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Can general exercise training and pelvic floor muscle training be used as an empowering tool among women with endometriosis? Experiences among women with endometriosis participating in the intervention group of a randomized controlled trial

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Abstract

Background The potential benefit of exercise in alleviating symptoms of endometriosis is unclear. Still, exercise may be used to empower women and manage disease symptoms. The purpose of this study was to explore how regular supervised group- and individual exercise training, including pelvic floor muscle training (PFMT), is experienced among women with endometriosis after participating in a randomized controlled trial (RCT).

Methods Among 41 women randomized to exercise training for four months, ten women were interviewed about their experiences with exercise training after participation in the trial. The weekly group training was led by women's health physiotherapists and included individualized and progressive muscular strength training of large muscle groups and the pelvic floor muscles, in addition to endurance-, flexibility, and relaxation training. An individual training program followed the same principles as the group training and was to be performed 3–5 times per week, depending on the level of intensity. PFMT was recommended daily. The women also received a group pain management course emphasizing exercise training as self-management. Using inductive reflexive thematic analysis, responses to the question "Did participation in the study change your view of exercise as part of the treatment for endometriosis?" were analyzed.

Results The women brought forward the importance of knowledge about the benefits of exercise to make informed decisions in disease management. Further, the women described how exercise training was perceived as less frightening and manageable when exposed to various intensities, dosages, and types of exercises in a safe and

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supportive environment. PFMT was especially brought forward as something new and appreciated, and for some of the women, to be performed on days when their bodies could not handle the general exercise training. They also expressed that the supervised exercise brought an extra dimension of belonging through group participation.

Conclusions Individualization and regular supervision seem important to empower women with knowledge about exercise training as self-management and to experience exercise training as safe and non-threatening. Further, creating a sense of belonging through group training may improve social support and build active coping strategies that are essential for disease management of endometriosis.

Trial registration NCT05091268 (registered 23.09.2021).

Keywords Endometriosis, Empowerment, Exercise, Pelvic pain; pelvic floor muscle training, Physical activity, Physiotherapy, Women's health

Background

Endometriosis is a benign gynecological disease characterized by chronic inflammation, defined by endometrial-like tissue outside the uterus [1]. The exact prevalence is not known, but it is estimated that up to 10% of women of fertile age may suffer [2]. The main symptom associated with the disease is pain with menstruation (dysmenorrhea) [1]. However, pain with intercourse (dyspareunia), chronic pelvic pain, fatigue, and loss of quality of life are also symptoms often found among women with endometriosis [1].

Non-pharmacological and non-surgical treatments may be an adjunct or an alternative to the current medical treatments to relieve endometriosis symptoms. One such treatment may be exercise. A recent study reported that 42% of women with endometriosis use exercise as a self-management tool [3]. However, the same study also reported that 36% of the women lack information on self-management strategies to make informed decisions about their disease management.

The World Health Organization defines empowerment as “a process through which people gain greater control over decisions and actions affecting their health” [4]. Further, empowerment includes participation with others to achieve goals and access resources [5]. A former qualitative study among women with endometriosis found that knowledge about one's body is a prerequisite for feeling empowered [6]. However, the knowledge deficit around endometriosis from healthcare professionals and society, resulting in a lack of agency to understand and learn active coping strategies, may result in women feeling disempowered and cause poor mental health [6, 7].

Exercise training has been defined as any bodily activity that is planned, structured, and repetitive to condition the body [8] and is well-known to benefit both mental health and reduce the risk of many medical conditions [9]. Physiotherapists may help women develop, maintain, and restore movement, activity, and participation for self-management of pain and to improve quality of life [10]. Moreover, women's health physiotherapists have

been especially viewed as an essential part of the treatment package by patients with endometriosis [11].

International treatment guidelines for endometriosis recommend research into evidence-based approaches to support self-management, such as exercise [1]. Moreover, patient satisfaction has been included as a core outcome measure in future endometriosis interventions [12]. However, limited knowledge exists about this population's satisfaction from participation in exercise interventions [13]. Anchoring the theoretical framework in empowerment theory, this study aims to explore how general exercise training, including pelvic floor muscle training (PFMT) and a pain management course, is experienced among women with endometriosis after participating in a randomized controlled trial (RCT).

