/13548506.2011.647703
Nicholas, M., Vlaeyen, J., Rief, W., Barke, A., Aziz, Q., Benoliel, R., Cohen, M., Evers, S., Giamberardino, M., Goebel, A. *et al.* 2019. The IASP classification of chronic pain for ICD-11: chronic primary pain. *Pain*, 160(1), 28-37. https://doi.org/10.1097/j.pain.0000000000001390
Nygaard, A.S., Rydningen, M.B., Stedenfeldt, M., Wojniusz, S., Larsen, M., Lindsetmo, R. O., Haugstad, G.K. and Øian, P. 2020. Group-based multimodal physical therapy in women with chronic pelvic pain: A randomized controlled trial. *Acta Obstet Gynecol Scand*, 99(10), 1320-1329. https://doi.org/10.1111/aogs.13896
Orsmond, G.I. and Cohn, E.S. 2015. The Distinctive Features of a Feasibility Study: Objectives and Guiding Questions. *OTJR (Thorofare N J)*, 35(3), 169-177. https://doi.org/10.1177/1539449215578649
Paquet, M., Rosen, N.O., Steben, M., Mayrand, M.H., Santerre-Baillargeon, M. and Bergeron, S. 2018. Daily anxiety and depressive symptoms in couples coping with vulvodynia: Associations with women's pain, women's sexual function, and both partners' sexual distress. *J Pain*, 19(5), 552-561. https://doi.org/10.1016/j.jpain.2017.12.264
Piran, N. 2017. *Journeys of embodiment at the intersection of body and culture: The developmental theory of embodiment.* San Diego, CA, US: Elsevier Academic Press.
Proctor, S. 1998. Linking philosophy and method in the research process: the case for realism. *Nurse Researcher*, 5 73-90. https://doi.org/10.7748/nr.5.4.73.s7
Pukall, C.F. 2016. Primary and secondary provoked vestibulodynia: A review of overlapping and distinct factors. *Sex Med Rev*, 4(1), 36-44. https://doi.org/10.1016/j.sxmr.2015.10.012
Pukall, C.F., Bergeron, S., Brown, C., Bachmann, G. and Wesselmann, U. 2017. Recommendations for self-report outcome measures in vulvodynia clinical trials. *Clin J Pain*, 33(8), 756-765. https://doi.org/10.1097/AJP.0000000000000453
Paavonen, J. and Eschenbach, D.A. 2021. Localized provoked vulvodynia-an ignored vulvar pain syndrome. *Front Cell Infect Microbiol*, 11, 678961. https://doi.org/10.3389/fcimb.2021.678961
Reed, B.D., Crawford, S., Couper, M., Cave, C. and Haefner, H.K. 2004. Pain at the vulvar vestibule: A web-based survey. *J Low Genit Tract Dis*, 8(1), 48-57.
Reed, B.D., Harlow, S.D., Sen, A., Edwards, R.M., Chen, D. and Haefner, H.K. 2012a. Relationship between vulvodynia and chronic comorbid pain conditions. *Obstet Gynecol*, 120(1), 145-151. https://doi.org/10.1097/AOG.0b013e31825957cf
Reed, B.D., Harlow, S.D., Sen, A., Legocki, L.J., Edwards, R.M., Arato, N. and Haefner, H.K. 2012b. Prevalence and demographic characteristics of vulvodynia in a population-based sample. *Am J Obstet Gynecol*, 206(2), 170 e171-179. https://doi.org/10.1016/j.ajog.2011.08.012
Reed, B.D., Legocki, L.J., Plegue, M.A., Sen, A., Haefner, H.K. and Harlow, S.D. 2014. Factors associated with vulvodynia incidence. *Obstet Gynecol*, 123(2 Pt 1), 225-231. https://doi.org/10.1097/AOG.0000000000000066
Rosen, N.O., Bergeron, S., Lambert, B. and Steben, M. 2013. Provoked vestibulodynia: mediators of the associations between partner responses, pain, and sexual satisfaction. *Arch Sex Behav*, 42(1), 129-141. https://doi.org/10.1007/s10508-012-9905-y

Rosen, N.O., Bergeron, S. and Pukall, C.F. 2020. Recommendations for the study of vulvar pain in women, part 1: review of assessment tools. *J Sex Med*, 17(2), 180-194. https://doi.org/10.1016/j.jsxm.2019.10.023

Rosen, N.O., Bergeron, S., Sadikaj, G. and Delisle, I. 2015. Daily associations among male partner responses, pain during intercourse, and anxiety in women with vulvodynia and their partners. *J of Pain*, 16(12), 1312-1320. https://doi.org/10.1016/j.jpain.2015.09.003

Rosen, N.O., Bergeron, S., Sadikaj, G., Glowacka, M., Baxter, M.L. and Delisle, I. 2014. Relationship satisfaction moderates the associations between male partner responses and depression in women with vulvodynia: A dyadic daily experience study. *Pain*, 155(7), 1374-1383. https://doi.org/10.1016/j.pain.2014.04.017

Rosen, N.O., Dawson, S.J., Brooks, M. and Kellogg-Spadt, S. 2019. Treatment of vulvodynia: pharmacological and non-pharmacological approaches. *Drugs*, 79(5), 483-493. https://doi.org/10.1007/s40265-019-01085-1

Rosen, C. Brown, J. Heiman, S. Leiblum, C. Meston, R. Shabsigh, D. Ferguson, R. D'Agostino, R. (2000). The Female Sexual Function Index 2000. The Female Sexual Function Index (FSFI): A multidimensional self-report instrument for the assessment of female sexual function. *J Sex Marital Ther*, 26(2), 191-208. https://doi.org/10.1080/009262300278597

Rosenbaum, T.Y. 2005. Physiotherapy treatment of sexual pain disorders. *J Sex Marital Ther*, 31(4), 329–340. https://doi.org/10.1080/00926230590950235

Rosenbaum, T.Y. 2006. The role of physiotherapy in sexual health: Is it evidence-based? *J Assoc Chart Physiother Women's Health*, 99:1–5.

Rosenbaum, T.Y. 2013. An integrated mindfulness-based approach to the treatment of women with sexual pain and anxiety: promoting autonomy and mind/body connection. *Sex. Relatsh. Ther*, 28(1-2), 20-28. https://doi.org/10.1080/14681994.2013.764981

Rost, S., Van Ryckeghem, D. M., Koval, P., Sütterlin, S., Vögele, C. and Crombez, G. 2016. Affective instability in patients with chronic pain: a diary approach. *Pain*, 157(8), 1783-1790. https://doi.org/10.1097/j.pain.0000000000000582

Sadownik, L.A. 2000. Clinical profile of vulvodynia patients. A prospetive study of 300 patients. *J Reprod Med*, 45, 679–684.

Sadownik, L.A. 2014. Etiology, diagnosis, and clinical management of vulvodynia. *Int J Womens Health*, 6, 437-449. https://doi.org/10.2147/IJWH.S37660

Sadownik, L.A., Seal, B. and Brotto, L.A. 2012. Provoked vestibulodynia: A qualitative exploration of women's experiences. *B C Med J*, 54(1), 22-28.

Sadownik, L.A., Smith, K.B., Hui, A. and Brotto, L.A. 2017. The impact of a woman's dyspareunia and its treatment on her intimate partner: A qualitative analysis. *J Sex Marital Ther*, 43(6), 529-542. https://doi.org/10.1080/0092623X.2016.1208697

Sadownik, L.A., Yong, P.J. and Smith, K.B. 2018. Systematic review of treatment outcome measures for vulvodynia. *J Low Genit Tract Dis*, 22(3), 251-259. https://doi.org/10.1097/LGT.0000000000000406

Santerre-Baillargeon, M., Rosen, N.O., Steben, M., Paquet, M., Macabena Perez, R. and Bergeron, S. 2018. Does self-compassion benefit couples coping with vulvodynia? Associations with psychological, sexual, and relationship adjustment. *Clin J Pain*, 34(7), 629-637. https://doi.org/10.1097/AJP.0000000000000579

Schlaeger, J.M., Patil, C.L., Steffen, A.D., Pauls, H.A., Roach, K.L., Thornton, P.D., Hartmann, D., Kobak, W.H., Yao, Y., Suarez, M.L. and Hughes, T.L. 2019. Sensory pain characteristics of vulvodynia and their association with nociceptive and neuropathic pain: an online survey pilot study. *Pain Rep*, 4(2), e713. https://doi.org/10.1097/PR9.0000000000000713

Sekse, R.J., Råheim, M. and Gjengedal, E. 2015. Shyness and openness-common ground for dialogue between health personnel and women about sexual and intimate issues after gynecological cancer. *Health Care Women Int,* 36(11), 1255-1269. https://doi.org/10.1080/07399332.2014.989436

Shallcross, R., Dickson, J.M., Nunns, D., Mackenzie, C. and Kiemle, G. 2018. Women's Subjective Experiences of Living with Vulvodynia: A systematic review and meta-ethnography. *Arch Sex Behav,* 47(3), 577-595. https://doi.org/10.1007/s10508-017-1026-1

Shallcross, R., Dickson, J.M., Nunns, D., Taylor, K. and Kiemle, G. 2019. Women's experiences of vulvodynia: An interpretative phenomenological analysis of the journey toward diagnosis. *Arch Sex Behav,* 48(3), 961-974. https://doi.org/10.1007/s10508-018-1246-z

Skivington, K., Matthews, L., Simpson, S. A., Craig, P., Baird, J., Blazeby, J. M., Boyd, K.A., Craig, N., French, D.P., McIntosh, E., ... and Moore, L. (2021). A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *bmj*, 374:n2061. http://dx.doi.org/10.1136/bmj.n2061

Smith, K.B., Pukall, C.F. and Chamberlain, S.M. 2013. Sexual and relationship satisfaction and vestibular pain sensitivity among women with provoked vestibulodynia. *J Sex Med,* 10(8), 2009-2023. https://doi.org/10.1111/jsm.12213

Smith, K.B., Sadownik, L.A., Dargie, E., Albert, A.Y. and Brotto, L.A. 2019. Multidisciplinary treatment for provoked vestibulodynia. *Clin J Pain,* 35(4), 335-344. https://doi.org/10.1097/AJP.0000000000000682

Staniszewska, S., Brett, J., Mockford, C. and Barber, R., 2011. The GRIPP checklist: strengthening the quality of patient and public involvement reporting in research. *Int J Technol Assess Health Care,* 27(4), 391-399. https://doi.org/10.1017/S0266462311000481

Stenson, A.L. 2017. Vulvodynia: diagnosis and management. *Obstet Gynecol Clin North Am,* 44(3), 493-508. https://doi.org/10.1016/j.ogc.2017.05.008

Stilwell, P. and Harman, K. 2019. An enactive approach to pain: beyond the biopsychosocial model. *Phenomenol. Cogn. Sci,* 18(4), 637-665. https://doi.org/10.1007/s11097-019-09624-7

Stockdale, C.K. and Lawson, H.W. 2014. 2013 Vulvodynia Guideline Update. *J Low Genit Tract Dis,* 18, 93-100. https://doi.org/10.1097/LGT.0000000000000021

Strand, B.H., Dalgard, O.S., Tambs, K. and Rognerud, M. 2003. Measuring the mental health status of the Norwegian population: a comparison of the instruments SCL-25, SCL-10, SCL-5 and MHI-5 (SF-36). *Nord J Psychiatry,* 57(2), 113-118. https://doi.org/10.1080/08039480310000932

Sullivan, M.J., Bishop, S.R. and Pivik, J. 1995. The pain catastrophizing scale: development and validation. *Psychological assessment,* 7, 524-532. https://doi.org/10.1037/1040-3590.7.4.524

Sutton, K.S., Pukall, C.F. and Chamberlain, S. 2009. Pain, psychosocial, sexual, and psychophysical characteristics of women with primary vs. secondary provoked vestibulodynia. *J Sex Med,* 6(1), 205-214. https://doi.org/10.1111/j.1743-6109.2008.01038.x

Sutton, K.S., Yessick, L.R., Wild, C.J., Chamberlain, S.M. and Pukall, C.F. 2020. Exploring the neural correlates of touch and pain in women with provoked vestibulodynia. *Pain,* 161(5), 926-937. https://doi.org/10.1097/j.pain.0000000000001778

Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L.P., Robson, R., Thabane, M., Giangregorio, L. and Goldsmith, C.H. 2010. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol*, 10(1), 1-10.

Thomtén, J. and Karlsson, A. 2014. Psychological factors in genital pain: the role of fear-avoidance, pain catastrophizing and anxiety sensitivity among women living in Sweden. *Scan J Pain*, 5(3):193–199. https://doi.org/10.1016/j.sjpain.2014.01.003

Thomtén, J. and Linton, S.J. 2013. A psychological view of sexual pain among women: applying the fear-avoidance model. *Women Health*, 9(3), 251-263. https://doi.org/10.2217/WHE.13.19

Tommola, P., Unkila-Kallio, L. and Paavonen, J. 2011. Long-term follow up of posterior vestibulectomy for treating vulvar vestibulitis. *Acta Obstet Gynecol Scand*, 90(11), 1225-1231. https://doi.org/10.1111/j.1600-0412.2011.01248.x

Torres-Cueco, R. and Nohales-Alfonso, F. 2021. Vulvodynia-it is time to accept a new understanding from a neurobiological perspective. *Int J Environ Res Public Health*, 18(12). https://doi.org/10.3390/ijerph18126639

Treede, R.D., Rief, W., Barke, A., Aziz, Q., Bennett, M.I., Benoliel, R., Cohen, M., Evers, S., Finnerup, N.B., First, M.B. et al. 2019. Chronic pain as a symptom or a disease: the IASP Classification of Chronic Pain for the International Classification of Diseases (ICD-11). *Pain*, 160(1), 19-27. https://doi.org/10.1097/j.pain.0000000000001384

Tribó, M.J., Canal, C., Baños, J.E. and Robleda, G. 2020. Pain, anxiety, depression, and quality of life in patients with vulvodynia. *Dermatol*, 236(3), 255-261. https://doi.org/10.1159/000503321

Tveter, A.T., Major, D.H. and Grotle, M. 2015. FysioPol–en ny elektronisk database for kvalitetssikring og kunnskapsutvikling i fysioterapi. *Fysioterapeuten*, 50-57.

van der Meijden, W.I., Boffa, M.J., Ter Harmsel, W.A., Kirtschig, G., Lewis, F.M., Moyal-Barracco, M., Tiplica, G.S. and Sherrard, J., 2017. 2016 European guideline for the management of vulval conditions. *J Eur Acad Dermatol Venereol*, 31(6), 925-941. https://doi.org/10.1111/jdv.14096

van Reijn-Baggen, D.A., Han-Geurts, I.J., Voorham-van der Zalm, P.J., Pelger, R.C., Hagenaars-van Miert, C.H. and Laan, E.T. 2022. Pelvic floor physical therapy for pelvic floor hypertonicity: A systematic review of treatment efficacy. *Sex Med Rev*, 10(2), 209-230. https://doi.org/10.1016/j.sxmr.2021.03.002

Vancampfort, D., Sánchez, C.P.R., Hallgren, M., Schuch, F., Firth, J., Rosenbaum, S., Van Damme, T. and Stubbs, B. 2021. Dropout from exercise randomized controlled trials among people with anxiety and stress-related disorders: A meta-analysis and meta-regression. *J Affect Disord*, 282, 996-1004. https://doi.org/10.1016/j.jad.2021.01.003

Vieira-Baptista, P., Lima-Silva, J., Cavaco-Gomes, J. and Beires, J. 2014. Prevalence of vulvodynia and risk factors for the condition in Portugal. *Int J Gynecol Obstet*, 127(3), 283-287. https://doi.org/10.1016/j.ijgo.2014.05.020

Vlaeyen, J. and Linton, S. 2000. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain*, 85, 317-332. https://doi.org/10.1016/S0304-3959(99)00242-0

Vlaeyen, J.W.S. and Linton, S.J. 2012. Fear-avoidance model of chronic musculoskeletal pain: 12 years on. *Pain*, 153(6), 1144-1147. https://doi.org/10.1016/j.pain.2011.12.009

Wammen Rathenborg, F.L., Zdaniuk, B. and Brotto, L.A. 2019. What do different measures of pain tell us? A comparison in sexually active women with provoked vestibulodynia. *J Sex Med*, 16(2), 278-288. https://doi.org/10.1016/j.jsxm.2018.12.001

Webber, V., Miller, M.E., Gustafson, D.L. and Bajzak, K. 2020. Vulvodynia viewed from a disease prevention framework: insights from patient perspectives. *Sex Med*, 8(4), 757-766. https://doi.org/10.1016/j.esxm.2020.07.001

Wesselmann, U., Bonham, A. and Foster, D. 2014. Vulvodynia: Current state of the biological science. *Pain*, 155(9), 1696-1701. https://doi.org/10.1016/j.pain.2014.05.010

Wiegel, M., Meston, C. and Rosen, R. 2005. The female sexual function index (FSFI): cross-validation and development of clinical cutoff scores. *J Sex Marital Ther*, 31(1), 1-20. https://doi.org/10.1080/00926230590475206

Wild, D., Grove, A., Martin, M., Eremenco, S., McElroy, S., Verjee-Lorenz, A. and Erikson, P. 2005. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (pro) measures: report of the ISPOR task force for translation and cultural adaptation. *Value Health*, 8, 94-104. https://doi.org/10.1111/j.1524-4733.2005.04054.x

Wisdom, J.P., Cavaleri, M.A., Onwuegbuzie, A.J. and Green, C.A. 2012. Methodological reporting in qualitative, quantitative, and mixed methods health services research articles. *Health Serv Res*, 47(2), 721-745.

Wright, D., Foster, C., Amir, Z., Elliott, J. and Wilson, R. 2010. Critical appraisal guidelines for assessing the quality and impact of user involvement in research. *Health Expect*, 13(4), 359-368. https://doi.org/10.1111/j.1369-7625.2010.00607.x

Xie, Y., Shi, L., Xiong, X., Wu, E., Veasley, C. and Dade, C. 2012. Economic burden and quality of life of vulvodynia in the United States. *Curr Med Res Opin*, 28(4), 601-608. https://doi.org/10.1185/03007995.2012.666963

Yamato, T.P., Maher, C.G., Saragiotto, B.T., Hoffmann, T.C., Moseley, A.M., Elkins, M., Lin, C. and Söderlund, A. 2016. The TIDieR checklist will benefit the physiotherapy profession. *J Physiother*, 62(2), 57-58. https://doi.org/10.1080/21679169.2016.1195042

Zhang, Z., Zolnoun, D., Francisco, E.M., Holden, J.K., Dennis, R.G. and Tommerdahl, M. 2011. Altered Central Sensitization in Subgroups of Women With Vulvodynia. *Clin J Pain*, 27(9), 755–763. https://doi.org/10.1097/AJP.0b013e31821c98ec

Paper I

Feasibility and acceptability of somatocognitive therapy in the management of women with provoked localized vestibulodynia – ProLoVe feasibility study

Kaarbø, M.B., Danielsen, K.G., Haugstad, G.K., Helgesen, A.L.O., and Wojniusz, S. 2022. Feasibility and acceptability of somatocognitive therapy in the management of women with provoked localized vestibulodynia – ProLoVe feasibility study. *Pilot Feasibility Stud*; 8(1), 1-11.
https://doi.org/10.1186/s40814-022-01022-2

Pilot and Feasibility Studies

RESEARCH

Open Access

Feasibility and acceptability of somatocognitive therapy in the management of women with provoked localized vestibulodynia—ProLoVe feasibility study

Mette Bøymo Kaarbø[1*], Kristine Grimen Danielsen[1], Gro Killi Haugstad[1,2], Anne Lise Ording Helgesen[3,4] and Slawomir Wojniusz[1,5]

Abstract

Background: Provoked vestibulodynia (PVD) is a prevalent chronic pain condition especially among young women. Pain is localized to the vulvar vestibule and is provoked by touch or pressure, such as penetrative intercourse. PVD can have profound consequences, adversely affecting a woman's sexual life, relation to her partner, and her psychological health. There is an urgent need for well-designed randomized clinical trials (RCTs) to identify the most effective interventions for this neglected women's health condition.

Aims: The primary aim of this study is to assess the feasibility of undertaking a full-scale RCT of somatocognitive therapy (SCT), a multimodal physiotherapy intervention, for women with PVD. The secondary aim is to evaluate the implementation and acceptability of SCT and its potential treatment effectiveness in PVD. In the full-scale RCT, SCT will be compared to standard PVD treatment.

Methods: A multimethod feasibility study with a single-arm before-after trial and qualitative interviews. Ten women with PVD, aged 18–33 were recruited from the Vulva Clinic at Oslo University Hospital. The intervention took place at Oslo Metropolitan University. Participants were assessed at baseline, post-treatment, and the 8-month follow-up with the tampon test and self-report questionnaires. The main feasibility outcomes were evaluation of recruitment rate, adherence to assessment tools, and follow-up rate. The participants' experiences with the primary outcome and the intervention were explored with semi-structured interviews.

Results: Ten out of 18 eligible patients were recruited over 11 weeks. None were lost to follow-up. Adherence to self-report questionnaires was excellent. Adherence to tampon tests and to the reporting of treatments was good, whereas adherence to the 14-day diary was poor. No adverse events were reported. The tampon test was suboptimal as a primary outcome. SCT was found to be an acceptable treatment, based on Global Perceived Effect scores and the participants' experiences.

Conclusion: The findings suggest that it is feasible to deliver a full-scale RCT of the SCT intervention for women with PVD. Some changes are suggested to optimize the protocol, such as increasing recruitment sites, change of primary outcome measures, and adding a booster session.

*Correspondence: metteboy@oslomet.no
[1] Faculty of Health Sciences, Department of Physiotherapy, Oslo Metropolitan University, Oslo, Norway
Full list of author information is available at the end of the article

Trial registration: ClinicalTrials.gov NCT04208204. Retrospectively registered on December 23, 2019.
Keywords: Provoked vestibulodynia, Vulvodynia, Vestibulitis, Somatocognitive therapy, Feasibility study

Key messages

What uncertainties existed regarding the feasibility?
We wanted to investigate the recruitment and follow-up rates, adherence to outcomes, the primary outcome measure, adverse events, and the acceptability of SCT.

What are the key findings?

- Follow-up rate, adherence to most outcomes, and acceptability to SCT were judged to be feasible
- The tampon test is suboptimal as a primary outcome in PVD
- The feasibility of the recruitment was below the expected level

What are the implications of the findings for the design of the main study?
The findings suggest that it is feasible to deliver full-scale RCT of the SCT intervention in this population, with some adjustments to the protocol:

- Include additional recruitment sites to optimize recruitment
- Replace the tampon test with the Female Sexual Function Index as a primary outcome
- Include a booster session 6 months post-treatment

Background

Vulvodynia is a multifactorial vulvar pain condition of unknown cause. In the general population, the lifetime prevalence of vulvodynia is estimated between 7 and 16% [1–3] with a higher incidence amongst young women [4, 5]. Although prevalent, vulvodynia is a neglected women's health condition, where empirically supported treatment guidelines are still lacking [6]. The most common subtype of vulvodynia is provoked vestibulodynia (PVD) [7]. In PVD, pain is localized to the vulvar vestibule and is provoked by touch or pressure such as sexual intercourse and tampon insertion. This pain condition represents the most common cause of painful intercourse [7, 8], adversely affecting women's quality of life [9–12], psychological health [13, 14], and relation to their partners [15].

The management of PVD is complex and challenging with several treatments available, including pharmacotherapy, surgical, physiotherapy, and psychotherapy. Research evidence, however, is scarce regarding which treatment approach is the most effective. Although physiotherapy is a common first-line treatment for PVD, a systematic review highlighted the need for well-designed randomized controlled trials [16]. Traditionally, physiotherapy treatments for PVD range from internal (vaginal) to external soft tissue mobilizations, joint manipulation, electrotherapy, therapeutic exercises, and pelvic floor exercises [17]. A recent multicenter randomized clinical trial (RCT) also found multimodal physiotherapy to be effective in the management of PVD [18].

Somatocognitive therapy (SCT) is an existing multimodal physiotherapy intervention developed at Oslo University Hospital, Norway, in an attempt to alleviate the burden of longstanding pelvic and gynecological pains [19–21]. In recent years, SCT has been modified and further developed to treat women with PVD, based on experiences from a pilot study [22], from PVD patients [23], and physiotherapy students treating PVD patients [24]. Whereas multimodal physiotherapy treatments are usually provided by physiotherapists specialized in women's health, SCT is intended to be implemented in primary care and designed to be easy to learn. Furthermore, this approach differs from other forms of physiotherapy for PVD by focusing somewhat less on pelvic floor rehabilitation. SCT is designed to target the multiple dimensions of vulvar pain utilizing a biopsychosocial approach, where the overall aim is to explore and improve body awareness, reduce vulvar pain, and improve sexual function. Other essential components include cognitive strategies to improve coping with negative emotions and thoughts and structured exposure to pain-associated activities. In a recent systematic review on psychosocial factors, a broader approach to PVD was supported [25].

The primary aim of this **pro**voked **lo**calized **ve**stibulodynia (ProLoVe) feasibility study is to assess the feasibility of undertaking a full-scale RCT of the SCT intervention for women with PVD. In the full-scale RCT, SCT will be compared to standard PVD treatment, of which the latter can include women's health physiotherapy, topical or oral medication, sex therapy, and/or psychological counseling. The main feasibility objectives will evaluate the recruitment rate, the follow-up rate, adherence to the data collection procedure, and number of adverse events. In addition, this study will evaluate the tampon test [26] as a primary outcome measure in preparation for the main trial. The secondary aim is to evaluate the implementation and

acceptability of the intervention for the participants and to assess if SCT has the potential to reduce pain, pain catastrophizing, and psychological distress, as well as improve sexual function.

Methods

Study design and procedure

This is a multimethod feasibility study with a single-arm before-after trial and qualitative interviews. Ten participants, aged 18–33, were recruited (from February to April 2019) from the Vulva Clinic, Department of Obstetrics and Gynecology, at Oslo University Hospital (OUH)). The SCT intervention took place in the outpatient clinic at the Department of Physiotherapy at Oslo Metropolitan University. The trial consisted of three evaluation points: pre-treatment, post-treatment, and 8 months of follow-up. In addition, the participants were interviewed twice; towards the end of the treatment period and 1 year later.

Participant's eligibility assessment was based on a comprehensive gynecologic examination and medical history, using a standardized protocol for PVD diagnosis [27]. Norwegian-speaking women, aged 18–35, diagnosed with PVD, experiencing pain during (1) penetrative intercourse, (2) pressure applied to the vulvar vestibule, or (3) usage of tampons, were eligible. Patients with an active infection or dermatologic disease in the vulvar region were excluded. Eligible patients were verbally informed about the study and received an information leaflet at the Vulva Clinic. Ten out of 18 eligible women contacted the primary investigator (last author) and received a detailed explanation about the study. All ten agreed to participate. Eight women, however, did not contact the primary investigator and the reasons for this are unknown. The flow of participants through the study is presented in Fig. 1. This study is not intended to be fully powered for the detection of statistically significant effects. The research team therefore decided that ten participants would be an adequate sample size to give a preliminary understanding of the feasibility of undertaking a RCT of the SCT intervention. In the design of the feasibility study, a priority was to interview the participants twice, hence this was one of the reasons we recruited only 10 participants.

Research ethics

The Regional Committee for Medical and Health Research Ethics in South East Norway (ref. no. 2018/1036, 01.10.18) approved the project. The trial

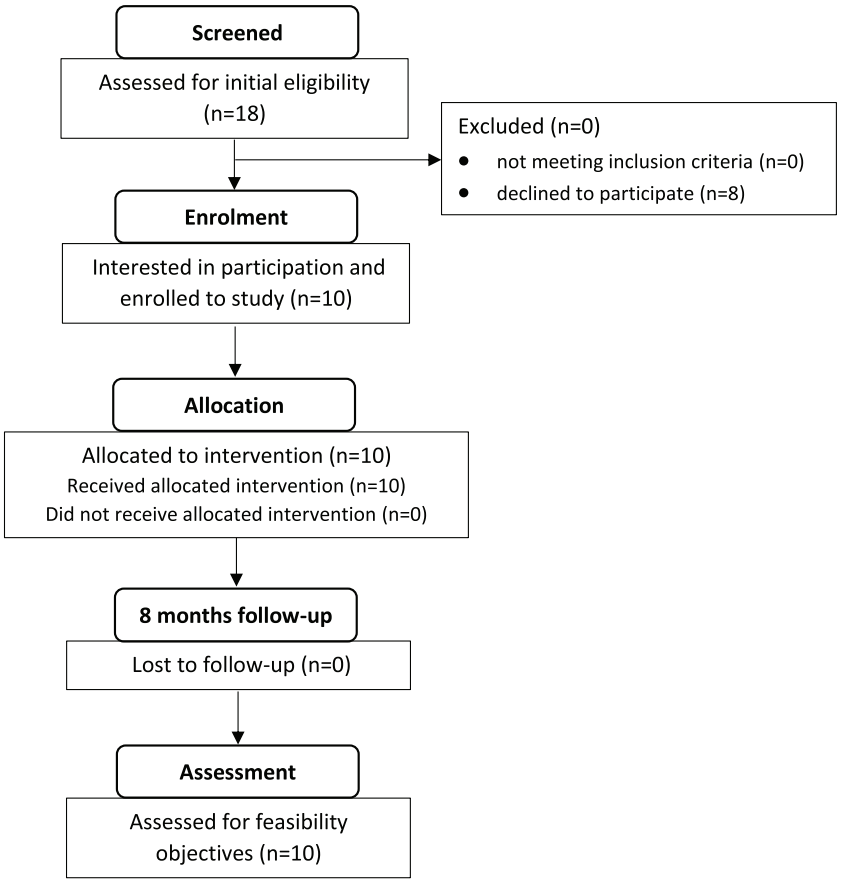

Fig. 1 CONSORT 2010 flow diagram. Design and flow of participants through the study

was also registered at ClinicalTrials.gov under the identifier NCT04208204. All participants provided written informed consent prior to participation in this research. The trial is reported according to the Consolidated Standards of Reporting Trial (CONSORT) 2010 statement: extension for pilot/feasibility studies (Additional file 1) [28].

Data collection

All quantitative data were collected via electronic forms and directly transferred in a secured manner to the Services for Sensitive Data (TSD) research server. Qualitative interviews were recorded with Dictaphone app, which insured immediate and direct transfer of the files to the TSD research server. The qualitative data collected through interviews was transcribed verbatim and uploaded into NVivo 12.

The patients received several electronic assessment packages throughout the study. There were three main assessment time points, baseline, post-treatment, and at 8 months of follow-up.

Assessment packages at baseline, post-treatment, and 8 months of follow-up

Assessment package 1

The participants received an electronic link to the main questionnaire package, which included sociodemographic and clinical characteristics and a battery of self-reported questionnaires such as Female Sexual Function Index [29], Pain Catastrophizing Scale [30], and Hopkins Symptom Check List-25 [31, 32]. The details of these measures are included in Additional file 2. Information about age, number of children, relationship status, education, work status, use of analgesics, body mass index, exercise, and intercourse frequency in the last 4 weeks was collected at baseline.

Assessment package 2

The baseline tampon test was undertaken in the evening on days 1, 7, and 14 to measure vulvar pain intensity using the numeric rating scale (NRS) (0–10), where a score of zero represented no pain and 10 meaning the worst possible pain.

Assessment package 3

A 14-day diary [33], an *index of emotional instability*, to assess day to day variance in emotional states.

Registration of received treatment

Assessment package 4

Participants received bi-weekly electronic forms up until the 8 months of follow-up recording all treatments received for PVD in the past 14 days. This included all visits to various health professionals, use of medication, and number of sick leave days. In the full-scale RCT, this information will be used to determine what kind of treatments the participants will be receiving and to conduct a cost-effectiveness analysis.

Tampon test as a primary outcome measure

One of the aims of this feasibility study was to evaluate the tampon test as the primary outcome measure. The tampon test was chosen as a primary outcome based on recommendations for self-report outcome measures in vulvodynia clinical trials [34]. This test has been used as a primary outcome measure in various clinical trials for vulvodynia, evaluating the effect of various treatments [35–41]. It is an alternative measure for pain associated with vulvovaginal penetration and allows the inclusion of women with PVD who are unable to have intercourse. The test has demonstrated good construct validity and reliability [26]. In this study, all women were provided with the same type of tampon as the validity study, the original Regular Tampax^{TM} Tampons [26]. Participants were provided with detailed instructions about how to undertake and record the tampon test, as described by Foster et al. (2009). The participants recorded the degree of pain on the entire tampon insertion and removal experience on the NRS.

