# The good pain consultation in endometriosis: Early introduction of biopsychosocial pain education.

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**Early introduction of biopsychosocial pain education.**

# 1 Introduction

This PhD project investigates the effect of "the good pain consultation" and early integration of biopsychosocial pain education with current standard management of endometriosis. Our goal is to facilitate self-management of pain and improve health-related quality of life (HRQOL) using limited resources.

Endometriosis is a common systemic disease affecting approximately 10% of reproductive-age women, with a considerable impact on physical and emotional well-being and HRQOL (1). The most commonly reported symptom and reason for specialist referral is pain: dysmenorrhea, dyspareunia, chronic pelvic pain, as well as back pain and painful bowel or bladder problems can be persistent and debilitating despite best-practice care (1-3). Delay of diagnosis up to several years is common (1, 4), which may in turn lead to increased personal suffering, emotional distress, feelings of dismissal as well as lost productivity (5, 6).

Pain, especially chronic pain, is recognized as a complex phenomenon within a biopsychosocial model. Within the biopsychosocial model, pain and disability arise and perpetuate through dynamic interactions among biological, psychological, and social factors (7, 8). Across various chronic pain conditions, including endometriosis and chronic pelvic pain, the pain is poorly correlated with tissue changes, while changes in pain detection and transmission such as central sensitization are shown to play important roles (1, 6, 7, 9-12). Psychosocial factors such as pain beliefs, catastrophizing, kinesiophobia, social isolation, and comorbid anxiety or depression strongly predict functional disability and HRQOL in patients with chronic pain across conditions (8, 12-14).

Conventional guidelines for treatment of endometriosis focus primarily on treatments targeting tissue changes, such as pharmacological, hormonal and surgical treatment (1, 4). Newer recommendations suggest a multimodal biopsychosocial approach by an interdisciplinary team for patients with significant pain problems, an approach which is also considered ideal by patients in a recent Norwegian survey (3, 15). However, this is not achievable in most clinical settings where the reality is often defined by limited time and resources. For many (or possibly most) patients in Norwegian hospitals, this means that biopsychosocial evaluation, pain education and pain self-management is not introduced before the pain has become chronic and/or extremely disruptive, if ever. Earlier access to biopsychosocial evaluation, pain education and pain self-management strategies may potentially prevent pain chronification and improve HRQOL, function and participation in daily life (4, 6).

Communication aimed at influencing patients' pain beliefs, understanding of pain mechanisms, giving reassurance and encouraging self-management behaviour are central evidence-based recommendations in approaching chronic pain (14, 16, 17). The example of the **brief (cognitive) intervention** for low-back pain demonstrates that a simple and concrete communication-based intervention can be a powerful tool to address chronic pain. Several studies have shown the brief intervention to be cost-effective and perform at least as well in improving outcomes as more complex interventions such as exercise, cognitive behavioural therapy or multidisciplinary interventions (18-23). The brief (cognitive) intervention for low back pain is a communication model for a single consultation using patient-centered communication, reassurance based on factual information and demonstration of clinical findings, explanation of pain mechanisms and presentation of simple self-management strategies. **Adapting this model for a "good pain consultation" to the case of endometriosis will provide early introduction of reassurance, biopsychosocial pain education and self-management strategies**. We believe this

represents a potentially simple, safe and cost-effective intervention which can improve outcomes and prevent chronicity in this important patient group.

### 1.1 Needs description

Recent evaluations of research gaps and unmet needs in endometriosis point to the need to prioritize research and development of treatment strategies such as patient information and support, self-management, and pain management programs (2, 4). A recent Norwegian patient survey identifies the need for multidisciplinary (i.e. biopsychosocial) care, improved information, being heard and taken seriously as important components in endometriosis care (15).

We aim to test early introduction of a "good pain consultation" and biopsychosocial pain education for patients with endometriosis. As argued above, this communication-based intervention has the potential to be a **powerful and cost-effective tool to improve patients' pain self-management skills and HRQOL**. As such, it fills a clear need for both patients and clinicians alike. Although research and general recommendations for communication exist (14), to our knowledge no such intervention has been developed for use in chronic pain outside the case of low back pain.

