

Take your sexuality back - a feasibility study of a new intervention for sexually traumatized women

Our goal of this PhD project is to establish a scientific foundation for a novel group-based treatment intervention to rehabilitate the sexuality of women who have experienced sexual trauma. There is an urgent need to gather insights into the experiences of participants and their partners in order to identify necessary improvements, evaluate the intervention's potential efficacy and gain a more comprehensive understanding of treatment outcomes before initiating a larger randomized controlled trial, and implementing the intervention in the healthcare system. We will obtain data from interviews with group participants and their partners, as well as from measurements taken before, after, and at follow-up. This feasibility study has the potential to improve the quality of health services, and benefit patients in specialist healthcare, sexually traumatized women and their partners in general, and the research community. Our research group has extensive experience and expertise in this field, and the project aligns with the research strategies of both STHF and HSØ.

1. Scientific background and significance

Traumatized sexuality is a significant women's health issue. According to a Norwegian study from 2023, 1 in 5 women report being subjected to rape by force or coercion, rape during sleep, or both (1). The risk of developing Post-Traumatic Stress Disorder (PTSD) following sexual abuse is higher than that associated with other types of traumas (2, 3), underscoring the severe impact on victims. Sexual abuse, characterized by violations of personal boundaries, can profoundly affect individual's relationship with their body and sexuality (4, 5). Common sexual symptoms post-trauma include dissociation or intrusive memories during sexual activity, shame and guilt concerning the body and sexuality, a perceived obligation to satisfy the partner's needs, engagement in high-risk sexual behaviors, relational difficulties, and sexual dysfunctions (4, 6, 7). For many abused women, intimacy with a partner is so closely associated with pain and trauma that it leads to dysfunctional relational patterns and sexual challenges within a partnership (8, 9).

Traditional approaches to trauma treatment have shown minimal improvement in sexual dysfunctions after abuse (10). Researchers and advocacy groups have emphasized the necessity of integrating a focus on intimacy and sexuality within psychological therapies to facilitate the rehabilitation of clients' sexual health and to include eventual partners in the process (8, 11-14). A growing body of research underscores that sexual shame plays a critical role in maintaining sexual dysfunctions, prompting researchers and clinicians to call for interventions that can resolve sexual shame (15-17). Group therapy has been suggested as a particularly effective intervention for targeting sexual shame, creating a space where it is possible to talk about both natural and traumatized sexuality, normalizing sexual trauma symptoms, and enabling connection with others in similar situations (13, 15, 18).

Gewirtz-Meydan's review of empirical research on the treatment of sexual dysfunctions after sexual abuse identified six therapeutic approaches (13). Only one of them was designed for use in a group setting; however, it was only tested and validated on a non-clinical population, included only two group sessions, relied on participants practicing on their own and did not involve partners (13, 19). This highlights a significant gap in evidence-based practices that integrate trauma-focused and sex therapy techniques for treating survivors of sexual trauma in a clinical population of patients with high symptom pressure (10, 13, 20). Consequently, to be able to respond to the needs of the large number of sexually traumatized women referred to Telemark Hospital Trust (STHF), we developed a new group-based intervention named "Take Your Sexuality Back" (TYSB), tailored to the needs of these women. Many of them had experienced long-term complex childhood traumas and had profound sexual post-traumatic symptoms that prevented them from experiencing intimacy as something positive.

We designed the TYSB intervention to be trauma-sensitive, focusing on traumatized sexuality and incorporating regulatory skills to prevent re-traumatization when addressing sex-positive themes, thus accommodating a wide range of trauma-related symptoms, sexual shame, sexual dysfunctions, and regulation difficulties (21-24).

We have continually evaluated and developed TYSB since 2019. A collaboration between the Norwegian Women's Sanitary Association (NKS) and STHF resulted in a psychoeducational book (23) and dissemination of knowledge about traumatized sexuality across women's health centers nationwide (25). The TYSB intervention consists of 12 weekly sessions (2.5 hours each) and a half-hour video session with repetition of exercises two days after each session. The treatment integrates psychoeducation, exercises, reflections, and sharing in a group (table 1). Examples of exercises include strengthening personal boundaries, self-regulation, awakening the senses, handling triggers, body awareness, and reflecting on sexual schemas. In sessions 4 and 10, we invite partners to participate. Participants without partners also join these sessions to gain valuable rehearsal and insight into how to communicate with a future partner.