Methods

Design

This present study is part of a larger two-armed parallel-group RCT and includes the women's voices in the intervention arm. It explores their experiences after participating in a pain management course and following four months of supervised group- and individual regular exercise training. The inclusion criteria for participating in the RCT was being between 18 and 45 years old with signs of endometriosis confirmed by laparoscopy. The total sample of 81 women (from both arms) was recruited from two Norwegian specialized hospitals for endometriosis care in Oslo and through the Norwegian Endometriosis Association between October 2021 and January 2023. The participating women had to present with pelvic and genital pain, be able to understand and speak the Norwegian language, and be able to participate in exercise classes. Exclusion criteria were severe pathology (malignancy), cardiovascular conditions and immune system diseases diagnosed by a specialist, pregnancy, childbirth in the last 12 months, and breastfeeding, and severe psychiatric disorders and personality disorders diagnosed by a specialist. In addition, women who had undergone intra-abdominal or vaginal surgery, receiving Botox injections into the pelvic area, or those recently

started or adjusting ongoing hormonal therapy had to wait 4–6 months before being included in the study. The study was approved by the Regional Medical Ethics Committee (date of approval 22.10.2019; reference number 2019/1236) and the Data Protection Officer at Akershus University Hospital (2019_135).

Participants

A total of 41 women were randomized to the intervention arm. Of these, a purposive sample of 14 women, who had first finished the four-month intervention period, were contacted by a research group member by phone or email with information about the study. If interested, the interview was scheduled on the day of their post-intervention assessment (as part of the main RCT). Ten women gave their consent. Reasons for non-response were a loss to follow-up from main RCT ($n=2$) and no time ($n=2$). Six of the women had a bachelor's or a master's degree, eight were either married or in a relationship, and two had children. Seven were working full-time or part-time, and two were regular exercisers, defined as >2 times per week of either strength training or endurance training. Background characteristics specific to the ten women participating are presented in Table 1. Relevant background information and informed consent were handled through Nettskjema.no, a secure online assessment tool developed and hosted by the University of Oslo, Norway.

Intervention description

The women attended a four-hour interdisciplinary pain management course run by a physiotherapist, gynecologist, and psychologist at Akershus University Hospital (March and April 2022). The pain management course had a biopsychosocial approach emphasizing general exercise as an empowering tool. In addition, the course focused on PFMT through muscular strength training and complete relaxation to manage pelvic floor pain [14].

Table 1 Background characteristics of the ten women with endometriosis participating in the intervention arm in the randomized controlled trial

	Age range	Years since diagnosis	Level of pain*
Elisabeth	30–34	6 years	8
Suzanne	20–24	3 years	8
Maria	30–34	6 years	7
Hannah	24–29	3 years	5
Olivia	35–40	14 years	7
Amelia	24–29	7 years	5
Isabel	30–34	8 years	8
Sandra	30–34	3 years	8
Emily	30–34	7 years	3
Jenny	24–29	5 years	7

*A numeric rating scale indicated the worst pelvic and genital pain in the last four weeks, ranging from 0–10, 10 being the worst pain experienced and 0 being no pain

Information about surgical and medical treatments for endometriosis was also provided. After the pain management course, the women were randomized to either an intervention or control group in blocks of two and four through the Blockrand package in R, version 1.5 [15]. A statistician handled the randomization sequence, while the allocation of participants into the intervention or control group was performed by a project member not involved in the recruitment of the participants.

The intervention group then attended a 60-minute weekly group training session led by three physiotherapists with specialist training in women's health. The exercise lasted four months and was held at three private physiotherapy institutes in and around Oslo. The group training was designed as circular training, including a 10-minute warm-up, followed by a combination of low to moderate- and moderate to high-intensity aerobic training and muscular strength training of large muscle groups, including PFMT for 40 min, in addition to flexibility and relaxation training for 10 min (Additional File 1). To control for a correct pelvic floor muscle contraction and complete relaxation, before entering the intervention group, the women were assessed by observation and vaginal palpation by an experienced women's health and pelvic physiotherapist [16, 17]. The intervention group was also asked to perform an individually tailored progressive home exercise program over the same period following the same exercises and principles as for the group exercise. Recommendations for weekly exercise followed the American guidelines for physical activity for adults: 30 min 5 times per week with low to moderate-intensity aerobic exercise or 20 min 3 times weekly with moderate to high-intensity aerobic exercise [18]. Recommendations for strength training were ten repetitions in 3 sets, 2 to 3 times per week, with training of large muscle groups. PFMT was recommended daily. Monitoring and adjusting training intensity were done following the principle of 2–3 repetitions in reserve for muscular strength training [19] and the Borg rating of perceived exertion [20]. The intensity, number, and length of home training sessions and any adverse effects were recorded through a training diary.