Further knowledge regarding modifiable predictors of outcome (eg. pain beliefs, emotional distress, dysfunctional coping strategies) will assist in development of future treatment strategies, for example by more accurately identifying patients in need of pain management programs and providing insight to guide content of pain management programs for endometriosis. Since tissue-based phenotyping correlates poorly with pain (1), the identification of alternative phenotyping methods such as pain profiles to target treatment may improve future outcomes (2, 6).

## 2. Hypotheses, aims and objectives

**Primary goal:**

The main goal of this study is to test the effect of early introduction of a "good pain consultation" including biopsychosocial pain education, compared to usual care. We hypothesize that the intervention will improve pain self-efficacy and HRQOL, compared to usual care at 3 months and 1 year. **(Paper I)**

**Secondary goals:**

- Identify effects of the intervention on intention to re-consult and on self-reported health care utilization after 1 year. **Hypothesis:** the intervention will reduce intention to re-consult and health care utilization. **(Paper I)**
- Identify predictors of pain, pain self-efficacy, and HRQOL after 1 year. **Hypothesis:** pain catastrophizing and emotional distress will more strongly predict outcomes than final diagnosis of endometriosis and degree of tissue changes. **(Paper II)**
- Investigate pain characteristics in patients who receive a verified diagnosis of endometriosis during the study, compared to those without a verified diagnosis of endometriosis. **Hypothesis:** many patients without a verified diagnosis of endometriosis also have significant pain-related problems, thus demonstrating a wider need for the "good pain consultation". **(Paper III)**

## 3. Project methodology

### 3.1 Project arrangements, method selection and analyses

This PhD project is part of a larger mixed-methods project carried out by the same research group (see 3.2.1 for Organization). **Phase 2 describes the PhD project in the current proposal**, while phases 1, 3 and 4 will be carried out by other members of the Q-safe research group (see 3.2.1). Preliminary results from the Qualitative Meta-synthesis (Phase 1) indicate a paucity of research regarding pain communication in endometriosis. Results from

Phase 1 will be used in the design of Phase 2. Phase 3 and 4 are based on in-depth and long-term follow-up of participants from the current study, respectively.

| **Pain communication in Endometriosis** | | | |
|---|---|---|---|
| Phase 1 | **Phase 2** | Phase 3 | Phase 4 |
| Pain communication in Endometriosis – *Qualitative meta-synthesis of qualitative studies of pain communication in endometriosis.* | **The good pain consultation in endometriosis – Early introduction of biopsychosocial pain education *(RCT and secondary analyses, current PhD proposal)*** | Experiences of pain communication in dysmenorrhea and endometriosis – *Qualitative study based on in-depth interviews of a selection of patients from the current study* | Long-term outcomes, predictors of pain and function in patients with endometriosis: *Long-term follow-up (5 years) of participants from the current study* |

3.1.1 Trial design

We plan an observer-blinded randomized controlled trial (RCT) comparing the addition of "the good pain consultation" and biopsychosocial pain education plus usual care, to usual care alone. Main outcomes Pain Self-efficacy and health-related life quality will be measured at 3 months and 1 year **(Paper I)**. Secondary analyses using 1-year outcome measures will be performed to identify predictors of pain, pain self-efficacy and health-related life quality **(Paper II)** and identify characteristics of patients who receive a verified diagnosis of endometriosis during the study, compared to those who do not **(Paper III)**.