Textbox 1: Overview of central themes covered in the TYSB intervention

Session	Theme	Session	Theme
1	The history of sexuality How to rebuild personal boundaries	7	Sexual arousal patterns and fantasies. The dynamics of change processes.
2	Reflecting over one's own sexual history. Strengthening self-compassion and selfcare	8	Relationships, communication skills and steps to overcome fear of intimacy.
3	Common aftereffects of sexual trauma. Sexual shame and self-regulation.	9	Ways to restart couple sexuality. Building sexual intimacy step by step.
4	Session with partners. Repetition and deepening of session 3	10	Session with partners. Repetition and deepening of sessions 8 and 9.
5	Handling of outer and inner triggers. The female body and functions of the vulva.	11	Deepening of themes from all sessions. New insights and experiences.
6	Self-touching, masturbation, and orgasm. Steps to overcome hindrances.	12	Further integration of themes. Plans for continued practice at home.

The next critical step in the development of TYSB is to conduct a comprehensive feasibility study. This will assess its potential efficacy and appropriateness for the target group before we can write a final course manual and proceed to a larger Randomized Control Study (RCT).

1.1 Innovations elements and improvements

Despite sexuality being a central aspect of human life and an important health factor, interventions targeting traumatized sexuality are missing in public healthcare. The TYSB intervention emerges thus as a novel contribution to this field, eliciting significant interest from mental health clinics and sexologists both within Norway and internationally.

Traditional trauma treatment has a limited effect on sexual symptoms, which leads to unsatisfactory treatment results and a poorer quality of life for victims of abuse (10, 20) . Furthermore, traumatized sexuality affects partners and the overall dynamics of the relationship, which can further complicate the healing process (9). There is very little research on partners' experiences in the context of treatment for traumatized sexuality, leaving a critical gap in the understanding of how to support both abused women and their partners in recovery. Consequently, there is a critical need for innovative treatment approaches that specifically address rehabilitation of traumatized sexuality, and which take partners and the relational context into account. Furthermore, with many sexually abused women seeking treatment in specialized mental health care, there is a need for efficient and cost-effective group treatment interventions that can accommodate women with a wide range of trauma-related symptoms and sexual problems. The novel TYSB intervention seeks to fill the gap concerning transdiagnostic, group-based approaches that integrate trauma-focused

therapy with a sex-positive framework and include partners in the treatment (20, 23, 25).

There is an urgent requirement to collect in-depth understanding of how participants and their partners experience the TYSB intervention to identify required improvements, investigate the potential efficacy of the intervention and to broaden the research on therapeutic methods for addressing sexual dysfunctions following sexual abuse.

Trauma patients exhibit a wide range of symptom profiles, making it essential to evaluate appropriate measures for assessing treatment outcomes (26). This heterogeneity is evident in the varying patterns of neural activation observed among patients. Incorporating physiological measurements provides objective indices to investigate treatment responses more accurately (27). **The complexity of trauma-related symptoms cannot be fully captured through quantitative data alone and there is a need to assess a more comprehensive understanding of treatment outcomes (26). Employing a mixed methods design that includes participants' own interpretations and understandings of quantitative results adds significant value and is a novel contribution to the research community (28).** Given the centrality of personal meaning in recovery-oriented practice, our application of a phenomenological perspective in researching this treatment represents a significant innovation (29).

2. Hypotheses, aims and objectives

The overall goal of this project is to ensure the quality of the novel TYSB intervention and lay the ground for a larger-scale RCT of the intervention. The project's overall goal is dispersed into three main aims, each in correspondence with a sub-study (study A, B and C):

Aim 1 (Study A): To investigate the lived experiences of participants in the intervention groups to evaluate the acceptability of the TYSB intervention and identify modifications required to improve the intervention.

Research question (RQ)1: What are the participants lived experiences and perceptions of the intervention, and how do they react to any positive or negative impacts attributed to it?

Aim 2 (Study B): To explore the experiences and perspectives of partners of the participants in the intervention groups, with the aim of identifying areas for potential improvement in the intervention and specifically how partners can best be involved in the rehabilitation process.