Qualitative interviews

All participants were interviewed one-to-one towards the end of the treatment period. Seven of the women also agreed to take part in a follow-up interview 1 year later. A phenomenological worldview informed the qualitative approach, where the aim was to explore and give voice to the subjects' perspectives and lived experiences [42]. The second author, a female physiotherapist experienced with qualitative interviews, conducted the interviews and was not involved in the delivery of the treatment. During the first round of interviews, each interview took place in the physiotherapy outpatient clinic at Oslo Metropolitan University. The second interview round was conducted using Zoom, a video meeting platform, due to COVID-19 restrictions. Each interview lasted 60–90 min. A semi-structured interview guide was used to ensure each area of interest was addressed during the interviews, while at the same time encouraging the women to speak freely about their experiences [42]. The interviewer introduced the central topics with open-ended questions, asking the participants to share their experiences with the outcome measures and their experiences with SCT. To elicit rich descriptions, the interviewer tried to follow up salient cues and themes in the participants' answers, inviting them to elaborate, provide examples, or clarify where appropriate. The interviewer was on the lookout for

variations, different angles, and conflicting viewpoints, to promote a nuanced data material [42].

Intervention

In recent years, SCT has been developed to treat women with PVD [22–24, 43, 44]. SCT is a multimodal physiotherapy treatment approach previously shown to be effective in the treatment of chronic pelvic pain [19–21]. In Table 1, an overview of the intervention is presented as it was provided in this trial, utilizing the template for intervention description and replication TIDierR [45]. The intervention was conducted by the first author, an experienced female physiotherapist trained in SCT.

Study outcomes

Primary feasibility outcomes

The primary aim of this study was to evaluate the feasibility of undertaking a full-scale RCT of SCT for women with PVD. This trial measured several feasibility outcomes in preparation for the main trial. These included the following:

- **Recruitment rate**. This was defined as the number of eligible patients and number of recruited participants per week, within a period of 5 months.
- **The follow-up response rate**. This was measured by the percentage of participants who were followed up successfully until the 8 months of follow-up.

Table 1 Overview of somatocognitive therapy as provided in the feasibility study, as per TIDierR criteria

TIDierR items [45]	Description
Brief name	Somatocognitive therapy for provoked localized vestibulodynia (ProLoVe feasibility study)
Why	Few RCTs exist, important to develop effective treatments that can easily be applied in primary care. Running a feasibility study is important in preparation for full-scale RCT.
What	SCT is a multimodal physiotherapy intervention designed to target the multiple dimensions of vulvar pain, utilizing a biopsychosocial approach. A bodily approach is combined with a cognitive restructuring of negative thoughts. Overall, the aim is to improve body awareness to reduce vulvar pain and psychological distress and improve sexual function.
Materials: Participants	Resources: vulva.no
Materials: Physiotherapist	Equipment included a treatment bench, mat, pillows, massage balls, mirror, Pilates ball, and educational material.
Procedures	Initial appointment: Assess participant—take a thorough history (including previous experiences, beliefs, and expectations) and clinical examination (quality of movement, breathing pattern). The main areas of SCT include the following: ***Therapeutic alliance*** is an essential component of SCT; patient and therapist are in a close working relationship, agreeing on treatment goals and home assignments. Participants take an active part in the decision-making process about their own treatment and progression. ***The bodily approach:*** breathing patterns, maladaptive movement, and postural patterns are addressed in various positions (sitting, standing, walking, and in supine). Through manual techniques and touch, participants are taught various techniques to increase body awareness, improve relaxation, and reduce muscle tension. ***Education*** about PVD, chronic pain, stress, and healthy vulvo–vaginal and sexual behaviors. ***Coping*** with emotions and thoughts related to bodily experiences. Participants learn to become aware of negative/catastrophizing thoughts and learn how to restructure or accept these thoughts as well as how to overcome fear avoidance behavior. An important aspect is the women's ability to adapt and to self-manage their condition such as coping with pain and flare-ups. ***Structured homework*** promoting the application of learned techniques in daily situations. Gradual exposure to activities associated with pain, desensitization exercises, and exercises to increase the pelvic floor and vulva awareness. Relaxation and breathing exercises. Last session—create a self-management toolbox with participant
Who provides	Experienced female physiotherapist trained in SCT, the first author of the article.
How	Each session has a three-phased structure: (1) The conversation, (2) the bodily intervention/exploration, and (3) the home assignment.
Where	In a closed room with access to the gym, outpatient physiotherapy clinic, Oslo Metropolitan University, Norway Home assignments performed by the participants integrated into ADL
When and how much	Initial appointment offered to patients after collection of baseline data. The median number of sessions: 12 (min 7; max 15) face to face with a physiotherapist Treatment period: minimum of 13 weeks and maximum of 22 weeks. Each session (including the initial session) lasted up to 60 min. The number of sessions required was personalized.
Tailoring	The treatment is personalized and tailored to the individual. The patient's participation and collaboration are important. The treatment principles are the same for all but are adapted to suit the individual's needs.

- **Adherence to completion of outcomes**. Adherence was defined as the number of participants who fully completed the battery of self-reported questionnaires, the 14-day diary, the number of performed tampon tests, and biweekly forms about the received treatment, within a time frame of 8 months.
- **Evaluation of the utility value of the tampon test** as a primary outcome measure based on tampon test data and the participants' experiences with the tampon test (reported in separate mixed methods study [46].)
- **Reporting of adverse events**. Events were recorded as adverse if participants were withdrawn from the study because SCT was deemed as an inappropriate treatment.

Secondary outcomes

The secondary aim of this study was to test the implementation and acceptability of the somatocognitive intervention, utilizing both quantitative and qualitative data. The 6-point Global Perceived Effect (GPE) scale was used to provide quantitative estimation of participants' perceived effect with the treatment directly after treatment and at the 8 months follow-up [47]. The participants were asked "Overall, how much did the treatment you received help your problems?". The scale ranges from one to six; very much better, much better, a little better, no change, much worse, and very much worse. During the semi-structured interviews, participants were asked about their experiences with SCT intervention, both towards the end of the treatment period and 1 year later. In addition, the aim was to evaluate if SCT has the potential to reduce pain, pain catastrophizing, and psychological distress, as well as the potential to improve sexual function. A description of the self-reported outcome measures is provided in Additional file 2.

Data analysis

For the feasibility analysis, the results will be expressed as numbers referring to recruitment rate, follow-up, adherence, and adverse events, respectively. Descriptive statistics were used to assess the feasibility objectives and the self-reported outcomes using SPSS (version 27, IBM, Armonk, NY, United States of America) and Microsoft Excel (2016). Due to the nature of a feasibility study and the low number of participants, no hypothesis testing was performed, hence the continuous variables were presented with median and quartile values.

In the qualitative phase, a semantic thematic analysis was performed by the interviewer [48]. Attentive reading and re-reading of the transcripts helped to discern central aspects in the women's experiences and initial codes were identified. Taking care to include both common and diverging experiences, these initial codes were then reworked and organized into a map of themes and subthemes, related to experiences with outcome measures, the somatocognitive intervention, and perceived benefits (included in Additional file 3). The first and second author independently reviewed and revised the map for validity against the dataset until an agreement between the authors was reached. The findings are presented as analytical summaries and illustrative quotes, which are fitted under relevant subheadings in the results section. All co-authors took part in the discussion of the final findings.

Results

Ten nulliparous women with PVD, the median age of 21 (18 to 33), participated in this feasibility study. The sociodemographic and clinical characteristics of the participants are presented in Table 2. Seven of the women reported different comorbidities including jaw pain, muscle pain and twitching, anal pain, endometriosis, headache, migraine, fibromyalgia, irritable bowel syndrome, and alopecia areata. Overall, the women were physically active, exercising from one to three times per week for 30–60 min at moderate to high-intensity levels. Only one reported never exercising. At baseline, four subjects were

Table 2 Sociodemographic and clinical characteristics of ten women with provoked vestibulodynia

Characteristics	Participants *n*=10
Age *(years)*, median (Q1; Q3)	21 (20; 26)
Pain duration *(years)*, median (Q1; Q3)	7 (3; 8)
Primary PVD	7
Relationship category	
Married/common law	2
In a relationship	2
Single	6
Childbirth	0
Intercourse past 4 weeks	2
Education category	
High school student	1
Undergraduate student	7
Completed bachelor's degree	2
Work category	
Student	9
Part-time work	5
Full-time work	1
Unemployed	0
Participants with comorbidities	7
BMI, median (Q1; Q3)	23 (20; 23)

on oral contraceptives; one on cerazette, one on marvelon, and two on oralcon. In terms of concurrent drug use, all participants reported to have tried topical lidocaine. At baseline, six patients used topical lidocaine on a weekly to daily basis. In addition, one participant was on systemic treatment with amitriptyline, another on levothyroxine, and one on diclofenac.

Results of feasibility outcomes

Recruitment rate

Eighteen women were found eligible for participation, and ten women contacted the primary investigator, agreeing to take part in the study. Ten participants were recruited over 11 weeks from the Vulva Clinic, achieving a recruitment rate of one participant per week. Recruitment was stopped when the targeted sample of ten participants was reached.

Follow-up rate

No participants were lost to follow-up. All the participants completed the SCT intervention, and all partook at all measurement time points up until the 8-month follow-up.

Adherence to assessment procedures

Overall adherence to the battery of self-report questionnaires was excellent, with all participants completing all the self-reported questionnaires at all three time points. In terms of adherence to the tampon tests across the three measurement time points, 81 out of 90 tampon tests were completed (90%). At baseline, there were nine full tampon test sets. At post-treatment, there were eight full tampon test sets and at the 8-month follow-up, there were six full tampon test sets. For the 14-day diary, there were six full data sets at baseline, three post-treatment, and two at the 8-month follow-up. Regarding adherence to the bi-weekly forms about received treatments, two women did not record any of the SCT treatments; however, all the other treatments received were recorded.

Evaluation of the tampon test as the primary outcome measure

Evaluation of the tampon test is reported in a separate paper [46]. We concluded that the test may be suboptimal as a primary outcome measure in PVD research. The tampon test data demonstrated large intra- and inter-individual variability; furthermore, the test seems to underestimate the severity of pain in some women with PVD. Out of ten women with PVD, four of the women had an NRS score that was equal to, or below four, whilst concurrently reporting high levels of pain during sexual intercourse. Participants with low pain scores would be excluded from studies where the tampon test is part of the trial eligibility criteria, even though severe pain was experienced during sexual intercourse. Several women also reported in the interviews that they experienced the test as an inadequate measure of their problem [46].

Reporting of adverse events

There were no adverse events reported, that is no participants were withdrawn from the study because SCT was considered as an inappropriate treatment. All participants turned up for their scheduled appointments and completed the intervention.

Results of secondary outcomes

Implementation and acceptability of somatocognitive therapy

In this study, the participants received a median number of 12 sessions. The SCT was personalized, hence the number of treatments delivered varied from seven up to a maximum of 15 sessions. In the original protocol, we stipulated that treatment duration would last for up to ten weeks. In this study, the treatment course lasted a minimum of 13 weeks and a maximum of 22 weeks. The frequency of the treatment delivery varied as it was personalized to the individuals' needs. Patients communicated to the therapist that they needed time to practice home assignments and incorporate what they had learned into their ADL. The frequency of treatment was also influenced by external factors, such as study and work commitments, exams, and holidays.

Half of the participants were content with the number of treatment sessions received and felt ready to continue by themselves when the treatment period ended. The other half reported that they would have preferred a slightly longer treatment period. Several found it more difficult to keep motivated to prioritize their recovery process when their progress was no longer monitored by the therapist. *P8:* "Immediately after the treatment period ended it felt a bit tough. You receive such close guidance, and then you are suddenly alone with it again. I found it a bit difficult to keep my motivation up". Most felt they would have benefited from one or two follow-up sessions a few months later, for repetition, motivation, and guidance on how to move forward. *P3:* "Perhaps it could have been possible with a follow-up session six months later, in case things should get worse or you need some repetition, or when things have just been a little too much."

Participants' perceived effect of SCT

The GPE scale was used to provide quantitative estimation of participants' perceived effect of the treatment measured directly after treatment and at 8 months of follow-up. Directly after treatment, three women reported to be *very much better*, four *much better*, and three *a*

little better. At 8 months of follow-up, one participant reported to be *very much better*, six participants reported *much better*, two reported *a little better*, and one reported *no change*.

Participants' experiences with the intervention

All participants expressed positive experiences with the SCT approach. They found it useful to learn techniques for deep breathing, relaxation, and self-management, as well as developing more constructive ways of thinking about and relating to their pain and sexuality. The participants largely expressed beliefs that PVD is complex and multidimensional in nature. They found it meaningful to combine physical and psychological aspects and not exclusively focus on the painful vulvar area. *P3:* "I feel that somatocognitive therapy is more focused on the long-term recovery process. That it is easier to get lasting results when you not only treat the local muscles or problem area, but also include everything else around". Furthermore, the importance of taking responsibility for their own recovery process was expressed by P6: "It makes so much sense that this is what I have to do. Not just talk about it and not just receive massage here or there. I have to make an active effort. Breathe. I have to relax". Three participants however (P2, P7, and P9), felt the intervention would have benefitted from a specific focus on the vulvar area, including manual techniques to release tensions in the pelvic floor muscles. Most of the participants however appreciated the gentle and desensitizing approach to the vulva. Several women also expressed that the encouragement to explore their own vulvas had helped them develop a more positive way of relating to this area. *P4*: I feel like I have made great improvements, as before my vulva felt very unfamiliar, I just didn´t want to think about it. But now I actually feel that I have developed a completely different way of thinking about it and how it also is about being less afraid of the area".

The secondary aim of this study was to evaluate if SCT intervention had the potential to improve sexual function and reduce pain, pain catastrophizing, and psychological distress. The women improved on all the outcome measures from baseline to post-treatment, with a slight deterioration of the effect at the 8-month follow-up. Table 3 includes all the measurements and number of participants who had experienced intercourse in the past 4 weeks, at the three time points.

Discussion

This study was designed to assess the feasibility of running a full-scale RCT of the SCT intervention for women with PVD. In addition, the implementation and acceptability of SCT were evaluated, including its potential as a treatment for PVD. The current study demonstrated that the study was feasible with respect to follow-up rate and adherence to the assessment outcomes. We would argue that the intervention was acceptable based on Global Perceived Effect scores, the participants' experiences with the intervention, and the changes seen on the outcome measures. No adverse effects were reported. Based on the feasibility findings, a few changes are suggested to optimize the protocol. In the following section, the feasibility outcomes and secondary outcomes will be interpreted and further discussed.

In terms of recruitment for the study, ten out of 18 patients were recruited over 11 weeks from one site,

Table 3 Measurements at baseline, post-treatment, and 8 months of follow-up (n=10), (none lost to follow-up)

	Pre-treatment	Post-treatment	8 months of follow-up
Tampon test NRS (0-10), median (Q1; Q3)	4.5 (2.5; 6)	2 (1.5; 4.2)	3.5 (1.8; 4.5)
Intercourse past 4 weeks, n	2	6	7
FSFI, median (Q1; Q3)			
Total sum (0–36)	14.8 (9.8; 19.8)	22.8 (15.8; 25.4)	20.9 (18; 27.1)
Desire	2.1 (1.6; 3.2)	3.6 (2.3; 3.8)	3.6 (2.7; 4.3)
Arousal	3.2 (1.6; 4.9)	4.4 (2.7; 5.7)	4.4 (3.0; 5.6)
Lubrication	4.2 (2.9; 5.2)	4.8 (3.5; 5.8)	4.7 (3.6; 6.0)
Orgasm	3.2 (0.9; 5.3)	4.8 (2.6; 5.3)	4.8 (1.2; 5.2)
Satisfaction	0.8 (0.4; 2.0)	4.2 (1.1; 5.2)	3.8 (1.2; 5.3)
Pain	0.0 (0.0; 0.3)	1.8 (0.0; 3.6)	2.0 (0.0; 3.6)
PCS (0–52), median (Q1; Q3)	20 (15.3; 29.3)	9.5 (5.3; 20)	12.5 (6.3; 22)
HSCL-25, median (Q1; Q3)	2.0 (1.7; 2.5)	1.6 (1.3; 2.4)	1.8 (1.6; 2.2)

NRS Numerical Rating Scale (higher scores indicate more pain), *FSFI* Female Sexual Function Index (higher scores indicate better sexual function), *PCS* Pain Catastrophizing Scale (higher scores indicate higher levels of catastrophizing, *HSCL-25* Hopkins Symptom Check List - 25 (higher scores indicate higher levels of psychological distress)

achieving a recruitment rate of one participant per week. In the planned future RCT, we aim to recruit 130 patients. Power analysis suggests that 128 participants, split equally between the study arms, will be enough to show the between-group difference in the total score on the primary outcome, Female Sexual Function Index (FSFI), at the 12 months of follow-up of at least three points (sd = 6.0). We will use $\alpha = 0.05$ and $1\text{-}\beta = 0.8$. In this feasibility study, we recorded an average improvement of six points on the FSFI in the course of 8 months in patients treated with SCT. To run a fully powered RCT with 130 patients, recruited in approximately 24 months, we will have to expand recruitment sites to other gynecologists experienced with PVD located at various clinics in the Oslo area.

Feasibility outcomes related to follow-up rate and adherence were overall satisfactory. No participants were lost to follow-up, and adherence to completion of the battery of self-reported questionnaires was excellent, with all ten participants fully completing the questionnaires. We demonstrated good adherence to the tampon test, with 81 out of 90 tampon tests completed (90%). Most of the missing tampon test data occurred at 8 months of follow-up. The 14-day diary, however, the *Index of emotional instability*, which was used to measure day-to-day variance in emotional states, had high levels of missing data. At the 8-month follow-up, there were only two complete 14-day diary sets, hence the diary will not be included in the main trial. During the interviews, many women found the diary time-consuming and difficult to remember, and for some, it also felt irrelevant. Adherence to the reporting of received treatment was satisfactory with eight full sets at the 8-month follow-up. Two women did not record any of the physiotherapy treatments received, possibly due to a misunderstanding as all the other treatments they had received had been recorded.

A further aim with this study was also to evaluate the feasibility of using the tampon test as a primary outcome measure. Many women with PVD abstain from penetrative intercourse and have difficulties with reporting pain. The tampon test was therefore chosen as a primary outcome measure as it was specifically designed to address this challenge [26]. Based on the tampon test data and the participants' experiences with the test and input from a user representative, we concluded in a separate paper [46] that the tampon test is suboptimal as a primary outcome measure in PVD research. Therefore, in the upcoming RCT, the primary outcome measure will be the Female Sexual Function Index (FSFI), while the tampon test will be applied as a secondary outcome. FSFI is widely used in PVD research [18, 49, 50]. In addition to pain experienced during intercourse, it captures several other dimensions of sexual functioning. In this study, the participants improved on average by 7.9 points (from 14.8 to 22.7 post-treatment) and 6.1 points (from 14.8 to 20.9) at the 8-month follow-up, when accounting for all subscales on the FSFI. We observed a very similar magnitude of changes on all subscales, which conforms to the notion of a multidimensional nature of this disorder. In preparation for the upcoming main trial, the choice and implementation of outcome measures, including the FSFI, will be based on the findings from this feasibility study and *Recommendations for the study of vulvar pain in women, part I: review of assessment tools* [51].

Overall, we would argue that SCT is an acceptable and promising intervention. These findings are in line with previous studies evaluating the effect of SCT for women with chronic pelvic pain [19–21] and women with PVD [22]. SCT is designed as a short-term therapy where one of the goals is to promote self-management of PVD and avoid over-treatment and therapist-dependency. Although approximately half the women were satisfied with the amount of treatment received, some expressed that the treatment ended too soon and described how a booster session would be valuable. This would provide an opportunity to receive support and guidance over time. Consequently, in the future RCT, the participants will be offered one booster session of 6 months after the end of the treatment.

Participants' perceived effect was measured with the GPE and was further supported by the qualitative interviews, with most women reporting a variety of improvements following the SCT intervention. In terms of pain reduction, most women described a recovery process characterized by periods of improvements and setbacks, but overall experienced a positive development. Meaningful changes also included improved body awareness; an improved ability to relax, feel more connected, and be comfortable in their own bodies. Several of the participants also described how the intervention had helped them develop a more neutral and less fearful way of thinking about their pain, which was also supported by the findings on the pain catastrophizing scale. Furthermore, the women had gained more healthy attitudes and strategies regarding their sexuality and some felt more confident involving their romantic partner in the recovery process.

This study allows us tentatively to assess the effectiveness of the intervention in a small sample of participants. This study was not powered to detect changes over time and results should therefore be interpreted with caution. Albeit, all outcome measures pointed in the same direction, as the participants improved on the primary outcome, i.e., the tampon test, and all the secondary outcomes in the main questionnaire packet following SCT. The results indicate that the intervention has potential

treatment effectiveness in a small sample of participants with PVD.

A limitation of this study was the small sample size, as it is challenging to compute precision around estimates for recruitment, follow-up, and adherence with such small numbers. A further limitation of this study was the lack of an active control group. In the main trial, SCT will be compared to standard treatment, hence the design of this study does not match the design of the future study. We therefore lack information regarding the participants' willingness to be randomized to either the intervention or the control group. A control group could also have provided us with valuable information about the treatments delivered in this group, as well as the feasibility of the randomization process, including the follow-up rate. The strength of this study is that both quantitative and qualitative methods were implemented to evaluate the feasibility and acceptability of SCT.

Conclusion

We conclude that it is feasible and practical to deliver a RCT of SCT, a multimodal physiotherapy intervention, in women with PVD. The aims of the feasibility study have been met. Some changes, however, are suggested to optimize the study protocol, before conducting a full-scale RCT. This includes replacing the tampon test with the FSFI, increasing the recruitment sites, and adding a booster session.

Abbreviations

FSFI: Female Sexual Function Index; HSCL-25: Hopkins Symptom Check List – 25; NRS: Numeric Rating Scale; PCS: Pain Catastrophizing Scale; PVD: Provoked vestibulodynia; RCT: Randomized clinical trial; SCT: Somatocognitive therapy.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40814-022-01022-2.

Additional file 1. Consort 2010 checklist.

Additional file 2. Patient reported outcome measures.

Additional file 3. An overview of the analytical process, moving from the preliminary themes to the main theme.

Acknowledgements

We would like to thank all the patients who participated in this study.

Authors' contributions

GKH, ALOH, and SW conceptualized and designed the study. Acquisition of data was performed by MBK, KGD, ALOH, and SW. MBK and KGD analyzed and interpreted the data. MBK drafted the manuscript, and KGD, GKH, ALOH, and SW revised the manuscript for intellectual content. The authors read and approved the final manuscript.

Funding

Funding from Oslo Metropolitan University and the Norwegian Fund for Post-Graduate Training in Physiotherapy. The funding bodies had no role in the design of the study and collection, analysis, and interpretation of data or the writing of the manuscript.

Availability of data and materials

Anonymized individual-patient datasets are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The Regional Committee for Medical Research Ethics in South East Norway (ref. no. 2018/1036) approved the project before the trial began. All patients gave their written informed consent after being provided verbal and written information. The trial adheres to the Declaration of Helsinki.

Consent for publication

Consent to publish results were obtained from all participants.

Competing interests

The authors declare that they have no competing interests.

Author details

[1]Faculty of Health Sciences, Department of Physiotherapy, Oslo Metropolitan University, Oslo, Norway. [2]Unit for Psychosomatics/CL Outpatient Clinic for Adults, Acute Psychiatric Department, Division of Mental Health and Addiction, Oslo University Hospital, Oslo, Norway. [3]Department of Obstetrics and Gynecology, Oslo University Hospital, Oslo, Norway. [4]Department of Dermatology, Oslo University Hospital, Oslo, Norway. [5]Cognitive Health Research group, Department of Neurology, Division of Clinical Neuroscience, Oslo University Hospital, Oslo, Norway.

Received: 25 June 2021 Accepted: 4 March 2022
Published online: 23 March 2022

References

1. Harlow BL, Kunitz CG, Nguyen RH, Rydell SA, Turner RM, MacLehose RF. Prevalence of symptoms consistent with a diagnosis of vulvodynia: population-based estimates from 2 geographic regions. Am J Obstet Gynecol. 2014;210(1):40.e1–8.
2. Gomez I, Coronado PJ, Martin CM, Alonso R, Guisasola-Campa FJ. Study on the prevalence and factors associated to vulvodynia in Spain. Eur J Obstet Gynecol Reprod Biol. 2019;240:121–4.
3. Vieira-Baptista P, Lima-Silva J, Cavaco-Gomes J, Beires J. Prevalence of vulvodynia and risk factors for the condition in Portugal. Int J Gynecol Obstet. 2014;127(3):283–7.
4. Reed BD, Legocki LJ, Plegue MA, Sen A, Haefner HK, Harlow SD. Factors associated with vulvodynia incidence. Obstet Gynecol. 2014;123(2 Pt 1):225–31.
5. Clare CA, Yeh J. Vulvodynia in adolescence: childhood vulvar pain syndromes. J Pediatr Adolesc Gynecol. 2011;24(3):110–5.
6. Bergeron S, Reed BD, Wesselmann U, Bohm-Starke N. Vulvodynia. Nat Rev Dis Primers. 2020;6(1):36.
7. Sadownik LA. Etiology, diagnosis, and clinical management of vulvodynia. Int J Women's Health. 2014;6:437–49.
8. Basson R, Driscoll M, Correia S. When sex is always painful: provoked vestibulodynia. BCMJ. 2016;58(2):77–81.
9. Desrochers G, Bergeron S, Khalife S, Dupuis MJ, Jodoin M. Fear avoidance and self-efficacy in relation to pain and sexual impairment in women with provoked vestibulodynia. Clin J Pain. 2009;25(6):520–7.
10. Xie Y, Shi L, Xiong X, Wu E, Veasley C, Dade C. Economic burden and quality of life of vulvodynia in the United States. Curr Med Res Opin. 2012;28(4):601–8.
11. Benoit-Piau J, Bergeron S, Brassard A, Dumoulin C, Khalife S, Waddell G, et al. Fear-avoidance and pelvic floor muscle function are associated with pain intensity in women with vulvodynia. Clin J Pain. 2018;34(9):804–10.

12. Dargie E, Gilron I, Pukall C. Provoked vestibulodynia: a comparative examination of mental health, sleep, sexual functioning, and relationship adjustment. Clin J Pain. 2017;33(10):870–6.
13. Aikens JE, Reed BD, Gorenflo DW, Haefner HK. Depressive symptoms among women with vulvar dysesthesia. Am J Obstet Gynecol. 2003;189(2):462–6.
14. Nylanderlundqvist E, Bergdahl J. Vulvar vestibulitis: evidence of depression and state anxiety in patients and partners. Acta Derm Venereol. 2003;83(5):369–73.
15. Shallcross R, Dickson JM, Nunns D, Mackenzie C, Kiemle G. Women's subjective experiences of living with vulvodynia: a systematic review and meta-ethnography. Arch Sex Behav. 2018;47(3):577–95.
16. Morin M, Carroll MS, Bergeron S. Systematic review of the effectiveness of physical therapy modalities in women with provoked vestibulodynia. Sex Med Rev. 2017;5(3):295–322.
17. Polpeta NC, Giraldo PC, Teatin Juliato CR, Gomes Do Amaral RL, Moreno Linhares I, Romero Leal Passos M. Clinical and therapeutic aspects of vulvodynia: the importance of physical therapy. Minerva Ginecol. 2012;64(5):437–45.
18. Morin M, Dumoulin C, Bergeron S, Mayrand MH, Khalife S, Waddell G, et al. Multimodal physical therapy versus topical lidocaine for provoked vestibulodynia: a prospective, multicentre, randomized trial. Am J Obstet Gynecol. 2021;224(2):189.e1–189.e12.
19. Haugstad GK, Haugstad TS, Kirste UM, Leganger S, Wojniusz S, Klemmetsen I, et al. Posture, movement patterns, and body awareness in women with chronic pelvic pain. J Psychosom Res. 2006;61(5):637–44.
20. Haugstad GK, Haugstad TS, Kirste UM, Leganger S, Klemmetsen I, Malt UF. Mensendieck somatocognitive therapy as treatment approach to chronic pelvic pain: results of a randomized controlled intervention study. Am J Obstet Gynecol. 2006;194(5):1303–10.
21. Haugstad GK, Haugstad TS, Kirste UM, Leganger S, Wojniusz S, Klemmetsen I, et al. Continuing improvement of chronic pelvic pain in women after short-term Mensendieck somatocognitive therapy: results of a 1-year follow-up study. Am J Obstet Gynecol. 2008;199(6):615 e1–8.
22. Haugstad GK, Wojniusz S, Kirschner R, Kirste U, Lilleheie I, Haugstad TS. Somatocognitive therapy of women with provoked vulvodynia: a pilot study. Scand J Pain. 2019;19(4):725–32.
23. Groven KS, Raheim M, Hakonsen E, Haugstad GK. "Will I ever be a true woman?" an exploration of the experiences of women with vestibulodynia. Health Care Women Int. 2016;37(8):818–35.
24. Fougner M, Haugstad GK. Treating gynaecological pain: the experiences of bachelor students in physiotherapy performing somatocognitive therapy. Physiother Theory Pract. 2015;31(5):318–26.
25. Chisari C, Monajemi MB, Scott W, Moss-Morris R, McCracken LM. Psychosocial factors associated with pain and sexual function in women with vulvodynia: a systematic review. Eur J Pain. 2021;25(1):39–50.
26. Foster DC, Kotok MB, Huang LS, Watts A, Oakes D, Howard FM, et al. The tampon test for vulvodynia treatment outcomes research: reliability, construct validity, and responsiveness. Obstet Gynecol. 2009;113(4):825–32.
27. Stockdale CK, Lawson HW. 2013 vulvodynia guideline update. J Low Genit Tract Dis. 2014;18:93–100.
28. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239.
29. Rosen R, Brown C, Heiman J, Leiblum S, Meston C, Shabsigh R, et al. The female sexual function index (FSFI): a multidimensional self-report instrument for the assessment of female sexual function. J Sex Marital Ther. 2000;26(2):191–208.
30. Fernandes L, Storheim K, Lochting I, Grotle M. Cross-cultural adaptation and validation of the Norwegian pain catastrophizing scale in patients with low back pain. BMC Musculoskelet Disord. 2012;13:111.
31. Derogatis LR, Lipman RS, Rickels K, Uhlenhuth EH, Covi L. The Hopkins symptom checklist (HSCL): a self-report symptom inventory. Behav Sci. 1974;19(1):1–15.
32. Strand BH, Dalgard OS, Tambs K, Rognerud M. Measuring the mental health status of the Norwegian population: a comparison of the instruments SCL-25, SCL-10, SCL-5 and MHI-5 (SF-36). Nord J Psychiatry. 2003;57(2):113–8.
33. Rost S, Van Ryckeghem DML, Koval P, Sütterlin S, Vögele C, Crombez G. Affective instability in patients with chronic pain: a diary approach. Pain. 2016;157(8):1783–90.
34. Pukall CF, Bergeron S, Brown C, Bachmann G, Wesselmann U, Group VCR. Recommendations for self-report outcome measures in vulvodynia clinical trials. Clin J Pain. 2017;33(8):756–65.
35. De Andres J, Sanchis-Lopez N, Asensio-Samper JM, Fabregat-Cid G, Dolz VM. Peripheral subcutaneous vulvar stimulation in the management of severe and refractory vulvodynia. Obstet Gynecol. 2013;121:495–8.
36. Phillips NA, Brown C, Foster D, Bachour C, Rawlinson L, Wan J, et al. Presenting symptoms among premenopausal and postmenopausal women with vulvodynia. Menopause. 2015;22(12):1296–300.
37. Brown C, Bachmann GA, Wan J, Foster D. Pain rating in women with provoked vestibulodynia: evaluating influence of race. J Women's Health. 2016;25(1):57–62.
38. Brown CS, Bachmann GA, Wan J, Foster DC, Group GS. Gabapentin for the treatment of vulvodynia: a randomized controlled trial. Obstet Gynecol. 2018;131(6):1000–7.
39. Foster DC, Kotok MB, Huang LS, Watts A, Oakes D, Howard FM, et al. Oral desipramine and topical lidocaine for vulvodynia: a randomized controlled trial. Obstet Gynecol. 2010;116(3):583–93.
40. Guillet AD, Cirino NH, Hart KD, Leclair CM. Mindfulness-based group cognitive behavior therapy for provoked localized vulvodynia: a randomized controlled trial. J Low Genit Tract Dis. 2019;23(2):170–5.
41. Lev-Sagie A, Kopitman A, Brzezinski A. Low-level laser therapy for the treatment of provoked vestibulodynia-a randomized, placebo-controlled pilot trial. J Sex Med. 2017;14(11):1403–11.
42. Kvale S, Brinkman S. Det kvalitative forskningsintervju (interviews: learning the craft of research interviewing). 2nd ed. Oslo: Gyldendal Akademisk; 2009.
43. Danielsen KG, Dahl-Michelsen T, Hakonsen E, Haugstad GK. Recovering from provoked vestibulodynia: experiences from encounters with somatocognitive therapy. Physiother Theory Pract. 2019;35:219–28.
44. Haugstad GK, Wojniusz S, Kirste UM, Kirschner RS, Lilleheie I, Haugstad TS. Pain, psychological distress and motor pattern in women with provoked vestibulodynia (PVD) – symptom characteristics and therapy suggestions. Scand J Pain. 2018;18(2):221–7.
45. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348:g1687.
46. Kaarbø MB, Danielsen KG, Haugstad GK, Helgesen ALO, Wojniusz S. The tampon test as a primary outcome measure in provoked vestibulodynia: a mixed methods study. J Sex Med. 2021;18(6):1083–91.
47. Kamper SJ, Ostelo RW, Knol DL, Maher CG, de Vet HC, Hancock MJ. Global perceived effect scales provided reliable assessments of health transition in people with musculoskeletal disorders, but ratings are strongly influenced by current status. J Clin Epidemiol. 2010;63(7):760–6.e1.
48. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77–101.
49. Smith KB, Pukall CF, Chamberlain SM. Sexual and relationship satisfaction and vestibular pain sensitivity among women with provoked vestibulodynia. J Sex Med. 2013;10(8):2009–23.
50. Smith KB, Sadownik LA, Dargie E, Albert AYK, Brotto LA. Multidisciplinary treatment for provoked vestibulodynia. Clin J Pain. 2019;35(4):335–44.
51. Rosen NO, Bergeron S, Pukall CF. Recommendations for the study of vulvar pain in women, part 1: review of assessment tools. J Sex Med. 2020;17(2):180–94.