3.1.2 Participants, recruitment and study timeline

To ensure the project goal of early intervention, we will offer inclusion to all patients between 16-50 years attending outpatient clinics at the Departments of gynecology at Sørlandet hospital (Arendal, Kristiansand and Flekkefjord) who are ***referred for evaluation of possible endometriosis due to pain,*** *OR* ***who are being followed for an established diagnosis of endometriosis.*** Since confirming diagnosis of endometriosis can take years (1), and the goal of the study is early implementation of biopsychosocial pain education, we will not require confirmed diagnosis of endometriosis as a condition of participation but will record confirmation of diagnosis (yes/no) and endometriosis staging during the course of the project for secondary analysis. A digital letter of invitation, study information and request for informed consent will be sent to potential participants. Following informed consent, all patients will receive a link to fill out baseline questionnaires and thereafter a link to digital information about primary and secondary dysmenorrhea, endometriosis and pain (see 3.1.3). Thereafter, patients will be randomized, and patients who are randomized to the intervention group will be invited to attend one extra consultation (see 3.1.3 "The good pain consultation").

- Inclusion criteria
  - ✓ Referred for evaluation of possible endometriosis due to pain OR
  - ✓ Being followed for an established diagnosis of endometriosis
  - ✓ Age 16-50 years
  - ✓ Biological female sex
- Exclusion criteria
  - ✓ Insufficient proficiency in Norwegian to participate in study procedures

3.1.3 Interventions

*Usual care*

All patients will undergo standard evaluation and treatment at the department of Gynecology to which they are referred. Currently, usual care consists of history, clinical examination, ultrasound, bloodwork, MRI and/or explorative laparoscopy if indicated, pharmacological treatments (hormonal and/or pain medication). The course of evaluation and follow-up may vary from one to several consultations.

*"The good pain consultation"*
In addition to usual care, patients in the intervention group will attend a "good pain consultation" inspired by the model for Brief cognitive intervention which has been shown to be effective for improving outcomes in low back pain (18-23). Users will be involved in development of patient education program and "good pain consultation" (see section 4).

Participants will receive a link to a digital pain education program. The program will include standard information about endometriosis, but will also introduce a biopsychosocial understanding of pain including influence of psychological factors such as excessive worry, stress, sleep disturbance and emotional distress. Self-management strategies including physical activity, relaxation and breathing techniques, cognitive techniques, psychosocial support and appropriate use of pain medication and supplemental treatment (e.g. physical therapy, TENS, heat), will be introduced.

Participants will then attend a single "good pain consultation", a patient-centered consultation with a clinician associated with the project, in which content from the educational package will be reinforced. The consultation will provide the opportunity to address the biopsychosocial factors including anxiety, previous trauma, emotional distress etc. Shared decision-making regarding preferred self-management strategies introduced in the digital educational material will be carried out, including need for referral to further follow-up (psychologist, physical therapy, etc.).

3.1.4 Outcome assessment
*Blinding, data capture and storage*
Invitations for participation, informed consent and outcome measures will be handled through use of *Nettskjema*, which employs internet-based questionnaires with secure login, approved for research involving patient sensitive data. This will simplify both recruitment and data collection. Data will be stored and handled within systems approved for this purpose (Services for sensitive data, TSD, University of Oslo). Group allocation will be coded in the research database, such that all researchers who handle outcome measures will be blinded to group allocation. The statistical analysis for the main RCT will be performed blinded (see 3.1.5)

*Primary outcome measure*
The *Pain Self-Efficacy Questionnaire (PSEQ)* (24) is a 10 item self-report questionnaire which assesses confidence people with ongoing pain have in performing activities despite pain. Self-efficacy regarding household chores, socializing, work and coping without medication are assessed. Each item is scored on a 6-point scale, for a total raw score of 0-10 where high scores indicate greater levels of confidence in dealing with pain. The PSEQ is translated to Norwegian and used in previous Norwegian studies (25)