RQ2: What are the partners' experiences of participating in the intervention and of being witness to and taking part in their partners (participants) process during the intervention?

Aim 3 (Study C): To establish foundational data, methodologies, and effect sizes for a subsequent full-scale RCT.

RQ3: What are the changes in patient-reported levels of PTSD symptoms, sexual satisfaction, sexual shame, interoceptive awareness and reactions to touch from pre intervention to post-intervention and at a 3-month follow-up?

RQ4: How do the capabilities for regulating the autonomic nervous system measured by cardiovascular measurement (ECG) during a script-driven imagery (SDI) procedure change from before to after treatment and at follow-up?

RQ5: What is the adherence rate (recruitment, dropout, and attendance rates among participants) to the intervention?

RQ6: How do the participants interpret and reflect on the quantitative data collected at pre-post intervention and follow-up, with a specific focus on data that stands out or are unexpected in relation to their lived experiences?

Hypothesis (H1): Measurements will show improvements in PTSD symptoms, sexual satisfaction, sexual shame, interoceptive awareness and capability to enjoy touch after the intervention and at follow-up compared to baseline.

H2: Cardiovascular measurement (ECG) during a script-driven imagery (SDI) is a promising method for testing in a RCT.

H3: The study will demonstrate that it is feasible to recruit participants and that at least 80% of them complete the intervention and the study

H4: Participants' reflections will generate new knowledge concerning trauma treatment evaluation identifying relevant primary outcome measures for a larger-scale RCT study.

3. Approach

3.1. Methods, analyses and technologies

The adoption of a mixed methods design is pivotal for a comprehensive exploration of the feasibility and potential challenges associated with a larger-scale randomized controlled trial (RCT) of the effects of an intervention (28). **Employing multiple perspectives allows for a more complete understanding and facilitates a nuanced assessment of the acceptability of the TYSB intervention.** It is crucial to incorporate the voices of sexually traumatized women and their eventual partners when the research project focuses on a treatment intervention to which they are subjected (29). A mixed methods study employs both qualitative and quantitative methods to collect and analyze data, as well as to organize procedures for investigating research questions. We have described the study design in Figure 1.

Recruitment of participants

To gain access to data that can shed light on the research questions, two groups will be conducted according to the TYSB intervention described above, each consisting of ten women (N=20). We will recruit participants from patients referred to specialized mental health care and the TYSB intervention at STHF. The recruitment process follows standard clinical practice to ensure the selection of appropriate participants for the study. *Inclusion criteria:* a) A history of sexual trauma, b) Experience trauma-related sexual problems, c) Age between 18 and 65 years, d) Enough competence in Norwegian to participate in a psychoeducational group. *Exclusion criteria:* a) Acute suicidality, b) Serious substance abuse interfering with treatment, c) Severe dissociative or psychotic disorders, d) Current life crisis interfering with treatment e) Living in an abusive relationship.

Data collection

Study A and study B: These are qualitative studies where we collect data from exploratory semi-structured in-depth interviews with participants (including possible dropouts) and partners post intervention. We will use interview guides to provide a framework to ensure that all participants are asked about the same core topics.

Study C: This is an explanatory sequential mixed methods study where we collect and analyze quantitative data from self-report forms and physiological measurements pre-post and 3- month follow-up, followed by collecting and analyzing qualitative data from semi-structured in-depth interviews with participants, focusing on how they understand quantitative data that stands out or are experienced as unexpected. Finally, we interpret how qualitative data can explain the quantitative data.

Self-report measurements: The *international trauma questionnaire (ITQ)* is a well-validated instrument that assess symptoms of post-traumatic stress disorder (PTSD) and complex PTSD (CPTSD) (30); The *Sexual Satisfaction Scale for Women (SSS-W)* is a widely used instrument with good psychometric properties designed to measure sexual satisfaction among women (31); *Sexual shame Index-revised (SSI-R)* is a 10-item scale used to measure sexual shame. Cronbach's alpha has been shown to range from 0.76 to 0.82, indicating an acceptable level of internal consistency for the SSI-R (32); *Multidimensional Assessment of Interoceptive Awareness (MAIA 2)* is a measure with robust psychometric properties, designed to assess interoceptive awareness, which is the ability to perceive internal bodily

signals (33); *Touch Body Map* is an instrument for mapping how the body reacts to touch, which is used in the TYSB intervention to deepen the reflection around personal experiences of touch (34). Participants color the outlines of a human figure with three colors to mark how different areas of the body react to touch. The body map gives a non-verbal expression of how trauma is embodied. The percentage of the different colors will be calculated to assess possible changes through the process; *Responses to script driven imagery (RSDI)* is an assessment tool to measure self-reported emotional, cognitive, and physiological responses in the script-driven imagery procedure (SDI) described below (35).