Publisher's Note

Overview of analytical process feasibility: Paper I

An overview of the analytical process, moving from the preliminary themes to the main theme.

Step 1 – Codes	Step 2 – Subthemes	Step 3 - Themes
Individual needs regarding session frequency and length of therapy Important with flexibility and tailoring Challenging to adjust from close follow-up to complete independency Experiencing ups and downs Difficult keeping up motivation after end of therapy Easy to slip back into old habits Booster session could be useful	Valuable that intervention dose and frequency is tailored to the individual Need for booster session	SCT implementation
Meaningful with a whole person approach Valuable to understand and experience how mind and body are connected Useful to learn techniques to handle pain, but also life in general, better Helpful with a gradual and desensitizing approach to the vulva, however some miss a more hands-on approach Pain reduction Improved awareness of and connection to the body More comfortable in the body Less fearful of vulva Better able to relax A new way of relating to the pain A more positive inner dialogue	A meaningful and educational approach Positive impact and change	SCT meaning and perceived benefits

Paper II

The tampon test as a primary outcome measure in provoked vestibulodynia: A mixed methods study

Kaarbø, M.B., Danielsen, K.G., Haugstad, G.K., Helgesen, A.L.O. and Wojniusz, S. 2021.The tampon test as a primary outcome measure in provoked vestibulodynia: A mixed methods study. *J Sex Med*, 18(6), 1083−1091. https://doi.org/10.1016/j.jsxm.2021.03.010

THE JOURNAL OF
SEXUAL MEDICINE

ORIGINAL RESEARCH & REVIEWS

PAIN

The Tampon Test as a Primary Outcome Measure in Provoked Vestibulodynia: A Mixed Methods Study

Mette Bøymo Kaarbø, MSc,[a] Kristine Grimen Danielsen, MSc,[a] Gro Killi Haugstad, PhD,[a,b] Anne Lise Ording Helgesen, MD, PhD,[c,d] and Slawomir Wojniusz, PhD[a,e]

ABSTRACT

Background: Provoked vestibulodynia (PVD) is characterized by severe pain, often induced by penetrative sex. This may lead to women abstaining from sexual intercourse, hence the recording of pain intensity levels in PVD research is often challenging. The standardized tampon test was designed as an alternative outcome measure to sexual intercourse pain and has frequently been used in clinical studies.

Aim: The aim of this mixed methods study is to evaluate the tampon test as a primary outcome measure for an upcoming randomized clinical trial for women with PVD.

Methods: An explanatory sequential design was applied, integrating quantitative and qualitative methods. In phase one, pain intensity levels were evaluated with the tampon test amongst 10 women, aged 18-33, with PVD. The test was repeated on day 1, 7 and 14. Pain intensity was rated on the Numerical Rating Scale (NRS), (0-10), 10 being worst possible pain. In phase two, the participants' experiences with the test were explored with semi-structured interviews using a descriptive and inductive qualitative design. All participants were recruited from the Vulva Clinic, Oslo University Hospital, Norway.

Outcomes: The tampon test data and interviews were brought together to see how the interviews could refine and help to explain the quantitative findings.

Results: The tampon test data demonstrated large intra- and inter-individual variability. Median tampon pain intensity was 4.5 (min=1.7; max=10; Q1=2.5; Q3=6). Many experienced the test as an inadequate representation of pain during intercourse as it was less painful, different in nature and conducted in an entirely different context. Four participants had a mean score of four or lower on the NRS, whilst concurrently reporting high levels of pain during sexual intercourse.

Clinical Implications: The findings indicate that the tampon test may underestimate severity of pain among some women with PVD. Participants with low pain scores would be excluded from studies where the tampon test is part of the trial eligibility criteria, even though severe pain was experienced during sexual intercourse. Large intra-individual variability in pain scores also reduces the test's ability to register clinical meaningful changes and hence necessitates repeated measurements per assessment time point.

Conclusion: Although the tampon test has many advantages, this study indicates several potential problems with the application of the test as a primary outcome measure in PVD. In our opinion the test is most useful as a secondary outcome, preferably undertaken repeatedly in order to increase precision of the pain estimation. **Kaarbø MB, Danielsen KG, Haugstad GK, et al. The Tampon Test as a Primary Outcome Measure in Provoked Vestibulodynia: A Mixed Methods Study. J Sex Med 2021;18:1083–1091.**

Key Words: Provoked Vestibulodynia; Vulvodynia; Vestibulitis; Tampon Test; Mixed Methods

Received December 18, 2020. Accepted March 17, 2021.

[a]Department of Physiotherapy, Oslo Metropolitan University, Oslo, Norway;

[b]Acute Psychiatric Department, Oslo University Hospital, Oslo, Norway;

[c]Department of Obstetrics and Gynecology, Oslo University Hospital, Oslo, Norway;

[d]Department of Dermatology, Oslo University Hospital, Oslo Norway;

[e]Department of Neurology, Oslo University Hospital, Oslo Norway

https://doi.org/10.1016/j.jsxm.2021.03.010

INTRODUCTION

Pain is a highly subjective phenomenon, modulated by social context, previous experience of pain, as well as psychological and biological factors. Due to its multifaceted and subjective nature estimating pain in a reliable and valid way is difficult, both in clinical practice and in research. This is especially the case in provoked vestibulodynia (PVD) which is a prevalent, but undertreated long lasting vulvar pain condition, representing the most common cause of painful intercourse.[1,2]

In PVD research, pain measurements are particularly challenging since pain is experienced upon provocation in a specific context, such as during sexual intercourse. In addition, some women may not engage in penetrative intercourse due to the lack of a partner, fear of pain, or previous medical recommendations.[3] Consequently, using intercourse pain as a primary outcome measure may be a challenge for recruitment, but also for data analysis and generalization of results.[4] An alternative method is to use the vulvalgesiometer or the tampon test as an outcome measure. The vulvalgesiometer standardizes the amount of pressure applied to the vestibule to quantify levels of sensitivity and is used primarily in research.[5] The tampon test on the other hand is self-administered. Pain is rated on the 11-point Numerical Rating Scale (NRS) from zero to 10, on the total tampon insertion and removal experience. The tampon test has previously been evaluated to be reliable and to have good construct validity and responsiveness for women with PVD [4]. The test has been used as a primary outcome measure in various clinical trials for vulvodynia ranging from case studies,[6] case series,[7] to several randomized clinical trials (RCTs).[8-12] Furthermore, the tampon test has been used as part of the trial inclusion process, where an average pain level of four, or greater, on the NRS has been required to fulfil the eligibility criteria.[9,10,13,14] Nevertheless, it is unknown if pain experienced during this test is proportional to, or representative, for the pain experienced during intercourse, or if such inclusion criteria may deprive some women with PVD from study participation. PVD women's experiences with the tampon test has, to our knowledge, not been previously studied. The aim of this study was therefore to evaluate the tampon test as a primary outcome measure in preparation for an upcoming RCT.

METHODS

Study Design

The data presented here are part of a preliminary study for an upcoming RCT. This coming trial will assess the effectiveness of a multimodal physiotherapy intervention versus treatment as usual in provoked localized vestibulodynia (ProLoVe project). In this mixed methods study we applied an explanatory sequential design (Figure 1). Tampon test data was collected first and these findings were subsequently used to guide the development of the interview protocol. In the final stages, tampon test data and interview findings were brought together to see how qualitative findings could help to explain the quantitative findings.[15]

Participants

Ten women with confirmed PVD were recruited from the Vulva Clinic, Department of Obstetrics and Gynecology, at Oslo University Hospital, Norway. Participant's eligibility assessment was based on a comprehensive gynecologic examination and medical history, using a standardized protocol for PVD diagnosis.[16] Patients were invited to participate in the study if they met the following inclusion criteria: 1) pain experienced during intercourse, pressure applied to the vulvar vestibule or usage of tampon; 2) aged between 18 and 35 and 3) fluent in the Norwegian language. Exclusion criteria included the presence of active infection or dermatologic lesion in the vulvar region. The same sample was used in the quantitative and qualitative phase of the study.

Procedure

The study was approved by the Regional Committee for Medical and Health Research Ethics in South East Norway (2018/1036), and registered at https://clinicaltrials.gov/ct2/show/NCT04208204 (NCT04208204). Data was collected in 2019.

At the Vulva Clinic, all eligible patients were verbally informed about the study and received an information leaflet. Those interested in study participation contacted the primary investigator, who invited them to a meeting at Oslo Metropolitan University for further information about the study. Eighteen patients were found eligible for participation between February and May 2019. Ten out of 18 patients contacted the primary

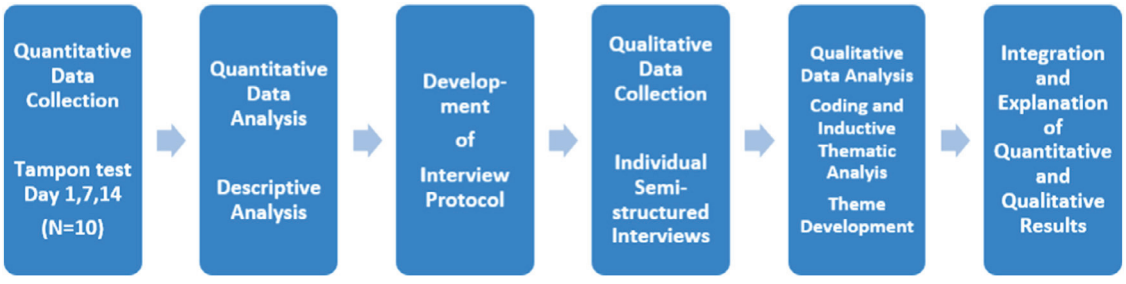

Figure 1. A diagram of the quantitative and qualitative phase and the procedures used in this explanatory sequential mixed methods study design. (Figure 1 is available in color online at www.jsm.jsexmed.org.)

investigator, agreed to take part in the study and signed informed consent after the meeting.

Data Collection

All the quantitative data were collected via electronic forms and then transferred directly in a secured manner to the Services for Sensitive Data (TSD), at the University of Oslo. The interviews were recorded and encrypted with a Dictaphone app developed by the university, called "nettskjema-diktafon". This again insured immediate and direct transfer of the files to the TSD research server. After decryption, the interviewer transcribed the interviews verbatim.

The Tampon Test

The tampon test was chosen as the primary outcome measure based on recommendations for self-report outcome measures in vulvodynia clinical trials.[17] This self-administered pain eliciting method measures degree of pain intensity during tampon insertion and removal. In this study, all participants were provided with the original Regular Tampax™ Tampons, supplied in standard cardboard applicator for insertion, which is the same type of tampon used in the validity study.[4] This specific type of tampon is no longer available in Norway and was therefore ordered from the Internet. At the first meeting detailed instructions about how to undertake and record the tampon test were given, as described by Foster et al (2009).[4] The test was undertaken in the evening on day 1, 7 and 14, a similar procedure to the Foster study, as a part of the baseline assessment. Day 1 was defined as the first day the participant performed the tampon test. The participants were instructed to insert and immediately remove the tampon, and then record the degree of pain on the NRS, based on the entire experience. The participants were instructed not to lubricate the tampon or use pain relief (i.e. topical lidocaine) prior to insertion. In addition, participants recorded whether they were menstruating during the time of the test. The tampon test together with other validated pain measures such as the Female Sexual Function Index [18] and pain intensity (NRS) during intercourse in the past four weeks were assessed at baseline, post-treatment and at the eight months follow-up.

Qualitative Interviews

As part of this preliminary study all participants received multimodal physiotherapy for PVD, after the completion of baseline assessment. The time frame for the intervention varied from two months up to four months. Towards the end of the treatment period (11.4 treatments on average), all participants were interviewed individually face to face. During the planning phase it was decided to interview every participant since the study would only include ten in total. After the quantitative data collection, baseline data was analyzed, discussed by the research team and used in the development of the semi-structured interview guide. The interviewer was provided with the participant's tampon test scores prior to the conduction of each interview.

A phenomenological worldview informed the qualitative approach, where the aim was to explore and give voice to the subjects' perspectives and lived experiences. [19] A descriptive and inductive qualitative design was chosen, seeking to gain a deeper understanding of the physiotherapy intervention and the tampon test.[20] For the purpose of this paper only the qualitative findings related to the women's experiences with the tampon test will be presented. The second author of this article, a female physiotherapist experienced with qualitative interviews, conducted the interviews and was not involved in the delivery of the treatment. The interviews took place in the physiotherapy outpatient clinic at Oslo Metropolitan University, each interview lasting between 60 to 90 minutes. A semi-structured interview guide was used to ensure each area of interest was addressed during the interviews, while at the same time encouraging the women to speak freely about their experiences.[19] The interviewer introduced the topic of the tampon test with an open-ended question, asking the participants to share their experiences with the test as a measure of their vulvar pain. To elicit rich descriptions, the interviewer tried to follow up salient cues and themes in the participants' answers, inviting them to elaborate, provide examples, or to clarify where appropriate. The interviewer was on the lookout for variations, different angles, and conflicting viewpoints, to promote a nuanced data material. [19] The final two interviews added little new information to the analysis, and we therefore consider that data saturation was reached at this point.

Mixed Methods Data Analysis

The quantitative and qualitative data were analyzed separately. First, an individual mean pain intensity score was calculated from the tampon test measurements. Intra-individual variability in pain intensity scores was calculated as a median spread difference between the highest and the lowest pain intensity score. The descriptive data has been presented as frequencies and median scores. Estimation of pain intensity with the tampon test is presented as median (min; max; Q1; Q3) scores and for all the other measures data are presented as median (Q1; Q3).

In the second qualitative phase an inductive thematic analysis was performed by the interviewer.[20] Attentive reading and re-reading of the transcripts helped to discern central aspects in the women's experiences and initial codes were identified. Taking care to include both common and diverging experiences, these initial codes were then reworked into a thematic map (included in supplementary materials Appendix A). This map consisted of themes and subthemes seeking to represent the main topics identified in the interviews. The first and second author independently reviewed the map for validity against the dataset and refined the themes and subthemes until agreement between the authors was reached. The findings are presented as analytical summaries and illustrative quotes for each of the main themes.

In the last stage, quantitative and qualitative data analysis were integrated in a joint display to illustrate both the tampon test data and qualitative interviews. This also showed how the

Table 1. Sociodemographic and clinical characteristics of 10 women with PVD

Characteristics	Participants n = 10
Age *(yrs.)*, median (Q1; Q3)	21 (20; 26)
Pain duration *(yrs.)*, median (Q1; Q3)	7 (3; 8)
Primary PVD	7
Relationship category	
Married/common law	2
In a relationship	2
Single	6
Childbirth	0
Intercourse past 4 weeks	2
Education category	
High school student	1
Undergraduate student	7
Completed bachelor's degree	2
Work category	
Student	9
Part time work	5
Full time work	1
Unemployed	0
Participants with comorbidities	7
BMI, median (Q1; Q3)	23 (20; 23)

qualitative data helped to explain the quantitative data (included in supplementary materials Appendix B).

RESULTS

The sociodemographic and clinical characteristics of the participants are presented in Table 1. Ten nulliparous women with PVD, median age 21 (18 to 33), took part in the study. Two women had sexual intercourse in the last four weeks, prior to the tampon test. Seven of the women reported different comorbidities including jaw pain, muscle pain and twitching, anal pain, endometriosis, headache, migraine, fibromyalgia, irritable bowel syndrome and alopecia areata. At baseline, four subjects were on oral contraceptives; one on cerazette, one on marvelon and two on oralcon. In terms of concurrent drug use all participants reported to have tried topical lidocaine. At baseline, six patients used topical lidocaine on a weekly to daily basis. In addition, one participant was on systemic treatment with amitriptyline, another on levothyroxine and one on diclofenac.

Individual pain intensity scores are presented in Figure 2. At baseline, the median pain intensity measured with the tampon test was 4.5 (min=1.7; max=10; Q1=2.5; Q3=6). Post treatment median pain intensity was 2 (min=0; max=7, Q1=1.5; Q3=4.2) and at the eight months follow up it was 3.5 (min=0.7; max=8; Q1=1.8; Q3=4.5). At baseline and post-treatment, the median spread difference in pain intensity between the highest and the lowest scores were two points, and at the eight months follow-up it was one point. At baseline, the maximum spread difference on the NRS was five and the minimum was zero (Figure 2). Post treatment and at the eight months follow-up the maximum spread difference was four and the minimum was zero.

Two participants reported to have had intercourse in the last four weeks prior to baseline assessment, rating their pain intensity levels during intercourse on the NRS. P2 scored 10 on the NRS during intercourse whereas the mean NRS tampon test score was 2.3. P5 scored seven on the NRS during intercourse while the mean NRS tampon test score was 4.7.

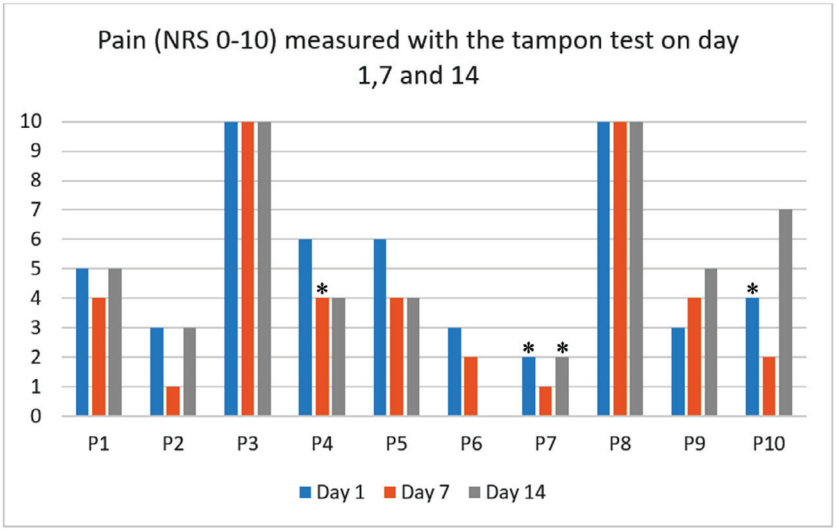

Figure 2. Individual pain intensity measured in 10 participants with the tampon test on day 1, 7 and 14 with the Numeric Rating Scale, where zero is no pain and 10 worst possible pain. One participant (P6) did not complete tampon test on day 14. P = participant. * = menstruation. (Figure 2 is available in color online at www.jsm.jsexmed.org.)

Qualitative Findings

Four main themes were conceptualized through the qualitative analytical process, representing central aspects of the participants' experiences with the tampon test: 1) pain sensation and pain intensity, 2) fluctuating pain intensity, 3) unfamiliar tampons and 4) the significance of context.

Theme 1: Pain Sensation and Pain Intensity

The analysis suggests that overall, the pain sensation and intensity experienced during the test was not comparable to intercourse pain. It was noted, however, that for P1 and P5, pain sensation and location was the same as experienced during intercourse. Although both reported that the test was less painful than intercourse, and the testing context entirely different, these women felt it to be both relevant and useful. P2, P4, P6, P7, P8 and P10 on the other hand reported that the pain sensation experienced during the test was different to pain during intercourse, as expressed by P10: "*For me, it was not the same feeling. Or it wasn't the same pain*." Intercourse pain was described as more complex, intense and extensive. P6 described how the pain during the test was comparable to intercourse pain in some ways, but different at the same time. To her the intercourse pain was much worse and more widespread: "*I experience some of the same pain, only a lot worse and at several different sites.*"

Some key differences between a tampon and a penis were emphasized as important distinctions influencing the character and intensity of the pain sensation. The tampon was described as smaller, softer and more bendable than a penis, as expressed by P10: *"It [the tampon] is smaller. And it is paper, so it's bendable in a way (laughs). So no, it's not the same."* Several pointed out that because of the smaller size and the more pliable nature of the tampon, it was possible to avoid the painful area: P4: "*I don't know if it [the test] is really relevant for me. . . because it is such an old type of Tampax. And it is not the same putting such a small thing in, which doesn't touch anything. So you see, it doesn't touch much of the area. It does hurt, but it is not the same pain as if you were having sex. . .*".

Because of its smaller size, the tampon also felt less intimidating. P2 reflects on the differences in psychological impact this might have had, where the tampon was experienced as a lot less threatening than a penis. Several participants also pointed out that the tampon is inserted once only, whereas a penis will move in and out repeatedly, causing significantly more friction and pain: P2: "*No the tampon test is not comparable to painful intercourse, it is something completely different. I think it is completely different having something in there all the time than something that goes in and out, because there is more friction.*" Although there is a dynamic aspect of the pain perception with the test, pain is short-lived, as expressed by P3: "*And it is really painful to put it in, but once it is inside it no longer hurts. So it's kind of short-lived.*"

P7 expressed frustration over the test as she felt it did not manage to capture her pain. To her, using tampons had never been an issue and she felt that the test did not allow her to demonstrate her pain: "*I felt the test failed to show how much pain I am in. Because putting a tampon in has never really been a problem for me. (. . .) The pain is there, but this test does not show it.*" This made her question if she had come to the right place for help, or indeed, if she even had a "real" problem at all. Including P7, four of the participants were already using tampons before entering the study (P1, P2, P6, and P7). To them using a tampon was associated with no or little pain and therefore not considered an issue. Sexual intercourse, however, was a major issue for all 10 participants.

Theme 2: Fluctuating Pain Intensity

P2, P4, P5, P8 and P10 reported large fluctuations and rapid changes in their day-to-day vulvar pain intensity levels. P2: "*It varies a bit because all days are different".* These fluctuations could be dramatic and frustrating, causing the women to question their own progress, as expressed by P4: *"It varies a lot from day to day. One day I can think 'Oh my god, it doesn't hurt at all', while the next day I can feel like I am back to scratch".* P8 had similar experiences: *"I don't know how others experience it, but for me the pain can vary a lot from one day to the next. So, I'm not sure that it [the test] will give a good indication of whether I have improved or not."* Consequently, she questioned what use this test held in informing the study of her recovery process.

For P2, P8 and P10, pain intensity would depend on where they were in their menstrual cycle: *P10: "Sometimes it (the tampon test) hurt a lot, and then sometimes when I had my period it didn't hurt so much".* While receiving multimodal physiotherapy, P8 discovered that inserting a tampon during her period was particularly easy. Increased lubrication during menstruation was viewed as a contributing factor.

Theme 3: Unfamiliar Tampons

Most women were unaccustomed to the test tampon. The Original Regular Tampax tampon was unfamiliar (P3, P5 and P6) and was described as old-fashioned (P4). The test tampons were described by P3 and P5 as more difficult than the ones they were used to, especially the cardboard sleeve: P3: "*I think those tampons are a lot harder to insert than OB [common tampon brand used in Norway], because they are so unfamiliar, I am unsure how to use them. This cardboard sleeve, how are you supposed to. . . It is much easier to use your own fingers on the tampon itself.*" Inserting the tampon with the cardboard sleeve gave a sense of less control and less physical sensation. Another woman described how she had to practice using the tampons prior to the test: P5: "*I thought those tampons were a bit difficult to figure out. I spent a really long time trying to understand how to do it (laughs). I had to practice first, but I think I found out how they work (laughs).*" One woman however, who was initially very skeptical to the test, found it

surprisingly easy and thought it was due to a different brand: P9: "*And it went surprisingly well. I was shocked. Because the tampon just slid right in and I thought 'what is happening?' (. . .) And I wonder if it might have had something to do with the brand, because I have normally used OB during my periods. It is not the same, so that might be the reason.*"

Theme 4: The Significance of Context

Another aspect complicating the comparison of pain is the fact that inserting a tampon and having sexual intercourse represents two very different situations. Contextual and interpersonal factors, such as perceived levels of control, wanting to perform for a partner or to safeguard a partner's feelings, were reported as important aspects. P2, P6, P8 emphasized that it was possible to experience more control whilst inserting a tampon compared to intercourse. Inserting a tampon can be done in the comfort of your own home and alone. If it sits in a painful position it is possible to remove it and place it in a more comfortable one. P2 emphasized that perceived control made a big impact on the way she experienced pain differently in these two situations. She described how a tampon could be maneuvered in a more predictable manner, whereas a penis to a larger extent is beyond her control. P2: *"A tampon stays in a fixed position, while during intercourse the penis moves and can touch several places in the vagina. Because sometimes when I insert a tampon I realize, wow, this was painful, I then take it out and try again. But you can't predict that if you have intercourse because you do not control it in a way".* P6 described how being in control during tampon insertion allowed her to adjust the angles and positions to minimize the tampon's contact with the painful areas. This, and the fact that using a tampon seemed a less menacing everyday event, made it easier for her to relax in the situation: P6: "*I am able to get a tampon in if I'm standing or something. But the body is totally different when you are having sex — how you are lying or sitting. . . The angles are different (laughs). (. . .) And you are less tense too, in a way. You are just inserting a tampon, which is something you do all the time.*"

P8 also considered the aspect of control to be an important difference between inserting a tampon and having sex. At home, by herself, in a safe, calm and comfortable setting, she finds it easier to relax her body and consciously let go of tensions in her pelvic floor as she tries to insert the tampon. Sexual intercourse is very different situation as it involves an interpersonal dimension. Whereas a tampon is an inanimate object without preferences and expectations, sexual intercourse is very much a dyadic activity. You are with another person and taking into account his feelings. P8 described how she would accept and force her way through significantly higher levels of pain during intercourse than she would inserting a tampon. She jokingly, but importantly, pointed out that she does not feel the same pressure to "perform" for the tampon: P8: "*In a way it is a different type of pain. Or. . . I often find that the tampon is not necessarily as painful as intercourse. During intercourse, I have to perform more because there is another person involved. Whilst the tampon is a thing, I do not care much about its feelings (laughs).*"

Mixed Methods Results

The findings were achieved by employing a mixed methods approach. The joint display table is included in the supplementary material, Appendix B, to illustrate how the qualitative results can help to provide an explanation and deeper understanding of the quantitative findings.

DISCUSSION

The aim of this study was to evaluate the tampon test as a possible primary outcome measure in PVD to be used in an upcoming RCT. The tampon test data demonstrated large intra- and inter-individual variability. In addition, four of the women had a NRS score that was equal to, or below four, which in some previous studies have been used as an exclusion criterion. These findings informed the set-up of the following qualitative phase exploring the women's experiences with the tampon test. In the following section, we discuss these mixed methods findings within three main topics: 1) pain intensity with the tampon test 2) variability in the tampon test data and 3) pain sensation and experience during the tampon test.

Pain Intensity With the Tampon Test

Pain experienced during sexual intercourse is the main reason for women with PVD to seek treatment. In order to evaluate the effect of treatment it is important to utilize an outcome measure that is sensitive enough to pick up change following treatment. In this study, the median pain intensity score was 4.5 (Q1=2.5; Q3=6).which was similar to the findings in the validity study by Foster et al (2009), reporting a mean NRS of 4.6 ± 2.7.[4] Other studies have reported higher mean tampon test scores, between 6.4 and 6.8.[8, 13] In all the above mentioned studies however, participants with a baseline score equal to four or lower were not included in the trials. In the current study four women had a mean pain intensity score of four or below on the tampon test. During the interviews, P1, P2, P6 and P7 reported that they normally use sanitary tampons. Interestingly three of these women (P1, P6 and P7) had an average pain score equal to four, or below. All 10 participants reported however, that sexual intercourse was a major challenge. These findings indicate that the tampon test might be a poor proxy for intercourse pain, especially for those with a low tampon test score. The test may underestimate the amount of pain some women experience during intercourse to a degree that it may lead to an exclusion of them from clinical studies. In comparing tampon test pain with intercourse pain, the latter was described as much worse, more intense and widespread. Foster et al. (2009) described similar findings, where some women reported a much higher level of intercourse pain compared to tampon test pain.[4] It is possible however, that

the tampon test can function better as a proxy for intercourse pain in women with high pain scores on the test.

P3 and P8 scored maximum pain intensity at each measurement point. P3 described how the Tampax tampon was difficult to understand how to use and both women found it impossible to insert, due to severe pain. P8 also described how she was not prepared to push herself and endure pain, in the same way she would during intercourse. She further described intercourse pain to be worse than tampon insertion, albeit she scored maximum on the tampon test. This can point to a possible ceiling effect and the test's inability to capture all relevant dimensions of the pain experience. Overall, these experiences highlight the complexity of pain, in her case the possible existence of a strong interpersonal pressure to perform during intercourse, despite severe pain. Several previous studies have found that women continue to have penetrative intercourse, despite pain, and avoid telling their partner.[21-23] Reasons for this phenomenon are described in the literature, but it is beyond the scope of this paper.

Variability in the Tampon Test Data

In the quantitative phase we found large variability in the tampon test scores, both intra- and inter-individually. A possible explanation for this variability could be the fluctuating and rapid change in the pain intensity levels experienced in daily life by several women. In addition, the interviewees described various factors that could have had an influence on pain intensity in the testing situation, such as fear of pain, the inability to relax, the extent of control, the type of tampon and cyclic hormonal changes. It is not possible however, to establish to what degree these factors contributed to day-to-day variability in experienced pain levels. It may be possible to reduce the variability in the tampon test data in future trials by selecting a test tampon familiar to the women, whilst giving clear instructions on how and when the test should be undertaken. Keeping a record of factors, such as menstruation, is important to investigate the potential influence of the menstrual cycle on pain during the tampon test. The most important aspect however, is to ensure that several repeated measurements are undertaken within a definite period, in order to provide an average pain intensity score.

Pain Sensation and Experience During the Tampon Test

Overall, the pain sensation and experience during the tampon test was not comparable to intercourse pain. Several women reported that the sensory aspect of pain experienced during the test was different to pain during intercourse. The tampon was smaller, softer and more pliable compared to a penis. Furthermore, the test was short-lived as once the tampon was inserted, the pain was gone. Intercourse however, involved repeated friction and movement over time, which possibly could have contributed to a more painful experience. The psychosocial context and setting was also described as entirely different. The psychological impact of experiencing the tampon as less threatening than a penis was reflected upon. Fear-avoidance variables, such as pain catastrophizing and pain related fear, have been shown to be associated with pain intensity in women with PVD.[24-26] Hence, for some women the tampon test may pose as less threatening, because during tampon insertion the women inflict pain on themselves, rather than pain being inflicted upon them by their partner. Three women also reported to perceive more control in the test situation, compared to intercourse, which again could have had an effect on the pain experience.

In summary, most participants did not experience the tampon test as an adequate representation of intercourse pain. The test was less intense, different in nature and conducted in entirely different context. This is in line with Rosen et al.'s (2020) argument that the tampon and the context in which it is applied does not equate to the real life experience of pain during penetrative intercourse.[27] In using the tampon test as a proxy for painful sexual activity, it may provide us with incomplete and insufficient estimates due to the lack of sexual context and sexual arousal in the testing situation. Nevertheless, not all women shared this opinion; P1 and P5 described how pain sensation and location was the same. Although the context was entirely different and pain intensity less with the test, they still found it to be both relevant and useful.

Clinical Implications

The tampon test has several clear advantages; it is easy to undertake by the individual participant without the involvement of health care professionals and it is inexpensive and easy to repeat within a specified period. In addition, the usage of tampons mimic a periodic activity, which for some patients might be a partial goal of the therapy.

Despite its advantages, it is questionable whether the tampon test is an adequate primary outcome measure in PVD trials. A particular problem seems to be its inability to reproduce high enough pain intensity among some of the PVD patients, who concurrently report high levels of pain during sexual intercourse. This can lead to the exclusion of these particular patients from further clinical studies. Furthermore, this can diminish the sensitivity of the test in terms of registering clinically meaningful changes in the patient's condition. An additional challenge is the large intra-individual variability found in test scores on different test days. Consequently, it necessitates several measurements per assessment time point in order to increase precision in the estimation of an overall pain intensity. The fact that for the majority of patients the test was not an instrument that represented their main problem adequately, i.e. pain during intercourse, is an issue we believe that should be taken into account. If the main assessment instrument seems irrelevant to the study participants, it may negatively influence their engagement and compliance.

Nevertheless, we would argue that the tampon test could serve well as a secondary outcome for measuring pain intensity in women with PVD. In contrast to memory-based self-report questionnaires, the tampon test provides a real time estimate of pain intensity in the vulvar vestibule. The usage of several different types of pain outcome measurements in clinical studies is in line with current IMPPACT guidelines[28] and vulvodynia research recommendations[27], as it provides a more comprehensive picture of the pain experience.