*Secondary outcome measures*
- Single question gives a simple and effective measure of life satisfaction. We use the question: "All in all, how satisfied are you with your life right now?" which is used by the World Health Organization (WHO). It is answered on a scale from 0 to 10, where 0 indicates *"Not at all satisfied" and* 10 indicates *"Very satisfied"(26)*
- The *SF-12/RAND-12* will be used as a generic measure of HRQOL (27). The questionnaire is translated to Norwegian and Norwegian reference values generated (28).
- *Pain catastrophizing scale (PCS)* measures pain catastrophizing and "exaggerated negative orientation toward pain stimuli and pain experience" (29). The scale consists of 13 items and includes subscale scores for rumination, magnification and helplessness. Cultural adaptation and validation to Norwegian context has been performed (30).
- Emotional distress will be assessed using the *Hopkins Symptom Checklist (HSCL-10)*. The HSCL-10 consists of 10 questions assessing symptoms of anxiety and depression

(range 1 to 4, most symptoms).(31, 32) Scores ≥1.75 are indicative of increased emotional distress.(33)

- Three 0-10 *numeric rating scales (NRS)* will be used to measure usual pain intensity, worst pain intensity and bothersomeness of pain, during the past month (34).
- The Decreased Sexual Desire screener (DSDS) is a simple, validated (35)diagnostic tool to help to identify and discuss hypoactive sexual dysfunction among women. There is a Norwegian translation, but DSDS is not validated in a Norwegian setting.
- The Brief Illness Perception Questionnaire (Brief IPQ) is used to assess the cognitive and emotional perception of their illness and consists of nine questions. Answers are scored on a Likert scale from 0-10 scale in the first eight questions and the latter question has an open-ended respons. Higher scores indicate more threatening/negative views of their pelvic pain. The instrument has evidence for reliability and validity in Norway (36)
- The 2016 fibromyalgia diagnostic criteria(37) are used to identify fibromyalgia based on symptom severity and pain distribution. These criteria are widely used in clinical and research settings and has shown high internal consistency, good validity and high diagnostic accuracy in a Norway(38). The criteria include two main components:
    - Widespread Pain Index (WPI), which Assess pain in 19 body regions over the past week with a Score range: 0–19 (1 point per painful area)
    - Symptom Severity Scale (SSS) measures severity (0–3) of fatigue, unrefreshing sleep, and cognitive symptoms with a score range: 0–12
    - Diagnosis is met if: WPI ≥ 7 and SSS ≥ 5, or WPI 4–6 and SSS ≥ 9 and symptoms have been present at a similar level for at least 3 months, with generalized pain in at least 4 of 5 body regions
- Verified diagnosis of endometriosis (yes/no) and grading of endometriosis will be recorded by a research assistant accessing patient electronic journal, with the consent of the patient.
- Additionally, we will collect information regarding duration of the pain (years since onset), previous traumatic experiences, previous pregnancy, and problems with infertility. As well, participants confidence in conclusion from the medical evaluation, intention to re-consult, use of health care services and use of medication will be elicited.
- Furthermore, we will collect relevant registry data from national and municipal sources, such as Statistics Norway (SSB), the Norwegian Patient Registry, and the municipal patient and user registry. These data sources will provide supplementary information on healthcare utilization, diagnoses, and other contextual variables that may be relevant to the study

3.1.5 Statistics

*RCT Primary endpoints*

All eligible patients, regardless of their compliance with the protocol (analysis by intention-to-treat) will be included in the main analysis for the RCT. The primary endpoints of the study will be analyzed with an Analysis of Covariance model using the baseline value as one of the covariates. A blinded statistical analysis and interpretation of the outcome measures is planned (39). Only after the writing committee members have agreed that there will be no further changes in the interpretation will be randomization code be broken. **(Paper I)**

*Secondary analysis*

Multivariable linear regression models with backward stepwise elimination will be used to identify baseline factors associated with outcomes Pain Self-Efficacy and HR-QoL at 1 year. Baseline independent variables will include: Treatment group (intervention/control), Pain catastrophizing scale, confirmed tissue-based endometriosis diagnosis (yes/no), emotional distress, and previous traumatic experiences. **(Paper II)**

Descriptive statistics will be used to describe demographics, pain characteristics and psychological characteristics of patients who receive a confirmed diagnosis of endometriosis

(Ultrasound, MRI or laparoscopy) and those who do not, during the course of the study. Independent T-tests will be used for between-group comparisons. **(Paper III)**

3.1.6 Sample size and feasibility
Sample size calculation is based on a standard superiority trial design. The main outcome measure is the Pain Self-Efficacy Questionnaire (24). The Minimal important change (MIC) is 5.5 (40). Based on previous studies, standard deviation is assumed to be 10. With these assumptions, 41 participants are required in each group to attain 80% statistical power with a 5% significance level for pain self-efficacy. To take into account possible missing data and drop-out we intend to include a minimum of 55 participants in each group, for a total of 110 participants.