Procedure for the qualitative study

Ten individual interviews were performed within one month after the cessation of the intervention period. The participants were chosen from the two groups first finishing the four-month intervention period ($n=14$), emphasizing variations in age, pain levels, previous experience with exercise, employment status, educational background, and the dosage and intensity of exercise performed during the intervention period. The sample was further based on the model from Malterud et al. [21], identifying five items of importance in determining

information power: a narrow study aim, participant characteristics highly specific to the study aim, the use of established theory in the analysis of the data, a strong interview dialog between the researcher and the participant, and a thematic analysis of each participant's narratives. Each interview started with verbal information about the participants' voluntary and ethical rights. The interviews were performed in a private room at Akershus University Hospital between August and November 2023, with one female researcher (MKT) present. The researcher (MKT) has over 15 years of experience as a women's health physiotherapist, holds a PhD in women's health, and has ten years' experience in pain research. The researcher also has experience as a qualitative interviewer and experience with thematic analysis. The researcher was not blinded to group allocation and was not involved in the participants' recruitment, assessment, or training, but attended the pain management course. Further, with the background in physiotherapy, preconceptions and preunderstandings about the topic could subconsciously have influenced the interviewer to seek confirmation of any prior beliefs. To avoid this, the interviewer consciously decided to take an open and active role and follow any cues the participants provided during the interviews. The interviews lasted 30–90 min and were recorded and stored using a secure Dictaphone application created with Nettskjema.no, an online assessment tool developed and hosted by the University of Oslo, Norway. In addition, notes on nonverbal behavior were taken.

The interview guide was semi-structured, and a user representative from the Norwegian Endometriosis Association participated in preparing the interview guide. The guide included several questions related to their subjective experiences after participation in the project (Additional File 2). For this specific study, the following questions were asked: "Did participation in this study change your view of exercise as part of the treatment for endometriosis?" referring to muscular strength training, PFMT, and endurance training of various dosages and intensities being experienced in the study, and "What are your perspectives on developing the best possible care for the treatment of endometriosis?" The researcher followed up with questions like: "How?" and "In what way?" to gain additional knowledge about their views and experiences. At the end of the interview, the women were asked to add anything that had yet to be discussed. The transcripts were written verbatim and supplemented by notes on nonverbal behaviors before being sent to each participant with an opportunity to read and correct the data sampled. No comments were returned, and no additional interviews or follow-up questions were needed.

The qualitative design was based on descriptive phenomenology, taking a predominately interpretative

approach [22]. An inductive reflexive thematic analysis was chosen to explore patterns of meanings from the participant's stories following the six steps proposed by Braun and Clarke: achieving familiarity with the data through open-minded reading while developing themes from codes that share commonalities [23, 24]. One researcher (MKT) performed the analytical process, consciously keeping an open and reflective attitude, emphasizing meanings to concrete expressions and descriptive text from the dataset while identifying the text's relevance to the study aim and theoretical framework [24, 25]. Coding and theme generation was stopped, when a diverse sample of experiences from all ten women were achieved. The initial codes and preliminary themes were discussed, and all authors who were educated and trained in women's health (RG, KB, and MEE) and qualitative methods (MM) reviewed the data underlying each theme. From this process, only minor changes to codes and themes were made, finalizing the report. NVivo was used for data coding and categorization of themes [26]. Statements were translated from Norwegian to English and slightly edited for better readability while remaining as close to the original statements as possible. The participants received fictitious names, and age categories were used instead of a specific age, to ensure anonymity. The study follows The Consolidated Criteria for Reporting Qualitative Research [27].

Results

Study participants

The training diaries revealed that during the intervention, the women exercised 160 min per week on average (aerobic exercise and muscular-strengthening training), ranging from 44 min up to 428 min, which was split into an average of 5.7 sessions a week of various lengths per woman. The reported average level of intensity on the Borg scale was 12.7, indicating low to moderate intensity [28]. The level of intensity ranged from 10 up to 16, where two women exercised on level 16, indicating moderate to high intensity [28]. There were no reports of adverse events.