Physiological measurements: Cardiovascular measurement (ECG) recorded during a *script-driven imagery (SDI)* can give valuable and complementary data when investigating treatment response in trauma patients (36, 37). A 'Root mean square of successive differences of adjacent inter-beat intervals' (RMSSD) reflecting Heart Rate Variability (HRV) will be used to index changes in cardiac vagal tone. HRV is influenced by the balance between sympathetic and parasympathetic nervous system activity and can give information about perceived stress and emotional regulation. *Sample Entropy (SampEn)* is a measure of cardiac entropy, which can give information beyond linear HRV. Lower SampEn has been linked with psychopathology while a higher value of SampEn indicates a less regular, more complex signal fine-tuned to the needs of the internal and external environment (38).

Script-driven Imagery procedure (SDI)

This study will use a modified protocol of the original script-driven imagery procedure (35), described by Rudstam et al. (39). Participants will be instructed to write down two memories, one traumatic and one peaceful. The main researcher then prepares two scripts of three minutes each, based on participants' texts. The physiological measurements will be done approximately one week later, after participants have completed the self-rating scales. The main researcher read the two scripts aloud in the following order: 5 min. relaxation baseline (BL) – 3 min. peaceful memory script – 3 min. break – 3 min. trauma script – 3 min break – 3 min. peaceful memory script – 3 min break. Following the psychophysiological recording, the participants will complete the RSDI questionnaire.

Data from journal: The following data will be collected from the intake interview, documented in participants' journal; age, marital status, type and extent of sexual trauma and other relational traumas, degree of support after trauma(s), prior treatment exposure, sexual problems and current social support network.