***Feasibility:*** At the Departments of Gynecology at Sørlandet Hospital, over 300 patients per year attend outpatient clinics under various diagnoses of pelvic pain (often the tentative diagnosis before confirmation of endometriosis) or endometriosis. Assuming an inclusion rate of >50%, we expect to achieve inclusion of 110 patients within the course of one year.

For multivariable analyses of predictors, 10-15 participants per variable is considered adequate (41). Thus, a sample size of 110 participants will be adequate for a pooled analysis of 7-10 predictors. To strengthen secondary analyses of patients receiving a confirmed diagnosis of endometriosis during the course of the study, and those who do not, we will collect outcome measures (see 3.1.4) from a further 100 patients in a prospective manner, in addition to those included in the RCT. This cohort will be followed up at 1 year and at 5 years, as a long-term follow-up to the current study (Phase 4 of the Pain communication in Endometriosis project, see 3.1)

3.1.7 Risk assessment and mitigation
The most obvious risk of this project is recruitment of participants. By a conservative estimate based on the sample size above (3.1.6), we consider the risk to be low. If recruitment is much slower than expected, the team will consider the following mitigation options: 1) increased marketing of the project through patient organizations and social media 2) including other hospitals in the project to expand the pool of participants.

## 3.2 Participants, organization and collaborations

3.2.1 Organization
The study is a collaboration between the Departments of Gynecology (Arendal, Kristiansand, and Flekkefjord), *Sørlandet hospital*, the Interdisciplinary Pain Clinic, Dept. of Physical Medicine and Rehabilitation, *Sørlandet Hospital* and Faculty of Health and Sport Sciences at *University of Agder*. All researchers are members of the research group Q-safe, which is a joint research group between University of Agder and Sørlandet Hospital, led by professor Gudrun Rohde.
PhD program: The PhD student will attend the PhD teaching program at the University of Agder, and will participate in the research group Q-safe at UIA, Faculty of Health and Sports Sciences, where all supervisors are members. The research group covers a wide range of health and research competence and brings substantial expertise and experience to this study.

3.2.2 Project manager and project group
- The project group is interdisciplinary and represents both an in-depth practical experience working with endometriosis, chronic pain in a biopsychosocial model, and use of cognitive methods. The study group also has as a wide base of competence in the scientific methods involved in the current project. The study will be led by *professor Gudrun Rohde, RN, PhD*, and *Alexandra Hott, MD, PhD*, who will function as co-primary investigators. As evidenced by their Curriculum Vitae, their competence is complementary and together includes an in-depth competence in the areas of chronic

pain, biopsychosocial models, interdisciplinary cooperation, project management and the planned scientific methods. Together they have experience in managing projects of various types, and a track record for achievement in research and clinical work.