Results from the thematic analysis

We identified three overarching themes related to women's views and experiences after participation in the pain management course and after supervised regular group exercise training and individual training for four months: (1) Information and guidance that meets the women's needs (2), Thought of exercise as less frightening and confronted the pain more often with exercise and (3) «All or nothing»: understanding that a little exercise can also help. We identified that information about exercise was vital, moreover that supervised group training brought an extra dimension of safety and belonging.

Theme 1. Information and guidance that meets the women's needs

The women viewed their treatment options as limited. They explained that only surgery and medications were offered to them, and only two of the women had previously received recommendations about non-pharmacological and non-surgical pain management and exercise from their doctors. After participation in the present study, most women expressed a need for more information at an earlier stage of the disease about how they could actively do something to improve their pain themselves. Hannah said it like this:

This [lack of information] is why I seek out and want to be part of this [project] and understand more of what it [endometriosis] is and how I can manage it since there are no such offers from the public health sector.

Maria further elaborated:

So, that has been very nice about this [project]. I have not taken a big risk participating. (...) It has been that [a risk] with those hormones. I have been told to do it [start with hormones], and then I have started wondering what will happen when I do it because there is very little information.

The wish for alternatives to the current management, including surgery and medications, was also expressed by Isabel:

To gain control over the pain without drugs involved. I want there to be more treatments that are not about surgery or medication. For me, these are not two good options to continue with in the long run.

Most women also emphasized the importance of supervised exercise led by an experienced physiotherapist and that exercise training in groups made them feel less alone with their condition. In this regard, PFMT was appreciated as a new and essential tool. Isabel said: «Exercise and those pelvic floor exercises are very important to continue with. However, more holistic, participating in this [project], meeting others, and not feeling so alone.» Olivia agreed: “I’m trying to become more aware of the pelvic floor. It [pelvic floor muscle training] is also training.” Some also expressed that the exercise classes had been an anchor during their daily struggle with the disease and that establishing weekly routines with training was essential for their coping. Two women also emphasized the importance of involving their partner to keep up the exercise routines. One of these women were Isabel, talking about how her partner would join her in her

practice: “If I say that I need to do these exercises, he will take me.” Independently of previous training experience, the women were positive, motivated, and more confident toward exercise. They expressed a wish to do more or continue what they had been introduced to during the study. Jenny said it like this:

Since I have noticed an improvement, it is easier to maintain it [the training]. I now know that if I fall out of it, I know what I can do to get back into it. Or at least try. Before, I thought a bit more about training to loose weight or those things; now, it's more to not be in pain - a greater motivational factor.

Theme 2. Think of exercise as less frightening and confront the pain more often with exercise

The second theme we identified was that most women no longer viewed exercise as harmful and frightening. Thus, they could confront the pain in more situations. An essential notion of this is that the women became more aware of the exercises that triggered pain. Although this had been a long journey that some had started before participation in the RCT, they became more aware of what to do and what not to do. Some women also expressed a lowered threshold for training at fitness studios, and three of these women had even made concrete plans with a personal trainer and signed a gym membership after study participation. Maria said, “I felt it was no longer so scary to exercise at that gym because I had practiced in this group.” She further elaborated: “It has lowered the threshold for trying other things [related to exercise]. Because if I can do this here, I can do it in the gym as well. So, it’s been nice». Her experience with exercise and PFMT through the project further boosted her confidence in confronting the pain with exercises:

Imagine if we were hiking and I got pain [on that hike]. So even if it's only been an hour [the supervised group training], there have been pelvic floor exercises to relax, which (...). I feel I've gained a bit more control over my body. And don't get so scared.

However, some days were too painful to exercise, or fatigue hindered them from exercising or simply moving around. Three women (Sandra, Isabel, and Amelia) were disappointed because they could not keep up the prescribed exercises, fearing that the training would increase the pain even more. Sandra explained it like this:

With everything available [referring to training equipment at home], I can't bear to get up from the sofa. I don't have any energy in my body, and I've had quite a lot of pain. When you have that pain in

your stomach and stuff like that, you're very afraid of, or I'm a little afraid of exposing myself to more [exercise], considering the days that are coming because it [the pain] is so unpredictable.