Strengths and Limitations of the Study

To our best knowledge, this is the first study investigating women's experiences with the tampon test in a sample of women with PVD. A strength of this study was how these experiences could be directly linked to the quantitative data, as all participants were interviewed. Nevertheless, although appropriate for a feasibility study, a limitation in this study was the small sample size in the quantitative phase, hence the quantitative findings should therefore be interpreted with caution. The findings are therefore not generalizable to a larger population.

CONCLUSION

To our best knowledge this is the first study investigating women's experiences with the tampon test in PVD. The experiences with the test could be directly linked to the tampon test data, as all participants in this study were interviewed. This study suggests that despite its merits, the tampon test by itself may be suboptimal as a primary outcome measure in PVD research. As a proxy for pain intensity during sexual intercourse, the tampon test may underestimate levels of pain intensity among some participants with PVD. This could lead to exclusion of these participants from clinical studies, or decrease the test's ability to register meaningful clinical changes. The majority of participants perceive the test as an irrelevant measure of their problem. For future clinical trials, we therefore recommend a primary outcome measure that is capable of capturing the multidimensionality of PVD, such as the Female Sexual Function Index[18]. Nevertheless, the tampon test may be important as a secondary outcome providing a real time estimation of vestibular pain intensity. The test should be undertaken repeatedly, in order to increase precision of the pain estimation.

Corresponding Author: Mette Bøymo Kaarbø, MSc, Department of Physiotherapy, Oslo Metropolitan University, Postboks 4, St Olavs plass, 0130 Oslo, Norway. Tel: +47 974 11 669; E-mail: metteboy@oslomet.no

Conflict of Interest: The authors report no conflicts of interest.

Funding: Funding from Oslo Metropolitan University and the Norwegian Fund for Post-Graduate Training in Physiotherapy.

Trial registration: This study is registered at https://clinicaltrials.gov/ct2/show/NCT04208204 (NCT04208204).

STATEMENT OF AUTHORSHIP

Category 1 (a) **Conception and Design** Gro Killi Haugstad; Anne Lise Ording Helgesen; Slawomir Wojniusz. (b) **Acquisition of Data** Mette Bøymo Kaarbø; Kristine Grimen Danielsen; Anne Lise Ording Helgesen; Slawomir Wojniusz (c) **Analysis and Interpretation of Data** Mette Bøymo Kaarbø; Kristine Grimen Danielsen **Category 2** (a) **Drafting the Article** Mette Bøymo Kaarbø (b) **Revising the Article for Intellectual Content** Mette Bøymo Kaarbø; Kristine Grimen Danielsen; Gro Killi Haugstad; Anne Lise Ording Helgesen; Slawomir Wojniusz **Category 3** (a) **Final Approval of the Completed Article** Mette Bøymo Kaarbø; Kristine Grimen Danielsen; Gro Killi Haugstad; Anne Lise Ording Helgesen; Slawomir Wojniusz.

REFERENCES

1. Sadownik LA. Etiology, diagnosis, and clinical management of vulvodynia. **Int J Womens Health 2014;6:437–449.**
2. Basson R, Driscoll M, Correia S. When sex is always painful: Provoked vestibulodynia. **B C Med J 2016;58:77–81.**
3. Wammen Rathenborg FL, Zdaniuk B, Brotto LA. What do different measures of pain tell us? A comparison in sexually active women with provoked vestibulodynia. **J Sex Med 2019;16:278–288.**
4. Foster DC, Kotok MB, Huang LS, et al. The tampon test for vulvodynia treatment outcomes research: Reliability, construct validity, and responsiveness. **Obstet Gynecol 2009;113:825–832.**
5. Goldstein AT, Pukall CF, Brown C, et al. Vulvodynia: assessment and treatment. **J Sex Med 2016;13:572–590.**
6. De Andres J, Sanchis-Lopez N, Asensio-Samper JM, et al. Peripheral subcutaneous vulvar stimulation in the management of severe and refractory vulvodynia. **Obstet Gynecol 2013;121:495–498.**
7. Phillips NA, Brown C, Foster D, et al. Presenting symptoms among premenopausal and postmenopausal women with vulvodynia. **Menopause 2015;22:1296–1300.**
8. Brown C, Bachmann GA, Wan J, et al. Pain rating in women with provoked vestibulodynia: Evaluating influence of race. **J Womens Health 2016;25:57–62.**
9. Brown CS, Bachmann GA, Wan J, et al. Gabapentin for the treatment of vulvodynia: A randomized controlled trial. **Obstet Gynecol 2018;131:1000–1007.**
10. Foster DC, Kotok MB, Huang LS, et al. Oral desipramine and topical lidocaine for vulvodynia: A randomized controlled trial. **Obstet Gynecol 2010;116:583–593.**
11. Guillet AD, Cirino NH, Hart KD, et al. Mindfulness-based group cognitive behavior therapy for provoked localized vulvodynia: A randomized controlled trial. **J Low Genit Tract Dis 2019;23:170–175.**
12. Lev-Sagie A, Kopitman A, Brzezinski A. Low-level laser therapy for the treatment of provoked vestibulodynia—A randomized, placebo-controlled pilot trial. **J Sex Med 2017;14:1403–1411.**

13. Hullender Rubin LE, Mist SD, Schnyer RN, et al. Acupuncture augmentation of lidocaine for provoked, localized vulvodynia. **J Low Genit Tract Dis 2019;23:279–286.**
14. Bachour CC, Bachmann GA, Foster DC, et al. Recruitment methods in a clinical trial of provoked vulvodynia: Predictors of enrollment. **Clin Trials 2017;14:103–108.**
15. Creswell JW, Plano Clark VL. Designing and conducting mixed methods research. 3rd ed Los Angeles: SAGE Publications, Inc.; 2018.
16. Stockdale CK, Lawson HW. 2013 vulvodynia guideline update. **J Low Genit Tract Dis 2014;18:93–100.**
17. Pukall CF, Bergeron S, Brown C, et al. Recommendations for self-report outcome measures in vulvodynia clinical trials. **Clin J Pain 2017;33:756–765.**
18. Rosen R, Brown C, Heiman J, et al. The female sexual function index (FSFI): A multidimensional self-report instrument for the assessment of female sexual function. **J Sex Marital Ther 2000;26:191–208.**
19. Kvale S, Brinkman S. Det Kvalitative Forskningsintervju (Interviews: Learning the craft of research interviewing). 2nd ed Oslo: Gyldendal Akademisk; 2009.
20. Braun V, Clarke V. Using thematic analysis in psychology qualitative research in psychology. **Qual Res Psychol 2006;3:77–101.**
21. Elmerstig E, Wijma B, Bertero C. Why do young women continue to have sexual intercourse despite pain? **J Adolesc Health 2008;43:357–363.**
22. Elmerstig E, Wijma B, Swahnberg K. Prioritizing the partner's enjoyment: A population-based study on young Swedish women with experience of pain during vaginal intercourse. **J Psychosom Obstet Gynaecol 2013;34:82–89.**
23. Braksmajer A. That's kind of one of our jobs": Sexual activity as a form of care work among women with sexual difficulties. **Arch Sex Behav 2017;46:2085–2095.**
24. Desrochers G, Bergeron S, Khalife S, et al. Fear avoidance and self-efficacy in relation to pain and sexual impairment in women with provoked vestibulodynia. **Clin J Pain 2009;25:520–527.**
25. Chisari C, Chilcot J. The experience of pain severity and pain interference in vulvodynia patients: The role of cognitive-behavioural factors, psychological distress and fatigue. **J Psychosom Res 2017;93:83–89.**
26. Benoit-Piau J, Bergeron S, Brassard A, et al. Fear-avoidance and pelvic floor muscle function are associated with pain intensity in women with vulvodynia. **Clin J Pain 2018;34:804–810.**
27. Rosen NO, Bergeron S, Pukall CF. Recommendations for the study of vulvar pain in women, part 1: Review of assessment tools. **J Sex Med 2020;17:180–194.**
28. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. **Pain 2005;113:9–19.**

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.1016/j.jsxm.2021.03.010.

Supplementary material Paper II

An overview of the analytical process, moving from the preliminary themes to the main theme.

Step 1 – Codes (Preliminary)	Step 2 – Subthemes	Steg 3 – Themes
The mind plays a role The tampon is not the same as a penis The tampon does not touch the same areas The tampon is smaller than penis The tampon is inserted only once, while penis goes in and out many times - more friction during intercourse Same pain, but milder The test doesn't feel relevant Gives a poor picture of my pain Does not get to "prove" the pain Don't miss being able to use a tampon Have I come to the right place when the test does not catch my pain?	Less friction with a tampon The tampon does not touch the painful area Provokes the same kind of pain, and in the same area, but the pain is less intense The test did not allow me to demonstrate my pain	Pain sensation and pain intensity
The tampon test as an expression of pain during intercourse Different situations More control when inserting a tampon compared to intercourse Body and angles are different	Inserting tampons and having sex are two different situations Control is an important aspect	The significance of context
The pain varies with the menstrual cycle Variation from day to day The intercourse pain does not vary in the same way	The pain varies	Fluctuating pain intensity
Previous experience with the use of tampons The tampons in the test are different from OB*	The test tampon is easier than the ones I am used to The test tampon is more difficult than the ones I am used to	Unfamiliar tampons

OB is type of tampon frequently used in Norway

Supplementary material Paper II

Joint display of mixed methods results

Findings	Quantitative findings	Qualitative findings How qualitative explains quantitative
Pain intensity scores with the tampon test	**Low pain intensity scores:** P2, P6, P7, P9 with NRS ≤ 4 **High pain intensity scores** P3 and P8 (NRS: 10)	P1, P2, P6, P7 use tampons with no difficulty *"The tampon just slid right in"* (P9) Possible to minimize the tampon's contact with the painful areas (P6) P2, P6, P8 perceived more control with TT Easier to relax (P2, P6), and relax pelvic floor (P8) Tampon - less threatening than a penis (P2). Tampon insertion difficult (P3) and impossible due to pain (P3, P8)
Variability in tampon test data	**Large intra-individual variability day 1,7 & 14** Median spread difference: 2 Maximum spread difference: 5 (P10) Minimum spread difference: 0 (P3 & P8) **Large inter-individual variability on TT:** Lowest mean: NRS=1.7 (P7) Highest mean: NRS=10 (P3 &P8)	Pain intensity levels fluctuate: P2, P4, P5, P8 & P10 Unfamiliar tampons; "*I am unsure how to use them"* (P3) &*"I had to practice first"* (P5) Variable experiences with the TT: P1, P2, P6, P7 normally use tampons with no difficulty *"The tampon just slid right in"* (P9) Tampax was unfamiliar and difficult (P3) and TT impossible due to pain (P3, P8) and tightness of the pelvic floor muscles (P8)
Pain sensation and experience during tampon test is different to intercourse	**Mean pain scores**: P1: 4.7 P2: 2.3 P3: 10 P4: 4.7 P5: 4.7 P6: 2.5 P7: 1.7 P8: 10 P9: 4 P10: 4.3	Pain sensation with TT is not comparable to intercourse pain (P2, P4, P6, P7, P8, P10) More friction and movement with intercourse (P2, P4) Intercourse pain much worse than TT (P1, P6, P8) *"So it's [the test] kind of short lived.*" (P3) "*And it is not the same putting such a small thing in, which doesn't touch anything"* (P4) *"The test failed to show how much pain I am in. Because putting a tampon in has never really been a problem for me"* (P7) Pain depends on context and interpersonal factors: *"During intercourse, I have to perform more because there is another person involved. Whilst the tampon is a thing, I do not care much about its feelings (laughs).*" (P8) Tampon - less threatening than a penis (P2).

TT = tampon test

Paper III

Toward improved sexual health among women with provoked vestibulodynia: experiences from a somatocognitive therapy approach.

Danielsen, K.G., Kaarbø, M.B., Groven, K.S., Helgesen, A.L.O., Haugstad, G.K. and Wojniusz, S. (2022) Toward improved sexual health among women with provoked vestibulodynia: experiences from a somatocognitive therapy approach. *Eur J Physiother.* https://doi.org/10.1080/21679169.2023.2168749

EUROPEAN JOURNAL OF PHYSIOTHERAPY
https://doi.org/10.1080/21679169.2023.2168749

Taylor & Francis
Taylor & Francis Group

ORIGINAL ARTICLE

Towards improved sexual health among women with provoked vestibulodynia: experiences from a somatocognitive therapy approach

Kristine Grimen Danielsen[a], Mette Bøymo Kaarbø[a,b], Karen Synne Groven[a,c], Anne Lise Ording Helgesen[d,e], Gro Killi Haugstad[a,f] and Slawomir Wojniusz[a]

[a]Department of Rehabilitation Science and Health Technology, Oslo Metropolitan University, Norway; [b]Department of Pain Management and Research, Division of Emergencies and Critical Care, Oslo University Hospital, Norway; [c]Faculty of Health Studies, VID Specialized University, Norway; [d]Department of Obstetrics and Gynecology, Oslo University Hospital, Norway; [e]Department of Dermatology, Oslo University Hospital, Norway; [f]Unit for Psychosomatics/CL Outpatient Clinic for Adults, Acute Psychiatric Department, Oslo University Hospital, Norway

ABSTRACT

Purpose: Provoked vestibulodynia (PVD) is a common reason for sexual pain in young women. Furthermore, this persistent vulvar pain condition can have a significant negative impact on an individual's sexual health and well-being. As knowledge about effective treatments is limited, the aim of this study was to gain insight into meaningful processes towards improved sexual health, supported by a multimodal physiotherapy intervention.

Methods: Through individual semi-structured interviews, this longitudinal, qualitative study explored the experiences of ten young women with PVD who took part in a somatocognitive therapy program. Participants were interviewed towards the end of their therapy period, and again one year later, to develop insight into therapeutic processes unfolding over time.

Results: Through analysis we identified the following themes: (1) Developing positive feelings of embodiment, (2) Developing a greater awareness of internal feelings and bodily states, and (3) Developing sex-positive beliefs and behaviours.

Conclusion: The findings show how individually tailored physiotherapy emphasising embodiment and sexual health can promote meaningful processes towards improved sexual health for women living with PVD.

ARTICLE HISTORY
Received 20 July 2022
Revised 30 December 2022
Accepted 6 January 2023
Published online 12 January 2023

KEYWORDS
Provoked vestibulodynia; vulvodynia; physiotherapy; somatocognitive therapy; embodiment; sexual health; sexual agency

Introduction

Longstanding vulvar pain, or vulvodynia, is an unexplained and distressing condition that can have a detrimental impact on the sexual health[1] of young women. Multifactorial in nature, the maintenance and severity of vulvodynia has been associated with various biological, social, and psychosexual factors [1–5]. With an estimated lifetime prevalence of 7–16% vulvodynia represents a significant personal, clinical, and societal challenge today [6–8].

Provoked vestibulodynia (PVD) is the largest subgroup of vulvodynia [9] and considered the most common cause of pain during sexual intercourse among premenopausal women [9,10]. The condition is characterised by burning or stinging pain, provoked by touch or pressure to the vulvar vestibule or attempted vaginal penetration. Although there are currently no evidence-based treatment guidelines available, a biopsychosocial treatment approach is generally recommended [11]. As knowledge about the condition and what constitutes effective treatment is limited, women with PVD are often misdiagnosed, misunderstood, or even dismissed by health care professionals [12]. Their road to recovery can be long, lonely, and costly, and many women explore different treatment options before experiencing any improvement of their symptoms [12]. This article explores women's experiences of addressing sexual health in a physiotherapy context and how experiences of sexual health might intersect with experiences of embodiment.

Sexual health is a key part of a person's overall health and well-being. When sex becomes a source of pain, the negative consequences for a woman's sexual health can be profound. Previous research has provided valuable insights into the subjective experiences of living with vulvar pain and of negotiating painful sex in the context of romantic relationships. In a study exploring women's experiences of vulvar pain, Katz [13] found that feelings of shame, guilt, social isolation and sexual inadequacy were very common. The women's narratives also revealed experiences of a loss of self and loss of femininity, as well as diminished self-confidence. Women with vulvar pain often discount their own needs to accommodate the sexual desires of their partners [14–17], indicating that the physical,

CONTACT Kristine Grimen Danielsen kgrdan@oslomet.no Department of Rehabilitation Science and Health Technology, Oslo Metropolitan University, Elisabeth Lampes hus, Pilestredet 44, Oslo 1067, Norway

emotional, sexual, and social dimensions of longstanding vulvar pain are tightly interwoven.

The limited existing literature exploring connections between the quality of one's embodiment and the quality of one's sexual health, suggests that embodiment can be linked to feeling more comfortable with one's sexual desire and feeling entitled to sexual pleasure, as well as a stronger sexual agency [18]. A recent study found that engaging in regular embodied practice encouraged a shift from experiencing sexuality from an objectified perspective to sexuality as a lived experience, connected to internal bodily states [19].

Physiotherapy is commonly recommended as a first line of treatment for women with PVD [20], although the optimal physiotherapy intervention in terms of pain reduction and improvement of sexual function remains unclear [21]. However, few studies have investigated the experiences of women with PVD interacting with physiotherapy, and we know little of their experiences addressing sexual health in a physiotherapy context. Insight into such experiences is paramount in developing targeted physiotherapy interventions in line with the women's preferences and perspectives on what constitutes meaningful processes of change. Hence, the purpose of our qualitative study was to gain insight into meaningful processes towards improved sexual health among women receiving somatocognitive therapy, a multimodal physiotherapy intervention, for PVD. More specifically, we address the following research question:

> What, from the perspective of the participants, are meaningful processes toward improved sexual health supported by somatocognitive therapy?

Theoretical perspective

A feminist embodiment framework informs this study and allows us to understand the women's body-anchored experiences within broader sociocultural contexts [22]. We draw on Piran's [22] Developmental Theory of Embodiment (DTE), a research-based social theory that aims to explain the development and experience of embodiment among girls and women. The DTE builds on Merleau-Ponty's understanding of embodiment as lived experience and of the mind and body as an inseparable whole, existing in a reciprocal relationship with culture. Referring to critical and feminist theorists such as Foucault [23], Bartky [24], and de Beauvoir [25], the DTE directs our attention to how a woman's body is a site of social control, where social discourses socialise women to inhabit 'compliant' and 'docile' feminine bodies.

The DTE outlines five dimensions that shape the quality of one's Experience of Embodiment, each representing a scale from positive to disrupted:

> Dimension 1 Body Connection and Comfort vs Body Disconnection and Discomfort.
>
> Dimension 2 Agency and Functionality vs Restricted Agency and Restraint.
>
> Dimension 3 Experience and Expression of Desire vs Disrupted Connection to Desire.
>
> Dimension 4 Attuned Self-care vs Disrupted Attunement, Self-harm, and Neglect.
>
> Dimension 5 Inhabiting the Body as a Subjective Site vs as an Objectified Site.

According to these dimensions, positive embodiment is defined as '*positive body connection and comfort, embodied agency and passion, and attuned self-care*' [22]. The opposite is disrupted embodiment, defined as '*disrupted body connection and discomfort, restricted agency and passion, and self-neglect or harm*' [22]. By collating these five dimensions previously understood and studied as distinct phenomena, under the wider concept of embodiment, the DTE provides an integrative framework from which to explore the women's embodied therapeutic journeys.

Context: somatocognitive therapy

The women who participated in this study had all taken part in a Somatocognitive therapy (SCT) intervention for PVD. SCT is a multimodal physiotherapy intervention originally developed to treat persistent pain disorders [26]. In later years SCT has been further adapted to treat women with persistent vulvar pain [27]. The participants had received a median of 12 SCT sessions over the course of 13–22 weeks, at an outpatient clinic at Oslo Metropolitan University, Norway.

SCT is based on therapeutic principles from the Mensendieck physiotherapy tradition [28] – a tradition emphasising body awareness and functional movements. In addition, SCT is inspired by Cognitive therapy in the sense that unhelpful pain-related cognitions and behavioural schemata are identified and addressed [29]. SCT as a therapy form is not connected with the DTE-framework used in this study. However, the DTE may provide a useful framework for how SCT can influence specific aspects of PVD. When SCT is applied to treat other types of conditions (e.g. chronic musculoskeletal pain), other theoretical frameworks may be applied.

Central components of SCT include therapeutic alliance, bodily exploration, pain education, coping with thoughts and emotions, and homework to be practiced between sessions.

Bodily exploration is at the core of the SCT approach, with the aim of promoting whole-body awareness and facilitating new bodily experiences and insights. Women are also encouraged to begin relating to their vulvas and sexuality in a more positive, embodied way. As a key part of their home assignments, women are encouraged to begin approaching their vulvas with more curiosity and compassion. When introducing home exercises that explicitly involve the genitals, the goal of SCT is not to stretch or release the pelvic floor muscles (PFMs), but rather to support a shift from fear, avoidance, and shame, towards a more comfortable and positive bodily connection. This direct approach to their vulvas is continuously integrated with and related to working with the whole body, to support a reintegration of the vulva into the whole-body experience.

Conversations about sexual health are integrated into the treatment sessions related to the women's own experiences and concerns, where topics such as setting boundaries,

communicating openly about one's pain and sexuality, and focussing on own pleasure are typically addressed.

An important goal of SCT is to empower women to take ownership of their own recovery process, through gaining bodily awareness, -insight, and -agency, and through developing individually adapted strategies to reduce pain and improve sexual function and health. To support these processes, SCT places a strong emphasis on developing a sound therapeutic alliance through empathy and a patient-centered approach. Table 1 provides a descriptive overview of the SCT treatment context relevant to this study. For more details on the SCT intervention as it is tailored to women with PVD, see Kaarbø et al. [27].

Methods

In line with our research question exploring *meaningful processes towards improved sexual health supported by somatocognitive therapy*, a longitudinal, qualitative study design was emphasised. This design entailed conducting two rounds of interviews in order to explore participants' experiences with somatocognitive therapy over time: the first author conducted semi-structured interviews of women with PVD towards the end of their treatment period, and follow-up interviews one year later. Semi-structured interviews enabled us to explore the women's experiences, allowing us insights into potentials and pitfalls with promoting sexual health as part of a physiotherapy treatment journey [31].

Participants and recruitment

The interviews were a part of the ProLoVe feasibility study in preparation for a randomised clinical trial. The feasibility study [30] took place at an outpatient physiotherapy clinic in Oslo. Participants were recruited from the Vulva Clinic at Oslo University Hospital and were included in the study if they were diagnosed with PVD and aged between 18 and 35 years. Women with an ongoing infection or a dermatological disease in the vulvar area were excluded from participation.

A total of ten women were included in the feasibility study and the participants received a median number of twelve treatment sessions. The same ten women also signed informed consent to take part in individual qualitative interviews towards the end of the treatment period, and seven participants accepted to take part in follow-up interviews one year later. During interviews nine and ten from the first interview round, no new major themes were identified analysing the women's experiences. However, the second round of interviews enriched themes from the first round of interviewing in the sense that the women's experiences entailed more nuances and insights into the unfolding of long-term therapeutic processes. Given that no new major themes

Table 1. Overview of Somatocognitive therapy as it was conducted in the context of this study (table adapted and used with permission from Kaarbø et al. [30]).

Overview	Description
Brief name	Somatocognitive therapy (SCT)
What	SCT is a multimodal physiotherapy intervention designed to target the multiple dimensions of vulvar pain, utilising a biopsychosocial approach. A bodily approach is combined with a cognitive restructuring of negative thoughts. Overall, the aim is to improve body awareness to reduce vulvar pain and psychological distress and improve sexual function.
Materials: Participants	Resources: vulva.no
Materials: Physiotherapist	Equipment included a treatment bench, mat, pillows, massage balls, mirror, Pilates ball, and educational material.
Procedures	Initial appointment: Assess participant – take a thorough history (including previous experiences, beliefs, and expectations) and clinical examination (quality of movement, breathing pattern). The main areas of SCT include the following: **Therapeutic alliance** is an essential component of SCT; patient and therapist are in a close working relationship, agreeing on treatment goals and home assignments. Participants take an active part in the decision-making process about their own treatment and progression. **The bodily approach**: breathing patterns, maladaptive movement, and postural patterns are addressed in various positions (sitting, standing, walking, and in supine). Through manual techniques and touch, participants are taught various techniques to increase body awareness, improve relaxation, and reduce muscle tension. **Education** about PVD, chronic pain, stress, and healthy vulvo-vaginal and sexual behaviours. **Coping** with emotions and thoughts related to bodily experiences. Participants learn to become aware of negative/catastrophizing thoughts and learn how to restructure or accept these thoughts as well as how to overcome fear avoidance behaviour. An important aspect is the women's ability to adapt and to self-manage their condition such as coping with pain and flare-ups. **Structured homework** promoting the application of learned techniques in daily situations. Gradual exposure to activities associated with pain, desensitisation exercises, and exercises to increase the pelvic floor and vulva awareness. Relaxation and breathing exercises. Last session – create a self-management toolbox with participant.
Who provided the treatment	Experienced female physiotherapist trained in SCT, the second author of the article.
How	Each session has a three-phased structure: (1) The conversation, (2) the bodily intervention/exploration, and (3) the home assignment.
Where	In a closed room with access to the gym, outpatient physiotherapy clinic, Oslo Metropolitan University, Norway. Home assignments performed by the participants integrated into ADL.
When and how much	The median number of sessions: 12 (min 7; max 15) face to face with a physiotherapist. Treatment period: minimum of 13 weeks and maximum of 22 weeks. Each session (including the initial session) lasted up to 60 min. The number of sessions required was personalised.
Tailoring	The treatment is personalised and tailored to the individual. The patient's participation and collaboration are important. The treatment principles are the same for all but are adapted to suit the individual's needs.

were identified during these interviews, the sample was considered adequate to ensure saturation on the topic.

The participants were nulliparous Norwegian women aged between 18 and 33 years. They had suffered with vulvar pain between three and fifteen years, with a median duration of seven years. Four were in stable relationships while six were single at the time the study started. Nine described themselves as heterosexual, while one discovered her bisexuality after the end of treatment. All had or were in the process of receiving higher education, and many had part-time jobs alongside full time studies.

Data collection

In line with our longitudinal, study design, the first round of interviews was conducted when the women were near the end of their treatment program. In this way, their experiences of participating in SCT were fresh in their memories. The first author conducted face-to face interviews in a private room at Oslo Metropolitan University based on a semi-structured interview guide. The second round of interviews took place approximately one year after the SCT treatment was ended, allowing insights into how the women's experiences of therapeutic processes changed over time. Due to Covid-19 restrictions, the second round took place on zoom, a digital communication platform that enables secure sound and video transfer [32]. Each interview lasted between 60 and 90 min and was carried out by the first author, a female physiotherapist experienced with qualitative research. The researcher was familiar with the SCT approach, but not involved in the treatment of the women. Furthermore, she had no previous contact with the participants.

Following a semi-structured interview guide, participants were invited to share their experiences with the SCT approach including meaningful changes (or lack thereof) related to the treatment process. Open-ended questions encouraged the women to talk about aspects of their therapeutic journeys that felt important to themselves. Homing in on their experiences related to sexual health, the women were further asked to share their experiences with and attitudes towards sexuality and sexual health growing up, their experiences with how PVD impacted on different aspects of their sexual health, and their experiences negotiating these aspects in the context of SCT. In the second round of interviews, central themes from the first round were followed-up, and the women were asked to share their experiences of the period following end of treatment. To encourage rich narratives, the women were asked to elaborate and exemplify where appropriate.

The interviews were recorded with a Dictaphone app, with direct and encrypted transfer to a secured research server. The interviews were transcribed verbatim, and immediate impressions and interpretations were noted down after every interview to complement the transcripts.

Data analysis

Following the thematic analysis approach described by Braun and Clarke [33], data were analysed inductively. This involved coding the women's embodied experiences related to processes towards improved sexual health with the SCT approach. The first author came across the Developmental Theory of Embodiment (DTE) during the course of analysis, and this theory functioned as a sensitising lens during the final stages of the analytical process.

The data processing software NVivo12 was used to organise transcripts, codes, and themes through the analytical process. The first author read through the transcribed texts several times to gain a good overview of each woman's account. During this process, preliminary themes both within and across the participants started to form, related to the research question and aim. Corresponding pieces of text were coded and collated, and different ways of organising the codes into themes and subthemes were explored until a tentative thematic map was in place. The second author independently read through the original transcripts and noted down her own immediate thoughts and impressions, before comparing her own interpretations with the preliminary thematic map. She then reviewed the map for validity against the original transcripts, considering alternative or contrasting excerpts, angles, interpretations, and missing or overrepresented statements. Alternative interpretations and themes were discussed among the authors until agreement was reached. The analytical development from initial codes to subthemes and themes is outlined in Table 2.

Ethical considerations

The study was approved by the Norwegian Committee for Medical and Health Research Ethics (2018/1036) and adhered to the Helsinki declaration. The participants received both verbal and written information about the nature and purpose of the study. Information included the right to refuse or withdraw participation. Any personal information was deidentified, and data were stored confidentially.

Sexuality can be a sensitive subject. Painful sex and topics related to disrupted sexual health is tied up with shame and taboo and can be embarrassing and even painful to talk about. Each interview therefore started with an informal chat about non-sensitive topics to establish an atmosphere of trust and comfort. As the interviews touched on sensitive and private experiences, the researcher was on the lookout for signs that the participants were uncomfortable sharing their stories and did not press for further elaboration if she felt a limit was being reached.

Results

Our findings will be organised through the three themes identified through our analysis: (1) Developing positive feelings of embodiment, (2) Developing a greater awareness of internal feelings and bodily states, and (3) Developing sex-positive beliefs and behaviours.

Table 2. Overview of the analytical process from codes to sub-themes and main themes.

Codes	Sub-themes	Main themes
Performing the body	Beginning to shift from performing the body, towards inhabiting the body with comfort and confidence	Developing positive feelings of embodiment
Negative feelings towards own body		
Using food and exercise to control the body vs. moving because it feels good	Beginning to relate to the body in more accepting and self-compassionate ways	
Beginning to experience the body from the inside		
Beginning to inhabit the body with more comfort and confidence	Outcast vulva: from avoidance to curiosity and acceptance	
From self-critical to a more friendly and patient internal dialogue		
Avoidance and alienation of the vulva		
Developing more positive feelings towards the vulva		
Would have preferred a more hands-on treatment of the pelvic floor muscles		
High-paced, high-stress lifestyles	From bodily distance to purposely directing attention inwards	Developing a greater awareness of internal feelings and bodily states
Not paying attention to or ignoring bodily and emotional needs		
Body as a fearful site	From vague and intimidating, to understandable bodily signals	
Daring to be present with bodily feelings and sensations	Learning to trust, learn from, and be guided by internal cues	
A movement from meeting internal cues with fearfulness, to more curiosity and calmness		
Contact is important to start a healing process		
Discovering and addressing unhelpful bodily habits		
Beginning to pay more attention to and prioritise own needs and wants		
A holistic approach feels meaningful, but can also be demanding/overwhelming		
Sex as duty, performance, and self-sacrificing care-work	From sex as duty and performance, to mutual satisfaction and intimacy	Developing sex-positive beliefs and behaviours
Difficulties with intimacy		
Beginning to assert personal boundaries (guided by internal cues)	Developing a healthy curiosity towards own body and sexuality	
Disrupted connection to sexual desire and pleasure	Taking ownership of own body and sexual health	
A new mindset around sexuality		
Exploring and reclaiming own sexual desire and pleasure		
A greater interest in own needs and wants		

Developing positive feelings of embodiment

For most of the women, the SCT process supported a shift from relating to the body as an object, towards experiencing the body as a subject. Several reflected on how they for a large part of their lives had adjusted and 'performed' their bodies to meet cultural expectations. Sophia linked her vulvar pain to early adolescence, when she was very conscious of how other people were perceiving her body:

> I was very concerned with being skinny and all those things. I would walk around and … because I knew that if I tightened my thighs like this then they looked right. And when I walked, I would tense my arms and legs. And after a while I just started doing it without even being aware of it.

Being guided to experience her body from the inside was a valuable shift for Sophia and an important part of her recovery process. Beginning to feel more comfortable and confident within her own body was a new experience for her:

> I feel in contact with and in control over my whole body. And that feels really nice. Not pushing it [the body] away. I have noticed that I have started to sweat more (laughs). And that is actually very good. And I can feel that I am breathing more, that I am more alive in a way. That my whole body is more connected.

For all ten participants the vulva had been a particularly difficult and alienated part of their body. The women described how they would ignore, avoid, and even push this painful area out of their awareness. They would rather not touch it, talk about it, or even think about it. For several of the women, the vulva did not even feel like a part of their body, but rather like something separate from themselves. Most of the women associated the vulva with painful experiences and disappointment, further giving them a feeling of powerlessness. Being encouraged to approach the vulva in a more curious and self-compassionate way helped several of the women break some of the patterns of fear and avoidance tendencies and develop a closer relationship with the vulva. Adele described how her relationship with her vulva had changed during the course of SCT. Where she had previously felt anxiety, she now experienced the vulva as a more integrated part of her body:

> I feel more comfortable with my vulva now. I have gradually developed a different relationship to it. Ím not so afraid of it. And maybe it is a little easier to place it, in a way. Because when it has been painful in the past, I have stayed away from it, I would avoid touching it, expecting pain. Whereas now it is not so scary anymore. I have started to become more aware of my contact with the pelvic floor, relaxing the tensions in these muscles. I think this practice has contributed to it. And to think about the vulva as part of the body. That it is not simply a problem area, being more kind to it.