- Project manager and co-supervisor will be *Gudrun Rohde*, RN, PhD and Professor at Faculty of Health and Sport Sciences, University of Agder and Department of Clinical research Sørlandet Hospital. Expert in Patients Reported Outcomes (PROM) research.
- Co-primary investigator and main supervisor will be *Alexandra Christine Hott*, MD, PhD. Consultant physician and Chief physician at the Multidisciplinary Pain Clinic, Sørlandet Hospital.
- Co-supervisor will be N*astasja Robstad*, PhD, MSc, RN. Associate professor at Faculty of health and sports sciences, University of Agder.
- Research associate and planned PhD candidate is *Inger Johanne W. Hansen*, MD. Consultant physician specializing in pain medicine and rheumatology, Multidisciplinary Pain Clinic, Dept. of Physical Medicine and Rehabilitation, Sørlandet Hospital. Dr. Hansen has long clinical and research experience, including co-authoring 9 scientific papers.
- *Anita Paulsen*, RN, Sexologist, PhD candidate and University lecturer, Institute for Psychosocial health, University of Agder/ Dept. of Gynecology, Sørlandet hospital.
- *Professor Ingvild Vistad*, Professor II, Dept. of Gynecology, Sørlandet hospital and Faculty of Medicine, University of Oslo is highly experienced researcher and clinician, and is an advisor to the project.
- *Advisors to the project: Cecilie Øvland Gravdahl, MD,* Dept. of Gynecology, Sørlandet hospital Kristiansand and *Jeanne Mette Goderstad, MD, PhD,* head of Dept. of Gynecology, Sørlandet hospital Arendal
- Reference group: *Tor O. Tveit*; MD, PhD. Senior consultant at Department of Anesthesia and Intensive care at Sørlandet hospital and medical advisor at Department of e-health and technology at the University of Agder, *Sandra Flohr-Madsen*, MD, PhD, Consultant physician, Multidisciplinary Pain Clinic, Sørlandet Hospital, and Department of Anesthesia, Sørlandet Hospital. *Ann-Helen Dolsvåg*, RN, MSC anesthesia and leader of the nurses at Department of Anesthesia, Sørlandet Hospital. The researchers in the reference group and the researchers in the current study collaborate in cooperating projects, providing feedback and suggestions in the conception, planning and execution of the project.
- Norwegian society for chronic pain patients is a partner in the study and will be represented by *Jorunn Arnesen* and *Marion Jakobsen.*
- Lokal user representatives: *Heidi Klungland Eikaas, Grete Stebekk Hommelsgård and Lene Røsstad Masternes*

## 3.3 Budget

The current application is for funding for a 50% research position for the PhD candidate, for 6 years. Based on current base salary of 873 200 NOK, this corresponds to 436 600 NOK x 6 years. The study is based around established patient flow and data collection systems and do not require additional funding. No special equipment is required for the project. The yearly running costs are not expected to exceed 37,500 NOK per year.

## 3.4 Plan for activities, visibility and dissemination

### 3.4.1 Work plan

| Milestones throughout the PhD study | 2024 | | 2025 | | 2026 | | 2027 | | 2028 | 2029 |
|---|---|---|---|---|---|---|---|---|---|---|
| Ethical applications | | | | | | | | | | |
| Courses in the PhD programme | | x | x | x | x | x | x | x | x | |
| Optimize intervention (user input) | | x | | | | | | | | |
| Inclusion | | | | x | x | x | | | | |
| Collection of data | | | | x | x | x | x | x | | |
| Analysis Study I | | | | | | | x | x | | |
| Writing paper I | | | | | | | x | x | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Analysis Study II | | | | | | | | x | x | |
| Writing paper II | | | | | | | | x | x | |
| Analysis Study III | | | | | | | | | x | |
| Writing paper III | | | | | | | | | x | |
| Writing a summary of the thesis | | | | | | | | | x | x |
| Dissemination | | | | | | | | x | x | x |

### 3.4.2 Visibility and dissemination

- The findings from the three studies will be reported in papers submitted for publication in refereed international scientific journals such as *Obstetrics and Gynecology, Acta Obstetricia et Gynecologica Scandinavica (AOGS), Journal of Endometriosis and Pelvic Pain Disorders (JEPPD), PAIN, Scandinavian Journal of Pain, and Pain Medicine.*
- We will participate in national conferences and courses in gynecology to introduce the model to relevant users. Live and/or digital courses and patient information materials which result from the project will be made available to relevant users and to patients.
- As well, results will be shared in relevant conferences and meetings in Norway and internationally (the Norwegian Pain Society (NOSF), Norwegian Society for Pain Medicine, Norwegian Multidisciplinary Pain Clinic network in Norway, European Pain Federation (EFIC) and International Associations for the Study of Pain (IASP).
- To make the results known to users, we will cooperate with user organizations including the *Norwegian society for chronic pain patients* and the *Norwegian Patients' Endometriosis Society* (project partners) in dissemination of the findings on social media and similar forums. A chronicle will be written for the regional newspaper. We expect that users will also be instrumental in encouraging clinicians to use the "good pain consultation" model in their practices.