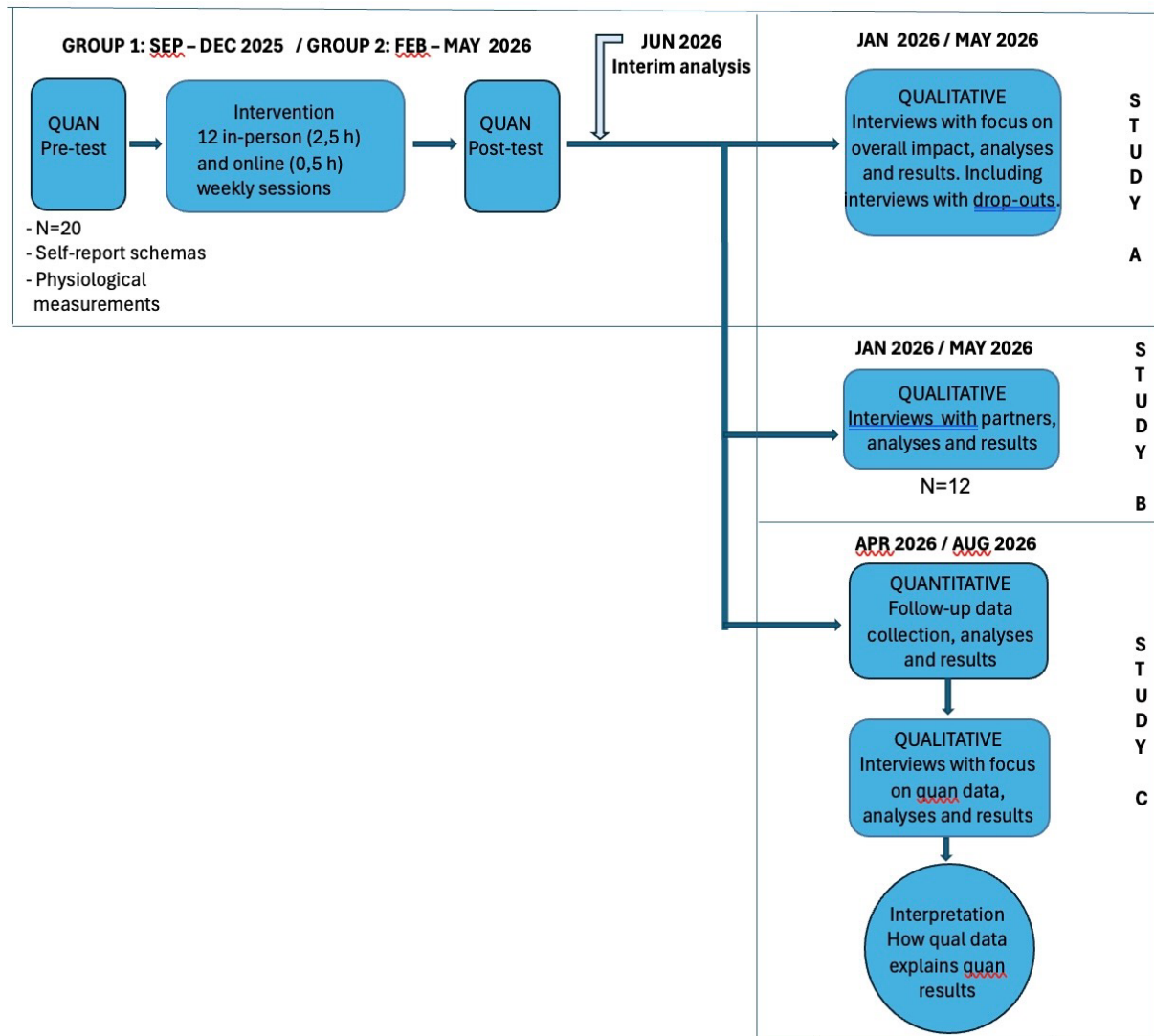
Data analysis

Qualitative data analysis (study A, study B and the qualitative part of study C): Qualitative data will be analyzed using Giorgi's descriptive phenomenological method: (1) reading descriptions to grasp the whole, (2) dividing into meaning units, (3) identifying invariant, general meanings in psychological terms, and (4) synthesizing them into a general meaning structure (40). To ensure that the results are reliable, valid and credible, both supervisors will read all the interviews, critically assess the PhD candidate's analysis, and discuss and resolve any discrepancies in interpretation.

Quantitative data analyses (study C):

Quantitative data will be analyzed through linear mixed model analysis (procedure MIXED in SPSS) for statistical comparison of pre-post and follow-up changes in psychometric variables and physiological reactivity. Paired samples t test (two- tailed) will be used for statistical comparison. Due to the small sample size and explorative nature of the study, no statistical correction for multiple testing will be applied. To ensure a 95% confidence interval, analyses will be performed with a bootstrapping technique. Missing responses will be handled through multiple imputation techniques. Overall significance level set at .05.

Figure 1: The projects study design



The doctoral thesis will utilize collected data and results to draw comprehensive conclusions about the TYSB interventions overall feasibility and associated risks and complications. These conclusions will inform the design of a future RCT, including power calculations, as well as primary outcomes, generating hypotheses, and providing insights into necessary modifications to optimize the TYSB intervention and its protocol, thereby improving validity and reliability.

Potential weaknesses and risks

We recognize the potential risk of participant drop-out. To ensure enough participants there will be conducted an interim analysis post intervention. A third group will be included in autumn 2026 if there is a larger dropout of women (>3) or less partners (<10) than expected or if the interim analysis reveals that a larger N is needed for designing an adequately powered future study. A potential source of bias in this study stems from the dual role of the PhD candidate, who is also developer of the treatment intervention. This overlap can introduce bias, affecting the impartiality of the study. To mitigate these risks, several strategies have been implemented: Independent therapists conduct the intervention groups, eliminating direct involvement from the researcher. In *studies A and B*, interviews are conducted by a co-researcher and user participant unconnected to the intervention, safeguarding impartial data collection and encouraging honest feedback. The analysis of the qualitative data will be done by the PhD candidate in close collaboration with the main supervisor and the co-supervisor who have no connection to the development of the