These three women, Sandra, Isabel, and Amelia demonstrated their resilience by adapting their exercise routines. They had to reduce the prescribed general strength training but managed to maintain the endurance training with fast or uphill walks. They also continued with PFMT during periods of increased pain. Amelia said: "When I haven't been able to exercise strength, the newest thing for me has been the pelvic floor exercises that I've been trying to do every day". Isabel also brought forward the importance of continuing with exercise and PFMT after being introduced to this during the project: "The general exercise training, and the pelvic floor exercises. Those things are tools I haven't quite known how to use before".

Theme 3. «All or nothing»: Understanding that a little exercise can also help

Most women said they had changed their view on how much exercise was necessary to achieve health benefits and better cope with their situation. This change of view was mainly related to the sessions' length and intensity. It resulted, for some, in that there were fewer periods with no training and a more even distribution of exercise throughout the month. Further, with this change of view, exercise was also more accessible for many women to adjust on days with pain. Isabel explained it like this:

Yes, previously, you have almost been told not to [exercise] because it has always triggered the pain. However, if I work out 20 min one time and 10 min another time, then I think it will help because my body cannot handle too much [exercise], but rather small doses.

Amelia further said:

It is OK to get some movement. That is something I will bring with me. If I don't have to push myself to the limit, it will be fine to gradually slow down the intensity. The most important thing is to be active.

Her experience with lowering the exercise intensity was expressed like this:

I have done that, slowed down on the intensity, and I do not hate to exercise as much as I did earlier. I am not too fond of it [exercise], but I do not hate it as much now as I did earlier.

Some women further strengthened the thinking of shorter exercise sessions or lowering of the training intensity after experiencing various intensities and exercises during supervision. Elisabeth said it like this:

I never really enjoyed working out; it has been terribly tiring. 'Why should I do something that hurts when I have so much pain' (...) So I think that the times I have tried to exercise, the sessions have been far too hard. So, what I liked so much about the project was that I felt I got in better shape from our training, but I didn't think it was terribly tiring. Of course, tiring, but.

Two women exercising at a moderate to high aerobic intensity level brought up thoughts about the length of the sessions. Sandra expressed:

(...) Maybe I can exercise slightly shorter sessions and perhaps adjust it myself, which also has an effect. That might be the biggest, the most important change for me.

Discussion

After participating in an RCT, including pain management education and regular supervised group- and individual exercise training, the women were more positive, motivated, and confident about continuing exercise in the future. The women further described supervision as a factor that made exercise less frightening and manageable when exposed to various intensities and types of exercises in a safe and supportive environment.

A recent multicenter cross-sectional study including 460 women with endometriosis and 460 healthy controls by Sachs et al. (2023), revealed that women with endometriosis exhibit fewer hours of weekly physical activity than healthy controls with no endometriosis [29]. Importantly, factors such as the disease itself, current dysmenorrhea, and depression were all associated with lower levels of physical activity. Thus, endometriosis is an independent factor leading to lower physical activity levels [29]. Lower levels of physical activity have also been illustrated in a former survey among women with endometriosis, referring to these women's pain levels extending to symptoms outside the pelvic area [30]. From our interviews, the participating women were positive towards exercise training as part of their self-management. Further, after being introduced to exercise through the pain management course, some of the women also discovered when their bodies could benefit from exercise and which days exercise could provoke the pain. Some also managed to break the circle of thinking of exercise as painful or harmful, thus performing exercises when they

usually would not. The exposure to various intensities and types of exercises amplified the thinking of exercise as non-threatening. A significant consideration of the beneficial effects of exercising with pain is the potentially associated learning involved [31]. Within this concept lies techniques to reconceptualize pain as safe and non-threatening, facilitated through supervision and patient education. Introducing patients to various exercises with different intensities in the clinical setting may reduce fear movement and pain-catastrophizing thoughts [31]. The results from our interviews further showed that only two women had been informed about self-management strategies by their medical doctor, and all women expressed a need for more information about the disease and how they could better manage disease symptoms. Active coping styles, including adaptive strategies like acceptance, self-management, and increasing physical activity, are related to better mental health. Avoidance and suppression may cause poor mental health [7]. Thus, empowering women with information and tools as stepping stones could enhance their ability to implement exercise as a self-management strategy [6].