### 3.5 Plan for implementation

The main output of this project is a simple pain education intervention for endometriosis-related pain in the specialist clinical setting, as such it is ready for implementation without further translation. Dissemination and implementation of the model will go hand in hand, see 3.4.2 for details regarding dissemination.

Successful implementation of the "good pain consultation" within endometriosis will have implications for use in other chronic pain settings. Further research and clinical implementation should focus on its utility as a generic tool to address chronic pain within other medical specialties.
The current project will help to identify what characterizes good health communication, and identify factors which can make health information more understandable and available, two of the stated research goals of the Norwegian strategy plan for improving health literacy (42, 43). As such, the results will be relevant for further development of communication and information strategies in chronic pain for other clinicians, research groups as well as Norwegian health authorities.

## 4. User involvement

The Norwegian society for chronic pain patients are partners in the study and are involved all phases of planning and execution including the current project description. Patients with endometrioses is included as user representatives. The users are involved in developing the intervention (content, timing, format etc) and the outcome measure questionnaires to ensure relevance, acceptability and ease of understanding for study participants.
We plan to cooperate with user organizations in assisting with dissemination and encouraging clinicians to use the intervention.

## 5. Ethical considerations

The project shall be conducted in accordance with the guidelines of the Norwegian National Research Ethics Committees and the principles of the Declaration of Helsinki regarding respect, no harmful consequences of participation, fairness and integrity (44, 45).

Participation will be based on informed consent. Approval will be obtained from the Regional Committees for Medical and Health Research Ethics (REC), Norwegian Centre for Research Data (NSD), The Faculty of Health and Sport Sciences Research Ethics Committee (FEK) at the University of Agder and the hospital. Sensitive data will be handled using solutions approved for these purposes.

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SØRLANDET SYKEHUS

REQUEST TO PARTICIPATE IN THE RESEARCH PROJECT

# "The good pain conversation for endometriosis" - early introduction of pain management tools with a holistic focus.

## THE PURPOSE OF THE PROJECT AND WHY YOU ARE ASKED

Many people with endometriosis struggle with severe pain. This is therefore an offer for you to participate in a research project that intends to test the effect of a pain management tool that can be useful for you and other women who struggle with pelvic pain.

It is normal for long-term pain to affect quality of life and how one functions in several areas of life. According to treatment recommendations for endometriosis and other long-term pain conditions in the pelvic area, a holistic approach to the pain and pain management is recommended, in addition to drug and surgical treatment aimed directly at the disorder. Today, the holistic approach to pain is often offered late in the course of the disorder, for example at an interdisciplinary pain clinic.

The purpose of this study is to investigate the usefulness of a holistic approach to pain through a "good pain conversation" and a toolbox for pain management, for patients who are referred to a gynaecological outpatient clinic for assessment of endometriosis.

You will be asked to participate in the study because you have been referred to a gynaecological outpatient clinic with questions about endometriosis or because you have recently been diagnosed with the disorder and have been referred for treatment. Doctors at the Department of Gynaecology have thought that you may be relevant for participation in the study.

The project is based at the Pain Outpatient Clinic at Sørlandet Hospital and is in collaboration with the Women's Clinic at Sørlandet Hospital and the University of Agder.

## WHAT DOES THE PROJECT ENTAIL?

If you agree to participate in the study, you will be randomly allocated either to an intervention group or to a control group. All participants, regardless of the group allocation, will still receive regular assessment and treatment at the gynaecological department.