intervention and no financial interests in the project. It is considered that the PhD candidate's in-depth knowledge of both the intervention and the topic will strengthen the quality of the analysis. The independent supervisors will thoroughly review all interviews, offering new perspectives and critical reflections. They will validate and challenge methodological choices throughout the entire process to ensure that the results are reliable, valid, and credible. Statistical analyses of the quantitative data will be carried out by the main supervisor in collaboration with an independent statistician at STHF, who has no connection to the intervention. Quantitative data from the questionnaires will be compared with objective physiological measures and participants' own understanding of the results. This triangulation of data sources helps to strengthen the dataset and offers a more robust and unbiased objective assessment of the feasibility and acceptability of the intervention. Collectively, these strategies are essential for ensuring the study's reliability and reducing the likelihood that results will be influenced by the researcher's personal interests or expectations.

3.2. Participants, organization and collaborations

The TYSB intervention and the research project are developed and rooted in STHF. The project leader and the PhD-candidate are employed at STHF where the TYSB intervention is carried out. The project builds on collaboration with University in Agder (UiA), Norwegian University of Science and Technology (NTNU), Modum Bad Trauma Clinic in Oslo and three user participants. The PhD candidate will be responsible for day-to-day organizing of the project, in close collaboration with the project group. She will have the main responsibility for collecting self-report measurements and physiological measurements, conducting the interviews exploring participants' understanding of quantitative data (study C), analysis of qualitative data and dissemination of results. The project group will meet monthly, and the meeting minutes will be documented. The steering committee will meet regularly.

Steering committee

Kjetil Christensen, chief for the clinic of mental health and substance abuse treatment, STHF. **Espen Halvorsen**, head of DPS department, STHF. **Idun Røseth**, project leader. **Malin Wästlund** PhD-candidate. **Anita Kristine Lindeboom**, user participant.

Project group

Idun Røseth (Co-supervisor), leader of the research group Mental Health at STHF and Professor at Department of Psychosocial Health, UiA is project leader and the supervisor in qualitative methods. **Tor-Ivar Karlsen** (main supervisor), Professor at Department of Psychosocial Health UiA, is the main supervisor and responsible for statistical analysis of quantitative data in collaboration with a statistician at STHF. **Malin Wästlund**, PhD candidate connected to the PhD-program at the Faculty of Health and Sport Sciences at UiA. Wästlund is also specialist physiotherapist and psychotherapist working at DPS Notodden, STHF. **Keson Jaoun**, statistician, STHF. **Charlotte Fiskum**, Associated Professor at Department of Psychology, NTNU, is a collaborative partner participating in the project group and will supervise regarding the psychophysiological assessments. **Ingunn Holbæk**, clinical psychologist and PhD-candidate at the Research Institute Modum Bad, is a collaborative partner with in-depth knowledge of the most vulnerable group of traumatized patients. **Anita Kristina Lindeboom**, **Silje Engbråten** and **Gunn-Marit Uverud**, user participants with different backgrounds. Gunn-Marit Uverud has research experience and will contribute as an interviewer in the study.

3.4 Plan for activities, visibility and dissemination

Activity	From	To
Approval PVO/REK. Planning, recruitment and implementation of study group 1. Pre- and post-test QUAN data collection. Recruitment of participants (group 2).	Jan 2025	Dec 2025
Study group 1: QUAL data collection for study A and study B	Jan 2026	Feb 2026
Study group 2: Pre-test QUAN data collection, post-test QUAN data collection and QUAL data collection for study A and study B.	Feb 2026	May 2026

Study group 1: Follow-up QUAN data collection, analyzing pre-post and follow-up QUAN data and collecting QUAL data for study C.	Apr 2026	Apr 2026
Study group 2: Follow-up QUAN data collection, analyzing pre-post and follow-up QUAN data and collecting QUAL data for study C.	Aug 2026	Aug 2026
Analysis of data study A and complete article study A.	Feb 2026	Feb 2027
Analysis of data study B and complete article study B. Presenting at a conference.	Jul 2026	Sep 2027
Analysis of data study C and complete article study C.	Jan 2027	Feb 2028
Complete mantle. Dissemination of the project at conferences and open lectures.	Oct 2027	Dec 2028

Plan for dissemination of results

We will disseminate the findings from this study through three scientific articles and presentations at scientific conferences. Potential titles of articles:

Study A: *Voices of transformation: A deep dive into the struggles and successes of reclaiming sexuality after sexual trauma.*