Physiotherapists have an important role in promoting exercise, and both therapist and patient describe individualization as a critical aspect, e.g., treating the person and not the disease and educating the patient about exercise [32]. Patients have further described individualization as critical to the experience of exercise promotion and the general experience with physiotherapy. However, from the latter study, most patients expressed a need for more supervision and guidance during physiotherapy treatment; contrasting what was the current practice with home-based exercise with minimal encouragement to attend exercise on their own [32]. From our interviews, through the weekly group training, three of the women were more motivated to attend fitness studios, although this was something previously avoided. This finding illustrates the importance of supervision and individualization during exercise to create a safe environment. Moreover, the effect of supervised exercise should be evaluated in the context in which it has been performed [33]. In our study, the participants perceived the therapeutic alliance and belonging to a group as equally important. Thus, we must recognize the importance of group participation while considering exercise as an empowering tool [5]. Seeking social support from family and friends has also been identified as a problem-focused coping strategy, as found in a previous critical narrative review in this patient population [7]. This support was illustrated by two of the women involving their partners to maintain the routines for exercise being introduced in the present study. Physiotherapists should help patients focus on living with endometriosis rather than on a specific cure to help patients pursue a fulfilling life [34].

Consequently, information and knowledge about exercise as self-management are essential [3, 34].

Strengths and limitations

To plan for future evidence-based models, including exercise training as part of the treatment for women with endometriosis, we need to get insight into how these women experience exercise training. Thus, the statements from the women included describing their fears and management of exercise training despite living with pain is a strength.

However, some limitations are important to highlight. One of the interview questions centered on how participants viewed exercise after participating in the pain management course and after regular supervised group- and individual exercise training for four months. Although our study incorporated various types of muscular strength training and endurance training at different dosages and intensities, this study may not answer to women's experiences with all kinds of physical activities and exercises. Further, our sample of ten participants may be biased due to an already interest in exercise. Although only two women were regular exercisers at the start of the RCT, willingness to participate could reflect that most women were motivated to use general exercise training as self-management. These limitations highlight the need for future studies exploring experiences of other types of exercises among women with endometriosis. Moreover, all but three women were in full-time or part-time work, which does not necessarily reflect all cases of endometriosis [35]. Investigating the experiences of general exercise training in a population that might have a more disadvantageous health condition than the present sample may be desirable. However, the women included presented with considerable levels of pain that for some interfered with their daily life and the prescribed exercise training received in the project. Although our project includes women with endometriosis, our results may therefore be transferable to other patients living with pain. Another limitation could be the sample of ten women. However, the interviews provided us with statements from the diverse experiences of women participating, answering the study's aim. Further, our reflexive approach throughout the analytical process strengthens our contextual understanding of the data [24]. Thus, we are confident that our sample holds adequate information power, providing new knowledge about general exercise training among women with endometriosis [21]. An important remark to this is that most women exercised on a low-to-moderate intensity level, and only two exercised on a moderate to high intensity level. Our results may, therefore, have looked different if more women exercising on a higher intensity level were included. However, the statements provided touched upon the same experiences after

participation regardless of intensity levels. We aimed to make the interviews open and curious to grasp their honest experiences after participation in the RCT. However, the motivation for exercise from both groups could also reflect the participant's attempt to please the interviewer. Lastly, many also spoke of how participation had led to their sense of belonging. Thus, the contextual factors in this RCT must not be overlooked [33] and must be seen as equally important as part of their self-management and empowering strategies [5].

Conclusion

This qualitative study found that empowering women with knowledge through a pain management course about the benefits of general exercise training, including PFMT as self-management of endometriosis, is critical to making informed decisions regarding treatment choices. Further, through regular supervised group- and individual exercise training, a sense of belonging was created, and a previous fear of exercise as something harmful or exhausting was diminished.

Abbreviations

PFMT Pelvic floor muscle training
RCT Randomized controlled trial

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12905-024-03356-w>.

Supplementary Material 1

Supplementary Material 2

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Author contributions

MKT planned the study, collected and analyzed the data, wrote the manuscript, and was responsible for its content and text. RG planned the study and wrote the manuscript. RG, KB, MEE and MM planned the study and wrote the manuscript. All authors read and approved the final manuscript.

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Data availability

The data material is in the Norwegian language and available upon request from the corresponding author.

Declarations

Ethics approval and consent to participate

The study was approved by the Regional Committees for Medical Research Ethics South East Norway (date of approval 22.10.2019; reference number

2019/1236) and the Data Protection Officer at Akershus University Hospital (2019_135). All participants gave their informed consent before inclusion.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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