Lily and Fiona, however, who had experienced little improvement following the SCT approach, felt it would have been more helpful if the therapy also included a more hands-on approach to the PFMs. From previous treatment interventions, such as physiotherapy or osteopathy, they had both experienced how manual techniques could help reduce tensions in their PFMs. Fiona also felt it would have been useful if the therapist could give her feedback on the state of tension in her PFMs and any progress, as she felt unable to assess this herself:

> It [SCT] is great for the mental aspect and for relaxation and those things, but I miss a more physical approach. The therapist doesn't do that here, it is me who is supposed to do things, if that makes sense? I particularly miss having the therapist being able to tell me if I am making progress.

Some of the other participants also had experiences with manual techniques for stretching and relaxing the PFMs from previous treatments but emphasised that being encouraged to familiarise themselves with their own vulvas and taking ownership of their own process was gentler and made more sense in a long-term perspective. As Tessa explained:

> I have appreciated both approaches, but I feel that I have benefited more from this approach in a long-term perspective. The previous treatment was more short-term. Maybe you felt better the next day, but the following week it was just as tight again. Whereas here we are working more holistically. I have more confidence in this approach because everything is connected; the tensions and the pain and the breath, the physical and the psychological …

Developing a greater awareness of internal feelings and bodily states

All ten women described having a distant relationship with their bodies at the start of treatment. Some described a lack of awareness of bodily signals and needs. Others described a more purposeful strategy to live from the neck and up, avoiding checking in with the sensations of the body. To some of the participants, this disconnection from the body was tied to a busy lifestyle. Adele explained how she sometimes would forget to meet her basic bodily needs such as eating and sleeping, because she was cramming too many activities into her daily schedule. Jenna experienced high levels of stress, responsibility, and a pressure to perform at work, and stopping to acknowledge her internal states felt like an inconvenience. For others, the bodily disconnection was due to fear. Some of the women described how bodily signals could feel threatening and could give rise to anxiety or even panic. For Emily, living disconnected from the sensations of her body was a conscious coping strategy. To her, the body felt unreliable and unpredictable, and bodily signals and sensations felt intimidating. These were often met with catastrophic interpretation:

> Before I had a fear that if I paid close enough attention, I might discover that there was pain, or that I might trigger pain in a way. Everything from the neck down was just gone. That part of me would have to manage on its own. I wouldn't think about it or talk about it or anything. And that is not good, because then when something actually happens, when you react to something, you think: Oh my God! This is very unusual or really painful, or this is something I haven't felt in a long time, this is really weird!

The explorative treatment approach encouraged the women to actively turn their attention inward, to become aware of and dare to be present with the different bodily sensations as they moved, breathed, and relaxed. Gradually, this inquisitive approach started a process moving towards listening to the body with greater calmness and curiosity, and with less fear. As bodily reactions and sensations became increasingly normalised and comprehensible, the body felt less threatening and unpredictable. Daring to be in contact with both pleasant and unpleasant feelings and sensations was viewed as an important part of the therapeutic process for most of the women. They increasingly felt better equipped to notice, understand, and address bodily reactions. To Isabelle, this process provided a greater confidence in being able to understand and regulate her bodily and emotional reactions:

> I feel that I am better able to control the reactions in my body and to be present in my body. At least compared to how it was before. Before when I felt an emotion, I would just shut it out. Because that

> was my best way of getting through it, or to deal with it. But now I have gained some tools to handle things better, and to be aware of how I am feeling. I feel that is very useful.

As well as developing a greater awareness of bodily feelings and states, several of the women also described an important shift towards starting to value, trust, and let themselves be guided by their internal bodily cues. Accessing bodily cues as an internal guide helped Olivia to sense how her body and PFMs would tense up, and how her breathing became restricted, at the prospect of painful intercourse. It also enabled her to notice unhelpful thoughts that would typically arise in anticipation of painful sex:

> In the beginning I could actually be really afraid, and then I would notice that I tensed up my entire body, I held my breath. And that is how it was before too, when I would think about having sex. So, I notice that there are a lot of negative thoughts associated with it, and then you want to protect yourself. When you expect that it will be painful, then you just sort of want to get it over with, you don't really want to.

Gaining more insight into these connections made it easier to start letting go of unhelpful muscular defense mechanisms, for example through various relaxation and breathing techniques.

Although the process of developing a greater awareness of internal feelings and bodily states was valued as meaningful by most women, it was found to be a challenging process. As guided explorative exercises could involve encountering intimidating sensations, thoughts, and feelings previously avoided, this was sometimes a process that required both courage and persistence. Having to uncover and address painful issues at the initial stages of treatment felt hard to some of the participants. This process caused Lily to experience a surge of difficult thoughts and feelings about her past and future. In a similar vein, Jenna explained how it brought up painful memories from her childhood that she had not processed:

> I guess I have tried to cover things up. That I have thought to myself that I am okay and that things are fine. And through filling out the questionnaires and talking with the therapist, I have become more aware of things .... That I actually carry with me some things that are quite difficult. So that has probably been very useful, but also hard.

Becoming aware of the complexity of different factors involved in their experiences of sexual pain could also feel overwhelming. Some found being confronted with the magnitude of different physical, mental, and behavioural habits to address at one time daunting. Although attributing a lot of her improvements to this process, Mary remembered feeling overwhelmed and even a little disheartened at first, becoming aware of her maladaptive habits and discovering how much she had to work on:

> It can feel like a lot. Like everything is wrong with me. The way I stand and walk and breathe... I am doing everything wrong (laughs). It can feel like a lot. But the therapist is very good at helping me address one thing at the time.

Developing sex-positive beliefs and behaviours

Almost all the participants recounted enduring painful intercourse with their current partners, or a history of doing so if not currently in a relationship. Several tied this to a sense of duty or expectation to be sexually available in an intimate relationship and expressed a sense of guilt or shame at not being able to offer their partner sex. Most of the women's accounts demonstrated self-effacing tendencies; down prioritising their own needs and not wanting to burden their partners with their problems. As Isabelle put it:

> I guess it [enduring painful sex] is motivated by a desire to perform, in a way. And you don't want to disappoint your partner either. Sort of trouble your partner with your own problems.

Thematizing sexual health and pleasure with the therapist, combined with an inquisitive approach to the body and its sensations, started a process of developing a new way of viewing sex. This process involved building confidence to safeguard bodily boundaries, as well as developing a healthy curiosity towards their own sexuality. Adele described how she had become inspired to be more tuned into her own needs and desires when it came to sex. She wanted sex to be *'for my own sake, to get more pleasure and enjoyment out of it myself. That this is about me now'*.

Becoming more curious about their own sexual needs and desires, several of the women expressed a stronger wish to safeguard their own boundaries concerning sex and pain, and to access sexual pleasure and joy. Feeling more empowered in sexual situations, they now felt ready to explore their own sexuality further, to try different ways of having sex, and to discover what could feel enjoyable for them. Already midway through the SCT course Olivia felt more confident in setting limits for her own body:

> I have always felt very strongly that I have to perform. Even if it [sex] is only barely achievable, I do it. But then there is no longer any joy associated with it. (...) So now I have learnt to say – 'No, this is my body, why should you ...'. Just put my foot down, no matter if they don't want me. And the more you say no, the more empowered you feel (laughs). (...) I am very positive to having sex now. I can even understand the enjoyment part better.

Rediscovering their potential for experiencing sexual desire and pleasure however, felt challenging to some of the participants. Particularly the women who had never experienced positive feelings or sensations in relation to sex found it difficult to know where to start this process of familiarising themselves with their sexuality. To Lily, being encouraged to approach her own sexuality with curiosity and patience felt frustrating as she felt at a loss as to what to look for. To her sex had only ever been associated with pain, anxiety, and shame:

> I don't really know what I am supposed to look for, because I don't know what feels good. The only thing I think of when I think about my vulva and my self is pain. Either I feel nothing, or it really hurts.

Although challenging, most of the women found this process of connecting with their positive sexuality meaningful. Through exploring her body and sexuality, Tessa had started to learn more about ways she could experience pleasure and what she needed to *'get in the right mood'* for sex. She had realised how important it was for her to be both mentally

and physically prepared for sex. She reflected on how getting in the mood for sex was not just like turning a switch. She needed time and ample stimulation to feel ready. She also described how she used these insights in intimate situations with her husband, explaining to him what she needed him to do and making sure that sex was something that they could enjoy and take pleasure in together.

Discussion

Our findings depict three central processes towards improved sexual health. The first process, *developing positive feelings of embodiment,* involves a shift from self-objectification and bodily shame towards experiencing the body as a subject, inhabiting the body with more comfort and confidence, and beginning to relate to the body in more accepting and self-compassionate ways. The second process, *developing a greater awareness of internal feelings and bodily states,* involves a shift from bodily distance to turning attention inward and learning to trust and value bodily cues. The third process, *developing sex-positive beliefs and behaviours*, involves developing a healthy curiosity towards one's own body and sexuality, developing a sense of comfort with and entitlement to sexual feelings of desire and pleasure, and developing agency to know and assert sexual boundaries and needs.

Developing positive feelings of embodiment

A major finding in our study was participants' feelings of disembodiment at the start of the SCT program. This involved being preoccupied with meeting objectified expectations, rather than experiencing enjoyment. Resonating with these findings, a recent study reported that women with PVD often score high on measures for body-exposure anxiety [4]. As women who objectify their bodies tend to be more preoccupied with looking good rather than feeling good, sex can transform into a performance act rather than a subjective and joyful embodied experience. Shifting from self-objectification towards experiencing the body as a subjective site, on the other hand, can allow women more freedom to immerse themselves in joyful activities; to engage in the world with agency, comfort, and well-being [22].

Central to this shift, the women described how they were guided and encouraged to focus their attention inward, experiencing how the body felt rather than looked as they explored different ways of breathing and moving their bodies. Consistent with previous findings [19,34], this shift towards a more subjective experience of the body empowered the women to begin resisting the objectifying gaze of their culture and enabled a greater attunement to bodily feelings of pleasure.

The narratives of all ten women included descriptions of body disconnection and discomfort at the beginning of the SCT treatment course, describing how they mostly engaged with the world from the neck-up and harboured negative feelings about their bodies. The vulva was emphasised as an especially alienated part of the women's bodies. Consistent with previous research, the vulva was for many associated with pain and shame, and experienced as a disconnected, 'useless', or 'dead' part of the body [35,36].

Developing more positive feelings of body connection and comfort can promote sexual comfort and agency [37]. Several of the women described how their relationship with their bodies (and vulvas) had started to change through the SCT course. They gradually began relating to their bodies in more friendly ways, where the vulva felt more connected to the whole-body experience. Home assignments aimed at approaching the vulva with curiosity, kindness, and compassion, while at the same time paying mindful attention to the whole-body, played a key role in this process for several of the women. The integrative impact of moving between part and whole in this way has previously been found to promote an experience of the body as a cohesive, interconnected unit [35]. The current findings further illuminate how daring to explore intimidating bodily sensations and emotions was also valuable to support a coherent experience of the body.

Developing a greater awareness of internal feelings and bodily states

Most of the women described either being unaware of, or actively suppressing, information from their bodies pertaining to their physical, emotional, and sexual needs. These needs could include the need for food, rest, or sleep, the need for emotional support, or the need to set limits for themselves in sexual interactions as well as in everyday life. Attunement to internal needs, and responding to these needs in self-caring ways, is fundamental to an individual's overall health and well-being [22], of which sexual health is part.

The degree of attunement to bodily cues can also impact women's sexual health in more direct ways. Women with disrupted attunement to internal needs and cues are more vulnerable to engage in sexual activities that they are not ready for or may not enjoy [34], feeling compelled to put other people's needs before their own [22]. It is also likely that living disconnected from bodily signals and sensations will impede positive experiences of sexual pleasure, comfort, and well-being [18]. Supporting a shift towards greater attuned self-care could therefore be essential in improving the sexual health and well-being of women with PVD.

Several of the women in our study began developing a greater attunement to their internal feelings and needs through the SCT treatment sessions. Several also began to act on these internal cues in more self-caring ways. This involved tuning into what was going on in their bodies, and interpreting what their bodies were telling them. Some of the women described how this contributed to a greater sense of bodily comfort and agency. Coming into contact with internal feelings and cues empowered the women to make necessary adjustments to feel better in everyday situations, as well as in sexual contexts.

As our findings demonstrate, however, the process of developing a greater awareness of internal feelings and bodily states could feel both intimidating and overwhelming. It

has been suggested that women with vulvodynia might find comfort in a mind-body split as a way of distancing themselves from the troublesome body [17,36]. In support of this, our findings illuminate how fear and avoidance of potential physical and emotional pain caused several of the women to distance themselves from listening inwards. By suppressing uncomfortable signals from their bodies, the women were to a certain extent able to 'escape' their condition and its painful implications in daily, non-sexual contexts. Avoiding attending to these internal messages however, left them out of tune with their own internal states and needs, making it difficult to accurately interpret and respond to their bodily signals in self-caring ways.

Combined with a troublesome relationship with the vulva and/or sexuality, relating to bodily feelings and internal states with anxiety and avoidance could sustain a cycle of anxiety, bodily tension, and pain in sexual contexts [38,39]. Beginning to approach and explore rather than avoid their internal feelings and sensations required both effort and courage. At the same time, counteracting these fear-avoidance tendencies was emphasised as an important part of their therapeutic process towards improved sexual health.

Developing sex-positive beliefs and behaviours

Sexual agency is an essential component of a woman's sexual health and can be conceptualised as her '*ability to act on her own behalf sexually, express her needs and desires, and advocate for herself*' [40]. When a woman is able to act with agency, she can navigate her sexual life and make active choices to ensure her own sexual health and well-being [41,42]. Women with PVD, however, often feel compelled to engage in sexual intercourse despite pain, to down-prioritise their own sexual needs and wants in favour of their partner's desires, and to keep their sexual and emotional problems secret [14,15,36,43,44]. In line with these previous findings, the sexual experiences of the women in our study seemed oriented towards meeting the needs of and pleasing the other, rather than engaging with their own internal subjective needs and desires. There was little talk of their own pleasure in the interviews, and some experienced difficulties envisioning what pleasurable sex could even feel like. Our findings also illuminate how several of the women found it difficult to (re)connect with their own feelings of sexual desire and pleasure, and that some felt shameful about exploring their sexual bodies.

Developing a healthy curiosity towards their own body and sexuality was emphasised as a meaningful path towards improved sexual health for several of the participants. Being encouraged to explore pleasurable sensations in their bodies, not limited to the genital area, but rather familiarising themselves with their bodies overall, was helpful in this regard. Several also began exploring their bodily feelings of sexual pleasure, and to notice contexts that either facilitated or disrupted their ability to experience sexual desire. Beginning to develop a greater confidence in and comfort with their own sexual bodies in this way helped several of the women start to (re)connect to subjective feelings of desire and pleasure.

Developing more comfort with, and a healthy sense of entitlement to, sexual desire and pleasure has previously been found to empower women to act with more agency in relation to sexuality [18]. An increased sense of sexual agency was also expressed by several of the participants in our study. Several felt that (re)connecting with their body and sexuality in more positive ways further empowered them to communicate more openly about their pain and sexuality with their partner and to engage their partner in mutual intimacy and pleasure.

Strengths and limitations

By combining an explorative, semi-structured interview design with a feminist embodiment perspective, this qualitative study has enabled novel insights into possible interactions between the sexual health and quality of embodiment among women with PVD. The chosen theoretical framework contributes to illuminate how disrupted embodiment plays an important role in the sexual narratives of these ten women, and why experiencing embodiment and engaging with the world in an embodied way, can be challenging for them.

Another strength of this study lies in its choice of a longitudinal design. Follow-up interviews after one year allowed insight into processes of change that developed over time and helped us see how embodiment was a state the women moved in and out of, a continuous back-and-forth process. Follow-up interviews also enabled informal member checking, where preliminary interpretations from the first interviews could be validated or clarified by the participants.

This study also has some limitations that need to be addressed. Our study sample represents women who have sought out and received relevant care for their pain, and who were willing to participate in a research study and be interviewed about their experiences related to sexuality. It is possible that the sample is therefore made up of particularly resourceful women well suited for the potentially demanding SCT approach. Moreover, all ten women received treatment at the same out-patient clinic and were treated by the same physiotherapist – a female therapist with long clinical experience working with persistent pain patients. Nevertheless, the therapeutic processes narrated by these ten women might be transferable to other women in similar contexts. To allow the reader to consider the transferability of our findings in their own contexts of use, we have provided thorough descriptions of settings and participants.

Another limitation is that three of the women from the first round of interviews (Lily, Olivia, and Sophia) did not, for various reasons, take part in a follow-up interview.

Conclusion

This exploration of women's experiences with meaningful processes towards improved sexual health has provided novel insights into disrupted embodiment as an important dimension of the reduced sexual health seen among women with PVD. Interpreted through the lens of a feminist embodiment framework, our findings identify experiences of

disembodiment among all ten participants at the start of the SCT program. Our findings further suggest that through supporting subjective experiences of bodily comfort, pleasure, and agency, a bodily explorative physiotherapy approach such as SCT can initiate and support several beneficial processes that promote embodiment and sexual health among women with PVD.

Clinical implications

Exploring and considering the individual patient's attunement to her internal states and comfort in inhabiting her body and her sexuality can be relevant when tailoring a treatment plan for women with PVD. Physiotherapeutic modalities aimed at promoting subjective experiences of body connection and comfort and attuned self-care may enhance the sexual health and well-being for those women who tend to live disconnected from their bodily needs and wants. By encouraging the patient's active engagement in her own recovery process, the physiotherapist can help strengthen her agency to access her own feelings of desire and pleasure, to engage in (sexual) activities aligned with her own needs and wants, and to assert herself and act on her own behalf when engaging with the world.

At the same time, the women's experiences reveal that therapeutic processes involving exploring and allowing difficult sensations and emotions can be demanding and require significant effort and courage from the patient. A flexible and patient-centered approach that enables the patient to influence the pace, intensity, and progress of her therapeutic processes is therefore important. Developing a sound therapeutic alliance with the patient, built on empathy, trust, and shared decision-making, is crucial when approaching challenges with sexual health in this context.

As highlighted in our discussion, women's experiences of embodiment and sexual health are strongly influenced by compelling social discourses that encourage them to act demure, to objectify their bodies, and to subvert their own needs to meet the needs of others. If unaddressed in therapy, these contextual factors can hamper the therapeutic progress by limiting the woman's agency to know, feel comfortable with, and assert her needs and desires. Supporting a shift towards an experience of the body as the self, can help these women resist the objectifying norms of their culture and to pursue pleasure and well-being on their own terms.

Note

1. Sexual health is defined by the World Health Organization (WHO) as *"a state of physical, emotional, mental, and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility to having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence"* (WHO, 2006).

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

This work was funded by Oslo Metropolitan University under grant number 201127; and the Norwegian Fund for Post-graduate Training in Physiotherapy under grant number 112220. The funding bodies had no role in the design of the study and collection, analysis, or interpretations of data or the writing of the manuscript.

References

[1] Benoit-Piau J, Bergeron S, Brassard A, et al. Fear-avoidance and pelvic floor muscle function are associated With pain intensity in women With vulvodynia. Clin J Pain. 2018;34(9):804–810.
[2] Bornstein J, Goldstein AT, Stockdale CK, et al. 2015 ISSVD, ISSWSH and IPPS consensus terminology and classification of persisten vulvar pain and vulvodynia. Obstect Gynecol. 2016;127:745–751.
[3] Chisari C, Chilcot J. The experience of pain severity and pain interference in vulvodynia patients: the role of cognitive-behavioural factors, psychological distress and fatigue. J Psychosom Res. 2017;93:83–89.
[4] Chisari C, Monajemi MB, Scott W, et al. Psychosocial factors associated with pain and sexual function in women with Vulvodynia: a systematic review. Eur J Pain. 2021;25(1):39–50.
[5] Thomtén J, Karlsson A. Psychological factors in genital pain: the role of fear-avoidance, pain catastrophizing and anxiety sensitivity among women living in Sweden. Scand J Pain. 2014;5(3):193–199.
[6] Gómez I, Coronado PJ, Martín CM, et al. Study on the prevalence and factors associated to vulvodynia in Spain. Eur J Obstet Gynecol Reprod Biol. 2019;240:121–124.
[7] Harlow BL, Kunitz CG, Nguyen RHN, et al. Prevalence of symptoms consistent with a diagnosis of vulvodynia: population-based estimates from 2 geographic regions. Am J Obstet Gynecol. 2014;210(1):40.e41–40.e48.
[8] Vieira-Baptista P, Lima-Silva J, Cavaco-Gomes J, et al. Prevalence of vulvodynia and risk factors for the condition in Portugal. Int J Gynaecol Obstet. 2014;127(3):283–287.
[9] Sadownik LA. Etiology, diagnosis, and clinical management of vulvodynia. Int J Womens Health. 2014;6:437–449.
[10] Moyal-Barracco M, Labat JJ. Vulvodynia and chronic pelvic and perineal pain. Prog Urol. 2010;20(12):1019–1026.
[11] Bergeron S, Reed BD, Wesselmann U, et al. Vulvodynia. Nat Rev Dis Primers. 2020;6(1):36.
[12] Connor JJ, Robinson B, Wieling E. Vulvar pain: a phenomenological study of couples in search of effective diagnosis and treatment. Fam Process. 2008;47(2):139–155.
[13] Katz SR. 1996. The experience of chronic vulvar pain: psychosocial dimensions and the sense of self (publication number 9610566) [Ph.D., The Fielding Institute]. ProQuest Dissertations & Theses Global. Ann Arbor.
[14] Ayling K, Ussher JM. If sex hurts, am I still a woman? The subjective experience of vulvodynia in hetero-sexual women. Arch Sex Behav. 2008;37(2):294–304.
[15] Braksmajer A. "That's kind of one of our jobs": sexual activity as a form of care work among women with sexual difficulties. Arch Sex Behav. 2017;46(7):2085–2095.
[16] Hinchliff S, Gott M, Wylie K. A qualitative study of heterosexual women's attempts to renegotiate sexual relationships in the context of severe sexual problems. Arch Sex Behav. 2012;41(5):1253–1261.
[17] Koops TU, Briken P. A woman should still be a woman – a grounded theory of the origins of sexual pain and difficulties with intercourse. J Sex Marital Ther. 2021;47(7):707–720.
[18] Chmielewski J, Bowman C, Tolman D. Pathways to pleasure and protection: exploring embodiment, desire, and entitlement to pleasure as predictors of black and white young women's sexual agency. Psychol Women Quart. 2020;44(3):307–322.

[19] Ellison T, Papps FA. 'Sexuality, without that mirror': the role of embodied practice in the development of sexual potential. Complement Ther Clin Pract. 2020;40:101205.
[20] Goldstein AT, Pukall CF, Brown C, et al. Vulvodynia. J Sex Med. 2016;13(4):572–590.
[21] Morin M, Carroll MS, Bergeron S. Systematic review of the effectiveness of physical therapy modalities in women With provoked vestibulodynia. Sex Med Rev. 2017;5(3):295–322.
[22] Piran N. 2017. Journeys of embodiment at the intersection of body and culture: the developmental theory of embodiment. London: Elsevier Academic Press.
[23] Foucault M. 1977. Discipline and punish: the birth of the prison. New York: Pantheon Books.
[24] Bartky SL. 1998. Foucault, femininity, and the modernization of patriarchal power. In Quinby IDL editor, Feminism & foucault: reflections on resistance. New York: Northeastern University Press.
[25] Beauvoir S. d. 1989. The second sex. New York: Vintage Books.
[26] Haugstad GK, Haugstad TS, Kirste UM, et al. Mensendieck somatocognitive therapy as treatment approach to chronic pelvic pain: results of a randomized controlled intervention study. Am J Obstet Gynecol. 2006;194(5):1303–1310.
[27] Kaarbø MB, Danielsen KG, Haugstad GK, et al. A conceptual model for managing sexual pain with somatocognitive therapy in women with provoked vestibulodynia and implications for practice. Physiother Theory Pract. 2022;2022:2096516.
[28] Klemmetsen I, Rugseth G. 2005. The mensendieck system of functional movements. Høvik: vett and Viten.
[29] Haugstad GK, Kirste U, Leganger S, et al. Somatocognitive therapy in the management of chronic gynaecological pain. A review of the historical background and results of a current approach. Scandinavian Journal of Pain. 2011;2(3):124–129.
[30] Kaarbø MB, Danielsen KG, Haugstad GK, et al. Feasibility and acceptability of somatocognitive therapy in the management of women with provoked localized vestibulodynia-ProLoVe feasibility study. Pilot Feasibility Stud. 2022;8(1):68.
[31] Kvale S, Brinkman S. 2009. Det kvalitative forskningsintervju (interviews: learning the craft of research interviewing, 2nd ed. Oslo: Gyldendal Akademisk.
[32] Archibald M, Ambagtsheer R, Casey M, et al. Using Zoom videoconferencing for qualitative data collection: perceptions and experiences of researchers and participants. Int J Qual Methods. 2019;18:1–8.
[33] Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3:77–101.
[34] Hirschman C, Impett E, Schooler D. Dis/embodied voices: What late-adolescent girls can teach us About objectification and sexuality. Sex Res Social Policy. 2006;3:8–20.
[35] Danielsen KG, Dahl-Michelsen T, Håkonsen E, et al. Recovering from provoked vestibulodynia: experiences from encounters with somatocognitive therapy. Physiother Theory Pract. 2019;35(3):219–228.
[36] Kaler A. Unreal women: sex, gender, identity and the lived experience of vulvar pain. Feminist Rev. 2006;82(1):50–75.
[37] Graham CA, Sanders SA, Milhausen RR, et al. Turning on and turning off: a focus group study of the factors that affect women's sexual arousal. Arch Sex Behav. 2004;33(6):527–538.
[38] Basson R. The recurrent pain and sexual sequelae of provoked vestibulodynia: a perpetuating cycle. J Sex Med. 2012;9(8):2077–2092.
[39] Darnell C. Tending to painful sex: applying the neuroscience of trauma and anxiety using mindfulness and somatic embodiment in working with genito-pelvic pain and penetration disorders. Sex Relationsh Ther. 2021;2021:1–13.
[40] Seabrook R, Ward L, Cortina L, et al. Girl Power or powerless girl? Television, sexual scripts, and sexual agency in sexually active young women. Psychol Women Quart. 2016;41(2):240–253.
[41] Kiefer A, Sanchez D. Scripting sexual passivity: a gender role perspective. Personal Relationships. 2007;14:269–290.
[42] Klein V, Becker I, Štulhofer A. Parenting, communication about sexuality, and the development of adolescent womens' sexual agency: a longitudinal assessment. J Youth Adolesc. 2018;47(7):1486–1498.
[43] Elmerstig E, Wijma B, Swahnberg K. Prioritizing the partner's enjoyment: a population-based study on young Swedish women with experience of pain during vaginal intercourse. J Psychosom Obstet Gynaecol. 2013;34(2):82–89.
[44] Groven KS, Råheim M, Håkonsen E, et al. Will I ever be a true woman? An exploration of the experiences of women with vestibulodynia. Health Care Women Int. 2016;37(8):818–835.

Paper IV

A conceptual model for managing sexual pain with somatocognitive therapy in women with provoked vestibulodynia and implications for physiotherapy practice

Kaarbø, M.B., Danielsen, K.G., Helgesen, A.L.O., Wojniusz, S. and Haugstad, G.K. (2022) A conceptual model for managing sexual pain with somatocognitive therapy in women with provoked vestibulodynia and implications for physiotherapy practice. *Physiother Theory and Pract*. Published online ahead of print on 10th of July 2022

https://doi.org/10.1080/09593985.2022.2096516

PHYSIOTHERAPY THEORY AND PRACTICE
https://doi.org/10.1080/09593985.2022.2096516

Taylor & Francis
Taylor & Francis Group

A conceptual model for managing sexual pain with somatocognitive therapy in women with provoked vestibulodynia and implications for physiotherapy practice

Mette Bøymo Kaarbø[a], Kristine Grimen Danielsen[a], Anne Lise Ording Helgesen[b,c], Slawomir Wojniusz[a,d], and Gro Killi Haugstad[a,e]

[a]Department of Physiotherapy, Oslo Metropolitan University, Oslo, Norway; [b]Department of Obstetrics and Gynecology, Oslo University Hospital, Oslo, Norway; [c]Department of Dermatology, Oslo University Hospital, Oslo, Norway; [d]Department of Neurology, Oslo University Hospital, Oslo, Norway; [e]Unit for Psychosomatics/CL Outpatient Clinic for Adults, Acute Psychiatric Department, Oslo University Hospital, Norway

ABSTRACT

Somatocognitive therapy is a multimodal physiotherapy treatment developed in the early 2000s to alleviate the burden of chronic pelvic pain. In recent years, somatocognitive therapy has been further developed to treat women with provoked vestibulodynia. This prevalent gynecological pain condition is a subgroup of chronic pelvic pain and the most common form of vulvodynia. Provoked vestibulodynia is a neglected multifactorial pain condition of unknown cause, adversely affecting women's sexual life, relation to their partners and their psychological health. Pain is located at the vulvar vestibule and is provoked by touch or pressure such as sexual intercourse. In the management of sexual pain, somatocognitive therapy combines bodily exploration, pain education, cognitive coping strategies and structured homework to improve sexual function and reduce pain. To support these processes, developing a sound therapeutic alliance with the patient is essential. The aim of this article is to provide a conceptual model for managing provoked vestibulodynia with somatocognitive therapy, including a theoretical rational for this treatment. We base our conceptual model on the biopsychosocial model, i.e., considering the complex interplay of biomedical, emotional/cognitive, psychosexual and interpersonal factors in provoked vestibulodynia management. In addition, implications for practice and a detailed description of somatocognitive therapy for provoked vestibulodynia will be provided, to allow replication in clinical practice and in clinical trials.

ARTICLE HISTORY
Received 12 January 2022
Revised 11 May 2022
Accepted 26 June 2022

KEYWORDS
Provoked vestibulodynia; vulvodynia; somatocognitive therapy; multimodal physiotherapy; sexual pain

Background

Somatocognitive therapy (SCT) is a multimodal physiotherapy approach developed at Oslo University Hospital in the early 2000s to alleviate the burden of longstanding pain. SCT was initially developed to treat patients with longstanding pelvic and gynecological pains of unknown etiology (Haugstad et al., 2006a, 2006b, 2008). SCT is built on therapeutic principles from both Mensendieck physiotherapy (Klemmetsen and Rugseth, 2005) and Cognitive therapy (Beck, 2005). The Mensendieck physiotherapy tradition is founded on principles of functional anatomy. Movement, both global quality of movement, and isolated movements, and a conscious sensory awareness of own body, which includes the state of muscle tension, are inherent principles of this tradition. Functional movements, relaxation and graded tasks are consciously practiced several times a day to learn new motor patterns that are applied, become automized and integrated to activities of daily living (Haugstad et al., 2011). The historical background of SCT is described in further detail by Haugstad et al. (2011).

In recent years SCT has been adapted and further developed to treat women with provoked vestibulodynia (PVD), a prevalent gynecological pain condition among young women. The development of SCT for the treatment of PVD, is based on promising findings from a feasibility study (Kaarbø et al., 2022) and a pilot study (Haugstad et al., 2019). In addition, it is based on findings from qualitative studies describing PVD patients' experiences with SCT (Danielsen, Dahl-Michelsen, Håkonsen, and Haugstad, 2019), and physiotherapy students' experiences with

CONTACT Mette Bøymo Kaarbø mettebkaarbo@gmail.com Department of Physiotherapy, Oslo Metropolitan University, Elisabeth Lampes hus, Pilestredet 44, 0167 Oslo,, Norway

This article has been corrected with minor changes. These changes do not impact the academic content of the article.

Supplemental data for this article can be accessed online at https://doi.org/10.1080/09593985.2022.2096516.

utilizing SCT in PVD management (Fougner and Haugstad, 2015). SCT is designed to target the multiple biopsychosocial (BPS) dimensions of PVD, utilizing a BPS framework, where the main goal of treatment is to improve women's sexual function and reduce vulvar pain. As part of the process toward improving sexual function, important subgoals of SCT are to develop body awareness, gain new bodily experiences and develop cognitive coping strategies, furthering their sense of self-efficacy and mastery of own life. In SCT, the women are encouraged to be actively engaged in their own therapeutic process and are empowered to take ownership of their body, sexuality and recovery process. SCT may ameliorate both physical symptoms and psychological distress in women with PVD, where the body and mind (i.e. cognitive and emotional factors) are equally important. To support these processes, a strong emphasis in SCT is on developing a strong therapeutic alliance with the patients through shared-decision making and setting patient-centered goals. The aim of this article is to provide a conceptual model for managing PVD with SCT, which includes a theoretical rational for this complex multimodal physiotherapy treatment. In addition, implications for practice and a detailed description of SCT for patients with PVD will be provided, seeking to provide full transparency to allow replication in clinical practice and in clinical trials.