Study B: *Healing together: partners' experiences in the journey of sexual trauma recovery through the intervention Take your sexuality back for sexually traumatized women.*

Study C: *A feasibility mixed methods study of the intervention Take your sexuality back for sexually traumatized women: Preliminary evaluations of efficacy and outcome measurements.*

3.4 Potential for implementation

The results will be used to develop a full-scale RCT study and to further develop and use TYSB in clinical practice. We experience a great demand for the treatment and receive referrals from other admission areas outside STHF. To address this demand, we will carry out training for health personnel at other health institutions. This initiative will lay the groundwork for a multi-center study and expand the reach and applicability of the TYSB intervention. Given the critical need for research on treatment methods for traumatized sexuality, the results have the potential to influence future guidelines and recommendations for treatment. In the final phase of the research project, the researcher and user participants will hold open lectures at women's health centers managed by NKS and NOK/SMISO centers. This public engagement is a crucial component of the project, aiming to reduce the taboo surrounding traumatized sexuality, share knowledge and foster a more open and supportive environment for affected individuals and their partners.

4. Budget

Expenses	2025	2026	2027	2028	Total
Wages and social security contributions	732 000	761 000	792 000	823 000	3 108 000
Purchased services/fees	128 000	131 000	115 000	118 000	492 000
Material/equipment	190 000	10 000			250 000
Other expenses	50 000	60 000	90 000	90 000	290 000
Total	1 100 000	962 000	997 000	1 031 000	4 090 000

The researcher will work 25% clinically throughout the project. The PhD project therefore has a timeframe of four years, with 75% of the position being dedicated to research. The study was funded by internal funds in 2025, and funding is being sought for the remaining years, 2026–2028.

5. User involvement

The TYSB intervention has been developed through a collaborative process involving close dialogue with participants from the intervention groups. Five user participants, who have previously participated in the TYSB intervention, were integral to a preliminary project focused on creating a manual for the psychoeducational component of the intervention (25). Their firsthand experiences provided valuable insights that shaped the content of the manual. Two of these user participants continue to contribute to the research study's project group, ensuring continuity and the integration of lived experiences into the project. Additionally, one

user participant, with research experience and no prior connection to the intervention, will participate in the project group bringing a fresh perspective and enhance the objectivity of the research process. The user participants will contribute with interview guides, interviews (GMU), input on data analyses and dissemination of results.

6. Ethical considerations

As standard clinical practice, the patients who are asked to participate in the study have undergone a thorough intake interview which can help them make an informed decision about whether to participate in the intervention and the study. To avoid any pressure, participants are informed about the study by the group therapists, and their decision to participate is communicated to a project secretary. Those who choose not to participate in the study still can receive the same treatment. Participants in the study are informed about their rights to withdraw at any time without needing to explain their reasons. The research interviews, self-rating tools, the SDI procedure, and the intervention itself carry potential risks causing distress. In order to minimize the burden, a critical assessment has been made of which forms and tests are necessary to cover the project's objectives. In accordance with standard clinical practice, the participants will have contact with a therapist outside the group and can thereby receive individual therapy sessions for issues that arise during the interviews, surveys or other assessments. All evaluations and measures will be conducted at the treatment site with the researcher, an experienced trauma therapist, available to manage any trauma reactions. Participants are informed that they can contact the project leader if they need more follow-up. Experiencing ongoing violence is an exclusion criterion for participation in the treatment and the research project. If it is nevertheless discovered, the woman's safety will be prioritized, and the partner will be excluded from the study. Research data will be de-identified, with forms marked by numerical codes. The key linking the codes to participant identities will be stored separately from the research data, in an access-restricted folder at the research server at STHF. All collected data will be stored on Services for Sensitive Data (TSD), University of Oslo. Participants in the study will be allowed to review the transcript of their interviews to ensure the quality of the transcripts and allow them to correct any errors and clarify statements. At the end of the project, de-identified data will be securely stored for five years. The results of the study will be communicated in a way that anonymizes the participants. As a whole, it is considered that this study will lead to greater societal benefit than possible burdens. The project is approved by the Regional Ethics Committee (Reknr 829297) and data protection officer (PVO) and its execution will adhere to the guidelines of the Helsinki and Madrid declarations.

7. References

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