Participants in the intervention group will receive a link to digital information about pain and pain management and join an individual outpatient pain conversation with the study physician (1 hour) with a focus on finding tools for pain management that suit you and your situation. All consultations in connection with the study are free of charge.

If you are randomized to the control group, you will be offered a pain conversation with the study doctor after the end of the study, if desired.

Everyone participating in the study will be asked to respond electronically to questionnaires immediately after inclusion in the study, after 3 and after 12 months. We ask questions about yourself, your suffering, about your pain and how you deal with the symptoms.

In the project, we will collect and register information about you, some general information will be collected from the patient record, about general condition and any other chronic diseases, about the assessment that is carried out by a gynaecologist and about the treatment that is offered. We will also be able to collect relevant registry data from registries such as Statistics Norway (SSB), the Norwegian Patient Registry and the municipal patient and user register. The research project will result in several scientific articles where the results are presented. Participants in the project will not be identifiable in the articles.

## POSSIBLE ADVANTAGES AND DISADVANTAGES OF PARTICIPATION

For participants in the intervention group, participation will mean that you will receive an extra offer while waiting for an appointment at the gynaecological outpatient clinic. Otherwise, all participants will receive regular treatment at the gynaecological department. Information from the study will be useful for improving services for patients in the future. There are not considered to be any direct disadvantages for you to participate, except for time spent, and that it may be challenging for some to think through some of the questions. If something comes up that you want to discuss, you can bring this up with the study doctor.

## VOLUNTARY PARTICIPATION AND THE POSSIBILITY TO WITHDRAW CONSENT

Participation in the project is voluntary. If you want to participate, click on "want to participate"

You may withdraw your consent at any time and without giving any reason. There will be no negative consequences for you or your treatment if you do not want to participate or later choose to withdraw. If you withdraw your consent, no further research will be conducted on your data. You can demand access to the information stored about you, and this will then be disclosed within 30 days.

If you withdraw from the study, you can demand that the collected data be deleted, unless the data has already been included in analyses or used in scientific publications.

If you later wish to withdraw or have questions about the project, you can contact the study doctor:

Inger Johanne W Hansen
E-mail: inger.johanne.hansen@sshf.no
Phone: 38149424

Or project manager:
Alexandra Christine Hott
E-mail: alexandra.hott@sshf.no
Phone: 38149348

## WHAT HAPPENS TO THE INFORMATION ABOUT YOU?

The information registered about you shall only be used as described in the purpose of the project. You have the right to access what information is registered about you and the right to have any errors in the information that is registered corrected. You also have the right to access the security measures when processing the data.

All information will be processed without name and national identity number or other directly recognizable information. A code links you to your information through a list of names. Only project manager Alexandra Hott and study physician Inger Johanne W Hansen have access to this list.

The information about you will be anonymized or deleted five years after the end of the project.

[Skriv her]

## INSURANCE

You are insured in the usual way through the Patient Injury Act.

## APPROVAL

The Regional Committee for Medical and Health Research Ethics has assessed the project and has given prior approval. Under the new Personal Data Act, the data controller at Sørlandet Hospital and the project manager have an independent responsibility to ensure that the processing of your data has a legal basis. This project has a legal basis in Article 6(1a) and Article 9(2a) of the GDPR and your consent.

You have the right to complain about the processing of your data to the Norwegian Data Protection Authority and to the institution's data protection officer.

## CONTACT INFORMATION

If you have any questions about the project, please contact
Inger Johanne W Hansen
E-address: inger.johanne.hansen@sshf.no
Phone: 38149424
The data protection officer at the institution is personvernombudet@sshf.no

## I CONSENT TO PARTICIPATE IN THE PROJECT AND TO MY PERSONAL DATA BEING USED AS DESCRIBED

……..

Place and date

Participant's signature

……..

Participant's name in printed letters

I confirm that I have provided information about the project

……

Place and date

Signature

……..

Rolle i prosjektet

[Skriv her]