Provoked Vestibulodynia

Provoked vestibulodynia (PVD) is a common gynecological pain complaint among premenopausal women. With an estimated prevalence between 7% and 16% (Gomez et al., 2019; Harlow et al., 2014; Vieira-Baptista, Lima-Silva, Cavaco-Gomes, and Beires, 2014) it represents the most common cause of painful sexual intercourse (Sadownik, 2014). PVD is the largest subtype of vulvodynia. According to the 2015 consensus terminology and classification of vulvar pain, vulvodynia is vulvar pain of at least 3 months without a clear identifiable cause, which may have potential associated factors (Bornstein et al., 2016). These include biomedical factors (peripheral and central pain mechanisms, inflammatory, hormonal, genetic predisposition, musculoskeletal, autonomic dysfunction) and psychosocial factors (Bergeron, Reed, Wesselmann, and Bohm-Starke, 2020).

PVD is characterized by a sharp burning pain provoked by touch or pressure localized to the vulvar vestibule, such as during penetrative intercourse, gynecological examination or tampon insertion. PVD can cause decreased sexual function (Smith, Pukall, and Chamberlain, 2013; Sutton, Pukall, and Chamberlain, 2009) and relationship difficulties, adversely affecting both women and their partners' mental, physical and sexual well-being (Sadownik, Smith, Hui, and Brotto, 2017). From January 2022, vulvodynia is included within the chronic pain syndromes, classified within the category "chronic primary visceral pain," in the 11th revision of the International Classification of Disease (Nicholas et al., 2019).

Although there are several pharmacological and non-pharmacological treatment options for PVD (Rosen, Dawson, Brooks, and Kellogg-Spadt, 2019) there is no gold-standard treatment guideline available (Bergeron, Reed, Wesselmann, and Bohm-Starke, 2020). Regardless of the treatment discipline, the overall treatment aims are to reduce pain and restore sexual function. Physiotherapy is recommended as a first-line treatment (Goldstein et al., 2016) although the optimal physiotherapy intervention is currently unclear (Morin, Carroll, and Bergeron, 2017). Until recently the efficacy of physiotherapy interventions have been supported by: uncontrolled studies (Bergeron et al., 2002; Goldfinger et al., 2009); one small controlled study (Gentilcore-Saulnier et al., 2010); and by a small pilot study (Goldfinger et al., 2016). A 2017 systematic review highlighted the need for high quality randomized clinical trials (RCTs) (Morin et al., 2017). This is supported by a newly published systematic review that underlines the need for more methodologically stringent trials on PVD interventions (Bohm-Starke et al., 2022). The authors stated that it was not possible to draw conclusions about the effects of treatments due to the very low certainty of evidence.

Traditionally, physiotherapy aims at rehabilitating the pelvic floor muscles and includes several modalities, used in combination or alone. The most commonly used physiotherapy interventions include pelvic floor muscle exercises with biofeedback, dilators and insertion techniques, manual therapy, electrotherapy, home exercises and education (Morin et al., 2017). In a recent study, Morin et al., 2021 found multimodal physiotherapy (i.e. combination of the above-mentioned modalities minus electrotherapy) to be effective in the management of PVD in a large multicenter RCT.

Research in the field of PVD has a long tradition of studying physical and physiological markers of genital pain, focusing primarily on causality. Moreover, there has been a tendency to conceptualize PVD in and dualistic fashion; either as a psychogenic sexual condition or biomedical condition (Chisari and Chilcot, 2017). The exact pathophysiological mechanisms of vulvodynia, including PVD, is not known, however there is an agreement in the literature that vulvodynia can be caused by various factors. In the past 20 years however, there has been a growing consensus that a BPS approach should be applied in the

management of PVD (Chisari et al., 2021b; Desrochers et al., 2010; Desrochers, Bergeron, Landry, and Jodoin, 2008; Thomtén and Linton, 2013) with emphasis on "improvement" in health, rather than cure of disease (Sadownik, 2000). This holistic model is considered one of the most appropriate conceptual frameworks for understanding chronic pain (Gatchel et al., 2007).

Conceptual model for managing PVD with SCT

The conceptual model for understanding and managing PVD with SCT is based on the BPS model, a model that was first conceptualized in 1977 (Engel, 1977). PVD appears to be the outcome of dynamic and reciprocal interactions among biomedical and psychosocial factors, including psychosexual and interpersonal factors, which perpetuates and exacerbates both the pain itself and the burden on patients. Like other chronic pain conditions, there is evidence of both peripheral and central pain mechanisms involved in the pathogenesis of PVD (Wesselmann, Bonham, and Foster, 2014; Zhang et al., 2011). An increase in the density of nerve endings in the vestibular endoderm has been found in PVD women (Bohm-Starke et al., 1998 Beck, 2005) as well as elevated levels of pro-nociceptive proinflammatory mediators (Falsetta et al., 2021). Their role in vulvodynia pathogenesis however, needs further investigation (Bergeron, Reed, Wesselmann, and Bohm-Starke, 2020). Some women with PVD display allodynia and hyperalgesia in response to stimuli applied to the vulvar vestibule and non-vulvar sites (Sutton et al., 2020). Torres-Cueco and Nohales-Alfonso (2021) argued that in vulvodynia pain is not associated with relevant peripheral nociception or injury or disease of the somatosensory system, but is a dysfunctional response of the central nervous system. The authors further suggest the use of the term complex pain. Multimodal neuroimaging studies support the possible role of central sensitization and alterations in endogenous pain modulatory systems in the central nervous system in PVD (Bhatt et al., 2019). This is further supported by the fact that PVD often coexists with other chronic pain conditions such as fibromyalgia, irritable bowel syndrome, painful bladder syndrome and orofacial pain (Reed et al., 2012) suggesting similar underlying pathophysiological processes.

In terms of musculoskeletal factors, PVD has been associated with a degree of pelvic floor muscle dysfunction, including hypertonicity, poor muscle control and altered contractility (Gentilcore-Saulnier et al., 2010; Morin et al., 2017). Whether the pelvic floor muscle hypertonicity is causally related to the etiology of PVD, or a consequence of pain remains unclear, due to the cross-sectional designs of studies (Pukall et al, 2016).

Psychological factors such as: depression (Burri, Hilpert, and Williams, 2020); catastrophizing thoughts (Thomtén and Karlsson, 2014); anxiety (Paquet et al., 2018); and early-life chronic stressors (Khandker et al., 2019) have been suggested to be important players in the development and maintenance of PVD. Several factors are associated with pain severity such as distress, illness perceptions, fatigue and cognitive-behavioral factors (Chisari and Chilcot, 2017; Chisari et al., 2021b) as well as fear avoidance and pelvic floor muscle function (Benoit-Piau et al., 2018). Chisari et al. (2021a) found body-exposure anxiety especially important in PVD, findings that are in line with one earlier study on body image in women with PVD (Maille, Bergeron, and Lambert, 2015). High pain anxiety and frequent solicitous partner responses to a woman's pain has also been found to predict higher pain-related sexual disability in PVD (Maunder, Dargie, and Pukall, 2022).

SCT is a complex physiotherapy intervention that addresses physical, psychological and psychosexual aspects of PVD with a multimodal approach, in order to improve sexual function and reduce vulvar pain. This involves several strategies to modulate altered central pain processing through bodily exploration, changing patients' erroneous thoughts about their pain, incorporating pain neuroscience education, reducing fear-avoidance or endurance behavior, and home exercises. There are five key components of SCT: 1) therapeutic alliance; 2) bodily exploration; 3) pain education; 4) coping with thoughts and emotions; and 5) structured homework (Fougner and Haugstad, 2015).

Therapeutic alliance

An essential goal of SCT is to develop a strong and positive therapeutic alliance with the patient (Haugstad et al., 2011). There are three elements required for a strong therapeutic alliance between the patient and the therapist: 1) agreement on goals; 2) agreement on tasks; and 3) an affective bond (Bordin, 1979, 1994). This involves the therapist and patient being in a close working relationship, collaborating on the treatment goals and home assignments. The affective bond between the two develops from mutual trust and is strengthened as goals are set and agreed upon (Bordin, 1994). The therapist's ability to be empathic is key in fostering a mutual emotional relationship (Fougner and Haugstad, 2015).

The therapist develops trust through empathic active listening, allowing the patient to express her true thoughts and feelings (Playford, 2015). In order to develop the therapeutic relationship, the physiotherapist needs to establish meaningful connections with their patients. This can consciously be done through: 1) acknowledging the individual (i.e. by meeting them as equals, validating their experiences and individualizing treatment); 2) giving-of self; and 3) using the body as a pivot point (i.e. respecting the patients' bodily experiences and helping patients develop body awareness) (Miciak et al., 2019). A key feature in the delivery of high-value care for patients with persistent pain conditions involves a patient-centered approach that includes establishing meaningful connections, self-management and shared decision-making (Hutting et al., 2022) which are important aspects in the SCT intervention.

In this empowerment-based SCT intervention there is an ongoing dialogue between the two where the physiotherapist explores the patient's inner dialogue by using Socratic questioning. This involves open and reflective questioning to identify and discover unhelpful pain-related cognitions and dysfunctional behavioral schemata as described by Beck (2005). The therapist also develops trust by creating a safe environment for raising sensitive issues, which may allow the patient to share personal information more readily and to actively engage herself in decision-making and change (Danielsen, Dahl-Michelsen, Håkonsen, and Haugstad, 2019). Being acknowledged as experts on themselves and being respected through dialogue can also contribute to giving patients a sense of control (Tveiten and Knutsen, 2011). The purpose of this empowerment process is to increase the patients' ability to think critically and act autonomously (i.e. activating the patients' own resources to be able to self-manage their condition, furthering their self-efficacy) (Anderson and Funnell, 2010). Emerging evidence from a 2018 systematic review suggests that for patients receiving physiotherapy for chronic musculoskeletal pain, a strong therapeutic alliance may improve pain outcomes (Kinney et al., 2018).

Patient participation and collaboration are especially important aspects of SCT. During SCT through shared decision-making common goals are set for each new treatment session and for the homework. Homework can be related to activities of daily living, breathing exercises, relaxation, and exploring ways of increasing intimacy and sexual activity. Initially, the patient may require more guidance in goal setting, as she will be challenged to undertake feared or painful tasks. The therapist actively encourages the patient, uses praise and highlights small improvements made by the patient, improvements that are not so easy to identify for her, to strengthen hope and motivation. Important learning processes occur especially in the space between the treatment sessions as new skills (e.g. slow deep breathing, sitting relaxed, and coping skills) are practiced. Homework is also practiced while the patient is alone and/or with a partner and consists of exploring pain sensitive areas of the vulva and engaging in meaningful sexual activities. At the start of each treatment session, new experiences are discussed and goals adapted accordingly.

Bodily exploration

The goal with bodily exploration is to achieve a new broader recognition through an exploratory approach, together with functional goals (e.g. relaxed sitting, tampon use, and penetrative intercourse) which are linked to activities of daily living (Klemmetsen and Rugseth, 2005). Emphasis is on acquiring new experiences through the body, shifting the focus from thoughts associated with pain, anxiety or fear, to the functions of everyday life. Haugstad et al. (2018) demonstrated findings of maladaptive movement and breathing patterns in women with PVD including reduced quality of movement especially for gait, but also for sitting and standing posture. In addition, these women demonstrated a reduced ability to let go of their arms and give into gravity, as well as reduced rotation of the pelvis during gait. Such findings have also been observed in other long-lasting musculoskeletal pain conditions (Kvåle, Ljunggren, and Johnson, 2003) and chronic pelvic pain (Haugstad et al., 2006b). These findings can possibly be explained by patients' reduced body awareness, that is, reduced contact with bodily sensations and emotions (Price and Mehling, 2016). In the case of women suffering with PVD, they may also have a negative and distanced relationship with their vulva, the vulva being disconnected from the body (Danielsen, Dahl-Michelsen, Håkonsen, and Haugstad, 2019). During SCT maladaptive habitual movement, postural, and breathing patterns and muscular tensions are explored and addressed. As previously mentioned women with PVD have been found to score high on measures of body-exposure anxiety (Chisari et al., 2021a) hence it possible that some women feel shameful or anxious about their body in intimate contexts. SCT aims to foster a healthy curiosity toward own body and sexuality, encouraging the women to apply these new bodily experiences to intimate and sexual situations.

During the treatments, exploration of the body and its functions occurs in various positions such as in sitting, standing, lying or walking. The patient is encouraged to direct her focus toward how movements are done (i.e. the quality of the movement and how this is

experienced) learning to move more freely and with less effort. During this process, the physiotherapist demonstrates with her own body and posture, actively using and guiding with her hands while speaking clearly in a calm voice. To increase interoceptive body awareness, the patient is encouraged to direct her attention inwards to become more aware of different sensations from the inside of her body. To increase awareness of the pelvic floor muscles, the patient is encouraged to be aware of the muscles in functional activities such as in sitting, during intercourse, stopping urination mid-flow or inserting a finger into the vagina to feel the muscle contraction and then let go, often combined with deep breathing.

At the core of body awareness lies the concept of sensitivity. Sensitivity to bodily signals is the tendency to be aware of bodily states, to notice subtle changes to internal and environmental conditions and to be able to distinguish between different sensations (Ginzburg, Tsur, Barak-Nahum, and Defrin, 2014). This sensitivity to bodily signals applies to both the patient and the therapist. Being bodily present with the patient enables the therapists to explore and understand their own bodies and to be sensitive to the body of their patients (Engelsrud, Øien, and Nordtug, 2019). The therapist's own body awareness affects both the relationship and therapeutic alliance with the patients and is an essential component of the SCT approach (Haugstad et al., 2011). Throughout the bodily exploration, the patient is encouraged to be attentive to the experiences that arise in her body and become more aware of internal feelings and states. Through silence, the therapist creates space for the patient to be mindful, to focus inwards, to make her own discoveries and hold on to the awareness of the body (Hedlund and Gyllensten, 2013). The patient may notice bodily sensations, experienced as negative, positive or neutral, but also become aware of how she reacts emotionally to these stimuli (Price and Mehling, 2016). These new insights and experiences are then shared with the physiotherapist and become the subject of a dialogue between the two.

During SCT, the physiotherapist uses massage to address muscular tension, which is combined with verbal instructions and open-ended questions. Massage and touch are naturally integrated in the bodily exploration of which gaining consent prior to touching the patient is essential. Massage and touch can be applied around the pelvis, abdomen and lower limbs in the form of manually releasing tensed muscles, such as the hip adductors and gentle stroking movements across the abdomen and pelvis. This is done to increase sensory stimulation furthering body awareness as well as inducing relaxation. Through touch, new sensory and motor experiences are elicited, increasing interoceptive awareness of sensations, to help the patient become aware of bodily sensations other than pain (Price and Mehling, 2016). How the patient directs and focuses her attention on bodily sensations and emotions can play an important role in pain regulation, but also in emotion regulation. Touch in SCT however does not involve direct palpation or intravaginal treatment unlike how it can be utilized in other physiotherapy treatments for PVD (Morin et al.,2021).

Empirical evidence on touch is limited within the physiotherapy field and comes predominantly from the nursing profession. Touch is especially important in the interaction between the physiotherapist and patient (Bjorbækmo and Mengshoel, 2016). Touch can build connections, thus fostering a sense of trust, which provides as a means of strengthening the bond between the therapist and patient (Miciak et al., 2018, 2019). The purposes of touch can be therapeutic, but also be a means of providing information (Roger et al., 2002) and communicate empathy (Paterson, 2007) and acceptance and support (Bjorbækmo and Mengshoel, 2016). Geri et al. (2019) described several purposes of touch; analgesic, regulation of emotions and reorganizing the body's mental representation. Through creative exploration, touch and movement, the therapist tunes into and senses the patient's bodily capacity and experience. This, which is a form of bodily empathy or embodied presence, is enhanced when therapists have an increased awareness of their own bodily sensations, thoughts, and emotions (Danielsen, Fougner, and Haugstad, 2021; Engelsrud, Øien, and Nordtug, 2019: Skjaerven, Kristoffersen, and Gard, 2010).

Another important aspect of the bodily exploration is addressing the patient's respiration pattern. In patients with longstanding pain, including PVD, altered breathing patterns can include shallow thoracic breathing or breath withholding during activities of everyday life. Tension in the accessory respiratory muscles combined with reduced thoracic cage compliance can limit normal chest movement and hamper the diaphragmatic descent (Chaitow, Bradley, and Gilbert, 2014). During SCT patients are taught slow deep breathing exercises where slow breathing is defined at a rate between 4 and 10 breaths per minute (Russo, Santarelli, and O'Rourke, 2017). As the patient inhales deeply the lower ribs expand laterally, the chest stays still while the abdomen expands, causing the dome-shaped diaphragm to descend and flatten (Vostatek et al., 2013). As the diaphragm descends caudally so does the pelvic floor muscles (Emerich Gordon and Reed, 2020). In SCT the patients are made aware of the co-work between respiration and the pelvic floor muscles; on inhalation the

pelvic floor muscles relax and on exhalation these muscles contract. Inhalation is followed by active prolonged expiration. The patient takes an expiratory pause prior to the next inspiratory breath. Studies have shown that slow deep breathing techniques can have a variety of therapeutic effects on the body and mind revealing benefits for: pain (Chalaye, Goffaux, Lafrenaye, and Marchand, 2009); stress (Gerritsen and Band, 2018); and negative mood (Busch et al., 2012). Breathing is also important in the modulation of the autonomic nervous system, where slower respiration has shown to result in stronger sympatho-inhibition (Jerath, Beveridge, and Barnes, 2019).

The patients are taught relaxation techniques as an active coping strategy, learning to feel the difference between muscular tension and relaxation. During the treatment session, progressive muscle relaxation, as first described by Edmund Jacobson in the 1920s (Mackereth and Tomlinson, 2010) are normally combined with gentle massage and slow deep breathing. These techniques can break a pain cycle by inducing a relaxed condition and by shifting anxious thoughts about pain to calmness and a sense of wellbeing. A recent systematic review found that relaxation techniques, such as progressive relaxation, can reduce pain among chronic pain patients. These techniques however, require ongoing practice over time and should be used as a supplement to other treatments (Vambheim, Kyllo, Hegland, and Bystad, 2021). In SCT the patients learn to recognize early signs of muscle tension and learn to apply relaxation and breathing exercises into their daily life such as during movement or when sitting or standing. The therapist and patient goes on to discuss how the patient can apply breathing and relaxation, in intimate or sexual situations, furthering the patient's sexual function, alone or with a partner.

Pain education

An important goal of SCT is to educate the patients about the multifactorial nature of PVD from a BPS perspective. As SCT is anchored in this model, an important goal is to apply and adapt this to the individual, helping the patients to view pain from a multidimensional perspective. Pain education in the form of pain neuroscience or cognitive behavioral therapy (CBT) has shown several therapeutic benefits, especially in combination with other modalities (Louw, Zimney, O'Hotto, and Hilton, 2016). A recent systematic review found a significant reduction in pain and disability when pain education was combined with traditional physiotherapy among patients with chronic pain (Marris et al., 2021). In SCT, pain neuroscience is an important part of the treatment. During treatment, the patients are encouraged to share their experiences, beliefs and understanding about their condition, such as pain, anatomical knowledge and vulvovaginal habits and how this affects them. This again becomes various topics of discussion between the patient and therapist. The educational component of SCT can be addressed and incorporated during any of the three phases of the treatment session (Table 1) and is further described in the Supplemental Material. Questions may arise during the initial conversation as the patient shares her experiences with the homework. The educational component is also frequently merged with bodily exploration as the physiotherapist and patient are in a close dialog.

Being well-informed is empowering and can help the patients self-manage their condition with more confidence, self-belief, hope and optimism, increasing their sense of self-efficacy (Bandura, 1977). In previous qualitative studies, women with PVD have described the positive impact and value of receiving comprehensive and accurate information about their condition (Danielsen, Dahl-Michelsen, Håkonsen, and Haugstad, 2019; Sadownik, Seal, and Brotto, 2012). In addition, it is important to validate and acknowledge patients' symptoms (Danielsen, Dahl-Michelsen, Håkonsen, and Haugstad, 2019) while assuring them about the absence of worrisome pathology. Fear associated with touch or penetration can gradually be reduced as the patients understand that pain does not equal danger or harm. For many women the painful vulva is associated with negative thoughts and emotions. Withdrawing from sexual intercourse due to pain is often associated with negative feelings of guilt, stress, and frustration (Groven, Råheim, Håkonsen, and Haugstad, 2016). As previously mentioned the vulva can be experienced as disconnected from the rest of the body. In approaching the body as a whole, demystifying the genital anatomy and function, women can develop positive associations with the painful area. Gaining a better understanding of how thoughts and emotions can influence the pain experience may reduce catastrophizing thoughts, rumination and worry about the condition.

PVD is an individual experience; however, the social context is especially relevant considering PVD primarily occurs in the context of sexual intercourse. An important aspect of the educational component incorporates discussions involving the patients' life situations and how PVD can affect the relationship, sexual desire, arousal and motivation. This is done to improve the women's sexual function, improve partner communication, promote non-painful sexual activities and guidance on steps toward resuming sexual intercourse. The patients are made aware that sexual activity is not

Table 1. Overview of somatocognitive therapy, as per TIDierR criteria.

TIDierR items	Description
Brief name	Somatocognitive therapy for Provoked Localized Vestibulodynia
Why	Few RCTs exist, important to develop effective treatments that can easily be applied in primary care.
What	SCT is a multimodal physiotherapy treatment designed to target the multiple dimensions of vulvar pain, utilizing a biopsychosocial approach. A bodily approach is combined with cognitive restructuring of negative thoughts. Overall, the aim is to improve sexual function and to reduce vulvar pain and psychological distress.
Materials: Participants	Resources: vulva.no and sexogsamfunn.no
Materials: Physiotherapist	Equipment: treatment bench, mat, pillows, massage balls, mirror, Pilates ball.
Procedures	**Initial appointment**: Assessment – take a thorough history (including previous experiences, beliefs and expectations) and a clinical examination (quality of movement, breathing pattern). The main areas of SCT include: ***Therapeutic alliance*** is an essential component of SCT; patient and therapist are in a close working relationship, agreeing on treatment goals and home assignments. Participants take an active part in the decision-making process about their own treatment and progression. ***The bodily approach***: breathing patterns, maladaptive movement and postural patterns are addressed in various positions (sitting, standing, walking and in supine). Through manual techniques and touch, participants are taught various techniques to increase body awareness, improve relaxation and reduce muscle tension. ***Pain education*** about PVD, pain neuroscience, stress and healthy vulvo–vaginal and sexual behaviors. Conversations on topics related to sexuality and relationship issues to improve partner communication and sexual health. ***Coping*** with thoughts and emotions related to bodily experiences. Participants learn to become aware of negative/catastrophizing thoughts and how to restructure or accept these thoughts as well as how to overcome fear avoidance behavior. An important aspect is the women's ability to adapt and to self-manage their condition, such as coping with pain and flare-ups. ***Structured homework*** promoting the application of learned techniques in daily situations. Gradual exposure to activities associated with pain, desensitization exercises and exercises to increase pelvic floor muscle and vulva awareness. Relaxation and breathing exercises. Last session – create a self-management toolbox with participant Booster session six months post treatment
Who provides	Female physiotherapists trained in SCT
How	Each session has a three phased structure: 1) conversation; 2) bodily intervention/exploration; and 3) home assignment.
Where	In a closed room with access to gym. Home assignments performed by the participants integrated into activities of daily living
When and how much	Number of sessions: maximum 15 face-to-face individual sessions, 10 sessions on average Treatment frequency: 2–4 sessions per month Number of sessions required and treatment frequency is personalized Booster session six months post treatment Each session lasts up to one hour
Tailoring	The treatment is personalized and tailored to the individual. Patients' participation and collaboration is important. Partner invited to session(s). The treatment principles are the same for all but are adapted to suit the individual's needs.

synonymous with penetrative intercourse, but instead can be manifold. Non-painful sexual activities are positive sexual experiences such as petting (i.e. kissing, caressing, and oral sex) or masturbation, either alone or with partner. The physiotherapist presents factors that can inhibit sexual desire, thereby interfering with the sexual response. Pain or fear of pain is a strong reflex inhibitor of lubrication, thereby impeding sexual arousal. Conversely, insufficient sexual arousal can in itself cause sexual pain during penetration (Giraldi, Rellini, Pfaus, and Laan, 2013). Encouraging the women to become more curious about their own feelings of desire and pleasure, as well as developing sexual agency to assert sexual boundaries and needs, are therefore important aspects of treatment. Topics related to sexuality is further described in Supplemental Material.

In some cases, it can be useful to have both the patient and partner together, hence the patient is invited to bring her partner to a session. The discussions and conversations related to sexuality are naturally adapted to the individual's needs. Findings from qualitative interviews from a feasibility study (Kaarbø et al., 2022) investigating the feasibility and acceptability of SCT for PVD, point to the importance of addressing sexuality and sexual health in SCT. Conversations related to sexuality and relationship issues have therefore been integrated into the SCT intervention for PVD. Promoting sexual health is an important part of this treatment, which is in line with earlier research, demonstrating how physiotherapy can promote sexual health (Areskoug-Josefsson and Gard, 2015a; Rosenbaum, 2005, 2006). Addressing topics on sexuality have also been incorporated in other interventions, such as multidisciplinary programs for PVD (Brotto, Yong, Smith, and Sadownik, 2015) and an integrated mindfulness-based approach (Rosenbaum, 2013).

Coping with thoughts and emotions

An important goal of SCT is to strengthen the women's ability to adapt and self-manage their condition. Self-managing PVD partly involves learning to cope with thoughts and emotions and learning how these closely interact with bodily reactions and sensations, thereby experiencing the

body as an interconnected unit. Women with PVD commonly present with avoidance behavior (i.e. abstaining from penetrative intercourse or other painful activities due to catastrophic misinterpretation of pain and pain-related-fear) (Benoit-Piau et al., 2018; Thomtén and Karlsson, 2014) which are in line with the Fear-avoidance model of pain (Vlaeyen and Linton, 2000). There are however many women who do not tell their partners about the pain and continue to endure sex despite pain (Elmerstig, Wijma, and Bertero, 2008), "fulfilling his needs not mine" (Carter et al., 2019). A recent PhD dissertation (Engman, 2021) introduced the Fear-avoidance-endurance model of vulvodynia a new model that combines the Fear-avoidance model and the Avoidance-endurance model (Hasenbring and Verbunt, 2010) in the same framework to demonstrate how psychological factors are involved in the development and maintenance of PVD.

In SCT the Fear-avoidance-endurance model is used during the treatment session to illustrate and describe how pain can generate catastrophic thoughts, fear, and muscle tension which in itself can increase the pain experience. The patient is guided to explore and recognize negative thoughts and feelings and find alternative and more constructive ways of thinking. Dysfunctional behavioral schemata (Beck, 2005) are also challenged through bodily exploration and dialog. In cases where patients endure painful sex it is important to identify the driving factor for this behavior, and thus promote partner communication and non-painful sexual activities. In utilizing an endurance coping strategy, interpersonal and social fears may be of greater importance than the pain itself (Ekdahl, Flink, Engman, and Linton, 2018) and may serve as an avoidance of negative consequences (Engman et al., 2018). This can be feelings of guilt or shame such as being an "inadequate sexual partner" (Ayling and Ussher, 2008) or fear of losing a partner (Elmerstig, Wijma, and Bertero, 2008). According to Engman et al. (2018) women who both avoid and endure painful sex have the most unfavorable outcome in terms of psychosexual functioning.

An important aspect of SCT is to reduce negative self-criticism, to encourage acceptance of themselves and nurture the ability to accept their emotional reaction to their vulvar pain, with self-compassion. Greater self-compassion, such as kindness and understanding toward oneself, has been found to be associated with lower anxiety and depression among women with vulvodynia and their partners (Santerre-Baillargeon et al., 2018). For some patients, it can also be useful to observe the pain sensations without judgment or evaluation, without trying to change the pain, thus allowing more acceptance. The patients are encouraged to focus on meaningful activities which are in line with their personal values, rather than avoiding the painful stimulus at all costs. Pain acceptance has been found to be an important psychosocial variable in PVD (Chisari et al., 2021a) where greater pain acceptance has been associated with lower pain during intercourse, lower anxiety and depression and greater sexual functioning in PVD (Boerner and Rosen, 2015).

Structured homework

An important goal with treatment is to facilitate integration of new bodily habits into patients' daily activities and various situations. In addition to suffering with pain during intercourse, PVD may limit the time a woman can sit on a chair, or on a bike and limit her choice of clothing, thereby affecting her quality of life. Structured homework is therefore essential and given in every session to promote the application of learned techniques and promote gradual exposure to activities (Broder, 2000). The therapist continuously ensures that the patient understands the importance of complying with the homework, emphasizing that the most important learning processes occur between the treatment sessions. The therapeutic techniques should be rehearsed several times a day in everyday situations and not as separate exercise sessions. The patient is encouraged to focus on normal functional movements in a relaxed manner incorporating relaxation and breathing exercises into practice throughout the day. This can be while walking to the bus, sitting watching television, lying down in bed or during sexual activities.

The homework also consists of self-exploration of the vulva, desensitization of the vulvar mucosa and graded exposure to feared activities. The goal with self-exploration is to increase the patients' curiosity and confidence in looking at and touching their own vulva, without negative expectations or catastrophic thoughts. In addition, the goal is to help them to integrate the genitals with the rest of their body image, developing positive feelings and connections toward their bodies, as some women have a difficult, distant and negative relationship with their vulva (Danielsen, Dahl-Michelsen, Håkonsen, and Haugstad, 2019). A poor genital self-image has also been associated with increased sexual distress and depression (Berman et al., 2003). However, women who experience positive feelings about their genitals measured on the Female Genital Self-Image Scale report better sexual functioning (Herbenick et al., 2011).

The women are taught desensitization exercises due to hypersensitivity to touch and pressure at the vulvar vestibule. During desensitization exercises, the painful vulvar area is touched and stimulated with the patients' own fingers to gradually reduce oversensitivity and normalize

the body's response to sensations. This can involve progressive stimulation with touch, pressure or massage, or the use of hot and cold water or cloths against the painful area starting with the least painful stimulation. The women are recommended to practice these exercises several times a day for a few minutes, while at the same time paying mindful attention to the whole-body including their thoughts and emotions. In a Swedish Cohort the use of desensitization exercises in combination with CBT has successfully improved sexual function and reduced the experience of pain in women with PVD (Lindström and Kvist, 2015). The desensitization exercises also serve the purpose of gradually exposing the patient to feared and/or avoided activities such as sitting with pressure on her vulva, using tampons of increasing size and/or penetrative sex. This structured exposure to activities associated with pain is an important aspect of SCT to reduce fear-avoidance behavior (Haugstad et al., 2019). At each session the homework is reviewed and adjusted, furthermore the physiotherapist will ask the patient about compliance with these exercises. The practical application of the homework is described in further detail in the Supplemental Material. In Table 1 an overview of SCT is presented, including the key components of SCT, utilizing the template for intervention description and replication (TIDieR) (Hoffmann et al., 2014).

Implications for practice

Physiotherapy treatments for PVD are usually provided by physiotherapists specialized in women's health. SCT however is designed to be easy to learn and easily implemented in primary health care. Female physiotherapy students have previously demonstrated their ability to both learn and deliver this treatment for women with PVD as part of their bachelor physiotherapy training (Fougner and Haugstad, 2015; Haugstad et al., 2019). Furthermore, the treatment is inexpensive, requires few resources, and no specialized equipment. As mentioned SCT differs from other physiotherapy treatments for PVD in that it does not involve intravaginal assessment or treatment. SCT aims to increase awareness of the vulva and pelvic floor muscles, although in a different manner to traditional treatment, as is further described in the Supplemental Material. Whether the inclusion of intravaginal pelvic floor muscle assessment and treatment in the SCT approach would improve its effectiveness in the management of PVD is not known. A direct comparison of SCT, with and without pelvic floor physiotherapy treatment, could potentially provide an answer to this question. This again could possibly provide further insights into the specific effects of pelvic floor physiotherapy in PVD management. A recent systematic review suggests that pelvic floor physiotherapy can be beneficial in patients with pelvic floor hypertonicity (van Reijn-Baggen et al., 2022). The quality of these studies, however, was low to moderate and only one of the studies in this review included women with PVD. In this study, 11 women with PVD were compared with 11 healthy controls (Gentilcore-Saulnier et al., 2010) results suggesting that pelvic floor physiotherapy may be beneficial in the management of PVD.

One of the goals of SCT is to promote self-management of PVD and avoid over-treatment and therapist-dependency. Based on findings from the feasibility study, the patients received a median number of 12 treatment sessions, each lasting 1 hour, allowing the incorporation of the multiple treatment components. The total number of treatment sessions provided and the treatment frequency is personalized. Initially, they receive one session per week which is reduced to one to two sessions per month, this to allow time for practice and integration of new skills into daily life. Although the focus for this article is SCT for PVD, SCT is a treatment approach that can be easily adapted to treat other complex disorders, such as multifactorial chronic pain conditions.

As part of the SCT approach for women with PVD, the physiotherapist promotes sexual health and aims to improve sexual function. Although physiotherapy has an important role in promoting sexual health, studies have found that sexual health is not sufficiently covered in physiotherapy education (Areskoug-Josefsson and Gard, 2015b). Furthermore, health professional students including physiotherapists lack competencies and preparedness in this field (Gerbild, Larsen, Junge, and Laursen, 2021).

Further descriptive details of the assessment and the practical application of SCT for PVD is provided in the Supplemental Material and should be utilized in conjunction with the main article.

Summary

SCT is a multimodal treatment utilized in the past 20 years in the management of patients with longstanding pain conditions. In recent years it has been further developed to manage women with PVD. SCT is a complex physiotherapy intervention, utilizing several modalities in combination to improve sexual function and reduce pain in women with PVD. A long-term aim is to improve

quality of life for these patients. In this professional theoretical article, a conceptual model for PVD with SCT has been presented (i.e. a BPS model for understanding and managing PVD with SCT). We further provided a theoretical rational for the key components of SCT, implications for practice, and detailed description of SCT to allow replication in clinical practice and clinical trials. Research has demonstrated that sexual health receives insufficient attention by physiotherapists; furthermore, this area is covered inadequately in physiotherapy education. In the treatment of PVD with SCT, the physiotherapist is in an ideal position to promote sexual health, where both the patient and the patient's partner can be involved in treatment to improve sexual function and quality of life.

Acknowledgments

Funding from Oslo Metropolitan University and the Norwegian Fund for Post-Graduate Training in Physiotherapy.

Disclosure statement

No potential conflict of interest was reported by the authors.

Funding

This work was supported by the Norwegian Fund for Post-Graduate Training in Physiotherapy; Oslo Metropolitan University

References

Anderson RM, Funnell MM, 2010. Patient empowerment: myths and misconceptions. Patient Education and Counseling. 79:277–282. doi:10.1016/j.pec.2009.07.025

Areskoug-Josefsson K, and Gard G, 2015a. Physiotherapy as a promoter of sexual health. Physiotherapy Theory and Practice. 31:390–395. doi:10.3109/09593985.2015.1023876

Areskoug-Josefsson K, Gard G, 2015b. Sexual health as a part of physiotherapy: the voices of physiotherapy students. Sexuality and Disability. 33:513–532. doi:10.1007/s11195-015-9403-y

Ayling K, Ussher JM, 2008. "If sex hurts, am I still a woman?" the subjective experience of vulvodynia in hetero-sexual women. Archives Sexual Behaviour. 37:294–304. doi:10.1007/s10508-007-9204-1

Bandura A, 1977. Self-efficacy: Toward a unifying theory of behavioral change. Psychological Review. 84:191–215. doi:10.1037/0033-295X.84.2.191

Beck A, 2005. The current state of cognitive therapy: A 40-year retrospective. Archives of General Psychiatry. 62:953–999. doi:10.1001/archpsyc.62.9.953

Benoit-Piau J, Bergeron S, Brassard A, Dumoulin C, Khalife S, Waddell G, Morin M, 2018. Fear-avoidance and pelvic floor muscle function are associated with pain intensity in women with vulvodynia. Clinical Journal of Pain. 34:804–810. doi:10.1097/AJP.0000000000000604

Bergeron S, Brown C, Lord MJ, Oala M, Binik YM, Khalife S, 2002. Physical therapy for vulvar vestibulitis syndrome: A retrospective study. Journal Sex and Marital Therapy. 28:183–192. doi:10.1080/009262302760328226

Bergeron S, Reed BD, Wesselmann U, Bohm-Starke N, 2020. Vulvodynia. Nature Reviews Disease Primers. 6:36. doi:10.1038/s41572-020-0164-2

Berman L, Berman J, Miles M, Pollets D, Powell JA, 2003. Genital self-image as a component of sexual health: relationship between genital self-image, female sexual function, and quality of life measures. Journal of Sex & Marital Therapy. 29:11–21. doi:10.1080/713847124

Bhatt RR, Gupta A, Rapkin A, Kilpatrick LA, Hamadani K, Pazmany E, Van Oudenhove L, Stains J, Aerts L, Enzlin P, et al. 2019 Altered gray matter volume in sensorimotor and thalamic regions associated with pain in localized provoked vulvodynia: A voxel-based morphometry study. Pain 160: 1529–1540. doi:10.1097/j.pain.0000000000001532

Bjorbækmo WS, Mengshoel AM, 2016. "A touch of physiotherapy" - The significance and meaning of touch in the practice of physiotherapy. Physiotherapy Theory and Practice. 32:10–19. doi:10.3109/09593985.2015.1071449

Boerner KE, Rosen NO, 2015. Acceptance of vulvovaginal pain in women with provoked vestibulodynia and their partners: associations with pain, psychological, and sexual adjustment. The Journal of Sexual Medicine. 12:1450–1462. doi:10.1111/jsm.12889

Bohm-Starke, N., Hilliges, M., Falconer, C., & Rylander, E. 1998. Increased intraepithelial innervation in women with vulvar vestibulitis syndrome. Gynecologic and obstetric investigation, 46(4), 256–260.

Bohm-Starke N, Ramsay KW, Lytsy P, Nordgren B, Sjöberg I, Moberg K, and Flink I, 2022. Treatment of provoked vulvodynia: A systematic review. The journal of sexual medicine 19:789–808.

Bordin ES, 1979. The generalizability of the psychoanalytic concept of the working alliance. Psychotherapy: Theory, Research and Practice. 16:252–260. doi:10.1037/h0085885

Bordin ES, 1994. Theory and research on the therapeutic working alliance: New directions. Horvath AO, Greenberg LS Eds The working alliance: theory, research, and practice. 13–37. New York: John Wiley and Sons

Bornstein J, Goldstein AT, Stockdale CK, Bergeron S, Pukall C, Zolnoun D, and Coady D, 2016. 2015 ISSVD, ISSWSH and IPPS Consensus terminology and classification of persistent vulvar pain and vulvodynia. Obstetrics and Gynecology. 127:745–751. doi:10.1097/AOG.0000000000001359

Broder MS, 2000. Making optimal use of homework to enhance your therapeutic effectiveness. Journal of Rational-Emotive and Cognitive-Behavior Therapy. 18:3–18. doi:10.1023/A:1007778719729

Brotto LA, Yong P, Smith KB, Sadownik LA, 2015. Impact of a multidisciplinary vulvodynia program on sexual functioning and dyspareunia. Journal of Sexual Medicine. 12:238–247. doi:10.1111/jsm.12718

Burri A, Hilpert P, Williams F, 2020. Pain catastrophizing, fear of pain, and depression and their association with female sexual pain. Journal of Sexual Medicine. 17:279–288. doi:10.1016/j.jsxm.2019.10.017

Busch V, Magerl W, Kern U, Haas J, Hajak G, Eichhammer P, 2012. The effect of deep and slow breathing on pain perception, autonomic activity, and mood processing - An experimental study. Pain Medicine. 13:215–228. doi:10.1111/j.1526-4637.2011.01243.x

Carter A, Ford JV, Luetke M, Fu TJ, Townes A, Hensel DJ, Dodge B, Herbenick D, 2019. "Fulfilling his needs, not mine": reasons for not talking about painful sex and associations with lack of pleasure in a nationally representative sample of women in the United States. Journal of Sexual Medicine. 16:1953–1965. doi:10.1016/j.jsxm.2019.08.016

Chaitow L, Bradley D, Gilbert C, 2014. The structure and function of breathing. Chaitow L, Bradley D, Gilbert C Eds Recognising and treating breathing pattern disorders: a multidisciplinary approach. 2nd 22–43 London:Elsevier

Chalaye P, Goffaux P, Lafrenaye S, Marchand S, 2009. Respiratory effects on experimental heat pain and cardiac activity. Pain Medicine. 10:1334–1340. doi:10.1111/j.1526-4637.2009.00681.x

Chisari C, Chilcot J, 2017. The experience of pain severity and pain interference in vulvodynia patients: The role of cognitive-behavioural factors, psychological distress and fatigue. Journal of Psychosomatic Research. 93:83–89. doi:10.1016/j.jpsychores.2016.12.010

Chisari C, Begleris I, Monajemi MB, Lewis F, Moss-Morris R, Scott W, McCracken LM, 2021a. A network analysis of selected psychosocial factors in vulvodynia and its subtypes. Pain Medicine. 22:2863–2875. doi:10.1093/pm/pnab265

Chisari C, Monajemi MB, Scott W, Moss-Morris R, McCracken LM, 2021b. Psychosocial factors associated with pain and sexual function in women with Vulvodynia: A systematic review. European Journal of Pain. 25:39–50. doi:10.1002/ejp.1668

Danielsen KG, Dahl-Michelsen T, Håkonsen E, Haugstad GK, 2019. Recovering from provoked vestibulodynia: Experiences from encounters with somatocognitive therapy. Physiotherapy Theory and Practice. 35:219–228. doi:10.1080/09593985.2018.1442540

Danielsen KG, Fougner M, Haugstad GK, 2021. Treating gynecological pain: Key factors in promoting body awareness and movement in somatocognitive therapy (SCT). A case study of a physiotherapy student's treatment approaches. Physiotherapy Theory and Practice. doi:10.1080/09593985.2021.1872125 Online ahead of print

Desrochers G, Bergeron S, Landry T, Jodoin M, 2008. Do psychosexual factors play a role in the etiology of provoked vestibulodynia? A critical review. Journal of Sex & Marital Therapy. 34:198–226. doi:10.1080/00926230701866083

Desrochers G, Bergeron S, Khalife S, Dupuis MJ, Jodoin M, 2010. Provoked vestibulodynia: psychological predictors of topical and cognitive-behavioral treatment outcome. Behaviour Research and Therapy. 48:106–115. doi:10.1016/j.brat.2009.09.014

Ekdahl J, Flink I, Engman L, Linton SJ, 2018. Vulvovaginal pain from a fear-avoidance perspective: A prospective study among female university students in Sweden. International Journal of Sexual Health. 30:49–59. doi:10.1080/19317611.2017.1404543

Elmerstig E, Wijma B, Bertero C, 2008. Why do young women continue to have sexual intercourse despite pain? Journal of Adolescent Health. 43:357–363. doi:10.1016/j.jadohealth.2008.02.011

Emerich Gordon K, Reed O, 2020. The role of the pelvic floor in respiration: A multidisciplinary literature review. Journal of Voice. 34:243–249. doi:10.1016/j.jvoice.2018.09.024

Engel GL, 1977. The need for a new medical model: A challenge for biomedicine. Science. 196:129–136. doi:10.1126/science.847460

Engelsrud G, Øien I, Nordtug B, 2019. Being present with the patient - A critical investigation of bodily sensitivity and presence in the field of physiotherapy. Physiotherapy Theory and Practice. 35:908–918. doi:10.1080/09593985.2018.1460431

Engman L, Flink IK, Ekdahl J, Boersma K, Linton SJ, 2018. Avoiding or enduring painful sex? A prospective study of coping and psychosexual function in vulvovaginal pain. European Journal of Pain. 22:1388–1398. doi:10.1002/ejp.1227

Engman L 2021 Vulvodynia: Understanding the Role of Pain-related Behavior. Doctoral Dissertation, Örebro University.

Falsetta ML, Wood R, Linder MA, Bonham A, Honn KV, Maddipati KR, Phipps RP, Haidaris CG, and Foster DC, 2021. Specialized pro-resolving mediators reduce pro-nociceptive inflammatory mediator production in models of localized provoked vulvodynia. European Journal of Pain. 22:1195–1209. doi:10.1016/j.jpain.2021.03.144

Fougner M, Haugstad GK, 2015. Treating gynaecological pain: The experiences of bachelor students in physiotherapy performing somatocognitive therapy. Physiotherapy Theory and Practice. 31:318–326. doi:10.3109/09593985.2014.1003343

Gatchel RJ, Peng YB, Peters ML, Fuchs PN, Turk DC, 2007. The biopsychosocial approach to chronic pain: scientific advances and future directions. Psychological Bulletin. 133:581–624. doi:10.1037/0033-2909.133.4.581

Gentilcore-Saulnier E, McLean L, Goldfinger C, Pukall CF, Chamberlain S, 2010. Pelvic floor muscle assessment outcomes in women with and without provoked vestibulodynia and the impact of a physical therapy program. Journal of Sexual Medicine. 7:1003–1022. doi:10.1111/j.1743-6109.2009.01642.x

Gerbild H, Larsen CM, Junge T, and Laursen BS Areskoug-Josefsson K, 2021. Danish Health Professional students' attitudes toward addressing sexual health: A cross-sectional survey. Sexual Medicine. 9:100323. doi:10.1016/j.esxm.2021.100323

Geri T, Viceconti A, Minacci M, Testa M, Rossettini G, 2019. Manual therapy: exploiting the role of human touch. Musculoskeletal Science and Practice. 44:102044. doi:10.1016/j.msksp.2019.07.008

Gerritsen RJ, Band GP, 2018. Breath of life: the respiratory vagal stimulation model of contemplative activity. Frontiers in Human Neuroscience. 12:397. doi:10.3389/fnhum.2018.00397

Ginzburg K, Tsur N, Barak-Nahum A, Defrin R, 2014. Body awareness: differentiating between sensitivity to and monitoring of bodily signals. Journal of Behavioral Medicine. 37:564–575. doi:10.1007/s10865-013-9514-9

Giraldi A, Rellini AH, Pfaus J, Laan E, 2013. Female sexual arousal disorders. Journal of Sexual Medicine. 10:58–73. doi:10.1111/j.1743-6109.2012.02820.x

Goldfinger C, Pukall CF, Gentilcore-Saulnier E, McLean L, Chamberlain S, 2009. A prospective study of pelvic floor physical therapy: pain and psychosexual outcomes in provoked vestibulodynia. Journal of Sexual Medicine. 6:1955–1968. doi:10.1111/j.1743-6109.2009.01304.x

Goldfinger C, Pukall CF, Thibault-Gagnon S, McLean L, Chamberlain S, 2016. Effectiveness of cognitive-behavioral therapy and physical therapy for provoked vestibulodynia: A randomized pilot study. Journal of Sexual Medicine. 13:88–94. doi:10.1016/j.jsxm.2015.12.003

Goldstein AT, Pukall CF, Brown C, Bergeron S, Stein A, Kellogg-Spadt S, 2016. Vulvodynia: assessment and treatment. Journal of Sexual Medicine. 13:572–590. doi:10.1016/j.jsxm.2016.01.020

Gomez I, Coronado PJ, Martin CM, Alonso R, Guisasola-Campa FJ, 2019. Study on the prevalence and factors associated to vulvodynia in Spain. European Journal of Obstetrics, Gynecology, and Reproductive Biology. 240:121–124. doi:10.1016/j.ejogrb.2019.06.005

Groven KS, Råheim M, Håkonsen E, Haugstad GK, 2016. "Will I ever be a true woman?" An exploration of the experiences of women with vestibulodynia. Health Care for Women International. 37:818–835. doi:10.1080/07399332.2015.1103739

Harlow BL, Kunitz CG, Nguyen RH, Rydell SA, Turner RM, MacLehose RF, 2014. Prevalence of symptoms consistent with a diagnosis of vulvodynia: Population-based estimates from 2 geographic regions. American Journal of Obstetrics and Gynecology. 210:40.e1–40.e8. doi:10.1016/j.ajog.2013.09.033

Hasenbring MI, Verbunt JA, 2010. Fear-avoidance and endurance-related responses to pain: new models of behavior and their consequences for clinical practice. Clinical Journal of Pain. 26:747–753. doi:10.1097/AJP.0b013e3181e104f2

Haugstad GK, Haugstad TS, Kirste UM, Leganger S, Klemmetsen I, Malt UF, 2006a. Mensendieck somatocognitive therapy as treatment approach to chronic pelvic pain: results of a randomized controlled intervention study. American Journal of Obstetrics and Gynecology. 194:1303–1310. doi:10.1016/j.ajog.2005.10.793

Haugstad GK, Haugstad TS, Kirste UM, Leganger S, Wojniusz S, Klemmetsen I, Malt UF, 2006b. Posture, movement patterns, and body awareness in women with chronic pelvic pain. Journal of Psychosomatic Research. 61:637–644. doi:10.1016/j.jpsychores.2006.05.003

Haugstad GK, Haugstad TS, Kirste UM, Leganger S, Wojniusz S, Klemmetsen I, Malt UF, 2008. Continuing improvement of chronic pelvic pain in women after short-term mensendieck somatocognitive therapy: results of a 1-year follow-up study. American Journal of Obstetrics and Gynecology. 199:615.e1–615.e8. doi:10.1016/j.ajog.2008.06.019

Haugstad GK, Kirste U, Leganger S, Haakonsen E, Haugstad TS, 2011. Somatocognitive therapy in the management of chronic gynaecological pain. A review of the historical background and results of a current approach. Scandinavian Journal of Pain. 2:124–129. doi:10.1016/j.sjpain.2011.02.005

Haugstad GK, Wojniusz S, Kirste UM, Kirschner RS, Lilleheie I, Haugstad TS, 2018. Pain, psychological distress and motor pattern in women with provoked vestibulodynia (PVD) - Symptom characteristics and therapy suggestions. Scandinavian Journal of Pain. 18:221–227. doi:10.1515/sjpain-2017-0173

Haugstad GK, Wojniusz S, Kirschner R, Kirste U, Lilleheie I, Haugstad TS, 2019. Somatocognitive therapy of women with provoked vulvodynia: A pilot study. Scandinavian Journal of Pain. 19:725–732. doi:10.1515/sjpain-2019-0011

Hedlund L, Gyllensten AL, 2013. The physiotherapists' experience of basic body awareness therapy in patients with schizophrenia and schizophrenia spectrum disorders. Journal of Bodywork and Movement Therapies. 17:169–176. doi:10.1016/j.jbmt.2012.10.008

Herbenick D, Schick V, Reece M, Sanders SA, Dodge B, Fortenberry JD, 2011. The female genital self-image scale (FGSIS): results from a nationally representative probability sample of women in the United States. Journal of Sexual Medicine. 8:158–166. doi:10.1111/j.1743-6109.2010.02071.x

Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, Altman DG, Barbour V, Macdonald H, Johnston M, et al. 2014 Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. BMJ 348: g1687. doi:10.1136/bmj.g1687

Hutting N, Caneiro J, Ong'wen OM, Miciak M, Roberts L, 2022. Patient-centered care in musculo-skeletal practice: key elements to support clinicians to focus on the person. Musculoskeletal Science and Practice. 57:102434. doi:10.1016/j.msksp.2021.102434

Jerath R, Beveridge C, Barnes VA, 2019. Self-regulation of breathing as an adjunctive treatment of insomnia. Frontiers in Psychiatry. 9:780. doi:10.3389/fpsyt.2018.00780

Kaarbø MB, Danielsen KG, Haugstad GK, Helgesen AL, Wojniusz S, 2022. Feasibility and acceptability of somatocognitive therapy in the management of women with provoked localized vestibulodynia - ProLoVe feasibility study. Pilot and Feasibility Studies. 8:68. doi:10.1186/s40814-022-01022-2

Khandker M, Brady SS, Rydell SA, Turner RM, Schreiner PJ, Harlow BL, 2019. Early-life chronic stressors, rumination, and the onset of vulvodynia. Journal of Sexual Medicine. 16:880–890. doi:10.1016/j.jsxm.2019.03.010

Kinney M, Seider J, Beaty AF, Coughlin K, Dyal M, Clewley D, 2018. The impact of therapeutic alliance in physical therapy for chronic musculoskeletal pain: A systematic review of the literature. Physiotherapy Theory and Practice. 36:886–898. doi:10.1080/09593985.2018.1516015

Klemmetsen I, Rugseth G, 2005. The mensendieck system of functional movements. Høvik:Vett and Viten

Kvåle A, Ljunggren AE, Johnson TB, 2003. Examination of movement in patients with long-lasting musculoskeletal pain: reliability and validity. Physiotherapy Research International. 8:36–52. doi:10.1002/pri.270

Lindström S, Kvist LJ, 2015. Treatment of provoked vulvodynia in a Swedish cohort using desensitization exercises and cognitive behavioral therapy. BMC Women's Health. 15:108. doi:10.1186/s12905-015-0265-3

Louw A, Zimney K, O'Hotto C, Hilton S, 2016. The clinical application of teaching people about pain. Physiotherapy Theory and Practice. 32:385–395. doi:10.1080/09593985.2016.1194652

Mackereth PA, Tomlinson L, 2010. Progressive muscle relaxation a remarkable tool for therapists and patients Chapter 6. Cawthorn A, Mackereth PA Eds integrative hypnotherapy: complementary approaches in clinical care. 82–96 Edinburgh:Elsevier Ltd

Maille DL, Bergeron S, Lambert B, 2015. Body image in women with primary and secondary provoked vestibulodynia: A controlled study. Journal of Sexual Medicine. 12:505–515. doi:10.1111/jsm.12765

Marris D, Theophanous K, Cabezon P, Dunlap Z, Donaldson M, 2021. The impact of combining pain education strategies with physical therapy interventions for patients with chronic pain: A systematic review and meta-analysis of randomized controlled trials. Physiotherapy Theory and Practice. 37:461–472. doi:10.1080/09593985.2019.1633714

Maunder L, Dargie E, Pukall CF, 2022. Moderators of the relationship between pain and pain-related sexual disability in women with provoked vestibulodynia symptoms. Journal of Sexual Medicine. 19:809–822. doi:10.1016/j.jsxm.2022.02.016

Miciak M, Mayan M, Brown C, Joyce AS, Gross DP, 2018. The necessary conditions of engagement for the therapeutic relationship in physiotherapy: an interpretive description study. Archives of Physiotherapy. 8:3. doi:10.1186/s40945-018-0044-1

Miciak M, Mayan M, Brown C, Joyce AS, Gross D, 2019. A framework for establishing connections in physiotherapy practice. Physiotherapy Theory and Practice. 35:40–56. doi:10.1080/09593985.2018.1434707

Morin M, Binik YM, Bourbonnais D, Khalifé S, Ouellet S, Bergeron S, 2017. Heightened pelvic floor muscle tone and altered contractility in women with provoked vestibulodynia. Journal of Sexual Medicine. 14:592–560. doi:10.1016/j.jsxm.2017.02.012

Morin M, Carroll MS, Bergeron S, 2017. Systematic review of the effectiveness of physical therapy modalities in women with provoked vestibulodynia. Sexual Medicine Reviews. 5:295–322. doi:10.1016/j.sxmr.2017.02.003

Morin M, Dumoulin C, Bergeron S, Mayrand MH, Khalife S, Waddell G, and Dubois MF 2021 , Multimodal physical therapy versus topical lidocaine for provoked vestibulodynia: A prospective, multicentre, randomized trial. American Journal of Obstetrics and Gynecology. 224:189.e1–189.e12 . doi:10.1016/j.ajog.2020.08.038

Nicholas M, Vlaeyen J, Rief W, Barke A, Aziz Q, Benoliel R, Cohen M, Evers S, Giamberardino M, and Goebel A 2019, et al. The IASP classification of chronic pain for ICD-11: chronic primary pain. Pain. 160:28–37. doi:10.1097/j.pain.0000000000001390

Paquet M, Rosen NO, Steben M, Mayrand MH, Santerre-Baillargeon M, Bergeron S, 2018. Daily anxiety and depressive symptoms in couples coping with vulvodynia: associations with women's pain, women's sexual function, and both partners' sexual distress. Journal of Pain. 19:552–561. doi:10.1016/j.jpain.2017.12.264

Paterson M, 2007. The senses of touch: haptics, affects and technologies. Oxford UK:Berg

Playford ED, 2015. Goal setting as shared decision making. London:CRC Press

Price CJ, Mehling W, 2016. Body awareness and pain. Thompson D, Brooks M Eds Integrative Pain management: massage movement and mindfulness based approaches. 235–251 Edinburgh:Handspring Publishing

Pukall CF G, Bergeron S, Foster D, Stein A, Kellogg-Spadt S, Bachmann G, 2016. Vulvodynia: definition, prevalence, impact, and pathophysiological factors. Journal of Sexual Medicine. 13:291–304. doi:10.1016/j.jsxm.2015.12.021

Reed BD, Harlow SD, Sen A, Edwards RM, Chen D, Haefner HK, 2012. Relationship between vulvodynia and chronic comorbid pain conditions. Obstetrics and Gynecology. 120:145–151 doi:10.1097/AOG.0b013e31825957cf

Roger J, Darfour D, Dha A, Hickman O, Shaubach L, Shepard K, 2002. Physiotherapists' use of touch in inpatient settings. Physiotherapy Research International. 7:170–186. doi:10.1002/pri.253

Rosen N, Dawson S, Brooks M, and Kellogg-Spadt S, 2019. Treatment of vulvodynia: pharmacological and non-pharmacological approaches. Drugs. 79:483–493. 5 doi:10.1007/s40265-019-01085-1

Rosenbaum TY, 2005. Physiotherapy treatment of sexual pain disorders. Journal of Sex & Marital Therapy. 31:329–340. doi:10.1080/00926230590950235

Rosenbaum TY, 2006. The role of physiotherapy in sexual health: Is it evidence-based? Journal of the Association of Chartered Physiotherapists in Women's Health 99:1–5.

Rosenbaum TY,2013. An integrated mindfulness-based approach to the treatment of women with sexual pain and anxiety: promoting autonomy and mind/body connection. Sexual and Relationship Therapy. 28:20–28. doi:10.1080/14681994.2013.764981

Russo MA, Santarelli DM, and O'Rourke D, 2017. The physiological effects of slow breathing in the healthy human. Breathe. 13:298–309. doi:10.1183/20734735.009817

Sadownik LA, 2000. Clinical profile of vulvodynia patients. A prospective study of 300 patients. Journal of Reproductive Medicine. 45:679–6848.

Sadownik LA, Seal BN, Brotto LA, 2012. Qualitative exploration of women's experiences. British Columbia Medical Journal. 54:22–28.

Sadownik LA, 2014. Etiology, diagnosis, and clinical management of vulvodynia. International Journal of Women's Health. 6:437–449. doi:10.2147/IJWH.S37660

Sadownik LA, Smith KB, Hui A, and Brotto LA, 2017. The impact of a woman's dyspareunia and its treatment on her intimate partner: a qualitative analysis. Journal of Sex & Marital Therapy. 43:529–542. doi:10.1080/0092623X.2016.1208697

Santerre-Baillargeon M, Rosen NO, Steben M, Paquet M, Macabena Perez R, and Bergeron S, 2018. Does self-compassion benefit couples coping with vulvodynia? Associations with psychological, sexual, and relationship adjustment. Clinical Journal of Pain. 34:629–637. doi:10.1097/AJP.0000000000000579

Skjaerven LH, Kristoffersen K, and Gard G, 2010. How can movement quality be promoted in clinical practice? A phenomenological study of physical therapist experts. Physical Therapy. 90:1479–1492 10. doi:10.2522/ptj.20090059

Smith KB, Pukall CF, and Chamberlain SM, 2013. Sexual and relationship satisfaction and vestibular pain sensitivity among women with provoked vestibulodynia. Journal of Sexual Medicine. 10:2009–2023. doi:10.1111/jsm.12213

Sutton KS, Pukall CF, and Chamberlain S, 2009. Pain, psychosocial, sexual, and psychophysical characteristics of women with primary vs. secondary provoked vestibulodynia. Journal of Sexual Medicine. 6:205–214. doi:10.1111/j.1743-6109.2008.01038.x

Sutton KS, Yessick LR, Wild CJ, Chamberlain SM, and Pukall CF, 2020. Exploring the neural correlates of touch and pain in women with provoked vestibulodynia. Pain. 161:926–937. 2020 doi:10.1097/j.pain.0000000000001778

Thomtén J, Linton SJ, 2013. A psychological view of sexual pain among women: applying the fear-avoidance model. Journal of Women's Health. 9:251–263.

Thomtén J, and Karlsson A, 2014. Psychological factors in genital pain: the role of fear-avoidance, pain catastrophizing and anxiety sensitivity among women living in Sweden. Scandinavian Journal of Pain. 5:193–199. doi:10.1016/j.sjpain.2014.01.003

Torres-Cueco R, and Nohales-Alfonso F, 2021. Vulvodynia—It is time to accept a new understanding from a neurobiological perspective. International Journal of Environmental Research and Public Health. 18:6639. doi:10.3390/ijerph18126639

Tveiten S, and Knutsen IR, 2011. Empowering dialogues - The patients' perspective. Scandinavian Journal of Caring Sciences. 25:333–340. doi:10.1111/j.1471-6712.2010.00831.x

Vambheim SM, Kyllo TM, Hegland S, and Bystad M, 2021. Relaxation techniques as an intervention for chronic pain: A systematic review of randomized controlled trials. Heliyon. 7:e07837. doi:10.1016/j.heliyon.2021.e07837

van Reijn-Baggen DA, Han-Geurts IJM, Voorham-van der Zalm PJ, Pelger RCM, Hagenaars-van Miert CHAC, and Laan ETM, 2022. Pelvic floor physical therapy for pelvic floor hypertonicity: A systematic review of treatment efficacy. Sexual Medicine Reviews. 10:209–230. 2022 doi:10.1016/j.sxmr.2021.03.002

Vieira-Baptista P, Lima-Silva J, Cavaco-Gomes J, and Beires J, 2014. Prevalence of vulvodynia and risk factors for the condition in Portugal. International Journal of Gynecology and Obstetrics. 127:283–287. doi:10.1016/j.ijgo.2014.05.020

Vlaeyen J, and Linton S, 2000. Fear-avoidance and its consequences in chronic musculoskeletal pain: A state of the art. Pain. 85:317–332. 3 doi:10.1016/S0304-3959(99)00242-0

Vostatek P, Novak D, Rychnovsky T, Rychnovska Š, and Yue J, 2013. Diaphragm postural function analysis using magnetic resonance imaging. PLoS One. 8:e56724. 3 doi:10.1371/journal.pone.0056724

Wesselmann U, Bonham A, and Foster D, 2014. Vulvodynia: Current state of the biological science. Pain. 155:1696–1701. doi:10.1016/j.pain.2014.05.010

Zhang Z, Zolnoun D, Francisco EM, Holden JK, Dennis RG, and Tommerdahl M, 2011. Altered central sensitization in subgroups of women with vulvodynia. Clinical Journal of Pain. 27:755–763. doi:10.1097/AJP.0b013e31821c98ec

Supplementary material Paper IV

The practical application of somatocognitive therapy for PVD

Introduction

The supplementary material provides further descriptive details of the assessment and the practical application of the SCT intervention for PVD. Importantly, the utilization of this material is best used in conjunction with the main article. As PVD is an individual subjective pain experience the treatment must be personalized and tailored to the individual. Furthermore, the patients will present differently, are in different personal or social circumstances and will have different levels of knowledge about PVD. The therapeutic alliance (i.e. building rapport and gaining trust is essential to gain a deeper understanding of the patients and how PVD affects their lives). Once therapeutic alliance is established, it is possible to work together towards meaningful change. In this supplementary material we describe examples of how the bodily exploration can be undertaken. The conversations about pain and sexuality, as well as how to cope with thoughts and emotions, are often interspersed with the bodily exploration and are not done in a strict order.

Assessment

A summary of the subjective history taking is presented in Table 1 which is based on the biopsychosocial (BPS) model. A BPS assessment of patients with chronic pain is supported in the literature (Wijma, van Wilgen, Meeus, and Nijs, 2016).

Table 1. Subjective history, adapted from Wijma, van Wilgen, Meeus, and Nijs (2016)

Date: Name: Date of birth: Physiotherapist:	Pain: description, mechanism of onset, duration, aggravating/easing, current complaints, beliefs about what is causing the pain	Psychological/emotional: use HSCL-25, "how does living with PVD make you feel?"
Medical history: other health complaints, past treatments, experiences with health care providers/system	Behavioural: avoidance, sex despite pain, sleep, functional difficulties	Cognitions: catastrophising - use PCS, negative fearfull thoughts
Social: interests/exercise, education, work	Psychosexual factors: partner support, intimacy, sexual arousal/desire/pleasure, trauma	Motivation, expectations, goals: What are your goals with the treatment? What is important to you?

HSCL-25: Hopkins Symptom Check List-25: PVD: Provoked vestibulodynia; PCS: Pain Catastrophizing Scale

The clinical observation begins as the patient enters the room and throughout the history taking; the physiotherapist observing body language, eye contact, sitting posture and breathing pattern. The patient undresses to her underwear. In standing, active functional movements, balance, coordination, spinal and hip movements are observed. In standing, the patient is asked to lift her arms into a horizontal and vertical position (i.e. horizontal and vertical arm lift, assessing the patient's ability to let go of the arms in a relaxed manner). Breathing is examined in all positions. On the treatment bench, the physiotherapist assesses passive rib movements and the patient's ability to be moved passively (i.e. neck, hips and arms). Muscles around the spine, abdomen, pelvis, and lower limbs are palpated. Emphasis is on observing quality of movement, noticing any tensed movement or postural patterns, noticing her ability to adjust, or let go of muscle tension, and her response to being touched. The physical assessment is naturally adapted to the individual, based on the subjective history. A

comprehensive differential diagnostic assessment, however, is undertaken due to comorbidities frequently seen among these patients.

Following the clinical examination, it can be useful to gather further information about psychosocial factors, such as anxiety, depression and catastrophizing, by asking the patient to complete self-report questionnaires. Several self-report questionnaires are available and Rosen, Bergeron, and Pukal (2020) provide useful recommendations for assessment tools to be utilized in vulvar pain.

At the end of the assessment the physiotherapist provides a brief description of SCT, describing the overarching aims of treatment and how the treatment sessions have a predictable three-phase structure: 1) Conversation; 2) Bodily exploration; and 3) Structured homework. This structure is not mandatory and can be adjusted to meet the individual's needs. It is important to clarify expectations early on i.e., what the patient can expect of the therapist and vice versa. This includes the importance of working together, collaborating and setting patient-centered goals and in the planning of homework. The importance of prioritizing and complying with the homework is emphasized, as the most important changes happen between the treatment sessions.

Somatocognitive Intervention

During the first treatment session, the physiotherapist starts by summarizing the main findings from the initial assessment on a sheet of paper, applying the BPS model as a foundation for this illustration. The scores from the self-report questionnaires measuring psychological distress can provide additional valuable information regarding psychosocial factors which can aggravate or maintain this patient's condition. The fear-avoidance model (Vlaeyen and Linton, 2012) is further used to demonstrate how unhelpful thoughts and feelings affect the pain experience and the development of pain and disability, creating a vicious cycle. The patient is directed towards further resources on PVD and sexual health such as the Norwegian websites vulva.no and sexogsamfunn.no.

Throughout the treatment sessions the therapist aims to increase the patient's knowledge about pain, PVD, vulva and the pelvic floor anatomy. Pain neuroscience education involves the therapist giving an overview of the neurobiology of pain, including the characteristics and purpose of acute versus chronic pain, including how pain becomes chronic. The therapist describes how pain is dependent on the situation and context and further explains how pain is modulated by both external (e.g. solicitous partner response) and internal factors (e.g. anxiety, fear, and catastrophizing) including the impact of pain on sexual function and partner relationships. As part of this, concepts of

neuroplasticity and nerve sensitization is explained, including how pain is created in the brain. Pain in PVD is not caused by unhealthy or damaged tissues, but hyperexcitability of the central nervous system (i.e. central sensitization). This is done using stories, examples or metaphors, to help patients reconceptualize their pain experience, decrease fear of pain and pain related activities, in order to self-manage and improve coping.

Bodily Exploration

Bodily exploration often starts in sitting, moving on to standing and/or supine and gradually progresses to walking. The relaxation and breathing exercises are described in the main article.

In Sitting

The patient is invited to explore how she sits. Initially the patient's attention is guided towards the distribution of her body weight. She is asked to uncross her legs, place feet apart on the floor and let her buttocks spread wide. The patient may be cautious to sit as it generates pressure on the vulva or be afraid of doing anything that could inflict further vulva pain. While sitting is explored, the physiotherapist can challenge the fearful prediction that "I worry that I will get much worse if I sit with pressure on the painful area" by exposure during the treatment, for example by exploring different sitting positions, or rolling back and forth on a Pilates ball, as she feels the touch of the ball against the vulva. Through these behavioral exercises, undertaken during the treatment sessions or at home, the patient learns to recognize unhelpful thoughts and behavior. Furthermore, she learns to redirect her attention from pain to other sensations in the body. In sitting, the physiotherapist uses gentle, calm strokes from hip to foot, enclosing the patient's leg, while encouraging her to turn her attention inwards and towards her breathing. The physiotherapist demonstrates with her own breathing and places her hands on the patient's lower ribcage. As the patient places her own hands on the chest, lower ribs, and abdomen she is asked to feel the difference during high and low-costal breathing. While this exploration is ongoing, there is a close dialogue between the physiotherapist and the patient. Example of questions posed to the patient during breathing exercises: *"How do you feel now?" "Are you able to fill your lungs to the very bottom?" "Where is the expansion?" "Is it in the chest or in the belly?" "Elevate your shoulders and breathe in in this position, how does it feel to breath in this position?" "Is it different?"*

During the next sessions, once the patient can sit relaxed and master slow deep breathing, treatment is progressed to incorporate the pelvic floor muscles (PFM). The objectives are to educate her about the role of the PFM in sexual pain, increase PFM awareness and to teach skills to control these muscles. In a relaxed sitting position, the patient is invited to turn her attention to the PFM. On exhalation she is asked to contract her PFM, hold for a few seconds and to fully let go on deep inhalation. Some may have limited anatomical knowledge, or find it difficult to isolate the PFM, as well as finding it difficult to fully relax. The treatment is therefore tailored to the individual's needs. Having an increased awareness of the PFM and knowing how to relax may ease reflex guarding and muscle spasm.

As part of the home exercises, the patient are taught different ways to increase awareness of the PFM. This can involve the patient placing her fingers on the perineum, lower abdomen, or inside the vagina and feeling the difference as she contracts and relaxes the PFM. The patient is also encouraged to insert a tampon, lubricated with some oil, on inspiration, hold the tension around the tampon on expiration, and then feel the relaxation in the PFM. The patient can stop urination mid-flow to get a sense of the PFM contraction and then let go, however this is only to increase awareness and not to be used an exercise to strengthen the PFM. The patient is also encouraged to be aware of the PFM in functional activities such as in sitting, squatting, on the toilet, or in various situations; intimate, relaxed vs threatening or demanding situations. The SCT sessions do not include biofeedback, the use of vaginal dilators or accommodators, or intravaginal/manual release of the PFM.

In Standing

In the clinic, the patient can present with several signs of a tense standing posture. This can include hyper extension of the knees, hip adduction, abdominal indrawing, shoulder adduction and elevation, clenched fists, and jaws. As the patient stands in her preferred position, on a mat without shoes, she is asked to become aware of how she stands, notice the central balance, her breathing or any muscular tension. The therapist provides verbal prompts and guides the patient through a body scan from the feet up to increase interoceptive body awareness. Some women find this task difficult. A useful starting point can therefore be weight shifting exercises to find central balance or the use of a spikey massage ball under the feet to increase sensory stimulation, helping her to feel the weight of her body in her feet. Various movement exercises are introduced to facilitate muscular relaxation, such as pelvic and spinal rotation and spinal flexion. Here the therapist facilitates the movements through

touch and by gently moving the patient to allow the release of tension. Through silence, the patient is given time to explore and to give feedback on new bodily experiences. Deep breathing is also facilitated by placing hands on the lower lateral ribs to encourage slow deep breathing while the patient lets go of her abdomen and PFM. Several sessions, exploring standing, are normally needed before the patient can stand fully relaxed, and be aware of her central balance, while breathing diaphragmatically and relaxing the PFM.

In Supine

In a quiet and calm atmosphere, the physiotherapist empathically guides the patient to feel the whole body relaxing as she is lying on her back, legs supported with pillows. The instruction: *"Start with the same exploration of the tension and relaxation as you did when you sat and when you stood. Squeeze your thighs a bit more together, feel the tension, hold a little while and let go. Can you feel the difference? Notice your breathing in this position. Take a slow deep breath in, breathe slowly out and feel the relaxation. Is it different to breathe in this position compared to the other positions?"*

The physiotherapist goes on to release the muscles around the hip. To finish off the treatment, a short session with progressive relaxation can be introduced, this time including muscles around the pelvis and lower limbs.

During the next sessions, the bodily exploration continues, on a mat on the floor or on the treatment bench. There is an ongoing dialogue between the two as the physiotherapist applies gentle strokes across the abdomen, around the pelvis, and lower limbs. This application of light touch is changing the sensory input which may help the muscles to relax. The patient is encouraged to be attentive to the different sensations in the body, gradually becoming aware of the difference between tensed and relaxed muscles. Lying on a matt on the floor different positions and exercises are explored to help the patient relax the PFM.

Walking

During the latter sessions, the emphasis is to further increase awareness of daily activities such as walking. In a large room, she is initially instructed to walk back and forth, as she normally does. The physiotherapist guides the patient to explore her breathing and become aware of her PFM. The next step is to explore different ways of walking; with longer or shorter steps, with increased rotation of the pelvis and feeling the differences. She is asked to move her attention to her arms, is encouraged

to relax and swing the arms naturally, while letting the pelvis naturally rotate. Some patients find this difficult, hence a natural and relaxed walking pattern can be demonstrated. As the patient explores different ways of walking, she can look at herself in a mirror. Once feeling comfortable with this, rather than solely focusing her attention inwards, the mirror can add a different dimension, providing visual feedback. Emphasis is on the quality of the movement (i.e. walking relaxed, breathing freely and letting go of tension, especially around the pelvis and PFM).

Topics and Conversations Related to Sexuality

As the connections between the body, thoughts and emotions are explored, the physiotherapist is in an ideal position to naturally integrate topics related to sexuality. The physiotherapist presents factors that can inhibit sexual arousal/desire, thereby interfering with the sexual response, such as stress, fatigue, depression and pain, including negative thoughts and feelings associated with pain. The latter is relevant as the anticipation of penetrative sex alone can cause a cascade of reactions; increased stress, fear of increased pain, reduced sexual arousal and desire and an automatic contraction of the PFM. The patient is therefore encouraged to explore her own sexuality, to identify factors that can contribute to her sexual difficulties and to communicate her concerns to the physiotherapist. The patient is also motivated to communicate openly about her sexual experiences and be direct about her sexual preferences to her partner or future partner. Emphasis is on working towards sexual pleasure, which can involve both penetrative and non-penetrative sexual activities (not achievements) while the couple learns to respect each other's boundaries, ensuring mutual feelings of safety and trust. Enhanced physical intimacy is also encouraged so that a couple can experience new bodily sensations through touch and breathing together and experience physical intimacy for its own sake, and not as foreplay to intercourse. The patient is encouraged to be present, be bodily aware and bring in elements from what she has discovered during the bodily exploration. She is encouraged to notice how she breathes and relaxes in intimate sexual situations, with or without a partner. In addition, enhancing intimacy may bring the couple closer and give them both a sense of belonging in the relationship. Topics such as setting boundaries, being open, and focusing on sexual pleasure are relevant for all patients, whether they are single, dating or in relationship. The patient is invited to bring her partner to a session.

Structured Homework

As part of the home exercises the patient is instructed to look at her vulva with a handheld mirror. Some women may have developed a difficult, fearful and distant relationship with their vulva. To overcome negative feelings associated with the vulva and overcome potential fears the physiotherapist will educate the women on the anatomy of the vulva utilizing resources such as vulva.no as well as reassuring her that all vulvas look different.

The patient are taught various desensitization exercises. The first exercise takes place in the shower. The patient is instructed to shower gently towards her vulva, comparing this sensation with other body parts being showered. The next step is the use of cold and warm cloths against the vulva. During these daily exercises she is encouraged to pay attention to these different physical sensations, rather than focusing on the pain itself. Self-exploration of the vulva using the mirror and through touch continues between the next sessions. To overcome fear of pain, the patient will need to challenge herself and take the necessary steps to move forward. The physiotherapist plays an important role in this process and will need to strike the right balance between emphatic support and firm encouragement. Desensitization exercises are then introduced, which involves progressive stimulation with touch, pressure or massage, against the painful area, starting with the least painful stimulation. The patient starts with gentle stroking movements across her vulva, fingers lubricated with some oil. She gradually approaches the painful area with the same light stroking movements, exercises which are repeated several times a day for a few minutes. The patient gradually progresses with increasing the pressure against the vulvar vestibule and can compare light dynamic touch with static pressure or deeper massage. Once she feels confident and more comfortable with touching her vulva, she goes on to inserting the smallest tampon or a finger (lubricated in oil) into the vaginal opening. During tampon or finger insertion, she takes a slow deep inspiratory breath to aid relaxation of the PFM. She is encouraged to use tampons of gradual increasing size. To ensure regular practice, she can combine these exercises with visits to the lavatory, while showering or while in bed. During these exercises, she is encouraged to be present and to be aware of her emotions, thoughts and bodily responses. In terms of bodily responses, the patient may notice how her body becomes guarded, how she holds her breath or how the PFM tightens as she approaches the painful area. The patient is encouraged to practice letting go of bodily tension, accept perceptions and feelings that arise and attend to thoughts in a non-judgmental way.

As she becomes more confident, her partner is invited to explore her vulva both visually and through touch, progressing to inserting the partner’s fingers. Although the patient is encouraged to reflect

and to reconceptualize sex as something with meaning and value, rather than an accomplishment, the goal may be to have penetrative sex with her partner. The therapist and patient discuss how the patient can use her new bodily experiences, in intimate or sexual situations. Summary of the daily homework includes: 1) Increase awareness of breathing patterns and daily practice of slow deep breathing exercises; 2) Practice a natural and relaxed movement and walking pattern; 3) Putting relaxation into practice at moments throughout the day; 4) Noticing when tension creeps into areas of the body, such as shoulders, jaw or PFM and practicing letting go of tension; 5) Daily practice of progressive relaxation or other relaxation techniques; and 6) Exercises to desensitize the painful vulva (e.g. hot and cold cloths, rolling back and forth on a ball, and stroking painful area daily progressing with increased pressure or massage).

Last Treatment Session - Creating a Self-Management Toolbox

The patients are strongly encouraged to recognize their own needs and to mobilize their own resources to feel in control of their lives. The empowerment that comes with learning new skills to address and self-manage their sexual pain can produce a profound sense of self-confidence. The process of gaining mastery allows the women to take control of their pain and gain the confidence to successfully progress towards activities that have been avoided, such as the use of a tampon or penetrative intercourse. The goal with the last treatment session is therefore to summarise what the patients have learned, to clarify what has been valuable for them during treatment and create a personalized self-management toolbox. The toolbox is intended to serve as a resource for the patients, to help them self-manage more effectively, to continue progressing and/or adapting to situations as needed on their journey. This toolbox belongs to the patients and is developed during this last session on a large piece of paper. See Figure 1 for an example. During this session, the patients are encouraged to reflect and take responsibility for what they would like to include in their toolbox, for some this task is easy but for others this is more challenging. The physiotherapist may need to provide prompts or examples to help the patients along. The patients are also informed that relapses are normal and a naturally occurring process towards improvement and change. Together they devise a plan for how to cope with flare-ups.

Overall, this process will hopefully allow the patients to feel more in control and may increase confidence and motivation to follow through on their plans. Furthermore, it may help the patients to continue with the good work, stay focused and to reach their goals, it may also help to prevent relapse and help them to cope with flare ups.

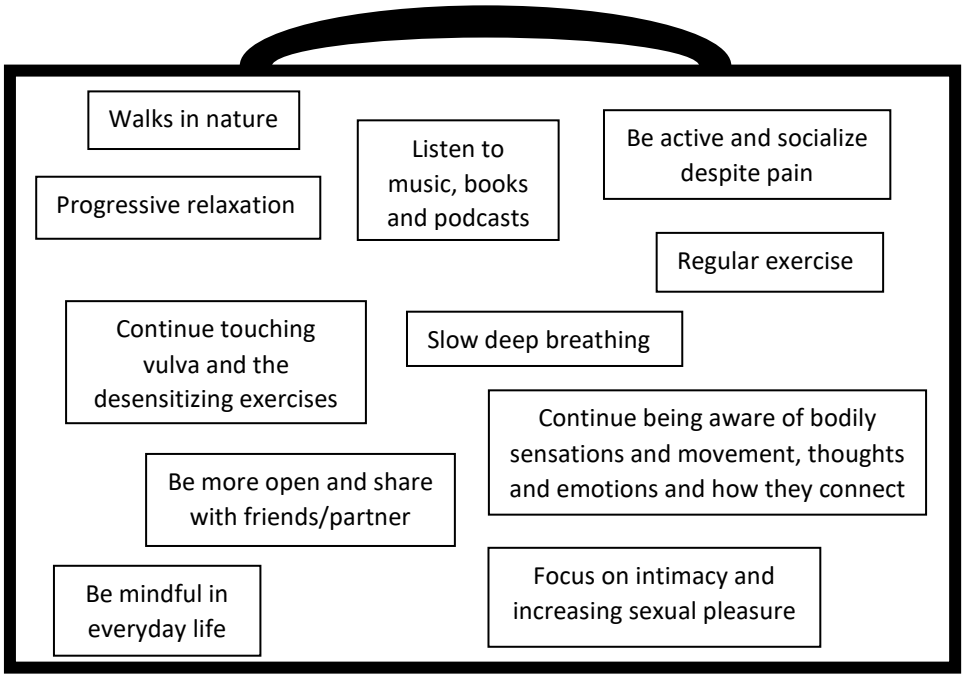

Figure 1. An example of a self-management toolbox, created together with the patient on the last session

Booster Session

The patients receive a booster session six months after the last treatment session. The 60-minute booster session is designed to both maintain the acquired improvement over an extended period and to reinforce and enhance the patients' self-management skills that they acquired during SCT. A booster session may also help the patients to keep motivated and committed to prioritize their progress, knowing that they will meet the physiotherapist again, as in CBT. In this session the patients are given the opportunity to discuss how they have managed and to discuss how they have coped with any setbacks. Furthermore, they are given the opportunity to describe their progress towards their goals, to ask questions and to practice or revise skills, such as breathing and relaxation. Furthermore, the patients will receive guidance on how to move forward and make further progress.

REFERENCES

Rosen NO, Bergeron S, Pukall C 2020 Recommendations for the study of vulvar pain in women, Part 1: Review of assessment tools. Journal of Sexual Medicine 17: 180-194.

Vlaeyen JW, Linton SJ 2012 Fear-avoidance model of chronic musculoskeletal pain: 12 years on. Pain 153: 1144-1147.

Wijma A, van Wilgen C, Meeus M, Nijs J 2016 Clinical biopsychosocial physiotherapy assessment of patients with chronic pain: The first step in pain neuroscience education. Physiotherapy Theory and Practice 32: 368-384.

Appendix 1 - Ethical approval

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Hege Cathrine Finholt, PhD	22857547	01.10.2018	2018/1036/REK sør-øst D
			Deres dato:	**Deres referanse:**
			30.09.2018	

Vår referanse må oppgis ved alle henvendelser

Slawomir Wojniusz
Høgskolen i Oslo og Akershus/Oslo Met

2018/1036 Somatokognitiv fysioterapi som behandlingsmetode for vulvodyni

Forskningsansvarlig: Høgskolen i Oslo og Akershus/Oslo Met
Prosjektleder: Slawomir Wojniusz

Vi viser til søknad om prosjektendring datert 30.09.2018 for ovennevnte forskningsprosjekt. Søknaden er behandlet av sekretariatet for REK sør-øst D på fullmakt, med hjemmel i helseforskningsloven § 11.

Endringene innebærer:
- Erstatte det opprinnelige skjemaet "Multidimensjonell perfeksjonisme skala" med skjemaet "seksuell funksjonsindeks (FSFI)".
- Endring i teksten til samtykkeerklaring.

Vurdering
REK har vurdert søknaden og har ingen forskningsetiske innvendinger til endringen av prosjektet.

Komiteen setter i midlertid som vilkår for godkjenning at det i informasjonsskrivet informeres om hvilken artikkel i EUs personvernforordning behandlingsgrunnlaget hjemles i, slik at informasjonen som gis til deltakerne er forenlig med ny personopplysningslov.

Vedtak
REK har gjort en forskningsetisk vurdering av endringene i prosjektet, og godkjenner prosjektet slik det nå foreligger, jf. helseforskningsloven § 11, under forutsetning av at ovennevnte vilkår er oppfylt.
Vi gjør samtidig oppmerksom på at etter ny personopplysningslov må det også foreligge et behandlingsgrunnlag etter personvernforordningen. Det må forankres i egen institusjon.

Klageadgang
REKs vedtak kan påklages, jf. forvaltningslovens § 28 flg. Eventuell klage sendes til REK sør-øst D. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst D, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Vi ber om at alle henvendelser sendes inn på korrekt skjema via vår saksportal: http://helseforskning.etikkom.no. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: post@helseforskning.etikkom.no.

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Knut Ruyter
Avdelingsdirektør
REK sør-øst sekretariatet

Hege Cathrine Finholt, PhD
Rådgiver

Kopi til: *hegben@oslomet.no; postmottak@hioa.no*

Appendix II - Informed Consent

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET

SOMATOKOGNITIV FYSIOTERAPI SOM BEHANDLINGS-METODE FOR VAGINALE SMERTER

Dette er et spørsmål til deg om å delta i et forskningsprosjekt hvor vi skal undersøke og videreutvikle fysioterapibehandling, kalt somatokognitiv terapi for kvinner med provosert vulvodyni. Diagnosen provosert vulvodyni omfatter hovedsakelig smerter i de ytre kjønnsorganer som opptrer i forbindelse med samleie eller ved trykk mot skjedeåpningen. Du blir spurt om du vil delta i prosjektet ettersom du er diagnostisert med provosert lokalisert vulvodyni og oppfyller prosjektets inklusjonskriterier.

OsloMet - storbyuniversitetet er den ansvarlige institusjon for gjennomføringen av prosjektet.

HVA INNEBÆRER PROSJEKTET?

Undersøkelse:
Hvis du samtykker i å delta i studien vil du bli bedt om å fylle ut en del spørreskjemaer. Skjemaer vil du fylle ut elektronisk, for eksempel hjemme på en PC. Utfylling av skjemaer vil ta cirka 60 min. I tillegg blir du bedt om å svare hver kveld i 14 dager på et kort elektronisk spørreskjema om hvordan du har følt deg den siste dagen. Dette skal ikke ta mer enn 2-3 minutter. I løpet av den samme 14-dagers perioden, på dag 1, 7 og 14, blir du også bedt om å innføre i skjeden en vanlig tampong og å registrere på en skala fra 0 til 10 hvor smertefullt du syntes dette var. På denne måten måler vi smertesensitiviteten i det aktuelle området. Dette vil du gjøre hjemme etter at du har fylt ut ovennevnt spørreskjema.
De beskrevne undersøkelsene vil også bli gjentatt etter avsluttet behandling og 3 måneder senere.

Intervjuer:
I tillegg til spørreskjema ønsker vi etter avsluttet behandling å intervjue deg om hvordan du opplevde somatokognitiv terapi som behandlingsmetode; hva synes du fungerte godt og hva som ikke fungerte. Tre måneder etter avsluttet behandling vil vi intervjue deg en gang til for å høre om hvordan plagene dine ble påvirket på lang sikt. Målet med intervjuene er å videreutvikle somatokognitiv terapi som behandling for vaginale smerter. Senere vil vi teste denne behandlingsmetoden i en større studie. Intervjuene i seg selv vil ikke ta mer enn 60 minutter hver.

Behandling
Du blir tilbudt individuell somatokognitiv behandling, ca 10-15 sesjoner i løpet av 10 uker, som enten vil foregå ved Oslo Universitetssykehus (Ullevål) eller på poliklinikken til Institutt for Fysioterapi ved OsloMet. Målet for behandlingen er å øke kroppskontakt, bedre evne til avspenning, oppnå nye kroppslige erfaringer og endre tanker relatert til kroppslige og emosjonelle opplevelser i positiv retning. Erfaringer fra behandlingen vil være nyttig for å oppnå høyere grad av avspenning, redusere stress og smerteopplevelse i tidligere utfordrende situasjoner, f.eks. under samleie.

Registrering av mottatt behandling
Hver 14 dag i løpet av hele studien blir du bedt om å fylle ut et kort elektronisk skjema om hvilken behandling du har mottatt i løpet av de siste 14 dager. Det skal ikke ta mer enn ett minutt å fylle skjema. Du skal bare krysse av hvilke type behandlere du har vært hos og om du har brukt smertestillende medisiner.

Registrering av opplysninger
I prosjektet vil vi innhente og registrere noen opplysninger om deg. Opplysningene vil bli samlet ved hjelp av elektroniske spørreskjemaer og intervjuer. Dette gjelder din bakgrunn (alder, utdanning, sivil status, arbeid, fysisk aktivitet), smerteintensitet knyttet til det aktuelle problemet, seksualfunksjon, livskvalitet, måten du

reagerer på i utfordrende situasjoner- for eksempel i forhold til bekymringer, stress, og liknende. Intervjuene vil bli tatt opp elektronisk. Dataene vil bli lagret på en forskningsserver spesielt designet for dette formålet (Tjenester for Sensitive Data - TSD 2.0) i en avidentifisert form, etter gjeldende regler. Avidentifisert form vil si at opplysningene vil være knyttet til en kode som gjør at de ikke kan bli sporet tilbake til deg uten kodenøkkel. Selve kodenøkkelen blir lagret adskilt og vil bare være tilgjengelig for prosjektlederen. Når det gjelder de lagrede, avidentifiserte data, er det bare de medlemmene av forskningsgruppen som skal analysere data som vil ha tilgang til disse.

MULIGE FORDELER OG ULEMPER

Hovedulempene ved å delta i studien dreier seg om den tiden du må bruke på å fylle ut spørreskjema og gjennomføre intervjuer.

Somatokognitiv behandling medfører ingen kjent risiko.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn, trekke ditt samtykke. Dette vil ikke få konsekvenser for din videre behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte Slawomir Wojniusz, tel: 41926564, e-post: slawomir@oslomet.no

DINE RETTIGHETER

Så lenge du kan identifiseres i datamaterialet, har du rett til:

- innsyn i hvilke personopplysninger som er registrert om deg,
- å få rettet personopplysninger om deg,
- å få slettet personopplysninger om deg,
- å få utlevert en kopi av dine personopplysninger (dataportabilitet), og
- å sende klage til personvernombudet eller Datatilsynet om behandlingen av dine personopplysninger.

HVA SKJER MED INFORMASJONEN OM DEG?

Vi behandler opplysninger om deg basert på ditt samtykke (jf. personvernforordningen artikkel 6 nr1). Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Studiens resultater vil bli publisert i vitenskapelige artikler på en måte som ikke gir noen mulighet for å identifisere studiens deltakere. Alle personopplysningene om deg vil bli slettet tre år etter at alle resultatene er publisert og senest 15.08.2026. Oppbevaring av data i minst tre år etter at alle resultater er publisert er et vanlig krav for å muliggjøre ettersyn av publiserte forskningsresultater.

Prosjektleder har ansvar for den daglige driften av forskningsprosjektet og for at opplysninger om deg blir behandlet på en sikker måte.

FORSIKRING

Ved eventuelle uhell og komplikasjoner vil forsøkspersoner være dekket av Pasientskadeerstatningsordningen.

GODKJENNING

Prosjektet er godkjent av Regional komite for medisinsk og helsefaglig forskningsetikk, hos REK (2018/1036).

KONTAKINFORMASJON

Prosjektleder/daglig ansvarlig:
Slawomir Wojniusz
Institutt for fysioterapi, OsloMet – storbyuniversitetet
epost: slawomir@oslomet.no
tel: 41926564

Personvernombud på OsloMet:
Ingrid Jacobsen
Avdeling for forskning og utvikling, OsloMet – storbyuniversitetet
epost: ingrid.jacobsen@oslomet.no
tel: 67235534

Norsk Senter for Forskningsdata (NSD)
internett: http://www.nsd.uib.no/
epost: nsd@nsd.no
tel: 55582117

SAMTYKKE TIL DELTAKELSE I PROSJEKTET

JEG ER VILLIG TIL Å DELTA I PROSJEKTET

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

Jeg bekrefter å ha gitt informasjon om prosjektet

Sted og dato

Signatur

Rolle i prosjektet

Appendix III - Interview guide

Intervjuguide ProLoVe (første runde)

Fokus 1: hvordan kan RCT forbedres? (pasienterfaringer – klargjøre/justere før RCT)

Fokus 2: tema seksualitet (mtp artikkel)

Aktuelt med bakgrunnsspørsmål, eller kan hente fra spørreskjema?

- Hvor lenge har du hatt disse smertene og hvor sitter de?
- Har du selv noen tanker om hva disse smertene kan ha en sammenheng med? (spørre direkte om tidligere belastende hendelser/traumer, eller blir det gjerne for voldsomt – evt litt senere i intervjuet?)

Hovedspørsmål

- Du har nå vært gjennom et fysioterapeutisk behandlingsforløp, kan du beskrive hvordan dette forløpet har vært?
    - Er det noe du husker spesielt godt fra behandlingen?
    - Hvordan opplevde du undersøkelsen?
    - Hvordan har du opplevd relasjonen med terapeuten din? Hva har dette forholdet betydd for deg?
- Opplever du at behandlingen har vært nyttig for deg?
    - Er noe annerledes nå, sammenlignet med før behandlingen startet? (kroppslig, følelsesmessig, tankemessig, endringer i livssituasjon.)
    - Hva i behandlingen tenker du kan ha bidratt til denne bedringen/endringen?
    - Hva har denne/disse endringene betydd for deg i livet ditt?
    - Er det deler av behandlingen du synes har vært unødvendige/lite nyttige/problematiske?
- Hva er dine erfaringer med
    - De kroppslige øvelsene, det å jobbe med pust og avspenning?
    - Hjemmeøvelsene som har handlet om å utforske og tilnærme seg underlivet?
    - Samtalene rundt smerte og smertemekanismer?
    - Spørreskjemaene og testene som er benyttet i denne studien? (relevante, irrelevante, problematiske?)
        - Generelt
        - Dagboken
        - Tampongtesten
- For mange kvinner med underlivssmerter kan dette med seksualitet være problematisk – hva er ditt forhold til dette med seksualitet?
    - Hvordan var dette ved behandlingsstart? (samliv på tross av smerter? Hvorfor? Ikke samliv? Følelser og tanker knyttet til dette)
    - Har dette med seksualitet vært et viktig tema/fokus for deg i behandlingen?
        - *Hvis ja*

- Hva var/er utfordringene dine her?
- Hva gjør disse utfordringene med deg (følelsesmessig, tankemessig, ift livsførsel..)?

▪ Har du opplevd noen endring i seksuell funksjon gjennom behandlingsperioden? (gjenopptatt samliv, smerter, lyst, tilfredshet, selvtillit, mestringstro..)?

- Kan du fortelle litt om disse endringene?
- Hva kan ha bidratt til disse endringene tenker du?
- Hva har disse endringene betydd for deg?

▪ *Hvis ikke*

- Hva har vært viktig for deg i behandlingen?
- Opplevelser av spørreskjemaet om seksualitet (masete/press på at dette med seksualitet er viktig/noe man burde være opptatt av?)

o Hvordan har det vært å snakke med terapeuten om slike tema?
o Har det vært viktig for deg at terapeuten har tatt opp dette med seksualitet? (hva har vært viktig i denne sammenhengen?)

Spennende fordypningstema ift seksualitet kan være

- Utforskning av egen seksualitet (blitt bedre kjent med seg selv og egen seksualitet? Hvordan jobbet med dette?)
  - Betydningen av veksling mellom helhet og del/forståelse av sammenhenger - tanker, følelser, kroppslige reaksjoner og smerte
- Endret forhold til seg selv? (større grad av selvaksept, ønske om å ta vare på seg selv, sette grenser, bli kjent med egne ønsker og behov)
  - «flink pike»? Høye krav til seg selv, setter andres behov først?
  - Endringer i livet – tatt grep?
- Hva er samliv for deg? Endrede holdninger i forhold til dette?

➢ Hva tenker du om tiden fremover?

Appendix IV - Consort 2010 checklist (Paper I)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4-5
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10-11 Table 1
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	12
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	6-7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A

	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	13-14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Fig 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6,8,9
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Table 3
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	NA
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	17
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	23
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	21-23
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	21-22
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	21-23
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	3,7
Protocol	24	Where the pilot trial protocol can be accessed, if available	Not available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24
	26	Ethical approval or approval by research review committee, confirmed with reference number	7, 24

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix V - COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	4
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	4
Occupation	3	What was their occupation at the time of the study?	4
Gender	4	Was the researcher male or female?	4
Experience and training	5	What experience or training did the researcher have?	4, 6
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	N/A
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	N/A
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	N/A
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	4
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	3
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	4
Sample size	12	How many participants were in the study?	3
Non-participation	13	How many people refused to participate or dropped out? Reasons?	3
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	4
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	3
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	5
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	4
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	N/A
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	3
Field notes	20	Were field notes made during and/or after the inter view or focus group?	N/A
Duration	21	What was the duration of the inter views or focus group?	4
Data saturation	22	Was data saturation discussed?	N/A
Transcripts returned	23	Were transcripts returned to participants for comment and/or	N/A

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	4
Description of the coding tree	25	Did authors provide a description of the coding tree?	4, Appendix A
Derivation of themes	26	Were themes identified in advance or derived from the data?	4
Software	27	What software, if applicable, was used to manage the data?	N/A
Participant checking	28	Did participants provide feedback on the findings?	N/A
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	4, 6-8
Data and findings consistent	30	Was there consistency between the data presented and the findings?	6-8
Clarity of major themes	31	Were major themes clearly presented in the findings?	6-8
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	6-8

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

POSTADRESSE:
OsloMet – storbyuniversitetet
Pilestredet 46
Postboks 4, St. Olavs Plass
0130 Oslo

OsloMet Avhandling 2023 nr 8
ISSN 2535-471X
ISBN 978-82-8364-468-5